Results of Proficiency Test
Overall migration (fcm)
October 2012

Organised by: Institute for Interlaboratory Studies
Spijkenisse, the Netherlands

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CONTENTS

1 INTRODUCTION

On request of a number of participants in the iis PT program it was decided to start PTs on food contact materials in 2012.
During the contact of the food contact materials with the food, 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 framework Regulation (EC) No. 1935/2004 applies to all food contact materials and describes a large number of requirements, e.g. limits for overall migration and specific limits for certain constituents. The determination of specific migration requires additional analytical testing following the migration step, while the determination of the overall (also called global, or total) migration requires weighing as only quantitative analytical technique.
In this first iis PT on Overall Migration conducted in October 2012, 46 laboratories from 16 different countries participated (See appendix 3).
In this report, the results of the proficiency test are presented and discussed.

2 SET-UP

The Institute for Interlaboratory Studies (iis) in Spijkenisse, The Netherlands, was the organiser of this proficiency test. It was decided to send one sample (4 identical gloves, 3 for replicate testing and one for determination of the contact surface), that gave a positive test result, labelled #12113, and to prescribe a number of test conditions (type of simulant, amount of simulant, exposure time and temperature) to be used. Participants were also requested to report the test conditions that the laboratory would have used in case these were not prescribed by iis.

2.1 QUALITY SYSTEM

The Institute for Interlaboratory Studies in Spijkenisse, the Netherlands, has implemented a quality system based on ISO guide 43, ILAC-G13:2007 and ISO/IEC 17043:2010. This ensures 100% confidentially of participant's data. Also, customer's satisfaction is measured on a regular basis by sending out questionnaires.

2.2 PROTOCOL

The protocol followed in the organisation was the one as described for proficiency testing in the report 'iis Interlaboratory Studies: Protocol for the Organisation, Statistics and Evaluation' of January 2010 (iis-protocol, version 3.2). This protocol can be downloaded from the iis website http://www.iisnl.com.

2.3 CONFIDENTIALITY STATEMENT

All data presented in this report must be regarded as confidential and for use by the participating companies only. Disclosure of the information in this report is only allowed by means of the entire report. Use of the contents of this report for third parties is only allowed by written permission of the Institute for Interlaboratory Studies. Disclosure of the identity of one or more of the participating companies will be done only after receipt of a written agreement of the companies involved.

2.4 SAMPLES

A batch of gloves for single use in the food industry that gave positive test results for Overall Migration was selected.
The homogeneity of the batch was checked by determination of the Overall Migration on 8 stratified randomly selected samples.

	Overall Migration in mg/dm^2 #12113
Sample 1	46.4
Sample 2	45.6
Sample 3	44.0
Sample 4	43.6
Sample 5	47.1
Sample 6	42.1
Sample 7	46.2
Sample 8	46.0

Table 1: results of the homogeneity test on the subsamples #12113

From the above results of the homogeneity test, the relative between sample standard deviations RSD_r were calculated and compared with 0.3 times the relative proficiency target standard deviations RSD_R in agreement with the procedure of ISO 13528, Annex B2 in the next table:

	Overall Migration in mg/dm^2 #12113
r(observed)	4.8
reference method	EN1186-8:2002
0.3 x RSD_R (reference method)	6.3

Table 2: relative repeatability standard deviations on the subsamples #12113

The calculated repeatability for Global Migration on the eight samples #12113 is in good agreement with the estimated target, calculated using EN1186-8 precision data.
Therefore, homogeneity of the samples #12113 was assumed.

To each of the participating laboratories one set of samples #12113, (4 identical gloves) was sent on September 26, 2012.

2.5 ANALYSIS

The participants were requested to determine Global Migration on the sample using the prescribed test conditions. It was requested to report the analytical results using the indicated units on the report form and to use a minimum number of digits and not to round the results more. It was also requested not to report ‘less than’ results, which are above the detection limit, because such results cannot be used for meaningful statistical calculations.
To get comparable results a detailed report form, on which the units were prescribed, was sent together with each set of samples. Also, a letter of instructions was added to the package.

The laboratories were also requested to report the test conditions that the laboratory would have used in case these were not prescribed by iis.

3 RESULTS

During four weeks after sample despatch, the results of the individual laboratories were received. The original data are tabulated per sample in the appendix 1 of this report.
The laboratories are represented by the code numbers.

Directly after the deadline, a reminder fax was sent to those laboratories that did not report results at that moment.
Shortly after the deadline, the available results were screened for suspect data. A result was called suspect in case the Huber Elimination Rule (a robust outlier test) found it to be an outlier. The laboratories that produced these suspect data were asked to check the results. Additional or corrected results are used for the data analysis and the original results are placed under 'Remarks' in the result tables in appendix 1.

3.1 STATISTICS

The statistical calculations were performed as described in the procedures in the report ‘iis Interlaboratory Studies, Protocol for the Organisation, Statistics and Evaluation’ of January 2010 (iis-protocol, version 3.2).

First, the normality of the distribution of the various data sets per determination was checked by means of the Lilliefors-test. After removal of outliers this check was repeated.

In accordance to ISO 5725 (1986 and 1994) the original results per determination were submitted subsequently to Dixon and Grubbs outlier tests. Outliers are marked by D(0.01) for the Dixon test, by G(0.01) or DG(0.01) for the Grubbs test. Stragglers are marked by D(0.05) for the Dixon test, by G(0.05) or DG(0.05) for the Grubbs test. Both outliers and stragglers were not included in the calculations of averages and standard deviations.

Finally, the reproducibilities were calculated from the standard deviations by multiplying them with a factor of 2.8.

For each assigned value the uncertainty was determined in accordance with ISO13528. Subsequently the calculated uncertainty was evaluated against the respective requirement based on the target reproducibility in accordance with ISO13528. When the uncertainty passed the evaluation no remarks are made in the report. However, when the uncertainty failed the evaluation it is mentioned in the report and it will have significant consequences for the evaluation of the test results.

3.2 GRAPHICS

In order to visualise the data against the reproducibilities from literature, Gauss plots were made, using the sorted data for one determination (see appendix 1). On the Y-axis the reported analysis results are plotted. The corresponding laboratory numbers are under the X-axis.
The straight horizontal line presents the consensus value (a trimmed mean). The four striped lines, parallel to the consensus value line, are the +3s, +2s, -2s and -3s target reproducibility limits of the selected standard. Outliers and other data, which were excluded from the calculations, are represented as a cross. Accepted data are represented as a triangle. Furthermore, Kernel Density Graphs were made. This is a method for producing a smooth density approximation to a set of data that avoids some problems associated with histograms (see appendix 4; nr.14 and 15).

3.3 Z-SCORES

To evaluate the performance of the participating laboratories the z-scores were calculated. As it was decided to evaluate the performance of the participants in this proficiency test (PT) against the literature requirements, the z-scores were calculated using a target standard deviation. This results in an evaluation independent of the spread of this interlaboratory study.

The target standard deviation was calculated from the target reproducibility (preferably taken from a standardized test method) by division with 2.8.
The z-scores were calculated in accordance with:

$$z_{(target)} = (\text{result} - \text{average of PT}) / \text{target standard deviation}$$

The $z_{(target)}$ scores are listed in the result tables in appendix 1.

When a laboratory did use a test method with a reproducibility that is significantly different from the reproducibility of the reference test method used in this report, it is strongly advised to recalculate the z-score, while using the reproducibility of the actual test method used. This in order to evaluate the fit-for-useness of the reported test result. See also: appendix 3, ref. 16.

Absolute values for z<2 are very common and absolute values for z>3 are very rare. Therefore the usual interpretation of z-scores is as follows:

	$\lvert z \rvert < 1$	good
$1 <$	$\lvert z \rvert < 2$	satisfactory
$2 <$	$\lvert z \rvert < 3$	questionable
$3 <$	$\lvert z \rvert$	unsatisfactory

4 EVALUATION

In this interlaboratory study, no problems were encountered with the dispatch of the samples. Two participants reported test results after the final reporting date and three other participants did not report any test results at all. Finally, 43 of the 46 participants submitted analysis results. These 43 laboratories reported 124 numerical test results. Observed were 7 outlying results, which is 5.3%. In proficiency studies, outlier percentages of 3% - 7.5% are quite normal.

A not-normal distribution was found for the reported global migration results in mg/kg. Therefore this statistical evaluation should be used with due care.

For the determination of Overall Migration (identical to Global migration or Total Migration), the EN1186 method series (parts 1 – 15) is considered to be the official EC test method.
In this PT, 95% ethanol was used as simulant as substitute for rectified olive oil, cfr. EN1186 part 14: Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol.
Regretfully EN1186-14 does not mention any precision data. Therefore it was decided to esti-mate the target reproducibility from the reproducibilities as mentioned in EN1186 part 8, annex F.

4.1 PERFORMANCE EVALUATION OF THE GROUP OF LABORATORIES

The calculated reproducibilities and the target reproducibilities derived from the literature standard method, here EN1186-8:02, are compared in the next table.

	unit	n	Average	2.8 * sd	R (target)
Residue after evaporation	mg	39	122.3	60.6	55.4
Global migration	mg/dm^2	42	47.1	30.0	22.2
Global migration	mg/kg	---	---	---	---

Table 3: performance overview for samples #12113

4.2 EVALUATION

In this section the results are discussed.

residue in mg: This determination was problematic for a number of laboratories only. Four statistical outliers were detected of which two results possible were reported in a different unit (grams). The calculated reproducibility, after rejection of the statistical outliers, is in agreement with the target reproducibility requirement of EN1186-8:02. This means that the quality of the analytical performance of the participating laboratories was sufficient.

migration in mg/dm^2: This determination was problematic. Only one statistical outlier was detected. However, the calculated reproducibility, after rejection of the statistical outlier, is not in agreement with the target reproducibility requirement of EN1186-8:02

migration in mg/kg: The reporting in mg/kg was very problematic. Two statistical outliers were detected. The calculated reproducibility, after rejection of the statistical outliers, is not at all in agreement with the target reproducibility requirement of EN1186-8:02. Apparently the majority of the participants did report test results in mg/L instead of the requested mg/kg. See also paragraph 5. Therefore it was not possible to evaluate these test results.

4.3 EVALUATION OF THE TEST METHODS USED

Most participants reported to have used a part of the EN1186 test method. Besides the general part 1 of this test method, also parts 8, 9 and 14 were all mentioned.
Also several participants referred to EUR24851 EN 2011, a report on the specific migration of aromatic amines and formaldehyde from melamine and polyamide kitchenware.
The reported details of the methods that were used by the participants are listed in appendix 2.

5 CONCLUSIONS

Before the start of this PT it was clear that a wide range of test results would be reported when the choice of the test conditions would have been left to the participating laboratories. Therefore a set of predetermined test conditions was given together with the instructions to all participants.
These preset conditions were:

Sample ID	**#12113**
Glove	turned inside out
Simulant	Ethanol 95%
Glove volume	600 cm^3 (*fictive figure*)
Simulant amount	200 ml (preheated)
Exposure time	2.0 hrs
Exposure temperature	40.0 °C
Contact surface	2.50 dm^2 (*fictive figure*)
Migration method	Article filling

Table 4: preset test conditions used in this PT

Not only a migration result was to be reported, but the participants were requested to report also the intermediate amount of residue after removal of the simulant. Using these intermediate test results it would be possible to check all calculations and corrections done by the laboratories.

As expected the spread in the intermediate test results (the residues in mg) is smaller than the spread in the migration results and in agreement with the target reproducibility. However, the Overall Migration results in mg/dm^2 show a larger spread, no longer in agreement with the target reproducibility. This is rather surprising as the calculation is not difficult:

Overall Migration results in mg/dm^2 = (residue in mg) / (2.5 dm^2 *cfr* table 4)

Upon investigation for the reason of the increased spread, it was found that a number of laboratories did not use the prescribed contact surface of 2.5 dm^2 (the factor between the residue and the migration result was not 2.5, but varied from 0.00 – 2.77).

The spread in the Overall Migration results in mg/kg again show a larger spread than the spread in the Overall Migration results in mg/dm^2. Again the calculation is not difficult:

Overall Migration results in mg/kg = (Overall Migration results in mg/dm^2) * 6 dm^2/kg

Upon investigation for the reason of the significant increase in spread, it was found that a number of laboratories did not use the conventional surface to volume ratio of 6 dm^2/kg cfr. EN1186-1, paragraph 12.1.2. The factor between the residue and the migration result was not 6, but varied from 0.2 – 330.1, see appendix 1 (page 13). Apparently a majority of the participants reported test results in mg/L ethanol (!) instead of the requested Migration in mg/kg.
None of the participants reported that reporting of the migration into mg/kg was not applicable as the volume of the glove (600 mL) was more than 500 mL and less than 10 L.
However, five participants did not report a test result for migration in mg/kg, possibly because the glove volume was over 500 mL and less than 10 L.

It is to be expected that the spread of the migration results will even be larger than observed in this PT when the test conditions like time, temperature, contact surface, etc. are not predetermined but chosen by the participating laboratories. See appendix 2 for the test conditions that the laboratories would have selected in case these were not prescribed as in this PT.
From the responses it became clear that the test conditions as set were quite realistic:

- All participating laboratories would have selected article filling.
- The majority of the participants (>80%) would have used an exposure of 2 hours, an exposure temperature of 40°C and would have reported the migration in mg/dm^2 only.
- A small majority of the participants (53%) would have selected 95% ethanol as simulant, while another 40% would have preferred 3% Acetic Acid as simulant.
- The amount of simulant to be used varies from 100 mL up to 720 mL (a 100% filled glove)
- The ratio amount of simulant per dm^2 contact surface varies from 48 – 167 (iis gave 80)

A number of methods to determine the contact surface were mentioned:

- measure by caliper and calculate using mathematical equations
- graphic millimeter paper method cfr JRC guidelines EUR24815 EN 2011
- by contour / measurement of projected area
- by dividing surface into polygons
- by cutting & measurement of rectangles
- by cutting and weighing

Although all mentioned methods may be sufficient to estimate the contact surface, a large spread in the estimated surfaces is observed, where the largest estimate is about 4 times the smallest estimate (see above and also appendix 2).

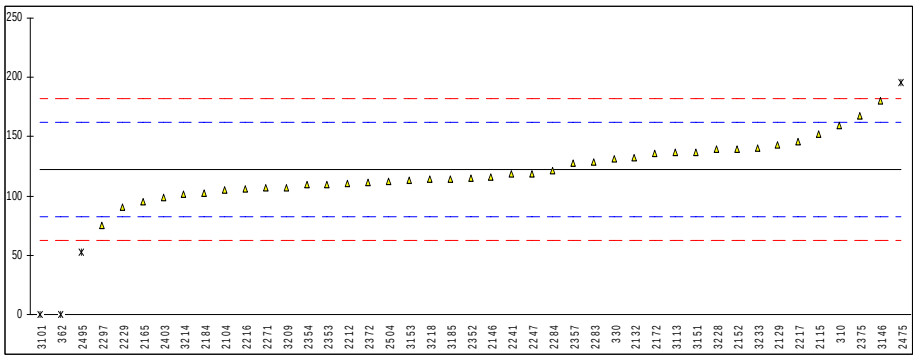
Each laboratory has to evaluate its performance in this study and make decisions about necessary corrective actions. Therefore, participation on a regular basis in this scheme could be helpful to improve the performance and the quality of the analytical results.

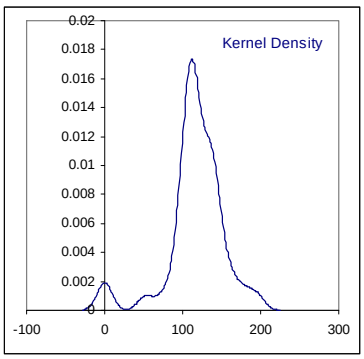
APPENDIX 1

Determination of Residue after evaporation of simulant on sample #12113; results in mg

lab	method	value	mark	z(targ)	remarks
310	EN1186-1	159.0		1.85	
330	EN1186-8	131		0.44	is average of 3 trials
362	EN1186-9	0.12	G(0.01)	-6.17	reported probably in grams?
2104	EN1186-9	105.0		-0.87	
2115	EUR24815EN	152.30		1.52	
2129	EN1811	142.67		1.03	
2132	EN1186-9&-14	132.00		0.49	
2146	standard method	116		-0.32	
2152	EN1186-9	139.85		0.89	
2156		-----		-----	
2165	EC 10/2011	94.80		-1.39	
2172	EN1186-1&-8&-14	136.30		0.71	
2184	EC 10/2011	102.5		-1.00	
2190		-----		-----	
2212	EN1186-1&CFR 175.300	110.23		-0.61	
2216	21 CFR 175.300	106.3		-0.81	
2217	in house	145.40		1.17	
2229	EN1186-14	90.85		-1.59	
2241	EN1186-9	118.77		-0.18	
2247	EC 10/2011	118.80		-0.18	
2271	in house	107		-0.77	
2283	EN1186-9	128.65		0.32	average of duplicates
2284	EN1186-1&-14	121.1		-0.06	
2297	EN1186-9&-14	75.20		-2.38	
2352	EN1186	115.24		-0.36	
2353	EN1186-9	110		-0.62	average of duplicates
2354	EN1186-9	110		-0.62	average of duplicates
2357	EN1186	127.80		0.28	
2372	EN1186-1&-14&EC 10/2011	111.30		-0.56	
2375	EN1186&EC 10/2011	167.3		2.27	
2403	EN1186-8&EC 10/2011	98.70		-1.19	
2475	EN1186-9	195.75	DG(0.05)	3.71	
2488		-----		-----	
2495	EN1186-12	52.23	DG(0.05)	-3.54	is average of 4 trials minus blank
2504	EN1186-9	111.95	C	-0.52	first reported 0.11 g
3101	EN1186-14	0.0753	G(0.05)	-6.17	reported probably in grams?
3113	EN1186	136.70	C	0.73	first reported 0.14 g
3146	EN1186	180.50		2.94	
3151	EN1186	137.1		0.75	
3153	EN1186-14	113.00		-0.47	
3185	EN1186-1&-9&EC 10/2011	113.95		-0.42	
3209	EN1186-9	107.0		-0.77	
3214	EN1186	101.74		-1.04	
3218	EN1186-9	113.85		-0.43	
3228	EN1186-1&-9&-14	139.6		0.87	
3233	EUR3814&EC 10/2011	140.10		0.90	

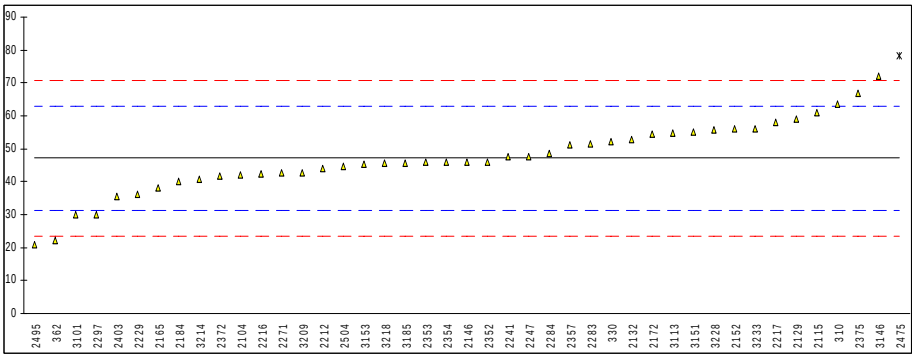
normality	OK
n	39
outliers	4
mean (n)	122.296
st.dev. (n)	21.6267
R(calc.)	60.555
R(EN1186-8:02)	55.445

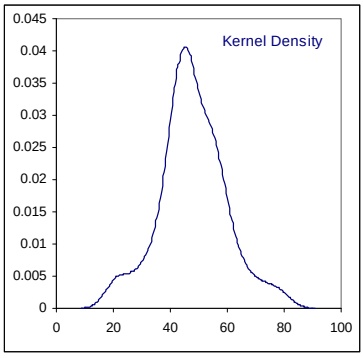




Determination of Overall / Global / Total Migration on sample #12113; results in mg/dm^2

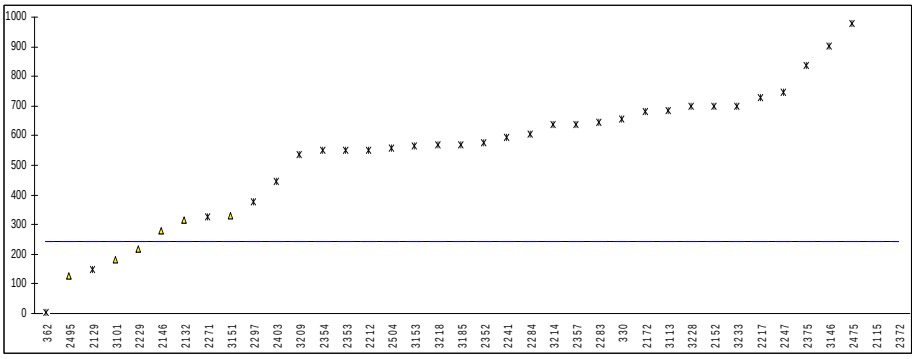
lab	method	value	mark	z(targ)	remarks
310	EN1186-1	63.6		2.08	
330	EN1186-8	52.3		0.65	
362	EN1186-9	22.11		-3.16	
2104	EN1186-9	42.15		-0.63	
2115	EUR24815EN	60.92		1.74	
2129	EN1811	59.17	E	1.52	calculation error or used a deviating contact surface?
2132	EN1186-9&-14	52.80		0.72	
2146	standard method	46		-0.14	
2152	EN1186-9	55.94		1.11	
2156		-----		-----	
2165	EC 10/2011	38.20		-1.13	
2172	EN1186-1&-8&-14	54.52		0.93	
2184	EC 10/2011	40.0		-0.90	
2190		-----		-----	
2212	EN1186-1&CFR 175.300	44.09		-0.38	
2216	21 CFR 175.300	42.53		-0.58	
2217	in house	58.16		1.39	
2229	EN1186-14	36.34		-1.36	
2241	EN1186-9	47.51		0.05	
2247	EC 10/2011	47.52		0.05	
2271	in house	42.6		-0.57	
2283	EN1186-9	51.46		0.55	
2284	EN1186-1&-14	48.44		0.17	
2297	EN1186-9&-14	30.10		-2.15	
2352	EN1186	46.10	E	-0.13	calculation error or used a deviating contact surface?
2353	EN1186-9	46.00	E	-0.14	calculation error or used a deviating contact surface?
2354	EN1186-9	46		-0.14	
2357	EN1186	51.12		0.50	
2372	EN1186-1&-14&EC 10/2011	41.71	E	-0.68	calculation error or used a deviating contact surface?
2375	EN1186&EC 10/2011	66.92		2.50	
2403	EN1186-8&EC 10/2011	35.69	E	-1.44	calculation error or used a deviating contact surface?
2475	EN1186-9	78.30	G(0.05)	3.94	
2488		-----		-----	
2495	EN1186-12	20.89		-3.31	
2504	EN1186-9	44.78		-0.30	
3101	EN1186-14	30		-2.16	
3113	EN1186	54.68		0.95	
3146	EN1186	72.20		3.17	
3151	EN1186	55.20	E	1.02	calculation error or used a deviating contact surface?
3153	EN1186-14	45.20		-0.24	
3185	EN1186-1&-9&EC 10/2011	45.58		-0.20	
3209	EN1186-9	42.78		-0.55	
3214	EN1186	40.70		-0.81	
3218	EN1186-9	45.54		-0.20	
3228	EN1186-1&-9&-14	55.8		1.09	
3233	EUR3814&EC 10/2011	56.04		1.13	
					theoretical data calculated by iis:
	normality	OK			OK
	n	42			39
	outliers	1			4
	mean (n)	47.128			48.919
	st.dev. (n)	10.7215			8.6507
	R(calc.)	30.020			24.222
	R(EN1186-8:02)	22.178			23.020

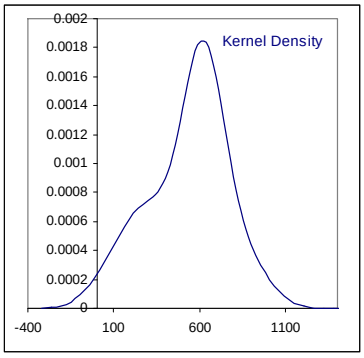




Determination of Overall / Global / Total Migration on sample #12113; results in mg/kg

lab	method	value	mark	z(targ)	remarks	conversion factor used
310		-----		-----		
330	EN1186-8	654.3		-----	reported in mg/L?	12.5
362	EN1186-9	3.68		-----		0.2
2104		-----		-----		
2115	EUR24815EN	9035.24	G(0.01)	-----		148.3
2129	EN1811	147.92		-----		2.5
2132	EN1186-9&-14	316.80		-----		6.0
2146	standard method	278		-----		6.0
2152	EN1186-9	699.25		-----	reported in mg/L?	12.5
2156		-----		-----		
2165		-----		-----		
2172	EN1186-1&-8&-14	681.50		-----	reported in mg/L?	12.5
2184		-----		-----		
2190		-----		-----		
2212	EN1186-1&CFR 175.300	551.15		-----	reported in mg/L?	12.5
2216		-----		-----		
2217	in house	727.00		-----	reported in mg/L?	12.5
2229	EN1186-14	218.04		-----		6.0
2241	EN1186-9	593.83		-----	reported in mg/L?	12.5
2247	EC 10/2011	746.11		-----		15.7
2271	in house	327		-----		7.7
2283	EN1186-9	643.25		-----	reported in mg/L?	12.5
2284	EN1186-1&-14	605.5		-----	reported in mg/L?	12.5
2297	EN1186-9&-14	376.00		-----	reported in mg/L?	12.5
2352	EN1186	576.20		-----	reported in mg/L?	12.5
2353	EN1186-9	550		-----	reported in mg/L?	12.0
2354	EN1186-9	550		-----	reported in mg/L?	12.0
2357	EN1186	639.00		-----	reported in mg/L?	12.5
2372	EN1186-1&-14&EC 10/2011	13768.96	G(0.01)	-----		330.1
2375	EN1186&EC 10/2011	836.5		-----	reported in mg/L?	12.5
2403	EN1186-8&EC 10/2011	446.12		-----	reported in mg/L?	12.5
2475	EN1186-9	978.75		-----	reported in mg/L?	12.5
2488		-----		-----		
2495	EN1186-12	125.35		-----		6.0
2504	EN1186-9	559.5		-----	reported in mg/L?	12.5
3101	EN1186-14	180		-----		6.0
3113	EN1186	683.48		-----	reported in mg/L?	12.5
3146	EN1186	902.50		-----	reported in mg/L?	12.5
3151	EN1186	331.2		-----		6.0
3153	EN1186-14	565.00		-----	reported in mg/L?	12.5
3185	EN1186-1&-9&EC 10/2011	569.75		-----	reported in mg/L?	12.5
3209	EN1186-9	535.00		-----	reported in mg/L?	12.5
3214	EN1186	636.27		-----		15.6
3218	EN1186-9	569.25		-----	reported in mg/L?	12.5
3228	EN1186-1&-9&-14	698		-----	reported in mg/L?	12.5
3233	EUR3814&EC 10/2011	700.50		-----	reported in mg/L?	12.5
					theoretical results using 6 as conversion factor:	
	normality	not OK			OK	
	n	36			41	
	outliers	2			2	
	mean (n)	533.38			293.71	
	st.dev. (n)	223.509			63.586	
	R(calc.)	625.83			178.04	
	R(EN1186-8:02)	251.00			138.22	





APPENDIX 2

Test conditions when selected by participants

lab	type of simulant	amount of simulant in ml	exposure time in hrs	exposure temperature in°C	contact surface in dm^2	reporting unit
310	95% EtOH	200	2	40	2.8	mg/dm^2
330	----	----	----	----	----	----
362	----	----	----	----	----	----
2104	3% HAc	200	0.25	40	2.5	mg/dm^2
2115	----	----	----	----	----	----
2129	3% HAc	300	2	40	3.0	mg/kg
2132	3% HAc	200	2	40	2	mg/dm^2
2146	----	----	----	----	----	----
2152	----	----	----	----	----	----
2156	----	----	----	----	----	----
2165	95% EtOH	200	2	40	2.48	mg/dm^2
2172	3% HAc	200	2	40	2.52	mg/dm^2
2184	95% EtOH	200	2	40	2.56	mg/dm^2
2190	----	----	----	----	----	----
2212	water	200	2	40	3.52	mg/dm^2
2216	water	----	2, 0.5	66, 38	13.6	mg/dm^2
2217	----	----	----	----	----	----
2229	95% EtOH	200	2.0	40.0	2.50	mg/kg
2241	----	----	----	----	----	----
2247	----	----	----	----	----	----
2271	95% EtOH	200	2.0	40.0	3.75	mg/dm^2 & mg/kg
2283	3% HAc	250	2.0	40.0	4.14	mg/dm^2
2284	95% EtOH	200	2	40	2.5	mg/dm^2
2297	----	----	----	----	----	----
2352	3% HAc	200	2	40	2.50	mg/dm^2
2353	3% HAc	200	2	40	2.5	mg/dm^2
2354	3% HAc	200	2	40	2.5	mg/dm^2
2357	3% HAc	200	2.0	40.0	2.5	----
2372	95% EtOH	200	2	40	2.6687	mg/dm^2
2375	95% EtOH	200	2	40	2.5	mg/kg
2403	----	----	----	----	----	----
2475	3% HAc	590	2	40	5.9	mg/dm^2
2488	----	----	----	----	----	----
2495	10% EtOH	200	6	40	4.14	mg/dm^2
2504	----	----	----	----	----	----
3101	95% EtOH	500	2	40	6.19	mg/dm^2
3113	95% EtOH	200	2	40	2.50	mg/kg
3146	3% HAc	100	2	40	0.6	mg/dm^2
3151	95% EtOH	200	2	40	2.5	mg/kg
3153	95% EtOH	720	2	70	5.9	mg/dm^2
3185	olive oil	600	2	40	6.0	mg/dm^2
3209	95% EtOH	200	2	40	2.5	mg/dm^2
3214	95% EtOH	200	2.0	40.0	2.5	mg/dm^2
3218	3% HAc	500	2.0	70.0	5.0	mg/dm^2
3228	----	----	----	----	----	----
3233	50% EtOH	200.00	2.00	40.00	2.50	mg/dm^2

APPENDIX 3

Number of participating laboratories per country

1 lab in	BULGARIA
1 lab in	DENMARK
1 lab in	FINLAND
4 labs in	FRANCE
3 labs in	GERMANY
8 labs in	HONG KONG
1 lab in	HUNGARY
1 lab in	INDIA
2 labs in	ITALY
1 lab in	MALAYSIA
16 labs in	P.R. of CHINA
2 labs in	TAIWAN R.O.C.
1 lab in	THAILAND
1 lab in	THE NETHERLANDS
2 labs in	TURKEY
1 lab in	U.S.A.

APPENDIX 4

Abbreviations:

C = final result after checking of first reported suspect result
D(0.01) = outlier in Dixon's outlier test
D(0.05) = straggler in Dixon's outlier test
G(0.01) = outlier in Grubbs' outlier test
G(0.05) = straggler in Grubbs' outlier test
DG(0.01) = outlier in Double Grubbs' outlier test
DG(0.05) = straggler in Double Grubbs' outlier test
n.a. = not applicable
E = possible calculation error

Literature:

1 iis Interlaboratory Studies, Protocol for the Organisation, Statistics & Evaluation, January 2010
2 EN 1186-1:02 - Guide to the selection of conditions and test methods for overall migration
3 EN 1186-8:02 - Test methods for overall migration into olive oil by article filling
4 EN 1186-14:02 - Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol
5 ASTM E1301-03
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8 M. Thompson and R. Wood, J. AOAC Int, 76, 926, (1993)
9 W.J. Youden and E.H. Steiner, Statistical Manual of the AOAC, (1975)
10 IP 367/96
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14 Analytical Methods Committee Technical Brief, No4 January 2001
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16 R.G. Visser, Reliability of proficiency test results for metals and phthalates in plastics, Accred Qual Assur, 14:29-34 (2009)