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**VALIDATION AND INTERPRETATION OF
ANALYTICAL METHODS, MIGRATION
TESTING AND ANALYTICAL DATA FOR
MATERIALS AND ARTICLES IN CONTACT
WITH FOOD - PART 1: GENERAL
CONSIDERATIONS**

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TECHNICAL REPORT
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English Version

Validation and interpretation of analytical methods, migration testing and analytical data for materials and articles in contact with food - Part 1: General considerations

Validation et interprétation des méthodes d'analyse, essais de migrations et données analytiques des matériaux et objets en contact avec les denrées alimentaires - Partie 1 : Considérations générales

Validierung und Interpretation analytischer Verfahren, Migrationsprüfung und analytischer Daten von Werkstoffen und Bedarfsgegenständen in Kontakt mit Lebensmitteln - Teil 1: Allgemeine Betrachtungen

This Technical Report was approved by CEN on 16 January 2006. It has been drawn up by the Technical Committee CEN/TC 194.

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Foreword

This document (CEN/TR 15356-1:2006) has been prepared by CEN /TC 194, "Utensils in contact with food", the secretariat of which is held by BSI.

CEN/TR 15356-1:2006 (E)

Introduction

0.1 Requirement for validation of analytical methods for enforcement of Directives

Regulation (EC) No. 1935/2004^[1] has laid down the requirements that may be included in specific Directives to protect human health. It allows for specific Directives to set overall migration limits and specific limits on the migration of certain constituents or groups of constituents into foodstuffs.

Commission Directive 90/128/EEC^[2] and its subsequent amendments (e.g.^[3]) introduced specific migration limits for more than 300 substances. A consolidation of these directives has since been issued as Commission Directive 2002/72/EC^[4]. In addition, some substances are subject to a maximum permitted quantity of the residual substance in the material or article. Some substances are subject to group limits. Continuously, additional substances are being evaluated and added to the Directive.

New technical dossiers are being prepared for substances which could eventually be listed in future amendments to Directive 2002/72/EC. Methods of control will be required for the majority of the abovementioned substances.

The two Food Control Directives (European Council Directive 89/397/EEC^[5] and Council Directive 93/99/EEC^[6]) require that methods used for control purposes must be correctly and fully validated. So far only the methods developed by CEN as parts of EN 13130 have been so validated. Methods developed in the project sponsored by DG Research (SM&T project, MAT1-CT92-0006, "Development of Methods of Analysis for Monomers") have only been validated by two competent laboratories. Most methods from technical dossiers have only limited validation data at best.

This Technical Report considers the background to whether or not acceptable validation of analytical methods could be achieved faster and at less cost. The Technical Report also considers the need for validation of the whole test procedure for enforcement purposes, for compliance purposes, and for the creation of data for risk assessment purposes. It should be noted that the considerations apply to both overall as well as specific migration.

The list of current legislation currently adopted by the Commission is given in Annex A.

The list of current methods adopted by CEN/TC 194/SC 1 is given in Annex B.

0.2 Variability in the migration contact stage

The determination of migration from plastics is quite unlike other measurement tasks in ensuring food safety and quality. Reliable measurements depend upon more than simply having validated analytical methods for measuring chemical concentrations in foods. The Directives allows that, as an alternative to the analysis of foodstuff itself, migration testing can be carried out with food simulants applied under conditions which simulate actual use of the plastic material or article with food. This introduces many potential sources of variability in the final migration value. These are discussed in Clause 8.

0.3 Quality of data submitted for risk assessment purposes

Migration data is usually an important part of the petition submitted for a risk assessment carried out by the Scientific Committee on Food (since 2003, by the European Food Safety Authority, EFSA). For new substances it is unlikely that a fully validated method in food simulants will exist. A single laboratory (in-house) system of validation is required as part of the demonstration that the data submitted is of adequate quality. For example, validation of a method's intended use, the determination of accuracy and precision, usually involves replicate analyses of appropriate matrices

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