1
Preservation of Quality Through Packaging

Albert Baner and Otto Piringer

Plastics are defined as processable materials based on polymers. These materials can be transformed into finished products, such as bottles, containers, films, hoses, coatings, lacquers, etc. As a result of today's multitude of plastic applications there is a corresponding enormous variety of plastic materials. The polymer matrix as well as the incorporated plastic additives can be made to differ in such a variety of ways with respect to their chemical composition and structure that one finds or can develop a tailor made product for every application.

Packaging is one major field of application for plastic materials. The development of self-service stores with their large variety of products is unimaginable without plastics. The most important function of a packaging material is the quality preservation of the packed goods. Among these goods, foods hold a place of special importance due to their principal chemical instability. This instability is also the characteristic for other products containing active substances, in particular pharmaceuticals.

In order to fulfill the task of quality assurance of the packed product with minimal impact both on the product and on the environment, the packaging must be optimized by taking into consideration various criteria. This book provides assistance in package optimization functions. Special emphasis is given for mass transport between plastic materials and packed goods and the consequences of such interaction for quality assurance and legislation.

1.1
Quality and Shelf-Life

Products being offered on the market can, thanks to the currently available manufacturing and preservation methods as well as the various transportation modes, come from all regions of the country, continent and other continents together.

Many products consist of numerous ingredients which have a relatively low chemical stability. Such labile goods are exposed to numerous spoilage possibilities and one of the most important factors leading to longer shelf-lives is their packaging.

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In order to describe what a product shelf-life is or what it means in terms of quality retention and measurement, the word "quality" must be defined. Whatever from a legal standpoint in different countries is used as definition, the quality (Q) determining properties of a product are in principle based on the product's components. Thus Q can be described as a function of the chemical composition of the product:

$$Q = f(c_1, c_2, \ldots, c_i, \ldots, c_n) \tag{1.1}$$

Let c_i designate the concentration of a specific component i in the product and n the number of different components. If Q_i is defined as a function of the concentration of component i, then the change in quality ΔQ_i over the time interval Δt becomes a function of the concentration change Δc_i in this time interval. In this case it is not necessary to know the change in concentration of all n ingredients and their change with time. If for example the change in concentration with time of ingredient i can be measured, then maybe this variation can be correlated with a quality change (Figure 1.1). Even though at constant concentrations (curve 1) there is no quality change taking place with respect to i, an increase in concentration (curve 2), for example resulting from mass transport of a plastic component into the product, leads to quality loss. There are of course cases where an increase in ingredient concentration during storage can lead to improvement in quality, for example, during the ripening processes of cheeses or alcoholic beverages. A reduction in quality also takes place through the loss of an ingredient (curve 3), for example diffusion of aromatic compounds through the packaging and into the atmosphere.

For various product ingredients or undesirable foreign substances, limits can be assigned (shaded field in Figure 1.1) outside which a significant quality reduction can occur compared to the initial quality. The importance of individual ingredients for product quality can vary considerably and therefore also the width of the allowable concentration. The importance and allowable concentration range are determined by the component's chemical structure.

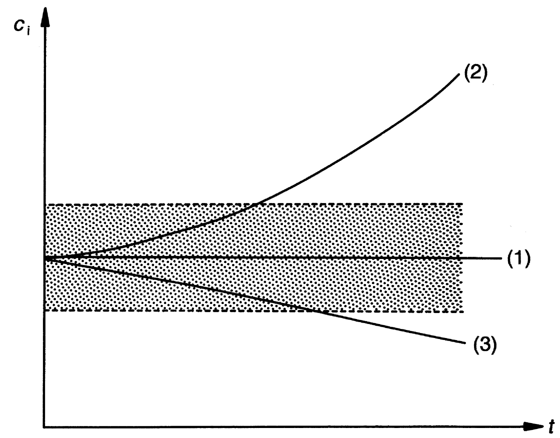

Figure 1.1 Concentration variation with time of food ingredients.

Quality preservation through packaging means therefore to maintain as long as possible a particular concentration c_i within a certain value range. The time interval within which the product quality remains completely unchanged can be very short. It is therefore more important in practice to define the shelf-life over a time interval up until the limit where the most important product quality characteristics just still remain. This means, amongst other things, that during this time in the product neither undesirable compounds that have health significance nor odor or taste is allowed to occur. This requirement has two important consequences: first, the necessity of an objective quality evaluation for changes in quality and second, the adaptation of packaging to this requirement resulting from the product shelf-life. The solution of both problems has to meet the legal requirements.

The quality requirements as well as requirements derived from them are subject to change over time. Besides objective criteria that result from technical advances there are also subjective, political, and media generated emotional criteria that also play important roles.

One goal of the present technological development is the production of food that still possesses as many quality attributes of the raw materials as possible. This leads to products which may still contain many naturally occurring, chemically unstable materials that are preserved by gentle processing methods. These types of product require a much higher initial quality compared to other foods manufactured or treated under harsher processing conditions. One consequence is that it is possible to have a more rapid quality decrease for the product with high initial value (1) than for the product with lower initial quality (2), both having ideal packaging (Figure 1.2). Q_{min} designates the minimal acceptable quality where sufficient or adequate product-specific characteristics are still maintained.

Unpackaged products show a faster time-related quality decrease (left sides of the hatched triangles) than ideally packaged products (right sides of triangles). The area

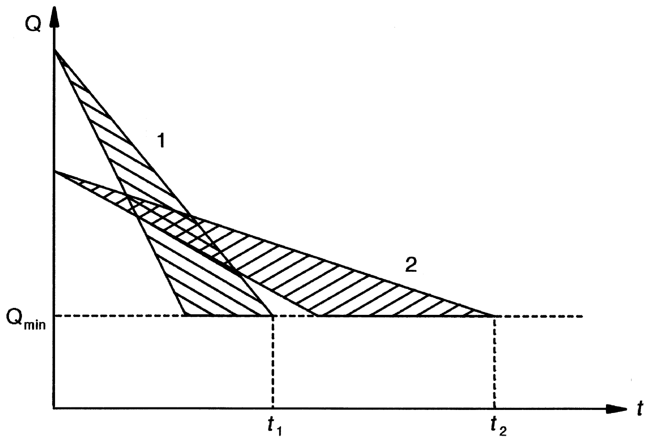

Figure 1.2 Quality loss over time of two foods (1 and 2) each having different initial quality. The left straight line shows the unpackaged and the right one an ideally packaged condition.

that can be influenced by packaging lies inside the hatched field for a given product. The straight line representation is a simplification because quality losses do not necessarily have to be linear. The conclusions are thus in some cases foods having high initial quality but shorter shelf-life can use lower quality packaging than products with lower initial quality and longer shelf-lives.

The shelf-life of milk is given here as an example. For the 6- to 7-day stability of high quality fresh pasteurized milk a relatively simple polyethylene coated carton package is satisfactory. However, the much longer stability of a lower quality aseptic milk requires a sophisticated package that includes for example an additional barrier layer.

There are of course areas in which a very long shelf-life is preferred over a high initial quality product. Examples of this are the establishment and maintenance of emergency reserves and the supplying of remote regions, some of which having high temperatures. The packaging requirements for these cases are particularly high. In general however, the trend today arising from higher product quality consciousness is away from product "mummification" and toward "fresh" appealing goods.

1.2
Physical and Chemical Interactions Between Plastics and Food or Pharmaceuticals

If one has knowledge of specific sensitivities of a food or the properties of another product, one can derive the necessary packaging requirements. The most essential requirement today compared to previous requirements is the simultaneous optimization with respect to several criteria. For example, these optimization criteria could include a protective function, material and energy expenditures during manufacture, as well as disposability and other environmental considerations. Such optimization is always a compromise between different solutions which can lead to the appearance of new problems. With reference to several criteria, optimization generally means the reduction of safety margins in reference to a certain criterion. Fulfilling for example the criterion of packaging minimization, the permeability is increased to the allowable maximum, that may mean that exceeding or falling short of a packaging specification value by even a small amount might lead to a significant change in the quality of a packaged product.

In future package development, optimization from an ecological viewpoint will play an especially important role and minimization of packaging will help make this possible. One should never forget however that quality assurance of the packaged product and therefore the guarantee of consumer safety will always have priority and must remain the most important criterion for optimization. The fulfillment of these requirements assumes complete knowledge of possible interactions between packaging and product during their contact time. In this respect the properties of both parts of package, the packaging material and the product, must be coordinated with one another. Here possible interactions between the two parts play an important role in the quality assurance of the product.

The term interaction encompasses the sum of all mass transports from the package into the product as well as mass transport in the opposite direction (Figure 1.3). The

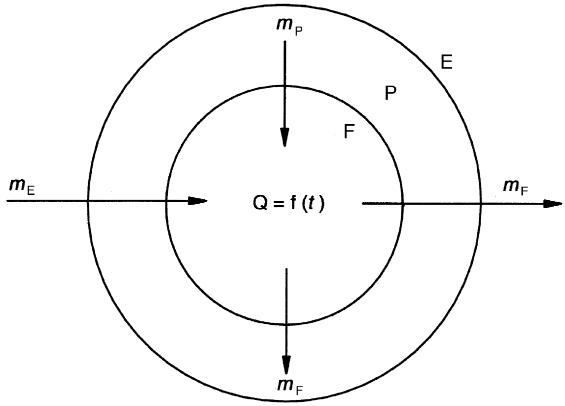

Figure 1.3 Mass transports in the packaged food. m_E and m_P represent the mass transport from the environment E of the package P and from P into the food F. m_F represents the mass transfer from F into P and E.

mass transfers, often coupled with chemical reactions, lead to quality, *Q*, changes in the product and packaging material.

Mass transport is understood to mean the molecular diffusion in, out and through plastic materials like that shown schematically in Figure 1.3. This figure represents most applications where there is a layer of plastic material separating an external environmental medium from an inner product medium. The product can be a sensitive medium with a complex chemical composition, e.g., food, that must be protected from external influences such as oxygen and contaminants. It can also be an aggressive chemical that must not escape into the surrounding environment. Because this plastic material barrier layer usually includes low molecular weight substances incorporated into the polymer matrix, there are many applications in which the transport of these substances into the product and environment must be minimized.

The mass transport of package components to the product is known as migration, and the mass transport of product components to the package is known as scalping. Permeation means the mass transport of components through the package in both directions.

1.3
The Organization of this Book

Chapter 2

The goal of Chapter 2 is to draw the attention of the reader to the enormous variety of plastic materials which results from their different chemical structures, synthetic routes, and contents of additives. The permeability of plastics to low molecular compounds is often uniquely obtained via specific processing routes. In order to select the appropriate material for specific applications some knowledge about the chemical composition, structure, and corresponding properties of the plastics is necessary. Knowledge of composition is also an indispensable requirement for successful search of potential migrants from plastic materials into a product with the aim of its quality assurance. The many chemical compounds mentioned in this chapter may help to identify an analytically separated compound as a rest monomer, oligomer, degradation product, or impurity of the investigated plastic.

From a short overview of the principal manufacturing procedures, the raw materials and processing aids, much useful information can be obtained especially concerning the permeability (functional barrier properties) of the plastic and potential migrants having relevant toxicological or sensorial properties.

Despite the enormous number of potential starting substances in practice only a finite number of basic polymeric structures with well-defined interaction and transport processes form the majority of practical applications. This is of great help for making theoretical estimations of transport properties. Nevertheless, it must not be forgotten that even for well-defined basic structures, e.g. polyethylene, there are hundreds of grades of polyethylenes available which differ more or less in their composition and structure. As a consequence the transport properties (diffusion coefficients of low molecular components) tend to scatter around an average value even for a well-defined plastic material over a more or less wide range, as can be seen from the values listed in Appendix I. This means one can predict transport processes and partition behaviors of such materials only within a limited range of precision. But this precision improves rapidly as more details about the composition and structure of the materials are known.

Chapter 3

The characteristic functions and the representative structures of plastic additives used to make marketable and durable materials are included in this chapter. In comparison to the polymeric matrix, the additives are in general low molecular compounds and the stabilizers in particular are much more reactive than polymers.

Due to the high reactivity of the important category of stabilizers, many reactions can occur in the polymeric matrix. As a result a variety of degradation products appear, a fraction of which are able to migrate into the product in contact with plastic while a fraction can remain immobilized in the polymer matrix. Both the chemical nature of the degradation products and their concentrations are of great importance for the quality assurance of the product in contact with plastic. Estimation of migration of the additives themselves or their degradation products is possible only if the mass balance of these products can be predicted or measured and their chemical nature known.

The formation of various transformation products from the stabilizers cannot be avoided. The sacrificial fate of stabilizers is part of their activity mechanism which is providing protection to plastics against degradation. In elucidating transport phenomena in commodity polymers, the presence of combinations of stabilizers along with varying amounts of their transformation products with sometimes very different molecular parameters, has to be taken into account.

Chapter 4

One of the two fundamental material constants which govern the mass transfer of a compound between two contacting phases, e.g., a plastic P in the liquid L or gas G, is the partition coefficient of the compound between the two phases. This chapter deals with the thermodynamic basis fundamentals of partition and some of the methods that can be used to estimate its magnitude.

Different estimation methods based on additive molecular properties are described. The oldest and best known treatment is based on the so-called regular solution theory. This method although widely used qualitatively has a very limited application range for quantitative calculations. Methods for estimating partitioning of almost any chemical structure based on structural increments (group contributions) are commonly used in chemical engineering. UNIFAC, one of the oldest and most comprehensive methods that can be used for polymers, is presented here as a typical example. Due in part to the extremely large variation range of partition values extending over many orders of magnitude, the precision of estimation with the UNIFAC method is in general within one order of magnitude which is sufficient for most practical applications. A serious drawback of the method is its rather complicated handling requiring programmable calculators or computer programs.

Estimation using quantitative structure activity relationship (QSAR) and quantitative structure property relationship (QSPR) is a field of computational chemistry.

In order to offer a simple procedure for practical applications an additional new method, the vapor-pressure-index (VPI) estimation method, is introduced. This method is easy to use and with the linear relationships and data from Appendices II and III the partition coefficients, especially between ethanol/water mixtures and polyolefins, can be estimated with reasonable agreement with experimental values.

Chapter 5

In addition to the partition coefficients discussed in the preceding chapter, the second fundamental material constant which governs the mass transfer of a compound i from a plastic P into a liquid L or gas G is the diffusion coefficient $D_{P,i}$ of i in the matrix of P. A brief review of the most frequently cited and used models for diffusion in polymers is presented in this chapter. The chapter discusses some "classical" approaches for analyzing and quantifying diffusion processes in polymers. It is pointed out that although some of these models can lead to quite remarkable agreements between theory and experiment, none of them is a truly predictive diffusion model.

A review is given of the more recent computational approaches describing the process of diffusion in polymers and the $D_{P,i}$ values estimated from them. These approaches have a true *ab initio* predictive character. At the same time these models are not yet capable of estimating diffusion coefficients for the complex polymer–migrant systems usually found in food packaging applications.

Chapter 6

An original deduction of an equation for diffusion coefficients of substances in plastic materials is presented in this chapter. The development uses a uniform model which is applicable to all aggregation states. One goal of this chapter is to demonstrate the reasonable agreement between calculated and measured diffusion coefficients in gases, liquids, and solids, with special emphasis of plastics. The model is based on assumptions about interaction of the molecules in a macroscopic system, starting in its critical state. The only needed parameters for estimations are the critical temperature, critical volume, and critical pressure of the compounds involved, as well as the glass and melting temperatures and molecular weights of the plastic matrices.

Chapter 7

The starting point for a mathematical treatment of all specific cases of interactions between packaging and product is a general mass transport equation. This partial differential equation has analytical solutions only for special cases. For solutions involving complicated cases, simplifying approximations are used or numerical solutions are carried out.

In order to understand the literature on this subject it is necessary to know how the most important solutions are arrived at, so that the different assumptions affecting the derivation of the solutions can be critically evaluated.

The selection of different equation solutions included here are diffusion from films or sheets (hollow bodies) into liquids and solids as well as diffusion in the reverse direction, diffusion controlled evaporation from a surface, influence of barrier layers and diffusion through laminates, influence of swelling and heterogeneity of packaging materials, coupling of diffusion and chemical reactions in filled products as well as permeation through packaging.

Despite the large number of analytical solutions available for the diffusion equation, their usefulness is restricted to simple geometries and constant diffusion coefficients. However, there are many cases of practical interest where the simplifying assumptions are introduced when deriving analytical solutions are unacceptable. This chapter also gives an overview of the most powerful numerical methods used at present for solutions of the diffusion equation.

Chapter 8

The principles of a numerical method to solve the diffusion equation for a monolayer packaging in contact with a liquid F are presented in Section 7.2. In the following this topic will be extended to the one-dimensional (1D) diffusion problem for multilayer (ML) materials in contact with various types of foods. In this respect a brief presentation of the main numerical approaches developed to solve this mass transfer problem will be made. Then the presentation will be focused on a numerical method developed to solve the transport equations for a ML packaging in contact with any type of homogenous foodstuffs, F. This method is based on a finite difference technique and was developed in 1D for the general case in which the transport processes are controlled not only by the diffusion coefficients (D_i) in the packaging and foodstuff (D_F) but also by partition coefficients (K_{ij}) between any two adjacent layers i and j of the packaging as well as partition coefficients between the packaging and foodstuff (K_{pf}). The numerical algorithms of this FD method were then implemented into a computer program which can be run on a regular PC. A major concern with this computer program was to check if it produces correct results. For this a series of test were designed/conducted and the results are presented.

Chapter 9

The application of the methods described in Chapters 7 and 8 in practice needs the use of adequate computer programs (software). Two user-friendly programs developed by FABES GmbH are described in this chapter.

The aim in developing MIGRATEST©Lite was to provide to a large spectrum of potential users from industry and research and development as well as from the enforcement laboratories a user-friendly tool for a quick and easy estimation of migration of substances from plastic (polymeric) films into foods and food simulants. A special emphasis was to conceive the software in such a manner to include the actual aspects and data from the EU documents related to migration regulation.

The second program for migration estimations is MIGRATEST© *EXP*. This user-friendly software is based on a numerical solution of the differential migration equation as described in Chapter 8. A series of examples from practice are described together with the principal operation steps. This program is especially adapted for multilayer plastics in contact with liquid, highly viscous and solid products.

Chapter 10

Sensitive foods and encapsulated technical products are generally sensitive to their surroundings, in particular to oxygen and water vapor. As the permeabilities of favorably priced commodity polymers (for food packaging) and also more expensive specialty polymers (for encapsulation of technical devices) to water vapor, oxygen, and other substances are far too high for most applications, a thorough understanding of the permeation processes is essential. To improve the barrier properties of single polymers, the following strategies are pursued: production of polymeric multilayered structures under inclusion of barrier polymers, multilayered structures which incorporate one, sometimes even several inorganic layers and hybrid structures where polymeric matrices are filled with inorganic particles.

For purely polymeric monolayer and multilayer structures, the permeation process can be represented mathematically via the one-dimensional form of the related transport equations.

In the case of nontrivially shaped inorganic particles, single or multiple thin inorganic layers and even thicker inorganic foils, all of them embedded in polymeric matrices, the whole three-dimensional geometry of the samples has to be taken into account on the microscopic scale: for particles incorporated in polymers, their size, shape and orientation have to be regarded. For inorganic layers, numbers of inevitable defects and their size distribution play the decisive role.

All these parameters can be combined to specific geometry factors, which, in combination with the coefficients of diffusion and solution of the polymeric matrix or of the polymeric substrate film and optional further polymeric top layers, determine the final permeation properties. This concept has been verified in many different cases, mostly for oxygen as the permeating substance.

An exception from this concept occurs when the permeation of condensable substances such as water vapor or flavors is involved. In such cases, much higher values of permeability are often observed than to be expected from the considerations mentioned above. It is to be expected – although it has still not been proven unambiguously – that substances may condense in inorganic structures, leading to much higher local concentrations and thus to a higher permeability.

In most technically relevant cases, however, especially in the case of the favored polymeric multilayers, the concept described in this chapter gives a sufficiently accurate quantitative description of the transport phenomena.

Chapter 11

This chapter provides a critical review of modern food packaging migration testing by addressing both the test requirements and their availability and the practicality of different migration assessment schemes and analytical methods. In order to enable the reader to select and tailor his own specific migration test approach the first section of Chapter 11 starts with an introduction to the principles of migration testing and the primary factors controlling migration processes. After that an efficient schematic for food law compliance testing is presented covering modern indirect, semidirect, and direct migration tests. A major focus in the second section is given to the analytical aspects of specific migration testing. After discussion of the general requirements for analysis methods, detailed and practical guidance is given on how to develop, validate, and document analytical methods that are suitable for compliance testing that fulfills food contact material legal requirements. An overview of existing methods currently used in Europe provides the necessary information to complete this topic. Additionally, practical examples of specific migration test methods are given along with their related difficulties and specific problems.

An important aspect discussed in this chapter is the recent results obtained with an EU project concerning migration into food.

Chapter 12

During the past decade regulatory processes in the United States have changed significantly with regard to components of food contact materials, allowing industry a variety of options for obtaining authorization for their safe use. A thorough understanding of the US regulatory processes for the substances, presently referred to as food contact substances (FCS), allows industry to determine the most appropriate regulatory option based on the intended use. In this chapter the US

Food and Drug Administration's (FDA) regulatory authority and premarket safety evaluation of FCS is discussed.

FDA's safety assessment relies on evaluating probable consumer exposure to an FCS, including all constituents or impurities, as a result of the proposed use and other authorized uses, and ensuring that such exposures are supported by the available toxicological information. A general discussion of the recommended chemistry, toxicology, and environmental information for a submission relating to an FCS follows.

FDA's approach to the safety assessment of the substances is exposure driven, in that it is specific to the intended use and the resultant dietary exposure, which determines the amount of toxicological data consistent with the tiered requirements.

Chapter 13

In order to harmonize the legislation in the European Community a broad program of action started in 1972. The Community legislation has established rules for the most complex and important area of packaging, that of plastic materials. The Commission of the Community is currently preparing a series of texts which should make it possible for legislation on plastics to be fully harmonized at the Community level by the year 2010.

This chapter describes the main aspects of current Community legislation on materials and articles intended to come into contact with foodstuffs.

Chapter 14

Off-flavors represent one of the major quality issues in the food industry and can result in significant economic damage to a company. Even if they may not represent any health risk, they can seriously damage the quality image of a brand, and the confidence that the consumer has in it. By law, for example in the European Union as well in the United States, packaging materials or substances transferring from the package to the foodstuff are not allowed to impart unacceptable changes to the organoleptic characteristics of the packed foodstuffs.

This chapter focuses on the off-flavors which are associated with packaging materials. Because of the number of raw materials, additives, adhesives, inks, solvents, and other chemicals used in the food packaging industry, and the number of suppliers/converters implicated in the manufacture of finished printed materials, many different sources of contamination are possible. The origin of the problems can be divided into three main categories: migration of odorous substances from package to food and to package headspace; inadequate protection of food from environmental influences; reaction of substances in packaging material with each other or with food components.

Sensory evaluation remains the most widely used method to assess the sensory quality of packaging materials. It represents the starting point in off-flavor investigations.

Sensory analysis is also a starting point for subsequent analytical work to identify the cause of the off-flavor and for taking corrective action. Since many different types of off-flavor contamination exist, specific and accurate descriptors are needed to characterize the problem with precision at an early stage of the off-flavor investigation.

Chapter 15

Worldwide investigations over the last 50 years have demonstrated that interactions between plastics and foodstuffs or other products occur as foreseeable physical processes. Standardization of migration measurements is based on this knowledge. However, the variety of substances occurring in interaction processes and the necessary time and cost requirements to carry out all the analysis for a complete quality assurance for consumer safety necessitate additional tools in order to fulfill this task. Such a tool is a recently finished EU Project for evaluation of migration models in support of Directive 2002/72/EC.

Beyond the characterization of the polymer and food (simulant), the key input parameters for the use of a migration model are the diffusion coefficient, D_P, of the migrant in the plastic material P, as well as the partition coefficient, $K_{P/L}$, of the migrant between P and the product (e.g. food, liquid) L. As already shown in Chapter 6 a considerable improved estimation of diffusion coefficients is now possible.

An improved estimation method for partition coefficients described in Chapter 4 has been found especially useful for migration modeling of additives from plastics into various products. The use of certain solvents as food simulants for controlling migration from plastics is widely practiced and allowed by food regulations. Nevertheless, there is a real danger in some cases when the food simulant has a significantly lower migration value compared to the food. Finding the correct food simulant is of great practical importance. In principle, ethanol/water mixtures are very appropriate for this application.

Possibilities and limitations of the actual knowledge in these fields are discussed.

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