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PACKAGING MATERIALS
5. POLYVINYL CHLORIDE (PVC) FOR FOOD PACKAGING APPLICATIONS

ILSI
International Life Sciences Institute

REPORT

Prepared under the responsibility of the
ILSI Europe Packaging Material Task Force

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By Jason Leadbitter

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INTRODUCTION

Polyvinyl chloride, known as PVC, is one of the world's leading synthetic polymers. It has many uses, ranging from long-term construction applications, such as pipes used in the transportation of potable water, to short-term uses, such as food packaging. Because of the presence of chlorine, it is a highly polar polymer, which allows a wide range of additives to be incorporated within it. This variety of additives permits a broad range of physical property characteristics; hence there is not one PVC composition but many. This also explains the great diversity of applications in which PVC has been used from the time of its original commercial development in the early 1930s, when a few hundred tonnes were produced, to its annual global consumption rate of nearly 25 million tonnes in the year 2000.

This report intends to provide the reader with a general overview of the use of PVC in food packaging applications. It describes the main additives used in PVC compositions in food packaging as well as the regulatory framework for the selection of these additives. Attention is given to the health and safety of the consumer regarding the safe use of the product. In addition, a section is devoted to environmental considerations in the manufacture and waste management of PVC.

WHAT IS PVC?

PVC resin

PVC is the acronym for polyvinyl chloride, which is a long-chain polymer produced by a free-radical polymerisation of vinyl chloride monomer (VCM). VCM is produced by a chemical breakdown process known as "cracking" of the chemical ethylene dichloride (EDC) also called dichloroethane. EDC is produced through the reaction of 43% ethene gas (also known as ethylene, derived from oil or natural gas) and 57% chlorine (derived from the electrolysis of salt).

VCM is polymerised into PVC in a pressurised vessel (autoclave) containing water. During this process, the VCM molecules are joined together (polymerised) into long chains and the liquefied gas (VCM) is transformed into solid material (PVC resin). The resin is then dried, sieved and packaged. In appearance the polymer is a white powder; it is fairly inert at room temperature, although it is heat sensitive. Its molecular weight can be varied during the polymerisation stage. The theoretical molecular weight range varies from about 30,000 to 95,000 Daltons (number average molecular weight). The properties of PVC are influenced by its average molecular weight and its molecular weight distribution. Commercial PVC polymers are essentially amorphous, but they also have a crystalline phase amounting to around 10% of the matrix. The glass transition temperature phase lies in the range of 70–80°C.

PVC compounds

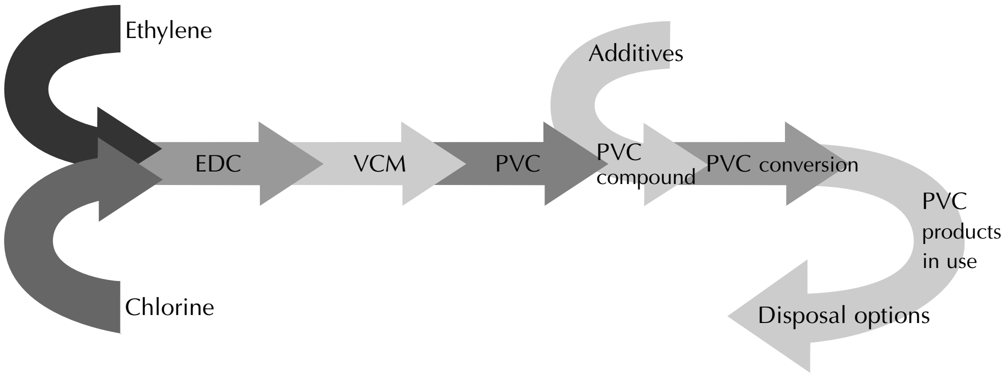
On its own, PVC is not particularly useful; it has very low thermal stability and rapidly degrades at temperatures required for processing, that are typically above 160°C. Hence, PVC resin is mixed with other chemicals and processed under heat (typically in the range of 140–180°C) and pressure by a compounding operation to form small granules or dice. This process yields an intermediate product known as "PVC compound." No chemical reactions are involved in the compounding operation. By using various additives, PVC can be made tough and rigid, in which case it is known as unplasticised PVC (PVC-U). Alternatively, by the inclusion of plasticisers, it can be made soft and flexible; in this form it is known as plasticised PVC (PVC-P). It can be transparent, opaque, or, by incorporating pigments and colourants, white, black or coloured.

After the compounding stage, the granules or dice are processed using a range of techniques such as extrusion, injection or blow moulding, and thermoforming.

The largest proportion of PVC in food contact use is PVC-U in the form of trays and containers produced from extruded sheet by the thermoforming process (around 50%) and in the form of bottles (35%). PVC-P has an important role in applications such as cling film (11%) and in closures and repeat-use flexible tube applications.

Figure 1 describes the life cycle of PVC, showing the various stages of manufacture.

Figure 1. The PVC ife cycle



Additives

A wide range of approved additives can be safely used in PVC compositions provided that they do not exceed certain migration limits as specified in the legislation on food contact plastics. Thus PVC is not a single composition but can contain a wide range of ingredients, and these may themselves be mixtures of other additives. The polar nature of PVC allows a much higher proportion of such additives than can be attained with other polymers. Hence the composition of PVC can be complex and range from rigid applications such as bottles to very soft rubbery cap seals. The regulation of additive migration limits and the measures that can be taken to ensure their safe use are discussed later on, under Regulatory Issues.

The main additives that can be incorporated in PVC for use in typical food packaging applications are listed in the following sections.

Stabilisers

Because of PVC's thermal instability, a thermo-stabiliser is the most essential ingredient in any PVC formulation. The purpose of the stabiliser is to protect the PVC during the compounding and processing stages, but it also helps maintain stability during use. Although a number of different types of stabiliser are available, only two are approved for use in food packaging applications because of the potential for migration into foods: organo-tin stabilisers and calcium/zinc stabilisers.

Organo-tin stabilisers are predominantly based on alkyl tin groups and in particular methyl or octyl derivatives. They impart a high degree of thermal stability coupled with clarity for use in transparent packaging. These stabilisers are used only in PVC-U applications, where their migration characteristics are extremely low. In PVC-P the mobility of the plasticiser could aid the migration of the stabiliser above a migration limit that would be considered toxic if it migrated into food. Consequently, only stabilisers based on calcium and zinc soaps, such as stearates of these metals, are used in PVC-P applications.

Impact modifiers

Unmodified PVC-U has relatively poor impact strength, i.e. low toughness at or below room temperature. In applications such as packaging, it is imperative that the material displays good resistance to sudden shock. The inclusion of an impact modifier significantly improves this performance. In this process, a dispersion phase is formed in the PVC matrix, which serves to block the propagation of cracks in the material. The additives used are themselves polymers; a typical modifier is based on a terpolymer of methacrylate-butadiene-styrene (MBS). These modifiers are not required in PVC-P.

Processing aids

In addition to the impact modifier, PVC-U formulations contain a processing aid, which helps significantly maintain melt flow during the compounding and processing stages. The two main types are based either on acrylic polymers (acrylates or methacrylates) or styrenic copolymers (containing methacrylates). Unlike impact modifiers, processing aids do not tend to influence the physical properties of the finished product. Such additives are not required in PVC-P.

Plasticisers

Plasticisers are incorporated to achieve flexibility in PVC-P. They are oil-like liquids with high boiling points and good thermal stability. The most common plasticisers are based on organic esters such as phthalates, adipates and trimellitates. However, most formulations also contain epoxidised soya bean oil (ESBO), which acts both as a plasticiser and as a secondary stabiliser for PVC cling films and plastisols. The main types of plasticisers used in food packaging are the adipates, which include low and high molecular weight versions of these esters. These are used to endow products such as cling film with their significant flexibility and may constitute as much as 40% of the product's weight. Phthalates tend not to be used in such applications, although some are used in PVC formulations for tubing designed to contain foodstuffs. However, these must only be used in contact with aqueous foodstuffs because phthalates are soluble in fatty foods.

Lubricants

While the addition of a lubricant in PVC-P is beneficial, for PVC-U it is essential. There are a number of different chemical types. Lubricants used in PVC-U include glycerol mono oleate and polyethylene wax, and those used in PVC-P include stearic acid and high molecular weight white mineral oils.

Pigments

Aesthetic characteristics are important in food packaging materials, and therefore pigments can be used in PVC for packaging applications. However, such pigments must be selected from food packaging materials approved lists (described later, under Regulatory Issues). Generally, these pigments are solids rather than liquid dyes, since solids are more difficult to extract from the polymer matrix.

PVC AND FOOD PACKAGING APPLICATIONS

PVC was one of the first polymers to be used in food packaging applications, and it replaced many traditional materials such as glass (used in bottles) and various forms of card and paper. PVC packaging for foodstuffs offers several advantages over the traditional materials:

- PVC is lightweight compared with glass, with the added benefit of reduced transport emissions due to the reduction in weight (Association of Plastics Manufacturers in Europe, 1990)
- It is shatter resistant, which was seen as an immense benefit, as it would reduce the number of accidents with glass from broken bottles at home and outside
- It has excellent organoleptic properties: PVC-U imparts no taint or taste to foodstuffs
- PVC can be made to have high clarity and to allow high visibility of the product
- It has good barrier properties for the preservation of food
- It has a good cost:performance ratio
- Innovative product shapes and complex designs are achievable
- PVC is easily processed, using automated machinery with high throughputs.

However, as is the case for materials that are well established in their life cycle, PVC has been challenged in some specific packaging applications, predominantly by other polymers and in particular by polyethylene terephthalate (PET). PET offers certain technical advantages over PVC for use in food containers, the main one being a lower permeability to carbon dioxide. This property has allowed PET to be used in the carbonated drinks market, where PVC's permeability to carbon dioxide is too high to ensure a long shelf life.

There have also been market pressures for manufacturers to replace PVC with alternative materials. This has been driven primarily by environmental concerns about PVC's life cycle. Nevertheless, after the construction industry, packaging constitutes the second largest market for PVC, representing around 3 million tonnes globally per annum in 2000 (Freedonia Group Inc., 1998). Some of the most important examples are discussed below.

Trays and containers

PVC-U is initially extruded into thermoformed sheet, which is subsequently shaped into trays and containers by a thermoforming process. Typical examples include modified-atmosphere extended-shelf-life food trays, general-purpose food trays, and collation or straight-on-shelf display trays.

Bottles

PVC's toughness combined with good clarity and resistance to oils and other substances makes it a suitable material for blow-moulded bottles for holding a variety of products. It also has the advantage of permitting the moulding of complex shapes, including blow-moulded handles for ease of use.

Flexible film

PVC-P has found wide acceptance for use in the preservation of foods, both in the supermarket and the domestic kitchen. These materials have "stretch" properties and unique "cling," and hence they are suitable for the hand-wrapping of fresh produce. Such films have high oxygen and water vapour transmission, keeping red meat "red" for longer periods on supermarket shelves. These materials can also be heat-sealed.

Closures and can linings

A number of enclosed containers such as cans may be coated with an adhesive or sealing material based on PVC polymers. These formulations are known as PVC "plastisols". The plastisol is manufactured from PVC produced by an emulsion polymerisation process that has a much finer particle size than resins produced by the more common suspension process. Plastisols are liquids at room temperature that can be poured into a cap or container and then "oven-cured" to form soft, rubbery seals. The main reasons for coating packaging materials in this way are to provide a heat-sealable surface that acts as an adhesive agent between two substrates and to achieve an airtight seal. Applications include the inner surface of caps, where a good seal is achieved when the inner face of an enclosure is drawn onto the container with a screw thread. In addition, if a diluent is incorporated into the plastisol, then an organosol is produced. PVC organosols are used in metal packaging as a coating and can be used for drawn cans and easy-open ends as well as closure fittings. Although stabilisers and plasticisers from these applications have included epoxy resins, manufacturers are moving away from these resins because of their tendency to form reaction products.

Repeat use tubing

PVC-P can be extruded into tubing for the transportation of foods in repeat-use applications such as beer tubing and soft drinks. These tubes tend to be reinforced with polyester fibres.

Some typical applications for PVC food packaging are summarised in Table 1.

Table 1. Typical food contact applications for PVC

Product Type	Application/Food Types
PVC-U	
Thermoformed sheet and foil	Blister packs/display trays for a wide range of fresh foodstuffs, including meats, vegetables and sandwich containers. Tamper evident packaging.
Bottles	Fruit squash, mineral water and cooking oils.
PVC-P	
Cling and stretch film	Supermarket stretch film. Household catering film. Particularly suitable for meats.
Cap seals	Canned and bottled food.
Hose and tubing	Transport of soft drinks and beers, etc.
Closures and can linings	Inner lining to coat metal cans and as seals for a range of foodstuffs.

REGULATORY ISSUES

European food packaging legislation

Initially, all European food contact legislation originated in, and was applied in, individual member states. However, with the formation of the European Union, member states elected to harmonise legislation in order to create a single market and overcome complications and barriers to trade. The basic principle of the European Union food contact materials and articles legislation is illustrated in a framework directive from 1976 (76/893/EEC (European Commission, 1976)), which states that "food contact materials should not transfer to foodstuffs any of their constituents in quantities that could endanger human health or cause a deterioration in the organoleptic characteristics of the foodstuff."

A second framework directive, which replaced 76/893/EEC, was published in 1989 (89/109/EEC (European Commission, 1989)) defining the basic requirements for all materials used in food contact applications and not just plastics. This directive laid the foundation for further directives, and the following year a specific directive for plastic materials was adopted (90/128/EEC (European Commission, 1990)), entitled "Plastic Materials and Articles Intended to Come into Contact with Foodstuffs." This directive was set out in two parts: a section detailing approved monomers for the production of food contact plastics, and a maximum overall migration limit of 10 mg per square decimetre of material/article or 60 mg per kilogram of foodstuff.

In its amendments additional monomers and an incomplete list of approved additives were introduced. The latest directive is a consolidated version of 90/128/EEC known as 2002/72/EC (European Commission, 2002a). However, none of these directives provide details for the testing of migration of substances into foodstuffs. These basic rules were established in separate legislation. They were outlined in Commission Directive 82/711/EEC and its amendments, 93/8/EEC and 97/48/EC (European Commission, 1982; European Commission, 1993a; European Commission, 1997). If a product complies with the compositional requirements of Directive 2002/72/EC then it can subsequently be tested for the desired condition of use. If it meets the migration requirements, then it is deemed suitable for use in applications covered by the appropriate test method.

Rather than using specific foodstuffs, the migration directives use four food simulants – water, ethanol, acetic acid and olive oil. These are listed in Commission Directive 85/572/EEC (European Commission, 1985).

Regulatory status of PVC resin

Directive 2002/72/EC (European Commission, 2002a) lists approved monomers rather than polymers; as far as PVC is concerned, vinyl chloride is referenced in Annex II, Section A of the list of permitted monomers. The reference in the directive quotes compliance to a much earlier directive, 78/142/EEC (European Commission, 1978). This latter directive is specific to PVC and states that vinyl chloride should not be detectable in foodstuffs by a specified test method, which has a detection limit of 0.01 mg/kg (10 ppb). (The concept of a "non-detectable" limit is used for very toxic monomers that ideally should not be present in the foodstuff.) Because analytical methods have finite detection limits, the detection limit of the specified method of analysis, Directive 81/432/EEC (European Commission, 1981), is set at such a low level that it ensures that any trace of the monomer that may have transferred to the foodstuff does not present a risk to the consumer's health. The specific directives for vinyl chloride, which are listed below, were issued in recognition of the toxicity of vinyl chloride.

- 78/142/EEC, 'VCM limits in materials and articles in contact with foodstuffs' (European Commission, 1978)
- 80/766/EEC, 'VCM analysis in materials and articles' (European Commission, 1980)
- 81/432/EEC, 'VCM analysis in foodstuffs' (European Commission, 1981).

All of these directives are in force to ensure that there is no harm to consumers from residual VCM transferring to foodstuffs. However, with today's modern manufacturing technology, PVC manufacturers who are producing PVC resins specifically for use in food contact applications can offer virgin polymer that meets the 1 mg/kg (1ppm) requirement set out in Directive 80/766/EEC, thereby obviating the need for the converter to test batches of packaged film for residual monomer.

Regulatory status of PVC additives

The task of European harmonisation in regulating the additives used in plastic compositions has been more onerous because of their huge number and chemical variety. For this reason, a helpful "synoptic" document was produced by the EC Scientific Committee on Food (SCF); this document has recently been updated (European Commission, 1994a). This document has no legal status, but additives listed in the document are placed in the "Incomplete Additives List" in amendments to Directive 90/128/EEC (now 2002/72/EC) after completion of evaluations by the SCF. The synoptic document only serves as a record of the status of each additive, with a summary of the SCF evaluation when completed. It continues to be a useful document listing additives that have national approval and giving prior indications of any specific migration limits (SMLs) or restrictions, which may be assigned when they are placed on the lists in the directive.

Before the recent consolidated Directive 2002/72/EC, Directive 90/128/EEC had been updated for a seventh time. From the third update onwards, this directive has included a section containing an incomplete list of approved additives. While the list remains incomplete, additives that are not listed can still be used in accordance with their existing national approvals. In addition, for certain additives, the mechanism for approval has not yet been fully decided by European legislation. These additives include aids to polymerisation such as catalysts. No pigments are currently covered by these regulations, so they must be selected from national lists that member states have produced, such as the French positive list of pigments, or from the Council of Europe Resolution on colourants.

The various amendments to 90/128/EEC are referenced at the end of the report (European Commission, 1992; European Commission, 1993b; European Commission, 1995a; European Commission, 1996; European Commission, 1999; European Commission, 2001; European Commission, 2002b). It is anticipated that it remains the Commission's objective to complete harmonisation to make available a positive list of additives by 1 January 2005.

It is important to note that some of these additives can be used without restriction provided they do not exceed an overall migration limit, whereas others, such as tin stabilisers and adipate plasticisers, have restrictions imposed on them with corresponding SMLs. Currently SMLs are based on the worst-case scenario, whereby it is assumed that a person may consume up to 1 kg daily of food in contact with the relevant food contact material. Clearly, the increasing number of additives with SMLs implies a greater extent of compliance testing to demonstrate safety.

Since these SML assumptions are rather extreme, a number of refinements have been proposed, principally by industry, in order to reduce onerous, and in some cases unnecessary, testing. These include the introduction of a fat reduction factor and a plastics use factor:

Fat reduction factor (FRF)

This refinement proposes to take into consideration the fact that not all foods are fatty, consequently there should be a reduction factor for additives that migrate predominantly into fatty foodstuffs. The current proposals are for a reduction factor of 5 for migration, to take account of the fact that 95% of the European population consumes less than 200 g fat per day and not 1 kg. Some factors already exist in legislation covered by 85/572/EEC (European Commission, 1985).

Plastics use factor (PUF)

This refinement proposes to take into account the fact that not all plastics are of the same type. Foodstuffs are wrapped in a variety of different packaging materials, such as polyethylene/polypropylene, PET, polystyrene, and others. For example, the European Plasticised PVC Film Manufacturers' Association (EPFMA) has proposed that a PUF factor could be applied to counter excessive migration testing in order to demonstrate compliance of an SML for di-2 ethylhexyl adipate (DEHA), which is used in cling film. In this example, the percentage of food that is wrapped in all flexible PVC-P food contact packaging is low and represents less than 4% of total plastics.

In the case of PVC-U, the PUF refinement could be helpful in increasing the SML for certain additives. A refinement of this type would not be new, since the US Food and Drug Administration (FDA) has taken into consideration the exposure of the population to different types of plastics and has derived "consumption factors" for each plastic in relation to the types of food with which it comes into contact. For example, the consumption factor for PVC-U is 0.1 (where PVC-U represents 10% of plastics used), and for semi-rigid and plasticised PVC, it is 0.05 (where PVC-P represents 5% of plastics used) (US FDA, 2002).

Compliance testing

In order to ease the burden of excessive compliance testing while retaining a high margin of safety, a number of initiatives have been developed on the basis of both modelling experiments and rapid extraction test methods. These are recognised by Commission Directive 2002/72/EC (European Commission, 2002a), provided that it can be demonstrated that they are a "more severe test." One example has been the modelling of the potential migration of organo-tin stabilisers from PVC-U. This work was completed as part of an Industry Consortium Migration Project undertaken by PIRA (a UK-based packaging consultant) (PIRA International, 2001). A total of six samples were submitted from industrial companies participating in the project. In all cases the actual migration of organo-tin stabilisers, using two extraction conditions, were lower than the lowest SML value for such stabilisers. This data can provide evidence to demonstrate that, provided the addition level of such stabilisers is not increased, the extraction of organo-tin stabilisers from those materials would be expected to comply with the SML.

Another development has been a rapid extraction test for PVC thermoformed articles and containers for food packaging. This was initiated between PIRA and the UK Packaging and Industrial Films Association (PIFA). The test uses olive oil as the food simulant, and the test conditions are 10 days at 40°C (Cooper, *et al.*, 1997). Results showed that the overall migration is less than 3 mg/dm^2. The rapid extraction test provides test results that are higher than those obtained from overall migration tests with food simulants and thereby complies with Commission Directive 2002/72/EC.

An example based on PVC-P from another report by PIRA (PIRA International, 2000), entitled "Evaluation of Migration of Plasticisers from Flexible PVC Materials", demonstrated that in a flexible PVC sample containing 40% by weight of the phthalate di-2-ethylhexyl phthalate (DEHP), extracted at 40oC for 10 days, there was no detectable migration either in the aqueous solutions containing 3% acetic acid or in that containing 15% ethanol. As a result of this work, it was concluded that it would be very unlikely that any proposed SML for DEHP would be exceeded in such applications.

Table 2 lists examples of the current status of some typical additives used in both PVC-U and PVC-P applications.

Table 2.

Function	**PVC Type**	**Additive Type**	**SML (mg/kg) According to 2002/72/EC**
Stabiliser	PVC-U	Organo-tin compounds	Mono octyl = 1.2 Di octyl = 0.04 Di methyl = 0.18 (SML(T) expressed as tin)
	PVC-U or P	Calcium/zinc stearates	No restriction
Impact modifier	PVC-U	Methylmethacrylate butadiene/styrene	(Polymeric additive)
Processing aid	PVC-U	Acrylate	(Polymeric additive)
Lubricant	PVC-U	Glycerol mono oleate Polyethylene wax	No restriction (Polymeric additive)
	PVC-P	Stearic acid White mineral oil	No restriction No restriction, must conform to specifications in Annex V
Plasticiser	PVC-P	Adipate Epoxidised Soya bean oil	DEHA = 18 Polymeric = 30 No restriction, must conform to specifications in Annex V

SAFETY AND TOXICOLOGY

In the long history of the use of PVC in food packaging, there have been two significant issues of concern: the use of vinyl chloride monomer and plasticiser migration from PVC-P. These concerns are described below.

Concerns about the use of vinyl chloride monomer

During the early 1970s VCM came to be suspected as a human carcinogen, and hence the potential migration of vinyl chloride monomer from PVC food packaging into food became a safety issue. Concern about this potential problem stimulated the development of robust legislation, and in particular the establishment of the three specific European directives (European Commission, 1978; European Commission, 1980; European Commission, 1981) for the limitation, measurement and detection of VCM both in the polymer and foodstuff itself. Not only did these directives establish firm safety limits, it could also be argued that they acted as one of the catalysts for the development of the huge growth in research undertaken to demonstrate the safety of all plastics used in food packaging.

Today's PVC manufacturing technology can produce resins with less than 1ppm of residual monomer content in the virgin resin. Since PVC does not depolymerise into its monomer during processing, it is relatively easy for manufacturers of the virgin polymer to demonstrate compliance with such standards, which obviates the need for the converter to test batches of packaged film for residual monomer. In addition, for thin films it eliminates the need for testing to meet the "non-detectable" migration standard, as it can be shown that total migration would be below the detection limit.

Concerns about plasticiser migration from PVC-P

Concerns have been raised about the potential migration of plasticisers from flexible PVC into foodstuffs. This concern may have been inevitable given the fact that the plasticiser is not chemically bound to the polymer. Consequently, there have probably been more studies done on the potential migration of plasticisers used in such applications than on any other single ingredient or additive. For example, a research directory of all the European studies on food packaging and migration published in 1994 lists at least 13 independent studies on the potential migration of adipates or phthalates from PVC-P (PIRA International, 1994).

The main issue concerns the potential migration of such additives into fatty foods. As a result of this work, there has been a general trend towards the use of adipates and, in particular, a combination of a polymeric adipate with di-2-ethylhexyl adipate. The toxicity of both phthalates and adipates in rats and mice has been well documented, particularly with regard to their carcinogenicity. Two evaluations were undertaken by the SCF to establish tolerable daily intakes (TDIs) for both plasticisers on the basis of toxicology studies (European Commission, 1995b). More recent research has focused on the potential for some phthalates to have adverse reproductive effects in rats and mice, although there is currently no evidence that such an effect occurs in humans. However, as a precautionary measure there remains a temporary ban on the use of six phthalates in PVC toys that can be sucked or chewed by infants (European Commission, 2002c). This ban is currently extended every 3 months. Furthermore, as part of the European directive on existing substances, several phthalates are the subject of risk assessment studies. This work will likely be published by the European Commission in 2003.

ENVIRONMENTAL ASPECTS

Of all the plastics that are used in packaging, PVC has been under the most pressure on grounds of environmental concern. While significant improvements have been made in the manufacturing processes, attention has focused on some of the additives used in PVC as well as on waste management issues. Increasingly, life cycle analyses (LCA) have been employed to compare environmental aspects of materials. A recent LCA commissioned by the UK Government compared on-shelf food display trays manufactured from both PVC and polystyrene (Entec UK Limited, 2000). The study found little difference between the two materials considering the various elements of the life cycle study. There is no discrimination against PVC in the EC Directive on Packaging and Packaging Waste (European Commission, 1994b). However, a ban was imposed on PVC in packaging in Switzerland, where the use of PVC bottles was previously prohibited. This ban was recently lifted (VGV Switzerland, 2001).

Like any other thermoplastic, PVC can be mechanically recycled, and recycling programmes have been established around Europe for both bottles and trays. Post-consumer PVC packaging waste is used in a number of applications, particularly in the building and construction industries. In these applications a product with a relatively short life can be recycled in long-term construction products, which is known as "up-cycling". Applications of this type also avoid the potential health and safety implications of recycling plastics back into food contact applications. A recent International Life Science Institute (ILSI) Report reviewed the complexities of recycling plastics for food contact use (International Life Sciences Institute, 1998).

For recycling purposes, PVC plastic packaging often contains the following internationally recognised symbol, which identifies the plastic as PVC by both the number 3 and the letters PVC or sometimes V (figure 2). This is typically found on the base of bottles, pots and containers.

Figure 2. International labelling symbol for PVC

PVC

While some PVC packaging items in the domestic waste stream are easier to recover for mechanical recycling, the other options for packaging waste include incineration and landfill. The incineration of PVC contained in municipal solid waste has been a contentious issue. Dioxins can be emitted when PVC or other chlorinated substances are incinerated unless modern pollution control and abatement systems that minimise releases of harmful emissions to the environment are used.

Another option currently in the development stage in Europe is feedstock recycling. In this technology the polymer is converted back into smaller molecules. In the case of PVC, this process leads to the generation of hydrogen chloride and an oil derivative known as "syngas." A number of pilot projects are under way around Europe to evaluate this technology. The process is being funded through a consortium of PVC-related industries, including four trade associations, under a voluntary commitment known as "Vinyl 2010" (see references).

Finally, there is the option of disposal by landfill, which is the least preferred environmental choice. The environmental fate of PVC in landfill has been extensively studied (Mersiowsky, *et al.*, 1999). In this research, degradation of the PVC polymer was not observed, although losses of plasticiser are expected to occur with PVC-P, but it is argued that since plasticiser is biodegradable, it is not considered to pose a risk to the aquatic environment.

GENERAL CONCLUSIONS

PVC packaging plays an important role in the protection of a variety of foodstuffs, from specialised tamper-proof packaging to commodity food display trays. PVC-U offers excellent barrier and organoleptic properties, whilst PVC-P is an important material for use in applications in the domestic kitchen and the supermarket.

PVC's unique range of physical properties and its good cost:performance ratio has maintained its continued use both to the retailer and consumer.

REFERENCES

Association of Plastics Manufacturers in Europe (1990). Plastics and the Environment. Fact Sheet 3

Cooper, I., Goodson, A. and Tice, P.A. (1997). PVC Thermoformed Containers for Food Packaging, Establishment of a Rapid Extraction Test for Overall Migration Compliance Testing, *Packaging Technology and Science*, **10**: 169-175.

Entec UK Limited (2000). Life Cycle assessment of Polyvinyl Chloride and Alternatives, Department of the Environment, Transport and Regions, Wetherby, UK.

European Commission (1976). Directive 76/893/EEC, O.J. L340, 9 December 1976, European Commission, Brussels, Belgium.

European Commission (1978). Directive 78/142/EEC, O.J. L44, 15 February 1978, European Commission, Brussels, Belgium.

European Commission (1980). Directive 80/766/EEC, O.J. L213, 16 August 1980, European Commission, Brussels, Belgium.

European Commission (1981). Directive 81/432/EEC, O.J. L297, 24 June 1981, European Commission, Brussels, Belgium.

European Commission (1982). Directive 82/711/EEC, O.J. L297, 18 October 1982, European Commission, Brussels, Belgium.

European Commission (1985). Directive 85/572/EEC, O.J L372, 31 December 1985, European Commission, Brussels, Belgium.

European Commission (1989). Directive 89/109/EEC, O.J. L40, 11 February 1989 (corrigenda in OJ L 347, 28 November 1989, p. 37), European Commission, Brussels, Belgium.

European Commission (1990). Directive 90/128/EEC, O.J. L75, 21 March 1990 (corrigenda in O.J. L349, 13 December 1990, p. 26), European Commission, Brussels, Belgium.

European Commission (1992). Directive 92/39/EEC (1st amendment to Directive 90/128/EEC), O.J. L 168, 23 June 1992, European Commission, Brussels, Belgium.

European Commission (1993a). Directive 93/8/EEC, O.J. L90, 14 April 1993, European Commission, Brussels, Belgium.

European Commission (1993b). Directive 93/9/EEC (2nd amendment to Directive 90/128/EEC), O.J. L 90, 14 April 1993, European Commission, Brussels, Belgium.

European Commission (1994a). Draft of provisional list of monomers and additives used in the manufacture of plastics and coatings intended to come into contact with foodstuffs, Synoptic Document No. 7 CS/PM/2536, 15 May 1994. 2002 updated version on http://cpf.jrc.it/webpack

European Commission (1994b). Directive 94/62/EC on packaging and packaging waste, O.J. L 365, 20 December 1994, European Commission, Brussels, Belgium.

European Commission (1995a). Directive 95/3/EC (3rd amendment to Directive 90/128/EEC), O.J. L 41, 14 Feb 1995, European Commission, Brussels, Belgium.

European Commission (1995b). Report CS/PM/2552, Compilation of New Documents of the Scientific Committee for Food, 3 April 1995, European Commission, Brussels, Belgium.

European Commission (1996). Directive 96/11/EC (4th amendment to Directive 90/128/EEC), O.J. L 61, 12 March 1996, European Commission, Brussels, Belgium.

European Commission (1997). Directive 97/48/EC, O.J. L222, 12 August 1997, European Commission, Brussels, Belgium.

European Commission Directive (1999). 1999/91/EC (5th amendment to Directive 90/128/EEC), O.J. L 310, 4 Dec 1999, European Commission, Brussels, Belgium.

European Commission (2001). Directive 2001/62/EC (6th amendment to Directive 90/128/EEC), O.J. L221, 17 Aug 2001, European Commission, Brussels, Belgium.

European Commission (2002a). Directive 2002/72/EC, O.J. L220, 15 August 2002, European Commission, Brussels, Belgium.

European Commission (2002b). Directive 2002/17/EC (7th amendment to Directive 90/128/EEC), O.J. L58, 28 Feb 2002, European Commission, Brussels, Belgium.

European Commission (2002c). Decision 2002/910/EC prohibiting for the 12th time toys and childcare articles made of soft PVC containing certain phthalates, O.J. L315/21, 18th November 2002, European Commission, Brussels, Belgium.

Freedonia Group Inc (1998). High Performance Plastics, Issue: February, Freedonia Group Inc, Cleveland, USA.

International Life Sciences Institute (European Branch) (1998). Recycling of Plastics For Food Contact Use, ILSI Press, Washington, D.C., USA.

Mersiowsky, I. et. al. (1999). Long-term behaviour of PVC products under soil-buried and landfill conditions, PVC'99 Conference Proceedings 20-22nd April, pp.132-141, Institute of Materials, London, UK.

PIRA International (1994). European food packaging and migration research directory, ISBN 1 85802 069 7.

PIRA International (2000). PVC-Thermoformed Migration Project Phase VI, Evaluation of migration of plasticisers from flexible PVC materials, PIRA Research Report.

PIRA International (2001). PVC-Thermoformed Migration Project Phase VIII, Generation of data for verification of mathematical modelling for PET/PEN/PVC, PIRA Research Report M543.

US FDA (2002). Guidance for Industry – Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations – Final Guidance April 2002, (http://www.cfsan.fda.gov/~dms/opa2pmnc).

VGV Switzerland (2001). Ordinance of 5th July 2000 on Beverage Containers, effective January 1st 2001.

Vinyl 2010 Industry Voluntary Commitment, http://www.vinyl2010.org/

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