SÚTN	**Vplyv materiálov používaných pri úprave vody na pitnú vodu. Vplyv spôsobený migráciou. Prognóza migrácie z organických materiálov pomocou matematického modelovania.**	**TNI CEN/TR 16364** 75 8720

Influence of materials on water intended for human consumption - Influence due to migration - Prediction of migration from organic materials using mathematical modelling

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Influence of materials on water intended for human consumption - Influence due to migration - Prediction of migration from organic materials using mathematical modelling

Influence des matériaux sur l'eau destinée à la consommation humaine - Influence de la migration - Utilisation de modèles mathématiques pour prévoir la migration depuis des matériaux organiques

Einfluss von Materialien auf Wasser für den menschlichen Gebrauch - Einfluss infolge der Migration - Abschätzung der Migration aus organischen Materialien mittels mathematischer Modellierung

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (CEN/TR 16364:2012) has been prepared by Technical Committee CEN/TC 164 "Water supply", the secretariat of which is held by AFNOR.

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Introduction

During the last two decades, several scientific investigations have demonstrated that migration from organic materials into liquid simulants is a physical process that can be modelled successfully. Mass transfer from an organic material into a liquid simulant is predictable because in many cases it follows Fick´s law of diffusion, i.e. the diffusion process is the rate determining step. To predict migration from organic materials into contacting media a corresponding diffusion model was established.

This Technical Report describes the application of predictive diffusion modelling to the estimation of the migration of a substance from a product intended for contact with water intended for human consumption – for convenience, and where appropriate, referred to as drinking water in this report. The application applies to organic materials, such as polymers, used to make such products.

The purpose of the report is to stimulate the use of such techniques in member states such that sufficient experience is generated to enable the value of such modelling to be assessed in relation to complementing or substituting the conventional approach.

Normally in member states the estimation of such migration is performed by standardised procedures based on laboratory testing and analysis, i.e. an experimental approach. Migration modelling is an alternative to this type of experimental testing. The experimental determination of the specific migration of substances into test water (simulated drinking water) often requires a considerable amount of time and it can be costly. This conventional approach has worked well and, of course, it generates data on the actual concentration of a substance in test water. However, in some cases the analysis is difficult or even impossible due to problems caused, for example, by chemical degradation, volatilisation of the substance. In addition, the substance may not be amenable to, or the target concentration of interest may be too low for, available analytical techniques Therefore, the application of a mathematical model could have considerable benefits for industry and regulators, as experience has shown in the control of migration from plastic materials in contact with foodstuffs.

Thus, the modelling approach is attractive because, in principle, it is quicker and more flexible than the conventional testing approach, in that different exposure conditions can be readily investigated - and it should be cheaper.

Modelling of migration has been used for several years in the United States as an additional tool in support of regulatory decisions. Also, the European Union has introduced such diffusion modelling by means of EU Directive 2001/62/EC (the 6th amendment of Directive 90/128/EEC), consolidated in Directive 2002/72/EC as a compliance and quality assurance tool for plastic materials intended to come in contact with foodstuff [3].

The European project SMT-CT98-7513, *Evaluation of Migration Models in Support of Directive 90/128/EEC*, successfully demonstrated the practical value of such diffusion models. The main objectives of this project were to demonstrate:

— the validity of migration models for compliance purposes;

— that a relationship between the specific migration limit (SML) and the concentration of a substance in the finished product can be established.

A report of this project has been finalised and the project results were published in a scientific journal [4]. As indicated above, a major advantage of migration modelling is that it enables calculation of migration values independent of the limitations that affect the experimental/analytical approach. For example, at low cost one can quickly investigate, for compliance or research purposes, a wide range of conditions of contact between material with test water.

The diffusion modelling approach described was originally developed for, and accepted by, the European Commission in the area of plastic materials in contact with foodstuffs. It has been successfully used to simulate the conventional experimental/analytical approach to compliance testing of plastics in contact with foodstuffs. In this latter approach different liquid food simulants, including aqueous simulants, are used.

In principle, the approach is applicable to many organic materials. However, today it has been applied mainly to different types of polyethene, polypropene, polystyrene and polyvinyl chloride.

Like the experimental approach, the mathematical approach has its limitations. An accurate prediction of the migration of a substance from an organic material to water requires detailed knowledge of the diffusion behaviour of the materials and substances under investigation. The level of information may well require extensive experimental studies – more than the experimental, analytical approach would require. An important feature of the mathematical approach is the possibility of generalisation. Based on known average diffusion behaviour of polymers and substances, a maximum or 'upper-limit' migration can be calculated. This so-called 'worst-case' result may then be used for compliance purposes.

1 Scope

This Technical Report describes a procedure, based on a diffusion model, to be applied to the estimation of specific migration of substances into drinking water from organic materials intended to come into contact with drinking water.

The modelling approach is readily applicable to certain organic materials, as explained in this report. In principle, the diffusion modelling approach is applicable to other organic materials but practical difficulties, in relation to obtaining data to feed into the diffusion model, may restrict or prevent its application. Accordingly, in addition to the diffusion model, scientific estimation procedures for the required data inputs need to be considered.

The approach is normally applicable to organic substances that are soluble in the material matrix. Substances applied externally to a product made of an organic material, e.g. antistatic agents, lubricants, etc. are excluded from the diffusion modelling approach, as are electrolytes, salts, oxides and metals. Only organic substances with well-defined molecular weight or mixtures with well-defined ranges of molecular weights are amenable to the diffusion modelling approach.

The diffusion modelling approach is readily applicable to amenable organic materials in the form of a pipe or a sheet, where data such as material thickness is readily calculable. More complicated product shapes, such as fittings, require assumptions to be made.

It may not be possible to model the effects of test waters that are chemically active, for example test waters to which chlorine has been added to simulate chlorinated drinking water. This is because substances that migrate from a material into water containing chlorine can be converted by chemical reaction into substances with different properties.

2 Normative references

Not applicable.