White paper on the determinations of Overall and Specific migration on food contact materials.

The Institute for Interlaboratory Studies organizes PTs on Overall and Specific migration on food contact materials since 2012. During the evaluation of the PT test results it became clear that the interpretation of (the text of) the Standardized Test Methods as well as the text of the regulatory documents is not easy and does have a negative effect on the comparability of the test results of different laboratories. Therefore, it was decided to prepare a white paper on this subject to give more transparency of the available documents and thus to improve the quality of migration test results.

Legislation

During the contact of food with food contact materials, molecules can migrate from the food contact material to the food. Because of this, in many countries regulations are made to ensure food safety. The EU regulation 10/2011 applies to all food contact materials and describes many requirements, e.g. limits for Overall migration (OML) and Specific migration limits (SML) for certain constituents.
Article 12 of this regulation declares the Overall migration limit to be 10 mg/dm^2. Only when determined for food contact intended for infants and children, the Overall migration is expressed in mg/kg food simulant with a limit of 60 mg/kg food simulant.
In article 11 of this regulation is referred to Annex I for "*Specific migration limits, expressed in mg of substance per kg of food (mg/kg)*". For substances for which no SML is provided, "*a generic SML of 60 mg/kg shall apply*".
In Annex V, paragraphs 2.1.6 (for Specific migration) and 3.3 (for Overall Migration) is stated "*Where a material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another sample of the food simulant on each occasion*".

Standardized Test Methods

For Overall Migration, the EN1186 method series (parts 1 – 15) are the official EC test methods.
EN1186 part 1 contains general guidelines, e.g. in clause 9.8 is stated that articles that are intended for repeated use are tested three times using fresh migration food simulant on each occasion. EN1186 parts 2 and 3 concern migration by total immersion. EN1186-2 describes in clause 8.1 and EN1186-3 in clause 3.6.1, the calculation of the Overall Migration in mg/dm^2 from the contact surface area and the measured masses. Both parts 2 and 3 mention that 1 dm^2 contact surface shall be used per 100 ml of food simulant for total immersion and that under no circumstances the sample may be washed with water or solvent.
EN1186 parts 8 and 9 concern migration by article filling. These parts mention that the test specimen should be filled to within 0.5 cm from the top and that the sample under no circumstances may be washed with water or solvent. EN1186-8 and EN1186-9 describe in clause 8.1 the calculation of the Overall Migration in mg/dm^2 from the contact surface area and the measured masses.

For Specific Migration, the most relevant literature is the EN13130 series (parts 1 – 28) and the JRC report EUR 24815 EN 2011. The JRC guideline and the standard test methods describe in identical way the Specific migration test in detail. For example, for total immersion in clause 10.3 of EN13130-1 is mentioned: "*The surface-to-volume ratio in the total immersion test is conventionally 6 dm² of food contact area to 1000 ml of food simulant.*". In clause 15.5.3 is mentioned "*Cut sections from the walls of the pot, container or article to give test specimens each of area approximately 0,6 dm²*".
Clause 19.2 of EN13130-1 mentions for article filling that "*Test specimens are filled with the food simulant or test medium, with the minimum of headspace*". In clause 19.5.2 is mentioned *"It is necessary to determine the surface area of these articles, which is exposed to food simulant or test medium, since the migration has to be expressed in milligrams per square decimetre of surface area".* When these guidelines are followed correctly, one will find that for many common articles (cups, glasses, beakers, etc) the requirement of clause 10.2 of EN13130-1 will be fulfilled: "*Where the surface-to-volume ratio to be used in contact with foodstuff is not known, conventional exposure conditions shall be used, i.e. 0,6 dm² of surface area of plastics in contact with 100 g of foodstuff or 100 ml of food simulant*".

Interpretation problems

1. Reporting units

During the evaluation of the PT test results, it became clear that many laboratories do report migration results in mg/kg. This may be caused by several reasons. Most important will be the fact that SML are published in mg/kg food. But one should know clause 13.1.1 of EN13130-1 that states: "*the specific migration limits, expressed in milligrams per kilogram (mg/kg), shall be divided by the conventional conversion factor of 6 in order to express them in milligrams per square decimeter (mg/dm^2)*".
Another reason may be clause 12.3.1 of EN1186-1 that states: "*The following analytical tolerances are allowed: 6 mg/kg or 1 mg/dm^2 for all aqueous food simulants*". This may incorrectly suggest that reporting the Overall migration in mg/kg is allowed next to reporting in mg/dm^2.
In clause 6.3 of EN1186-9 is mentioned: *"NOTE 1 For some articles it is recognized that it is impractical to measure the surface area intended to come into contact with foodstuff. For such articles, the overall migration is measured as milligrams of substance released per kilogram of food simulant."*
From the above, it may incorrectly be concluded that reporting Overall migration in mg/kg is allowed next to reporting in mg/dm^2. The reporting of Specific migration in mg/kg of foodstuff is only correct for articles that can be filled with more than 500 ml and less than 10 liters and for articles for which it is impractical to estimate the surface area in contact with foodstuffs (clause 8.1.1 of EN1186-9). This may be the case when solid food items (cookies, candy, lettuce, etc.) are packed in a non-flexible packaging (box, can, etc.).

2. Severe testing

In EN1186-1 clause 9.3 and in EN13130-1 clause 10.3 a more severe test is discussed. During total immersion, not only the part of the article that is intended to come into contact with foodstuffs, may be in contact with the food simulant, but also other parts of the article. The second paragraph of this clause describes to consider only half of the contact surface in this case. However, in paragraphs 3 and 4 is mentioned that in some cases the full contact surface is used in the calculation. These exceptions may cause the final reported migration test result to vary a factor 2. Therefore, it was decided to exclude this possibility to calculate the migration test result in two ways in the iis-PTs.

3. Surface to volume ratios in actual use

Clauses 12.1.3 and 12.1.4 of EN1186-1 are on the migration of articles with known surface to volume ratios. This 'known' refers to the actual surface to volume ratios when the article is filled with foodstuffs. In many case this actual ratio is unknown (e.g. the amount of tea that one pours in a teacup is dependent of the person filling the cup) and known in fewer cases (e.g. the amount of beer in a beer bottle of a certain brand and type is printed on the label of the bottle).

Overview (cell, pouch and reverse pouch not included):

	Overall migration		Specific migration	
	article filling (<0.5L)	total immersion	article filling (<0.5L)	total immersion
usual reporting unit	mg/dm^2	mg/dm^2	mg/dm^2	mg/dm^2
calculation	from contact surface and residue (-blank)	from contact surface and residue (-blank)	from contact surface, volume simulant and measured concentration	from contact surface, volume simulant and measured concentration
ml simulant/dm^2 surface	variable	100 ml : 1 dm^2	variable	100 ml : 0.6 dm^2
contact surface to use	variable	1 dm^2	variable	0.6 dm^2
other test detail(s)	fill article to 0.5 cm from top min. use 200 ml		fill article with minimum of headspace	
standard method(s)	EN 1186 (1-15)	EN 1186 (1-15)	EN13130 (1-28)	EN13130 (1-28)
legislation reference(s)	EU 10/2011	EU 10/2011	EU 10/2011	EU 10/2011
Unit of migration limit	mg/dm^2 (*)	mg/dm^2 (*)	mg/kg food	mg/kg food

(*) except for infants and children for which the regulatory migration limit is in mg/kg food