‘Plastic Planet’ Information Pack

FOR INTERNAL INDUSTRY USE ONLY

Date: 10 September 2009

Introduction

In preparation for the release of the film 'Plastic Planet', this information pack has been prepared to provide background and knowledge to help non-specialist employees in the plastics industry to be informed about key questions that it could raise. The industry does not believe that it should take any proactive action to bring this information into the public domain.

The pack contains a lot of information but does not provide exhaustive answers and, in a situation where your organisation is approached by the media, it will not provide you with the experience to be able to handle journalists to minimise the risk of adverse media coverage. If you do not have such experience yourself, our advice is to plan ahead and identify, and brief, an appropriate expert or spokesperson to represent your organisation, in case you are approached.

We would strongly advise you to refer enquiries to an appropriate expert from the industry and have included contact details to help you to do this.

This information pack contains:

1. Plastic industry's general statements about the film

2. Basic information responding to the 5 key issues addressed in the film:

- the plastic industry's approach to waste management
- the challenge of dealing with the issue of marine littering
- facts about VCM and PVC manufacturing
- facts the use of phthalate plasticisers in PVC
- facts about the chemical bisphenol A

Each section contains details of sources for more information and the contact details of experts who may be approached to respond to the issues raised in the film.

Industry spokespeople who can support you on specific issues or media enquiries:

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1. Plastic industry's general statements about the film

Key Messages:

- The plastic industry welcomes Mr. Boote's personal engagement in addressing some important current topics.
- But only certain aspects are dealt with and, in some cases, very simplistic answers are given to very complex matters. Therefore, in terms of public debate, the film can only be viewed as an impetus for further more in-depth debate.
- It is important to put the film's message into a broader context in order to avoid the development of one-sided public opinion on the subject.
- Together with the scientific community and industry experts, the plastic industry is always willing to engage in, and indeed would welcome, constructive dialogue on these subjects.
- We are committed to making information about the plastics industry transparent.

A documentary film with the title "Plastic Planet" will be screened in Austrian cinemas in September 2009. It is planned to show the film throughout the entire German-speaking region while translation and worldwide sales are under consideration. Working in the style of Michael Moore's "Bowling for Columbine", Austrian director Werner Boote uses the film to address the production and the use of plastic in everyday life.

The plastic industry welcomes Mr. Boote's personal engagement in addressing some important current topics. For the purpose of balanced reporting – only certain aspects are dealt with in the film and unfortunately, in some cases, very simplistic answers are given to very complex matters – it is however necessary to thoroughly address many other facts and content that are not mentioned in the movie.

Therefore, in terms of public debate, the film can only be viewed as an impetus for further more in-depth debate.

The industry welcomes a constructive dialogue, open exchange of opinion and is committed to making information about the plastics industry transparent; and to inform the public about it in an objective and comprehensive way.

The plastic industry also considers it important to bring the film's message into a broader context in order to avoid the development of one-sided public opinion on the subject.

Specifically the following aspects are – according to our understanding – insufficiently documented in the film and would require more in-depth information in order to be fully understood:

- The position of the plastics industry on waste management
- The challenge of dealing with the issue of marine littering
- Facts about VCM and PVC production
- Facts about phthalate plasticisers in PVC
- Facts about the chemical bisphenol A

Together with the scientific community and industry experts, the plastic industry is always willing, and indeed would welcome, constructive dialogue on these subjects.

2.1 The plastic industry's approach to waste management

Key Messages:

- Plastics offer society lots of helpful properties, and they are also eco-efficient in many ways - including when a product comes to the end of its useful life. This is when end-of-life management becomes necessary.
- Plastic is too valuable to waste. All plastics can either be recycled as material and or chemical feedstock for further use; or recovered as energy.
- The high calorific value of plastics is actually similar to that of fuel oil. Therefore, plastics waste can either be recycled into new products or it can partly substitute for fuel conserving primary resources.
- In order to achieve the economically and ecologically optimised management of plastics waste, society needs to learn how.
- To achieve the high level of waste recovery, which is already in evidence in several European countries (optimising the value of plastics and diverting plastics waste from landfill), a combination of all end-of-life management techniques is required.
- Education is a key part of this. The plastics industry has invested, and continues to invest, in a widespread programme to transfer its knowledge about end-of-life waste management and share it with relevant stakeholders.

Plastics are too valuable to be just thrown away

In some regions significant quantities of end-of-life plastics are already being recovered, in others the industry is working extremely hard to help society understand that it needs to capture the value of plastics and avoid the negative impact of land filling. The plastics industry has developed its own long-term vision for waste management. The goal being to reduce the impact of plastics waste on the environment and at the same time to help society to reduce its environmental footprint and become more sustainable:

- Through diverting organic-rich waste streams (such as municipal solid waste or industry and commercial waste) from landfills as much as possible, thus conserving primary resources
- Through utilising a mix of recovery options in order to save material or energy resources, taking eco-efficiency into account
- By promoting the treatment and recovery of plastics waste-streams under defined environmental quality standards
- By taking a comprehensive approach, at every stage of the life-cycle, to ensure that the largest environmental benefit, which can be achieved during the use-phase of the plastic product, is not impaired by too-detailed regulation of another stage in the life cycle.

How can the value of either material or energy be recovered at product's end-of-life?

There are different recovery options to recover the value from products that are made of plastics. In principal terms, an optimised eco-efficient recovery mix is required in order to divert plastics waste from landfill.

Mechanical recycling **-** This is the mechanical washing, sorting and grinding of used plastics and processing it directly back into granulates, so the material can be processed into useful new products.

Feedstock recycling **-** This is the breaking down of the chemical bonds within plastics into its chemical components, using heat or shear; or a via a chemical reaction. The chemicals produced are mostly oils or gases, from which new plastics or other chemical feedstock can be manufactured. Feedstock recycling can be used where different materials are mixed together or soiled.

Energy recovery **-** This can be either using the plastics as a fuel substitute in industrial processes such as power, cement, lime or other furnaces; or using it in mixed-waste incineration plants such as municipal solid waste incinerators, or for industrial steam electricity production.

What can the plastics industry do?
Effective waste management requires intelligent solutions for both material recycling and energy recovery of plastic-rich waste streams. Plastics manufacturers have been:

- Actively involved in advising European and national government bodies to optimize cost benefits of legislation, to help identify solutions which meet the requirements of the market. As a consequence, over recent years, laws and standards have been introduced that begin to guide society towards more responsible management of its waste. Legislation and implementation guidelines are now in force for packaging, electrical and electronic equipment and automotive vehicles at their end-of-life; and there are also framework regulations with stringent environmental provisions that determine the basic principles for treating all kinds of waste.
- The industry has significant expertise in market economics, processing technologies as well as innovative waste management processes, gathered over years of experience, and has an in-depth knowledge about all recovery options for plastics. Working through their trade associations, the plastics producing industry is active in supplying knowledge about the options, sharing best practices, developing concepts and providing information so that:
    - efficient operations and infrastructures can be developed avoiding excessive costs
    - environmental performance of waste management practices (with low emissions into air, water and soil) can be secured with high recovery efficiency for material and energy resources.
- The industry also participates in voluntary commitments, like the Vinyl 2010 initiative, with millions of euros being invested each year into promoting and supporting plastic recycling systems and the development of innovative new technologies like the Vinyloop feedstock recycling plant in Ferrara, Italy.

For further information on the plastic industry's approach to waste management go to:

www.plasticseurope.org
www.plasticsconverters.eu
www.vinyl2010.org
www.kunststoffverwertung.ch
www.isopa.org

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2.2 The challenge of dealing with the issue of marine littering

Key Messages:

- The plastics industry is seriously concerned about the issue of marine litter. It is unacceptable that unwanted plastic is found discarded in marine and river environments.
- More effort is needed by all concerned to: improve waste management on shore and on vessels; to educate and change littering behaviour.
- The industry is very active in promoting end of life waste management on land and is actively participating in workshops to discuss the problem and possible solutions of marine litter with experts.
- We need to find out if there are any cost effective solutions to removing plastic waste in the oceans that has accumulated over the past years.
- We need to better understand the consequences to the environment of the material that may remain in the ocean in years to come.

How much is plastic contributing to marine litter?
Marine litter is found in all the oceans of the world – not only in densely populated regions, but also in remote places far away from any obvious sources. Over the last few years it has become apparent that a large amount of debris is being collected by ocean currents into large 'gyres' in specific areas of the oceans (e.g. North Pacific). It has been reported that in certain areas of the ocean there are 46,000 pieces of floating plastic litter per square mile. If these estimates are accurate, then it is a serious messenger of a deep societal behavioural problem.

The fact that 83% of litter floating in the oceans has been found to be plastic is not all that surprising given that most other waste material entering water either sinks or disintegrates. The very slow rate of degradation of most marine litter items, together with the continuously growing quantity of the litter and debris disposed, is leading to a gradual, but steady increase in the quantities of marine litter in our oceans and world shores.

The amount of plastic found on beaches varies from region to region.

- Recent surveys report that in the Mediterranean 40% of litter on the beaches and seabed is actually smoking related (cigarette stubs, packets etc), with plastic bottles and bags accounting for only 18%.
- But plastic debris accounts for 58% of all litter found on UK beaches and 80% of the litter on Belgian beaches; and 30-60% of the litter on beaches in the Baltic is made up of plastic bottles.

The, recycling industry funded, Kaisei expedition, that recently returned from investigating the North Pacific 'gyre', should provide us with a better understanding of the extent of the problem of floating debris in the oceans.

How does the plastic in the oceans get there?
Unwanted plastic waste gets into the oceans via a number of routes.

- According to the United Nations Joint Group of Experts on the Scientific Aspects of Marine Pollution (GESAMP), land-based sources account for up to 80% of the world's marine pollution.
- The rest comes from ships, much of it thrown overboard illegally. The International Maritime Organisation (IMO) states that, "in some areas most of the rubbish found comes from passing ships which find it more convenient to throw rubbish overboard rather than dispose of it in ports."
- Poor waste management practices in ports and in landfill sites are also a source.
- 14% of waste found on beaches appears to be fishing related (fishermen and fishing boats losing or dumping nets, tackle and equipment) and most of this is plastic. In the Baltic for example although marine litter on the coast is typically from tourism and recreation, 24km of lost fishing net was collected in a 2004 cleanup.
- Only around 40% of litter on UK beaches appears to be traceable to beach visitors but in the Mediterranean more than 50% of marine litter originates from shoreline and recreational activities.
- Pre-processing plastic pellets from industry are also sometimes found on beaches. These may originate from containers toppling off container ships in bad weather (although a rare event, a single

20 tonne container holds about 50 billion pellets, which can spread a long way) ; or from poor housekeeping in plastics factories allowing pellets to be flushed down drains. But it's not just the plastic products industry that may be responsible for plastic pellets found in the ocean. Cosmetics producers also use micro-sized plastic pellets in skin care products (scrub) which are flushed with the waste water and may escape the waste water treatment plants and flow back into rivers.

How much is the plastic in the oceans harming wildlife?
Plastics are inert materials and a study published in 1997 reported that it was fishing gear, ropes, lines and strapping bands which mostly adversely affect larger mammals and birds, rather than plastic bags and bottles. Through the International Coastal Cleanup actions over the past 10 years incidence of entanglement have been reported for seabirds, seals and other marine mammals like marine turtles as well as for sharks.

It is also of deep concern that, apart from entanglement; birds, turtles and fish ingest pieces of plastic, mistaking it for food, causing injury and death. Ingestion data is obtained by examination of stomach contents of dead seabirds or through examining regurgitations. At least some beach strandings of whales have been attributed to ingested litter blocking their digestive tracts.

Does plastic floating in the sea release toxins?
Marine biologists have done a lot of experiments to show that micro plastic fragments are transported or digested like other micro debris (e.g. sand) and these experiments clearly show the potential for the transfer of chemicals from plastic particles to tissue. However toxicity requires a combination of hazard and exposure and the potential for hazard lies in the ability of plastics to absorb and transport persistent hazardous chemicals from the environment rather than chemicals originating from the plastics themselves.

Claims that plastics in the marine environment will accumulate and concentrate toxic chemicals from the surrounding sea water are based on early research on two types of plastic granules in heavily polluted Japanese coastal waters. However, plastics can absorb all kinds of chemicals (toxic or non-toxic) from their immediate environment, provided that the chemical is compatible with the plastics. The NOAA concluded in their latest report of July 2008 that "toxicology studies are necessary to investigate the possibility of uptake of toxins from plastics or other inorganic debris particles in marine ecosystems. The likelihood of ingestion is minimal due to the low mass and concentration of debris particles relative to zooplankton organisms."
The International Workshop on Microplastics in marine debris (Tacoma, USA September 2008) concluded that, "at current levels in the open ocean, microplastics are unlikely to be an important global chemical reservoir for historically released POPS (persistent organic pollutants)."
The Belgian project ÁS-Made is an attempt to better understand the consequences of toxicity in the marine environment.

What can society do about the problem of plastics getting into the sea?
The UNEP (United Nations Environmental Programme) report 'Marine Litter, a Global Challenge' has called for: integrated waste management to better address litter; raise public awareness and education; improved port waste reception facilities and stronger economic instruments and incentives.

- For individuals, education has a big role to play with beach visitors encouraged not to litter but take their waste home or put it in a bin. Sponsored litter bins are now used widely on beaches but there need to be more of these, as well as signage and warnings of fines for littering, combined with increased surveillance of beaches and more severe fines.
- In terms of the illegal dumping of rubbish from ships and leisure craft, the 1973 MARPOL Convention sought to eliminate and reduce the amount of garbage being dumped in the sea from ships. Annex V prohibits the disposal of plastics anywhere into the sea. The Annex also obliges Governments to ensure the provision of facilities at ports and terminals for the reception of garbage. By February 2009, 139 countries had ratified Annex V. The Mediterranean is a MARPOL 'special area' so from 1st May 2009 it is prohibited for ships to dispose into the sea all plastics, synthetic ropes and fishing nets and plastic garbage bags. A new Regulation 9 came into force for ships from 1st July 1998. All ships of 400 gross tonnage and above and every ship certified to carry 15 persons or more will have to carry a Garbage Management Plan and Record Book. The EU Port Waste Directive 2001 required implementation of a prior notification system for ships' waste. Under new regulations to be introduced by the UK as part of the EU Directive on Port Waste Reception Facilities nearly all ships travelling to UK ports will have to notify them in advance of the waste they will be off loading. These rules also apply to leisure craft and the UK Royal Yachting Association in its Managing Waste policy states, "Put no garbage in the sea" and warns of "substantial penalties for offenders." In Germany good environmental behaviour is part of the skipper's licence examination. HELCOM, the Helsinki Convention requires all ships to deliver garbage to reception facilities before leaving port and that they should not be charged for this. In the US the cruise ship 'Royal Princess' was fined €336,000

for dumping 20 bags of garbage overboard. So stricter regulations and fines are in place for ships, boats and ports to prevent waste being dumped in the sea. BUT it's a fair assumption that illegal dumping is still occurring at sea.

- The plastics industry understands that it must focus on proper containment of its raw material to ensure that none of it gets flushed down drains into waterways, and eventually into the sea. The British Plastics Federation has launched Operation Clean Sweep – Plastic Pellet Loss Prevention. This is a manual on best practice in ensuring zero pellet loss into the environment. The BPF is seeking a commitment from every company, from top management to shop floor employees, to use this manual on prevention, containment and cleanup of plastic materials, to ensure no escape into the environment. PlasticsEurope and national plastic associations will be rolling out this program to all 27 European member states as part of the Responsible Care program.

Can we clean up the seas of plastic waste?

In terms of cleaning up what is already in the oceans there may be a potential to collect larger floating items. The recently returned Project Kasei investigation into the composition of the North Pacific gyre is funded by international recyclers. However in the 'no man's land' of international waters global coordination is going to be essential to deal with this issue.

- In a 'Fishing for Litter' campaign in Sweden, Denmark, the Netherlands and the UK, fishermen who returned all litter caught in their nets to the shore are compensated. In 2004 the scheme collected 500 tonnes of litter from 60 boats. The Belgian government as well as OSPAR are also considering paying fishermen for the waste they catch during their fishing voyages.
- Across the world there are numerous local initiatives to regularly clean up beaches
- Fishing communities in Massachusetts collect discarded plastic fishing gear which is picked up to provide electricity through Energy from Waste
- In the Cote d'Azur the authorities have employed Veolia to screen and rake through the coastal waters for floating waste with a specially equipped catamaran.

Wouldn't moving to bio-degradable plastics be a solution to ocean litter?

Bio-degradable plastics may have a role to play in some applications but they are technically unsuited to meet all of our needs and may also be less sustainable in other ways (for example: pipes for water supply window frames, electric cables, etc) . Contrary to popular belief, biodegradable plastics might potentially make the problem worse. Since degradation mechanisms heavily depend on the surroundings. Articles that might bio-degrade on land will not degrade in saltwater as it is hostile to the micro-organisms normally degrading the article on land. The idea of products that will 'rot away' would also be likely to encourage more littering and irresponsible waste management behaviour by society. The answer to marine litter has to be the improved management of society's waste.

For further information on the issue of marine litter go to:

http://www.projectkaisei.org/press.html
http://www.marinedebrissolutions.org/
http://marine-litter.gpa.unep.org
http://www.io-warnemuende.de
http://www.oceanconservancy.org
http://www.espo.be/Home.aspx
http://www.medasset.org/medas.htm
http://www.costalcleanup.org
http://www.oceanfutures.org
http://www.eucc.net
http://www.noaa.gov
http://www.ifremer.fr

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2.3 Vinyl chloride monomer (VCM) in PVC manufacturing

Key Messages:

- By the end of the1960s the industry had discovered that VCM presented a potential hazard to its employees' health (acroosteolysis of the fingers of autoclave cleaners).
- Prior to that, this substance was not considered as having any substantial risk associated with being exposed to it.
- This was followed in the early 1970s by the findings that VCM could also induce a rare type of liver tumour. Once confirmed, the industry behaved very transparently in acknowledging the problem and procedures were rapidly implemented to protect workers' safety.
- Today, manufacturing with VCM is highly regulated and carefully controlled to ensure employee safety.
- There is no risk from VCM emissions to persons outside of PVC production plants.

Is it true that in the past the PVC industry knowingly exposed its workers to vinyl chloride monomer, which is a known carcinogen?
It has been understood since the mid 1970s that exposure to Vinyl Chloride Monomer (VCM), the main chemical used in the production of PVC, can cause some forms of liver cancer.
Until then VCM was perceived to be so innocuous that it was even considered for use as a narcotic gas in hospitals during the 1950s. But in 1974 the potential risk of long term exposure to VCM within PVC plants was identified by studies commissioned by the industry and the industry responded quickly to take effective measures to seal processes involving VCM and to protect workers from exposure to this chemical. The industry has never 'covered up' the problem and has responded to it responsibly and quickly.

How is exposure to VCM controlled in PVC production plants to protect workers?
Today the management of the potential hazard of working with VCM within the PVC industry is an example cited of how to responsibly, and effectively, solve such a problem.
The levels of VCM in the atmosphere of PVC plants is monitored and controlled extremely closely. Control of emissions, personal protection, training and medical control of plant personnel ensure that exposure to VCM remains well within the margins of safety. Maximum permitted exposures were set out in a E.U. Directive of 1978. Expert opinion and research has led European authorities to consider that an exposure of 3 ppm, for 8 hours a day, through a full career of 40 years, poses no significant risk to health. Typical exposure levels to VCM in E.U. VCM and PVC manufacturing plants are lower and are monitored continuously.
All liver cancer cases recorded so far have been observed among workers whose VCM exposure began before 1975. No worker who started work after 1975 should currently be at risk in plants located in the countries (such as Western Europe) where strict controls were introduced following the discovery of this problem. But some new cases of liver cancer may however still appear in workers who had high exposures before 1975.

Is there any exposure risk from VCM for people living close to PVC production plants?
Any unintended low level emissions of VCM from production facilities pose no toxic risk to humans, or the environment, as VCM is a gas that dissipates very rapidly in the open atmosphere to a highly diluted form and is naturally destroyed by daylight within a few hours.

For further information on VCM and its use in PVC manufacturing please go to:

www.PVC.org

Or contact:

Arjen.sevenster@plasticseurope.org

2.4 The use of phthalate plasticisers in PVC

Key Messages:

- Phthalates are plasticisers used to make PVC soft and flexible. Without plasticisers, unique PVC products such as electrical cables, synthetic leather and many life-saving medical devices would not exist today.
- Although phthalates are commonly referred to as if they were a single substance, this is misleading because there are a number of different types of phthalate, each with very different characteristics.
- No phthalates are classified as carcinogens.
- The most widely used phthalates, DINP and DIDP, are not endocrine disruptors and in the case of DEHP, endocrine disrupting effects have only been seen in rodent studies at many times the level of exposure that would normally be experienced by humans.
- The fact is that in the 50 years during which phthalates have been used, there is no reliable evidence that they have caused any health problems when used as intended.
- The presence of phthalates in products does not mean that they will enter the body at levels that might pose a risk. Indeed, US government data has demonstrated that real life exposure is within safe limits.
- The difference between the level of exposure in animal models that have shown additive effects at extremely high doses and the potential to exposure in humans is substantially broad enough to ensure that a sufficient margin of safety exists.
- The main phthalates used in PVC are recognised as having no adverse effects on the environment. They are not persistent or bio accumulative.
- The plastics industry is very conscious of public concern and if there was evidence that any single product presented a serious health risk the industry would have no hesitation in withdrawing it.
- The EU risk assessments show little evidence to suggest that large-scale substitution is necessary and any replacement of the tried, tested and well-understood phthalates with less well-studied substances would be irresponsible.

What are 'Phthalates' and why are they used in PVC plastic?

Phthalates (pronounced THAL-ates) are colourless, odourless liquids which are used to make PVC soft and flexible. They are produced by a simple chemical reaction, whereby molecules of water are eliminated from commercially produced petrochemical products.

Without plasticisers, unique PVC products such as electrical cables, synthetic leather and many life-saving medical devices would not exist today.

Plasticisers are not just additives (like pigments or fillers), they are major components that determine the physical properties (e.g., degree of flexibility, resistance to heat, durability) of polymer products.

More than 90% of all plasticisers used in PVC in Europe are phthalates. The most common phthalates are di-isononyl phthalate (DINP); di-isodecyl phthalate (DIDP); and di-2-ethyl hexyl phthalate (DEHP, also sometimes called DOP). DINP and DIDP account for nearly 70% of all plasticisers used in Europe.

Phthalates are widely used as general-purpose plasticisers because they offer the advantage of lower costs and increased production efficiency. This is achieved through the improved melt viscosity and production speeds conferred by phthalates. In addition improved flow characteristics give better workability and reduced out-of service time due to fewer breakdowns of equipment.

Are phthalate plasticisers all the same?

Phthalates are often collectively referred to as a family of plasticisers. However, grouping substances by family is entirely inappropriate as many "families" of chemicals consist of substances which are both structurally and toxicologically quite different.

Phthalates are one such example. The phthalate "family" consists of numerous substances, each of which has a different chemical structure which gives it its own characteristics. Whereas phthalates such as DEHP, DBP, DIBP and BBP are classified as category 2 reproductive toxicants, there are those such as DINP and DIDP which have no hazardous properties and which are therefore quite different.

This distinction is exemplified under the European chemicals legislation REACH. Three of the four CMR category 2 substances – DEHP, DBP and BBP – have been placed on the EU Candidate list and proposed for authorisation, whilst the fourth (DIBP) has been nominated for inclusion on the Candidate List. By contrast, DINP and DIDP have no hazard classification so they only have to be registered for use.

Can the phthalates used in soft PVC products cause cancer?

The World Health Organisation (WHO) does not classify any phthalates as human carcinogens and there is no evidence to suggest that any phthalates can cause cancer in human beings.

It was once thought that DEHP might have been a carcinogen based on results seen in rodent studies. However, the evidence has since been reviewed and the International Agency for Research on Cancer (IARC) now states that DEHP is "not classifiable as to carcinogenicity to humans".

Are phthalates used in soft PVC responsible for reduced sperm count in men or do they cause any other human reproductive problems?

Thorough scientific risk assessments have been conducted on the most commonly used phthalates by the European Union authorities to ensure that people are not put at risk from their use.

In the case of the most widely used phthalates, DINP and DIDP, the EU risk assessments clearly concluded that there is no health or environmental risk from any of their current uses. Neither of these two phthalates is classified for any health or environmental hazard.

In the case of DEHP, the EU risk assessment identified some potential risks but risk reduction measures were agreed upon and, in most cases, have already been put in place.

Certain phthalates, such as DEHP, DBP, DIBP and BBP are classified as toxic to reproduction by the European Union as a result of effects seen in rodents at very high dose levels. However, humans are highly unlikely to be exposed to the high dose levels of these chemicals that rodents have been exposed to in laboratory conditions.

Numerous scientific studies have been carried out to investigate whether exposure to phthalates is likely to have any short or long term effects on humans but most scientists agree that any effects that have been seen do not pose a threat to the health of the general population. Any phthalates that are absorbed do not accumulate as our bodies very quickly excrete them.

Are phthalates endocrine disruptors?

The most widely used phthalates, DINP and DIDP, are not endocrine disruptors. DINP and DIDP do not meet the internationally accepted definitions for endocrine disruption (the Weybridge definition and the International Programme for Chemical Safety (IPCS) definition) and they are not endocrine disruptors according to the criteria in the EU REACH Guidance.

DINP and DIDP have shown no evidence of adverse health effects related to the endocrine system in sub chronic, chronic and two-generation reproductive studies in rodents. The two-generation study is considered by the OECD to be one of the most important studies in determining endocrine effects related to the reproductive system.

The EU risk assessments clearly concluded that neither substance should be classified as a reproductive toxicant under Directive 67/548/EEC.

In the case of DEHP, endocrine disrupting effects have only been seen in rodent studies at many times the level of exposure that would normally be experienced by humans.

Is the high proportion of phthalates found in some soft PVC products a cause for concern?

The amount of phthalates found in a finished product has little to do with potential exposure. That is entirely dependent on the amount that might migrate from the article which in turn is dependant on how the article is manufactured and how it is used.

The fact is that in the 50 years during which phthalates have been used, there is no reliable evidence that they have caused any health problems when used as intended. The presence of phthalates in products does not mean that they will enter the body at levels that might pose a risk. Indeed, US government data has demonstrated that real life exposure is within safe limits.

Does the use of phthalates in so many everyday products mean that we should be concerned about total exposure to these plasticisers rather than to each individual substance?

It is clear that health effects that may be caused in animals by exposure to phthalates differ among the various compounds and depend on the timing and size of the dose. Not all phthalates act the same way, and none have acted at all on laboratory animals unless the dose is very large.

Some data, generated at exceedingly high doses, indicate that some phthalates produce an additive effect in animal models. The levels of exposure in these studies are many orders of magnitude greater than human exposures. The difference between the level of exposure in animal models and potential to exposure in humans is substantially broad enough to ensure that a sufficient margin of safety exists.

Are phthalates used in PVC dangerous to the environment?

While phthalates are widely distributed in the environment, their levels are low because they are subject to relatively rapid photochemical and biological degradation.

Three phthalates, DBP, BBP and DPP are classified in the EU for their potential environmental hazard but the main phthalates used in PVC have no such classification and are recognised as having no adverse effects on the environment. They are not persistent or bio accumulative.

Does the plastics industry really care about potential harm from its products - can't we just swap to less controversial plasticisers?

The plastics industry is very conscious of public concern which exists around the use of phthalates in PVC.

The Industry welcomes a responsible public debate, and accepts that it has a responsibility to respond to public concern by ensuring that there is an open exchange of information about the performance of its products. Clearly, if there was evidence that any single product presented a serious health risk the industry would have no hesitation in withdrawing it.

Substitution of one substance for another should only be made either on grounds of performance or for health and/or environmental reasons. In the case of performance there are a number of different plasticisers available but they are generally used because specific properties are required. The most widely used phthalates remain the most popular choice because they usually provide the best all-round performance.

In the case of health and the environmental safety of phthalates, the EU risk assessments show little evidence to suggest that large-scale substitution is necessary, particularly as there is no risk to human health or the environment from those that are most widely used.

It must also be remembered that a great deal more is known about the health and environmental risks of phthalates than from many of their substitutes. Any replacement of the tried, tested and well-understood phthalates with less well-studied substances would be irresponsible.

For further information on plasticisers and phthalates please go to:

- The Plasticisers Information Centre: www.plasticisers.org
- The Phthalates Information Centre: www.phthalates.com
- The DINP Information Centre: www.dinp-facts.com
- The DEHP Information Centre: www.dehp-facts.com
- Green Facts: http://www.greenfacts.org/en/digests/phthalates.htm
- European Commission: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_014.pdf

or contact:

The European Council for Plasticisers and Intermediates (ECPI)
- Maggie Saykali: msa@cefic.be
- Tim Edgar: ted@cefic.be

2.5 The facts about the chemical Bisphenol A

Key Messages:

- The EU Risk Assessment, one of the most comprehensive and authoritative studies of potential risks, has concluded that BPA poses no risk to consumers or the environment.
- EFSA, the European Food Safety Authority, after assessment of the available data including recent ones, has concluded that BPA-based materials are safe for use in these products; consequently, BPA is listed positively for use in food contact applications.
- Migration of BPA is extremely low, and exposure to BPA is far below any safety-based standards set by the authorities.
- The uses of BPA in the manufacture of plastic food contact articles meet the strict safety requirements of the national and regional authorities responsible for consumer health in Europe as well as globally.

What is Bisphenol A?
Bisphenol A (BPA) is the basic building block for the plastics materials polycarbonate and epoxy resins. These high performance materials are used in the manufacture of many applications that contribute to modern, safe and convenient life. Because of their special characteristics, for example heat resistance and chemical and mechanical stability, polycarbonate and epoxy resin are used in areas, where safety, hygiene and durability are of key importance. Examples of articles made from polycarbonate and epoxy resin are CDs, medical equipment for intensive care, transparent roofs, safety helmets, car parts, housings for electronic equipment, windmill blades and epoxy coated articles such as lined cans, as well as food contact products such as baby bottles, water bottles or food storage containers.

Why would I hear someone say that BPA is an endocrine disruptor?
Like many naturally-occurring products and everyday foodstuffs such as carrots, soy beans or other vegetables, BPA shows very weak, estrogen-like effects. But technically it does not fulfil the scientific definition of an endocrine disruptor. In fact BPA was tested (together with many other substances) in the 1930s for its potential to be used as a hormone and failed to show relevant potency. The very weak, estrogen-like potency of BPA only shows effects at levels that can realistically never be reached in daily life. And even those potential effects are 10,000 to 100,000 times *weaker* than those of the naturally occurring oestrogen, oestradiol.

Can BPA get into our bodies through using products made from it?
During the production of polycarbonate and epoxy resin, the BPA molecules are firmly bound to one another and incorporated into the polymeric structure of the material itself. Therefore, you can neither eat nor drink BPA as such, nor can BPA penetrate your skin (as alleged in the film). Migration from BPA-based materials such as polycarbonate or epoxy resin has been proven to be extremely low and far below any safety-based standards set by government bodies. Polycarbonate is also a highly stable material. As with any other material, there is some potential for extremely small amounts of BPA to migrate. However, several scientific studies have shown that even heating liquids in polycarbonate containers under normal household conditions does not lead to any significant increase in migration.

What if products made from BPA are scratched (as alleged in the film Plastic Planet)?
Polycarbonate is a very stable material. As with any other material, there is some potential for extremely small amounts of BPA to migrate. However, several scientific studies including several done by national food safety authorities (e.g. from Norway, Switzerland or France) have shown that use under household conditions and including operations like heating or scratching or microwaving does not lead to any significant increase in migration and migration kept very low. Even with used articles, recorded BPA migration was by far too low to come near to the safety limit set by the regulatory authorities.

Is there a level at which BPA would be dangerous for me?
The European Food Safety Authority (EFSA) set the safe level for life long daily uptake of BPA (the "Tolerable Daily Intake" or TDI) at 0.05 mg/kg bodyweight/day over a lifetime. Using food contact articles made from materials based on BPA, it is more than unlikely that a person could consume the amount of food or beverage necessary to cross this safety limit. In order to reach the TDI, a person weighing 60 kg would have to eat at least 600 kg of food (10 times their own bodyweight) using polycarbonate utensils; or consume the contents of at least 120 food cans (@ 500 g); or drink 600 litres of water from polycarbonate containers, every day, for his/her whole lifetime. In practice, obviously, this is quite impossible.

Do we have proof that BPA doesn't affect us?
Regulatory authorities worldwide, responsible for consumer safety, have thoroughly assessed the characteristics of BPA. Over 50 years of research and extensive use throughout the world have provided convincing evidence about the safety of BPA. The EU Risk Assessment for BPA was published in 2003. An update covering more recent studies was published mid 2008. Both Risk Assessment Reports, conducted by the European Commission and experts from the European Member States, concluded that BPA does not pose a risk to consumers or to the environment in their intended applications.
The uses of BPA in the manufacture of plastic food contact articles meet the strict safety requirements of the European Commission and its expert body, the European Food Safety Authority EFSA. With the understanding of the metabolic processes in the body, and after evaluating the available data on the realistic, extremely low exposure to BPA -based food contact applications, the authorities responsible for consumer safety have concluded that the use of polycarbonate plastic and epoxy resin coatings in applications that come into direct contact with food poses no concern. Consequently, BPA is positively listed for approved use in food contact applications in the EU.
Similarly, polycarbonate and epoxy food contact coatings meet the safety requirements of the U.S. Food and Drug Administration (FDA), the Japanese Ministry of Health, Labour and Welfare and other responsible international regulatory bodies, including the national regulatory authorities in the UK, Germany, France, Switzerland, the Netherlands, Ireland, Denmark and Norway. The standards set by all of these bodies incorporate considerable margins of safety. This is unchanged in updated views on BPA published in 2008 and 2009 by EFSA and other competent authorities in the world.

What if I just don't want to use a product that contains BPA – are there alternatives?
Products containing BPA offer huge advantages in product performance and with our current level of scientific knowledge there is absolutely no rational justification to support any concerns about using them. In fact, alternative materials that may not contain BPA will probably be far less well understood. The German government stated *"[…]For hardly any chemical are there as comprehensive and specific toxicological and exposure data, which makes a valid risk assessment possible and an accurate TDI estimation feasible […]"*And the Swiss Bundesamt für Gesundheit noted: "*A ban on BPA would inevitably cause manufacturers of packaging and consumer products (food contact materials) to have to switch to other substances, the toxicity of which is less well known. This would mean a well characterized risk would be replaced with a conspicuously unpredictable risk."*

For detailed information on BPA go to:
www.bisphenol-a-europe.org

Please find here a selection of authority opinions about the safety of BPA in food contact:
European Union Risk Assessment Update:
http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf
European Food Safety Authority:
Summary and full EFSA opinion:
http://www.efsa.europa.eu/EFSA/efsa_locale-117862075 3812_1211902017492.htm
Statement:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902017373.htm
Abstract:
http://www.efsa.europa.eu/etc/medialib/efsa/science/afc/afc_opinions/bisphenol_a.Par.0001.File.dat/afc_op_ej428_bpa_op_en.pdf
summary:
http://www.efsa.europa.eu/etc/medialib/efsa/science/afc/afc_opinions/bisphenol_a.Par.0002.File.dat/afc_op_ej428_bpa_sum_en.pdf
statement: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620835386.htm
Germany
Statement: http://www.bundestag.de/aktuell/hib/2009/2009_178/02.html
statement:
http://www.bfr.bund.de/cm/216/neue_studien_zu_bisphenol_a_stellen_die_bisherige_risikobewertung_nicht_in_frage.pdf
Q&A on BPA and baby bottles
http://www.bfr.bund.de/cm/276/ausgewaehlte_fragen_und_antworten_zu_bisphenol_a_in_baybflaeschchen.pdf
France:
Report: http://www.afssa.fr/Documents/MCDA2008sa0141.pdf
Switzerland:
Statement: http://www.bag.admin.ch/themen/lebensmittel/04861/06170/index.html?lang=de

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