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# Measurement of the migration of low-molecular substances from food packaging

*Werner Zillger*

*LABC-Labortechnik*

Food packaging protects contents such as perishable goods. It carries information, both for the consumer and the entire supply chain down to the retail business. Many foods cannot be stored and thus marketed without suitable packaging. Consumers first see the packaging on the supermarket shelf. The incentive to buy the product increases with packaging quality. Packaging materials include plastic, cardboard/paper/carton, aluminium, tin plate, glass and composite film.

Packaging with direct contact for foods is governed in Germany by the Foods, Consumer Goods and Feedstuffs Code, § 31, Section 1 (Date of document 07/24/2009, last amended on 08/03/2012): "It is prohibited to use objects as consumer goods or to market them for such purposes so that substances emanate from them to foods or their surfaces, except for portions that are harmless in terms of health, odour and taste, which are technically unavoidable."

In the EU the requirements of the Plastics Directive 2002/72/EEC apply which regulates the use of plastic materials for food packaging, EU Regulation 1935/2004, which constitutes the basis of the EU regulation on materials and articles of food packaging, EU directive 2023/2006 for good manufacturing practice of materials and articles intended to come into contact with foods, EU directive 10/2011 (Plastic Implementation Measures, PIM) [1], as well as the BfR recommendations on materials for contact with food (former "plastics recommendation"), which only still includes substances for which no harmonised regulations are available on the European level: In the area of plastics, they are "Aids to polymerisation", including the components of the catalytic system (catalysts and initiators) as well as the "Polymer production aids", including, for example, emulsifiers required in the production process. In addition, the database also includes recommendations on materials other than plastic (e.g. paper) and EN 1186-1 2002. The general requirements are listed in Section 3 of EU Regulation 1935/2004. The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. This means concretely [2]:

- Carcinogenic, mutagenic, reproduction-toxic substances (CMR) must not be employed.
- The values for substances rated toxicologic shall be complied with.
- A limit of 60ppm (mg/kg) must not be exceeded as total function for global migration.
- A limit of 0.01mg/kg has been stipulated for substances not rated toxicologic.

Other legal regulations in the EU [2] for the prevention of migration:

- Resolution AP (2004) 1 on coating coming into contact with foods
- Resolution AP (89) 1 on the use of dyes in plastics coming into contact with foods
- Resolution AP (2002) 1 on paper and cardboard materials for products coming into contact with foods
- Resolution AP (92) 2 on the control of aids to polymerisation of plastics and plastic products
- Resolution ResAP (2005)2 on inks on the side of packaging facing away from foods or on articles coming into contact with foods (Ink Resolution). This resolution establishes a list for substances are allowed in inks and paints. Inks and prints shall be produced according to GMP. Details on this are included in the Technical Document 2. Regulations on the ordinance of migration are included in the Technical Document 3.

According to a study commissioned by the German Federal Ministry of Food and Agriculture (BMELV) more than 250 harmful substances have been identified, which, for example, may migrate from the carton packaging material into foods, e.g. carcinogenic polycyclical aromatic hydrocarbons (PAK), adhesives, plasticizers and photo initiators.

On January 15, 2011 EU Regulation 10/2011 for plastics in contact with food (Plastics Implementation Measure, PIM) was published. Companies processing or using plastics must therefore verify whether their products still legally conform to the new regulation. The PIM is very detailed and contains a whole series of new stipulations.

The modified test conditions prescribed in the PIM apply without restriction from January 1, 2016. In addition to the "Overall Migration Limit" (OML) a "Specific Migration Limit" (SML) and/or a total specific migration value (SML(T)) shall be complied with. Furthermore, the 'Multi-Material - Multi-Coat Materials', materials or articles from two or more layers of different materials, of which at least one consists of plastic, are now governed by the area of application of the new plastics regulation.

Substances listed in the appendix of the new European regulations may now also no longer be used behind a functional barrier but it must be checked whether the limit of 0.01 mg/kg is also complied with for these substances.

**Overall Migration Limit (OML)** is the maximum allowed quantity of non-volatile substances that may be given off from a material or article into food simulants.

**Specific Migration Limit (SML)** is the maximum allowed quantity, given off into foods or food simulants.

**Total Specific Migration Limit (SML(T))** the maximum allowed sum of certain substances that are given off into foods or food simulants, calculated as maximum content of the substances given off.

Substances in nano-format, just as the CMR substances (carcinogenic, mutagenic, reproduction-toxic substances ), however, may no longer be used behind a functional barrier unless they have been classified as safe by the European Food Safety Association (EFSA) and have also been explicitly listed in the European list in the appendix of EU Regulation 10/2011.

The so-called NIAS (non-intentionally added substances) are receiving increased attention. In the future, the actors in the supply chain must also provide information on contamination from the production process of the substances used. This should be the biggest challenge in the interest of food safety.

Measuring the migration of migration-capable substances from packaging materials requires excellent analytic and laboratory-specific know-how. To obtain comparable results when verifying compliance with the total migration limit, testing should be performed under standardised test conditions, including test duration, test temperature and medium (food simulant) corresponding to the least favourable usage conditions of the material or article from plastic.

Thanks to their modular design and high density of the Sieg-Mi-Flex migration cells they simplify achieving comparable results through testing under standardised test conditions and subsequent migration analysis significantly. Using the Sieg-Mi-Flex migration cells migration estimation of migration-capable substances, e.g. of film patterns, in reference to a defined area, can be made with normally liquid food simulants.

Following preparation with a single-sided or additional film pattern (double-sided) of the Sieg-Mi-Flex migration cells and storage depending on temperature, time and liquid food simulant, e.g. in heating cabinets, the simulant solutions can be quantified directly by employing a suitable analysis method (GC/MS, HPLC-MS, HPLC-DAD or DC) and after possibly prior sample concentration with SPE, SPME, DLLME or rotation evaporation. In the heating cabinet the Sieg-Mi-Flex migration cells are normally stored upright saving space.

The glass migration cell “Sieg-Mi-Flex” (System Siegwerk) expands the product range of the “Sieg-Mi-Flex” (System Siegwerk) from stainless steel (VA 1.4571) and provides additional application options.

The “Sieg-Mi-Flex” glass migration cell, just as the stainless steel Sieg-Mi-Flex cells, has a circular volume and area element (centre ring) from borosilicate glass 3.3 with nominal diameter DN120, where sealing elements (silicon O-rings with FEP jacket) are arranged at the face areas. The circular area is interrupted by two openings with filler necks inserted in each of them. The filler necks with laboratory-standard GL thread is closed with a screw-on cap. The volume and area element (centre ring) is clamped between a front and base plate from glass using four screws where the ergonomically formed thumb nuts are made from stainless steel.

Manufacturing of the “Sieg-Mi-Flex” migration cell from borosilicate glass requires maximum machining experience for glass applications and reached the limits of feasibility. For this reason a “Sieg-Mi-Flex” glass migration cell is currently only available with a centre ring DN120 (for one-sided sample placement with packaging material = 1.00 dm² or double-sided sample placement = 2.0 dm²; the filling volume is approximately 200 ml).

The development of the “Sieg-Mi-Flex” migration cell from inert, chemical-resistant and transparent laboratory glass allows testing packaging solutions in research and development also with food simulants that may chemically attack stainless steel materials.

Furthermore, the combination of fixing plates from glass and stainless steel centre rings (with all available diameters!) allows making migration processes visible followed by photographic documentation.

Another very interesting use is the combination of stainless steel fixing plates with the DN120 centre ring from glass. To test for taste changes through barrier films as film packaging, the surfaces of the stainless steel fixing plates are covered on both sides and loaded with the glass centre ring. Specified water is used as test solution. The test solution water thus only comes into contact with the surface of the barrier film and the materials glass and FEP. The sealed Sieg-Mi-Flex migration cells in the stainless steel-fixing plate combination with the DN120 centre ring from glass are then tempered in an autoclave at 130 °C according to the time. This is followed by sensory taste examination and possibly analytically assessment.

**Advantages of Polyfluoroethylene propylene (FEP)**

With the O-rings from silicon, clad in FEP, the test sample and food simulant only come into contact with the FEP material.

FEP is a copolymer from PTFE and hexafluoropropylene. Contrary to PTFE, FEP can be processed thermoplastically processed because of its lower melting viscosity.

FEP is food save, FDA-conform, nearly universally chemically resistant and free from extractable substances. The probability of substance carry-over is therefore ruled out.


Fig. 1: Sieg-Mi-Flex migration cells

Fig. 2: Sieg-Mi-Flex glass migration cell

The Sieg-Mi-Flex system as high-density and chemical-resistant space with defined areas offers additional, so far unknown, application options.

**References**

[1] REGULATION (EU) No. 10/2011 OF THE COMMISSION of 14 January 2011 plastic materials and articles intended to come into contact with foods replaces Regulation (EC) No. 1935/2004 of the European Parliament and the Council from 27 October 2004 and Directives 80/590/EEC and 89/109/EEC (1) ABl. L 338 of 13/11/2004, p. 4., especially Article 5 Section 1 Letters a, c, d, e, f, h, I, j.

The European Regulation No. 10/2011 is a single measure according to Article 5 Section 1 of Regulation (EC) No. 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use.

Furthermore, the Regulation should repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foods. In the past, Directive 2002/72/EC and its amendments have had to be transposed into national legislation – A period of 12 months was normally required for transposition into national law, which resulted in a delay with the approval of new substances thereby slowing down the speed of innovation. It therefore seems appropriate to adopt rules on plastic materials and articles in the form of a Regulation directly applicable in all Member States, which no longer has to be transposed into national legislation.

[2] "Wissenswertes zum Thema Migration" (facts about migration) on EasyFairs 23/01/2014 Dr. Monika Kaßmann, Bund der Verpackungsingenieure, RG Südost, Dresden