**Institute for
Interlaboratory Studies**

Results of Proficiency Test
Overall Migration on
Food Contact Materials
October 2023

CONTENTS

Appendices:

1   INTRODUCTION

During the contact of materials with 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 (EU) No. 10/2011 (lit. 13 and lit. 14) 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. Article 12 of this regulation describes the Overall Migration limit, which is 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 of food simulant. 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 September 2020 the 15th amendment of this EU 10/2011 (lit. 15) was published. This amendment especially describes methods for repeated use articles, how to test and to reject them.

Since 2012 the Institute for Interlaboratory Studies (iis) organizes a proficiency scheme for the determination of Overall Migration on Food Contact Materials every year. During the annual proficiency testing program of 2023 it was decided to continue the proficiency test for the determination of Overall Migration on Food Contact Materials.

In this interlaboratory study 49 laboratories in 16 countries registered for participation, see appendix 4 for the number of participants per country. In this report the results of the Overall Migration proficiency test are presented and discussed. This report is also electronically available through the iis website www.iisnl.com.

2   SET UP

The Institute for Interlaboratory Studies (iis) in Spijkenisse, the Netherlands, was the organizer of this proficiency test (PT). Sample analyzes for fit-for-use and homogeneity testing were subcontracted to a laboratory that has performed the tests in accordance with for ISO/IEC17043 relevant requirements of ISO/IEC17025.
It was decided to send one sample, a set of three identical items and labelled #23715. The participants were requested to report rounded and unrounded test results. The unrounded test results were preferably used for statistical evaluation.

2.1   ACCREDITATION

The Institute for Interlaboratory Studies in Spijkenisse, the Netherlands, is accredited in agreement with ISO/IEC17043:2010 (R007), since January 2000, by the Dutch Accreditation Council (Raad voor Accreditatie). This PT falls under the accredited scope. This ensures strict adherence to protocols for sample preparation and statistical evaluation and 100% confidentiality of participant's data. Feedback from the participants on the reported data is encouraged and customer's satisfaction is measured on regular basis by sending out questionnaires.

2.2 PROTOCOL

The protocol followed in the organization of this proficiency test was the one as described for proficiency testing in the report 'iis Interlaboratory Studies: Protocol for the Organisation, Statistics and Evaluation' of June 2018 (iis-protocol, version 3.5). This protocol is electronically available through the iis website www.iisnl.com, from the FAQ page.

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 white plastic disposable knives for repeated use was selected. The knives were positive for Overall Migration. Randomly from the batch 60 sets of three knives were put into a bag and labelled #23715.
The batch for sample #23715 was used in a previous proficiency test on Overall Migration as sample #20675 in iis20P09GM. Therefore, homogeneity of the subsamples was assumed.

To each of the participating laboratories one sample, a set of three knives, labelled #23715 was sent on September 6, 2023.

2.5 ANALYZES

The participants were requested to determine Overall Migration using the prescribed test conditions (total immersion, single use and 3% M/V Acetic Acid as simulant for 2 hours at 70 °C). Each participant received three knives to be tested separately, where also the average of the three tests was requested.
It was also requested to report if the laboratory was accredited for this test and to report some analytical details.

It was explicitly requested to treat the samples as if they were routine samples and to report the test results using the indicated units on the report form and not to round the test results, but report as much significant figures as possible. It was also requested not to report 'less than' test results, which are above the detection limit, because such test results cannot be used for meaningful statistical evaluations.

To get comparable test results a detailed report form and a letter of instructions are prepared. On the report form the reporting units are given as well as the reference test methods (when applicable) that will be used during the evaluation. The detailed report form and the letter of instructions are both made available on the data entry portal www.kpmd.co.uk/sgs-iis-cts/. The participating laboratories are also requested to confirm the sample receipt on this data entry portal. The letter of instructions can also be downloaded from the iis website www.iisnl.com.

3   RESULTS

During five weeks after sample dispatch, the test results of the individual laboratories were gathered via the data entry portal www.kpmd.co.uk/sgs-iis-cts/. The reported test results are tabulated per determination in appendices 1 and 2 of this report. The laboratories are presented by their code numbers.

Directly after the deadline, a reminder was sent to those laboratories that had not reported test results at that moment. Shortly after the deadline, the available test results were screened for suspect data. A test 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 reported test results (no reanalyzes). Additional or corrected test results are used for data analysis and the original test results are placed under 'Remarks' in the result tables in appendices 1 and 2. Test results that came in after the deadline were not taken into account in this screening for suspect data and thus these participants were not requested for checks.

3.1   STATISTICS

The protocol followed in the organization of this proficiency test was the one as described for proficiency testing in the report 'iis Interlaboratory Studies: Protocol for the Organisation, Statistics and Evaluation' of June 2018 (iis-protocol, version 3.5).
For the statistical evaluation the *unrounded* (when available) figures were used instead of the rounded test results. Test results reported as '<…' or '>…' were not used in the statistical evaluation.

First, the normality of the distribution of the various data sets per determination was checked by means of the Lilliefors-test, a variant of the Kolmogorov-Smirnov test and by the calculation of skewness and kurtosis. Evaluation of the three normality indicators in combination with the visual evaluation of the graphic Kernel density plot, lead to judgement of the normality being either 'unknown', 'OK', 'suspect' or 'not OK'. After removal of outliers, this check was repeated. If a data set does not have a normal distribution, the (results of the) statistical evaluation should be used with due care.

The assigned value is determined by consensus based on the test results of the group of participants after rejection of the statistical outliers and/or suspect data.

According to ISO13528 all (original received or corrected) results per determination were submitted to outlier tests. In the iis procedure for proficiency tests, outliers are detected prior to calculation of the mean, standard deviation and reproducibility. For small data sets, Dixon

(up to 20 test results) or Grubbs (up to 40 test results) outlier tests can be used. For larger data sets (above 20 test results) Rosner's outlier test can be used. Outliers are marked by D(0.01) for the Dixon's test, by G(0.01) or DG(0.01) for the Grubbs' test and by R(0.01) for the Rosner's test. Stragglers are marked by D(0.05) for the Dixon's test, by G(0.05) or DG(0.05) for the Grubbs' test and by R(0.05) for the Rosner's test. Both outliers and stragglers were not included in the calculations of averages and standard deviations.

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. In this PT, the criterion of ISO13528, paragraph 9.2.1. was met for all evaluated tests. Therefore, the uncertainty of all assigned values may be negligible and need not be included in the PT report.

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

3.2   GRAPHICS

In order to visualize 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 test results are plotted. The corresponding laboratory numbers are on 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 reference test method. 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. Also, a normal Gauss curve (dotted line) was projected over the Kernel Density Graph (smooth line) for reference. The Gauss curve is calculated from the consensus value and the corresponding standard deviation.

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 (derived from e.g. ISO or ASTM test methods), the z-scores were calculated using a target standard deviation. This results in an evaluation independent of the variation in this interlaboratory study.

The target standard deviation was calculated from the literature reproducibility by division with 2.8. In case no literature reproducibility was available, other target values were used, like Horwitz or an estimated reproducibility based on former iis proficiency tests.

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 whether the reported test result is fit-for-use.

The z-scores were calculated according to:

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

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

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:

|z| < 1   good
1 < |z| < 2   satisfactory
2 < |z| < 3   questionable
3 < |z| unsatisfactory

4   EVALUATION

In this proficiency test no problems were encountered with the dispatch of the samples. Four participants reported test results after the final reporting date and two other participants did not report any test results. Not all participants were able to report all tests requested. In total 47 participants reported 47 numerical test results for average Overall Migration per contact surface. Observed were 2 outlying test results, which is 4.3%. In proficiency tests outlier percentages of 3% - 7.5% are quite normal.

The data set did not prove to have a normal Gaussian distribution and is referred to as "suspect". The statistical evaluation of this data set should be used with due care, see also paragraph 3.1.

4.1   EVALUATION OF THE TEST RESULTS

In this section the reported test results are discussed. The test methods which were used by the various laboratories were taken into account for explaining the observed differences when possible and applicable. These test methods are also in the tables together with the original data in appendix 1. The abbreviations, used in these tables, are explained in appendix 5.

In the past iis has observed that for the Overall and Specific Migration methods, limits and calculations are mixed up and used inappropriately by participants. Therefore, iis issued a White Paper on this subject in February 2018 (see lit. 16) to help participants understand the differences between the two methods, the units used for reporting and the regulated limits.

For the determination of Overall Migration (also called Global or Total Migration) on food contact material by total immersion, the EN1186 method is considered to be the official EC test method. In August 2022 a new version of EN1186-3 has been published. In this version a sufficient number of materials or articles should be used to provide a surface area of 1 dm^2. For testing a surface area of 1 dm^2 and a volume of 100 mL are recommended.

In this 2023 PT a set of three samples (knives) were available for both surface area determination and the migration test. The surface area of the three knives together was smaller than 1 dm^2. Therefore, the participants were requested to test the knives separately and report the average overall migration of the three knives. In future PTs iis will provide a (set of) sample that has a surface area of at least 1 dm^2.

Overall Migration: The group of participants had difficulty to meet the target requirements. Two statistical outliers were observed. The calculated reproducibility after rejection of the statistical outliers is not in agreement with the target reproducibility estimated from EN1186-3:22.
When the test results of reported for the 2022 version are evaluated separately, the calculated reproducibility is lower but still not in agreement with the target reproducibility estimated from EN1186-3:22.

4.2 PERFORMANCE EVALUATION FOR THE GROUP OF LABORATORIES

A comparison has been made between the reproducibility as declared by the reference test method and the reproducibility as found for the group of participating laboratories. The number of significant test results, the average, the calculated reproducibility (2.8 * standard deviation) and the estimated target reproducibility derived from the reference method is presented in the next table.

Parameter	unit	n	average	2.8 * sd	R(lit)
Overall Migration	mg/dm^2	45	21.17	15.95	10.21

Table 1: reproducibility of tests on sample #23715

Without further statistical calculations it can be concluded that for Overall Migration per contact surface there is not a good compliance of the group of participating laboratories with the target reproducibility estimated from EN1186-3:22.

4.3 COMPARISON OF THE PROFICIENCY TEST OF OCTOBER 2023 WITH PREVIOUS PTS

	October 2023	October 2022	October 2021	October 2020	October 2019
Number of reporting laboratories	47	46	44	46	49
Number of test results	47	46	131	45	122
Number of statistical outliers	2	2	7	2	5
Percentage of statistical outliers	4.3%	4.3%	5.3%	4.4%	4.1%

Table 2: comparison with previous proficiency tests

In proficiency tests outlier percentages of 3% - 7.5% are quite normal.

The performance of the determinations of the proficiency test was compared to uncertainties observed in PTs over the years, expressed as relative standard deviation (RSD) of the PTS, see next table.

year	article filling	total immersion	# of items	EN1186
2013	-----	25-30%	2	11% (part 3)
2014	18%	-----	3	17% (part 8)
2015	14%	-----	3	8% (part 9)
2016	17%	29%	3 – 1	8% (part 9) – 13% (part 3)
2017	-----	32-36%	1	17% (part 3)
2018	13-17%	-----	1	17% (part 9)
2019	-----	16-22%	1	17% (part 3)
2020	-----	19%	3	17% (part 3)
2021	13-21%	-----	1	17% (part 9)
2022	16%	-----	3	17% (part 9)
2023	-----	27%	3	17% (part 3)

Table 3: development of the uncertainties over the years

The uncertainty observed in this PT is in line with the uncertainties observed in previous PTs for total immersion.

Sample #23715 was used in a previous iis PT as sample #20675 in the PT iis20P09GM. The result of this 2023 PT (sample #23715) is in line with the result of the 2020 PT (sample #20675).

	unit	sample #23715			sample #20675		
		n	average	R(calc)	n	average	R(calc)
Overall Migration	mg/dm^2	45	21.17	15.95	42	21.55	11.17

Table 4: comparison of sample #23715 with #20675

4.4   EVALUATION OF THE ANALYTICAL DETAILS

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 selected by the participating laboratories. Therefore, a set of prescribed test conditions (known to give a positive test result) was given together with the instructions to all participants:

Sample #20675	3 identical plastic disposable knifes
Simulant	3% M/V acetic acid
Time of exposure	2 hours
Temperature of exposure	70°C
Method of migration	Total immersion, single use
Volume of simulant	as per method used

Table 5: prescribed test conditions in this PT

The participants were requested to report the intermediate test results for the three knives and the average Overall Migration. Additional details regarding preparation, residue, surface area, simulant volume and details about the evaporation step were also requested. See appendices 2 and 3 for the reported details.

Test method and accreditation
About 95% of the reporting participants mentioned to have used test method EN1186-3. Not all participants used the 2022 version of EN1186-3, twelve participants used another part or an older version of EN1186.
From the reporting participants 87% mentioned that they are accredited for this test.

Preparation
Twenty-seven participants reported not to clean the sample, three participants reported to clean without specifying how and nine participants cleaned with a lint free cloth/tissue or soft brush. Method EN1186-3:22 states in paragraph 4.4.1: "Before preparing test specimens, remove any surface contamination from the sample by gently wiping it with a lint-free cloth, or by brushing with a soft brush or with a compressed air stream." This new version also states in the same paragraph: "As a general rule, do not wash the test specimens with water or solvent. However, if the articles are accompanied by instructions for use intended for the user advising cleaning before use, these instructions should be followed for the test."
iis did not specify cleaning instructions for this sample. Surprisingly, six participants reported to have used water and/or a detergent/soap to clean the test item prior to use.
However, in general can be concluded that it appears that these cleansing methods have a negligible effect on the Overall Migration in mg/dm^2 in this PT.

Ratio dm^2 per 100 mL, contact surface and volume of simulant
In method EN1186-3:22 the ratio of 1 dm^2/100mL is prescribed (see paragraph 4.5). In appendix 2 the ratio calculated by iis is given based on the reported details of the participants.
Only twenty-six of the reporting participants used a surface to volume ratio of 1 dm^2/100mL, on average over all participants the volume to surface ratio was nearly 1.5 dm^2/100mL. Remarkably, this did not have an effect on the Overall Migration test results in this PT.

Evaporation: temperature and time
After exposure of the plate to the simulant for the selected time, the simulant must be evaporated to dryness. The reported evaporation temperature varied from 65 to 300°C. About 65% of the reporting participants used an evaporation temperature between 100°C and 150 °C. The reported evaporation time varied from 120 minutes to overnight. About 55% of the reporting participants used an evaporation time less than 300 minutes.
The differences in evaporation temperature and time did not appear to be of influence on the test results of the samples in this PT.

5   DISCUSSION

Limits for Overall Migration from EU regulation No 10/2011
The EU regulation No 10/2011 describes in article 12 that the limit for Overall Migration is 10 mg/dm^2. In this PT the Overall Migration found should comply with this limit for Overall Migration. According to this limit all reporting participants, except one, would have rejected sample #23715.

6   CONCLUSION

It is to be expected that the variation of the migration test results in real life practice will be larger than observed in this PT as the test conditions like time, temperature, etc. will not be prescribed but will be selected by the individual laboratories.

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

Average Overall Migration (per contact surface) on sample #23715; results in mg/dm^2

| lab	method	value	mark	z(targ)	remarks
339	EN1186-3:02	13.11		-2.21	
362	EN1186-3:22	18.27	C	-0.79	first reported: 10.512
551		-----		-----	
2108	EN1186-3:22	26.82		1.55	
2115	EN1186-3	26.53	C	1.47	reported 3.92, iis calculated 26.53
2132	EN1186-3:22	15.98		-1.42	
2156	EN1186-3:22	23.333		0.59	
2165	EN1186-3:22/GB31604.8:21	21.597		0.12	
2184	EN1186-3:22	19.762		-0.39	
2215	EN1186-3:22	20.333		-0.23	
2216		13	C	-2.24	first reported: 10.3
2241	EN1186-3:22	21.340		0.05	
2247	EN1186-3:02	25.317		1.14	
2284	EN1186-3:22	20.732		-0.12	
2300	EN1186	18.07		-0.85	
2353	EN1186-3:22	21.07		-0.03	
2365	EN1186-3:22	21.176		0.00	
2366	EN1186-3:22	21.3		0.04	
2384	EN1186-3:22	22.9		0.48	
2385	EN1186-3:22	20.44		-0.20	
2406	EN1186-3:02	26.72		1.52	
2424		-----		-----	
2429	EN1186-3:22	27.92		1.85	
2475	EN1186-3:22	12.432		-2.40	
2482	EN1186-3:22	17.097		-1.12	
2495	EN1186-3:02	18.93		-0.61	
2553		42.6	DG(0.05)	5.88	
2573	EN1186-3:22	32.764		3.18	
2734	EN1186-3:22	15.01		-1.69	
2797	EN1186-3:22	12.39		-2.41	
2798	EN1186-3:22	17.98		-0.87	
2826	EN1186-3:22	21.67		0.14	
2850	EN1186-3:22	23.7		0.69	
2862	EN1186-3:22	23.3		0.59	
2901	EN1186-3:02	36.76	DG(0.05)	4.28	
2936		3.66	C	-4.80	first reported: 89.14
2976	EN1186-3:22	25.1		1.08	
3002	EN1186-3:02	20.852		-0.09	
3024	EN1186-1	19.8502		-0.36	
3100	EN1186-3:22	20.693		-0.13	
3172	EN1186-3:22	29.9225		2.40	
3185	EN1186-3:22	27.937		1.86	
3192	EN1186-3:22	13.2826		-2.16	
3218	EN1186-3:22	30.758		2.63	
3225	EN1186-3:22	23.97		0.77	
3228	EN1186-3:22	21.508		0.09	
3233	EN1186-3:22	20.5		-0.18	
3248	EN1186-3:02	21.9		0.20	
8030	EN1186-3	31.56		2.85	

					Only EN1186-3:22:
	normality	suspect			OK
	n	45			33
	outliers	2			0
	mean (n)	21.166			21.606
	st.dev. (n)	5.6979	RSD = 27%		4.9443　　RSD = 23%
	R(calc.)	15.954			13.844
	st.dev.(EN1186-3:22)	3.6463			3.7220
	R(EN1186-3:22)	10.210			10.422
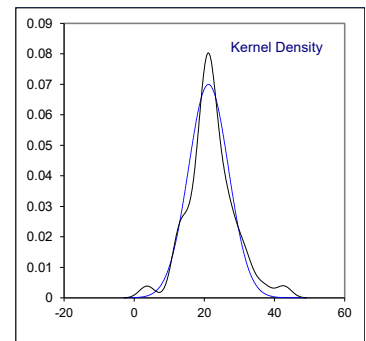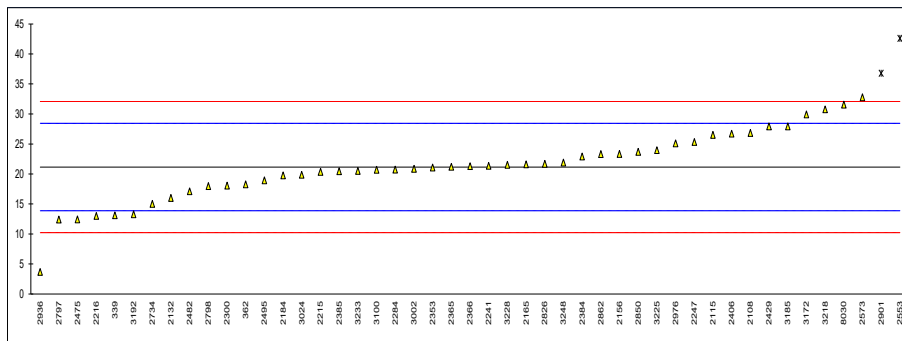
APPENDIX 2
Details on reported intermediate test results on sample #23715: knife 1

lab	total residue (mg)	surface area (dm²)		volume simulant (ml)	Overall Migration (mg/dm²)		remarks
339	8.4	0.61		60	13.61		
362	5.4	0.52		100	18.27	C	first reported: 10.384
551	-----	-----		-----	-----		
2108	11.4	0.435		100	26.21		
2115	4.82	0.1431		50	32.65		
2132	7.4	0.4819		48	15.36		
2156	9.7	0.43		69.0	22.558		
2165	10.2	0.48		80	21.250		
2184	83	0.42		70	19.762		
2215	9.760	0.48		80	20.333		
2216	5	0.4577	C	100	11	C	first reported: 0.6139 and 8.1
2241	9.35	0.46		46	20.326		
2247	10.100	0.404		50.00	24.987		
2284	10.7	0.492		65	21.748		
2300	8.6	0.45		45	19.11		
2353	10.71	0.5030		50	20.60		
2365	9.3	0.425		42.5	21.882		
2366	8.7	0.42		42	20.7		
2384	8.7	0.3472		50	23.7		
2385	6.2	0.3		30	20.67		
2406	8.5	0.3618		37	23.49		
2424	-----	-----		-----	-----		
2429	12.0	0.43		43.0	27.91		
2475	7.6	0.5648		85	13.102		
2482	7.4	0.464		100	15.948		
2495	7.56	0.41		40	18.90		
2553	13.4	0.3212		53.53	41.7		
2573	13.0 C	0.41		41	31.707		first reported: 13.2
2734	3.3	0.2736		50.0	12.11		
2797	6	0.5003		100	11.99		
2798	9.1	0.53		50	17.17		
2826	10.9	0.4806		50	21.8		
2850	8.97	0.38		38	23.6		
2862	10.2	0.44		57	23.2		
2901	12.8	0.355		170	36.056		
2936	3.7	0.5022		42	3.52	C	first reported: 88.09
2976	12.9	0.549		54.9	23.5		
3002	8.423	0.3644		60.74	19.705		
3024	5.70	0.3560		100.00	16.0112		
3100	10.7	0.512		51	20.898		
3172	12.8	0.43		71.6	29.7674		
3185	12.1	0.418		42	28.810		
3192	7.88	0.516466		0.95	15.2575		
3218	13.6	0.44		100	30.909		
3225	9.8	0.40		67	24.5		
3228	9.1	42.55		70	20.952		
3233	11.4	0.48		48	23.8		
3248	7.9	0.36		40	21.9		
8030	11.19	0.35		35	31.97		

Details on reported intermediate test results on sample #23715: knife 2

lab	total residue (mg)	surface area (dm²)		volume simulant (ml)	Overall Migration (mg/dm²)		remarks
339	7.2	0.61		60	11.64		
362	5.6	0.52		100	18.08	C	first reported: 10.769
551	-----	-----		-----	-----		
2108	11.8	0.435		100	27.13		
2115	3.69	0.1431		50	25.17		
2132	7.0	0.4819		48	14.53		
2156	10.1	0.43		69.0	23.488		
2165	10.1	0.48		80	21.040		
2184	86	0.42		70	20.476		
2215	9.690	0.48		80	20.187		
2216	5.7	0.4559	C	100	13	C	first reported: 0.5737 and 9.9
2241	9.65	0.46		46	20.978		
2247	9.800	0.404		50.00	24.245		
2284	10.1	0.492		65	20.528		
2300	8.5	0.45		45	18.89		
2353	11.03	0.5030		50	21.23		
2365	8.9	0.425		42.5	20.941		
2366	8.9	0.42		42	21.2		
2384	8.3	0.3472		50	22.6		
2385	6.1	0.3		30	20.33		
2406	10.8	0.3618		37	29.85		
2424	-----	-----		-----	-----		
2429	12.0	0.43		43.0	27.91		
2475	7.0	0.5648		85	12.039		
2482	8.2	0.464		100	17.672		
2495	6.97	0.41		40	17.43		
2553	13.5	0.321		53.50	42.1		
2573	13.4 C	0.41		41	32.683		first reported: 13.6
2734	4.40	0.2718		50.0	16.19		
2797	6.2	0.5003		100	12.39		
2798	9.5	0.53		50	17.92		
2826	10.6	0.4806		50	21.20		
2850	9.15	0.38		38	24.1		
2862	10.7	0.44		58	24.2		
2901	13.3	0.355		170	37.465		
2936	3.7	0.5022		42	3.76	C	first reported: 88.09
2976	14.6	0.549		54.9	26.6		
3002	9.690	0.3644		60.74	23.183		
3024	8.10	0.3560		100.00	22.7528		
3100	9.8	0.510		51	19.216		
3172	12.5	0.43		71.6	29.0698		
3185	12.2	0.418		42	29.048		
3192	5.24	0.516466		0.95	10.1459		
3218	13.9	0.44		100	31.591		
3225	9.3	0.40		67	23.25		
3228	9.2	42.14		70	21.429		
3233	8.5	0.48		48	17.7		
3248	7.8	0.36		40	21.7		
8030	10.90	0.35		35	31.14		

Details on reported intermediate test results on sample #23715: knife 3

lab	total residue (mg)	surface area (dm²)		volume simulant (ml)	Overall Migration (mg/dm²)		remarks
339	8.7	0.61		60	14.10		
362	5.4	0.52		100	18.46	C	first reported: 10.769
551	-----	-----		-----	-----		
2108	11.8	0.435		100	27.13		
2115	3.21	0.1431		50	21.77		
2132	8.7	0.4819		48	18.05		
2156	10.3	0.43		69.0	23.953		
2165	10.8	0.48		80	22.500		
2184	80	0.42		70	19.048		
2215	9.830	0.48		80	20.479		
2216	7.4	0.4561	C	100	16	C	first reported 0.5737 and 9.9
2241	10.45	0.46		46	22.717		
2247	10.800	0.404		50.00	26.710		
2284	9.8	0.492		65	19.919		
2300	7.3	0.45		45	16.22		
2353	11.10	0.5030		50	21.37		
2365	8.8	0.425		42.5	20.706		
2366	9.2	0.42		42	21.9		
2384	8.2	0.3472		50	22.3		
2385	6.1	0.3		30	20.33		
2406	9.7	0.3618		37	26.81		
2424	-----	-----		-----	-----		
2429	12.3	0.44		44.0	27.95		
2475	6.5	0.51		85	12.156		
2482	8.2	0.464		100	17.672		
2495	8.18	0.41		40	20.45		
2553	14.1	0.3214		53.57	43.9		
2573	13.9 C	0.41		41	33.902		first reported: 13.6
2734	4.70	0.2810		50.0	16.72		
2797	6.4	0.5003		100	12.79		
2798	10.0	0.53		50	18.87		
2826	11.0	0.4806		50	22.00		
2850	8.87	0.38		38	23.3		
2862	9.93	0.44		58	22.5		
2901	13.05	0.355		170	36.761		
2936	3.9	0.5022		42	3.69	C	first reported: 88.09
2976	13.9	0.549		54.9	25.3		
3002	8.410	0.3644		60.74	19.668		
3024	7.40	0.3560		100.00	20.7865		
3100	11.4	0.519		52	21.965		
3172	13.3	0.43		71.6	30.9302		
3185	10.9	0.418		42	25.952		
3192	7.46	0.516466		0.95	14.4443		
3218	13.1	0.44		100	29.773		
3225	9.7	0.40		67	24.2		
3228	9.9	42.29		70	22.143		
3233	9.6	0.48		48	20.0		
3248	8.0	0.36		40	22.2		
8030	11.05	0.35		35	31.57		

APPENDIX 3
Summary of reported analytical details

lab	ISO17025 accredited	sample cleaned prior to migration step	sample exposed of simulant
339	Yes	No	Further cut, all pieces of one sample were used per determination
362	---	---	---
551	---	---	---
2108	No	Yes, Cleaned with a lint-free cloth	Used as received (one sample per determination)
2115	Yes	No	Further cut, but only a part of a sample was used per determination
2132	Yes	Yes, use DI water to clean the sample	Used as received (one sample per determination)
2156	Yes	No	Used as received (one sample per determination)
2165	Yes	No	Used as received (one sample per determination)
2184	Yes	No	Used as received (one sample per determination)
2215	Yes	Yes, Brushing with a soft brush	Used as received (one sample per determination)
2216	Yes	Yes, washed with DI water at 190 °F	Used as received (one sample per determination)
2241	Yes	No	Used as received (one sample per determination)
2247	Yes	Yes, Surface cleaned by tissue paper	---
2284	Yes	No	Used as received (one sample per determination)
2300	No	Yes, with lint free cloth	Used as received (one sample per determination)
2353	Yes	No	Used as received (one sample per determination)
2365	Yes	No	Further cut, all pieces of one sample were used per determination
2366	Yes	No	Further cut, all pieces of one sample were used per determination
2384	Yes	No	Further cut, all pieces of one sample were used per determination
2385	Yes	No	Further cut, all pieces of one sample were used per determination
2406	No	No	Used as received (one sample per determination)
2424	---	---	---
2429	Yes	Yes, Soft cloth.	Further cut, all pieces of one sample were used per determination
2475	Yes	No	Used as received (one sample per determination)
2482	No	Yes, with a lint free cloth	Used as received (one sample per determination)
2495	Yes	Yes, with soap and cold water	Used as received (one sample per determination)
2553	No	Yes, cleaned using a lint free clothing	Used as received (one sample per determination)
2573	Yes	No	Further cut, but only a part of a sample was used per determination
2734	---	---	---
2797	Yes	No	Used as received (one sample per determination)
2798	Yes	No	Used as received (one sample per determination)
2826	Yes	No	Further cut, all pieces of one sample were used per determination
2850	Yes	No	Used as received (one sample per determination)
2862	Yes	No	Used as received (one sample per determination)
2901	Yes	No	Used as received (one sample per determination)
2936	Yes	Yes	Only the parts in contact with food were exposed to the simulant
2976	Yes	Yes	Used as received (one sample per determination)
3002	Yes	Yes, cleaned with water	Used as received (one sample per determination)
3024	Yes	Yes, rinsed with purified water	Used as received (one sample per determination)
3100	Yes	Yes, wiping with a lintfree cloth.	Used as received (one sample per determination)
3172	Yes	No	Used as received (one sample per determination)
3185	Yes	Yes	Used as received (one sample per determination)
3192	Yes	No	Used as received (one sample per determination)
3218	Yes	Yes, Rinse with distilled water	Used as received (one sample per determination)
3225	Yes	Yes, cleaned with dusk free cloth	Used as received (one sample per determination)
3228	Yes	No	Used as received (one sample per determination)
3233	No	No	Further cut, all pieces of one sample were used per determination
3248	Yes	No	Further cut, all pieces of one sample were used per determination
8030	Yes	No	Used as received (one sample per determination)

Summary of reported analytical details – continued --

lab	equipment used for migration step	evaporation time (min)	evaporation temperature (°C)
339	Oven	---	90°C
362	---	---	---
551	---	---	---
2108	Oven	Synchore 5,5 h Sand bath 22 h Drying cabinet	Synchore 80°C, 30 mbar Sand bath 100-200°C
2115	Incubator	250 min	110 °C
2132	Oven	1 hour	
2156	Oven	240 minutes.	100 °C.
2165	Oven	over night	105°C
2184	Incubator	180 mins	105°C oven
2215	Oven	8h	100℃
2216	Oven	Approx. 210 minutes	Approx. 300 degrees C
2241	Oven	150min	150℃
2247	Oven	120 Mins	100 ± 2°C
2284	Oven	12h	105°C
2300	Oven	115 minutes	200°C
2353	Oven	around 60 minutes	105
2365	Oven	8h	105℃
2366	Oven	---	---
2384	Oven	300 min.	220
2385	Oven	over night	105 °C
2406	Water bath	60 mins	~90 degC
2424	---	---	---
2429	Incubator	About 2.5 hours.	270 degrees Celsius.
2475	Oven	18H	105
2482	Oven	about 14 h	105 °C
2495	Oven	Around 2 hours	105
2553	Oven	45 minutes	105
2573	Oven	about 2hours	200-250℃
2734	---	---	---
2797	Incubator	---	---
2798	Oven	6h	105
2826	Oven	Overnight	105°C – 110°C
2850	Incubator	1440	105
2862	Oven	5 h 15 min	125-175°C
2901	Oven	540 min	220
2936	Oven	120	70
2976	Oven	8 hours	105°C
3002	Oven	2 hours	70°C
3024	Oven	---	At 105°C and above
3100	Oven	120min	105℃
3172	Oven	300	105
3185	Oven	about 90 minutes	about 150℃（hot plate）
3192	Oven	459	65-75°C
3218	Oven	2hours	300℃-105℃
3225	Oven	60	100
3228	Oven	24h	105
3233	Oven	1020 min	105°C
3248	Oven	3 hours	70
8030	Oven	1.30 hr	200 Degree Celsius

APPENDIX 4

Number of participants per country

```
 2 labs in BRAZIL
  1 lab in BULGARIA
  1 lab in CROATIA
 3 labs in FRANCE
 5 labs in GERMANY
 7 labs in HONG KONG
 2 labs in INDIA
  1 lab in ISRAEL
 6 labs in ITALY
 2 labs in MALAYSIA
13 labs in P.R. of CHINA
  1 lab in SERBIA
  1 lab in SRI LANKA
  1 lab in THAILAND
 2 labs in U.S.A.
  1 lab in VIETNAM
```

APPENDIX 5

Abbreviations

C   = final test result after checking of first reported suspect test 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
R(0.01)   = outlier in Rosner's outlier test
R(0.05)   = straggler in Rosner's outlier test
E   = calculation difference between reported test result and result calculated by iis
W   = test result withdrawn on request of participant
ex   = test result excluded from statistical evaluation
n.a.   = not applicable
n.e.   = not evaluated
n.d.   = not detected
fr.   = first reported
f+?   = possibly a false positive test result?
f-?   = possibly a false negative test result?

Literature

1   iis Interlaboratory Studies, Protocol for the Organisation, Statistics & Evaluation, June 2018
2   ISO5725:86
3   ISO5725 parts 1-6:94
4   ISO13528:05
5   M. Thompson and R. Wood, J. AOAC Int, 76, 926, (1993)
6   W.J. Youden and E.H. Steiner, Statistical Manual of the AOAC, (1975)
7   P.L. Davies, Fr. Z. Anal. Chem, 331, 513, (1988)
8   J.N. Miller, Analyst, 118, 455, (1993)
9   Analytical Methods Committee, Technical Brief, No 4, January 2001
10   P.J. Lowthian and M. Thompson, The Royal Society of Chemistry, Analyst, 127, 1359-1364, (2002)
11   W. Horwitz and R. Albert, J. AOAC Int, 79.3, 589-621, (1996)
12   Bernard Rosner, Percentage Points for a Generalized ESD Many-Outlier Procedure, Technometrics, 25(2), 165-172, (1983)
13   Commission regulation (EU) No 10/2011 of January 2011 on plastic materials and articles intended to come into contact with food, published in the official journal of the EU on the 15th of Janary 2011
14   Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, 21st of February 2014, website: ec.europa.eu
15   Commission regulation (EU) No 2020/1245 of September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, published in the official journal of the EU on the 3rd of September 2020
16   iis memo 1801: White paper on the determinations of Overall and Specific migration on food contact materials, February 2018, www.iisnl.com