

**Results of Proficiency Test
Specific migration (fcm)
October 2016**

Organised by: Institute for Interlaboratory Studies
Spijkenisse, the Netherlands

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CONTENTS

1	INTRODUCTION	3
2	SET-UP	3
2.1	ACCREDITATION.....	4
2.2	PROTOCOL.....	4
2.3	CONFIDENTIALITY STATEMENT	4
2.4	SAMPLES	4
2.5	ANALYSES	5
3	RESULTS.....	5
3.1	STATISTICS.....	6
3.2	GRAPHICS	6
3.3	Z-SCORES.....	7
4	EVALUATION	7
4.1	EVALUATION PER TEST	8
4.2	EVALUATION OF THE TEST METHODS USED	9
4.3	PERFORMANCE EVALUATION FOR THE GROUP OF LABORATORIES	11
4.4	COMPARISON WITH PREVIOUS PROFICIENCY TESTS	11
5	DISCUSSION.....	11

Appendices:

1.	Data, statistical results and graphical results	13
2.	Details reported by the participating laboratories.....	23
3.	Other results reported by participating laboratories on Specific Migration.....	24
4.	Number of participating laboratories per country	25
5.	Abbreviations and literature	26

1 INTRODUCTION

Since 2012, the Institute of Interlaboratory Studies (iis) organizes a proficiency test scheme for food contact materials. During the annual proficiency testing program 2016/2017, it was decided to continue the proficiency test for the determination of Specific Migration.

During the contact of food with materials like kitchenware, molecules can migrate from the 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. 3) 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 11 (and Annex II) of this regulation describes the specific migration limit, expressed in mg/kg food or food simulant. It has been recently amended with regulation 1416/2016/EU in which a limit for Aluminium and a lower limit for Zinc is published (implementation date is September 2018, see lit. 19).

For metals, the following specific migration limit applies:

Metal	Specific Migration Limit (mg/kg food simulant) 10/2011/EU	Specific Migration Limit (mg/kg food simulant) amendment 1416/2016/EU
Aluminium	not restricted	1
Barium	1	1
Cobalt	0.05	0.05
Copper	5	5
Iron	48	48
Lithium	0.6	0.6
Manganese	0.6	0.6
Zinc	25	5

Table 1: specific migration maximum limits

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. This makes the specific migration of metals from food contact materials more difficult than determination of the overall migration.

In the interlaboratory study of September 2016, 35 laboratories from 16 different countries participated (see appendix 4). In this report, the results of the 2016 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 Spijkensisse, the Netherlands, was the organiser of this proficiency test (PT). Sample analyses for fit-for-use and homogeneity testing were subcontracted to an ISO/IEC 17025 accredited laboratory. It was decided to send one sample, that was artificially fortified with different metals, and to prescribe a number of test conditions (migration method, type of simulant, exposure time and temperature) to be used. Participants were also requested to report some intermediate test results and 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/IEC 17043:2010 (R007), since January 2000, by the Dutch Accreditation Council (Raad voor Accreditatie). This PT falls in 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 organisation 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 April 2014 (iis-protocol, version 3.3). 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 polypropylene plates of 15 x 15 cm containing a relevant concentration of the metals Barium, Cobalt, Copper and Zinc was prepared. The homogeneity of the batch #16620 was checked by determination of the specific migration of Cobalt on 8 stratified randomly selected plates.

	migration of Cobalt in mg/kg food simulant (3% acetic acid, 60 min at 100°C)
Sample #16620-1	0.19
Sample #16620-2	0.22
Sample #16620-3	0.22
Sample #16620-4	0.23
Sample #16620-5	0.21
Sample #16620-6	0.19
Sample #16620-7	0.20
Sample #16620-8	0.19

Table 2: results of the homogeneity test on the subsamples #16620

From the above results, the observed repeatability was calculated and compared with 0.3 times the corresponding reproducibility of the target method in agreement with the procedure of ISO 13528, Annex B2 in the next table:

	migration of Cobalt in mg/kg food simulant (3% acetic acid, 60 min at 100°C)
r(observed)	0.04
reference	Horwitz
0.3 x R (reference)	0.04

Table 3: evaluation of the repeatability of subsamples #16620

The calculated repeatability was in good agreement with 0.3 times the corresponding target reproducibility, estimated from the Horwitz equation. Therefore, homogeneity of the sub samples was assumed.

To each of the participating laboratories one sample #16620 was sent on September 7, 2016.

2.5 ANALYSES

The participants were requested to determine the metals Barium, Cobalt, Copper, Iron, Lithium, Manganese and Zinc on sample #16620 using the prescribed test conditions (total immersion, 2.0 hrs at 100°C and 3% Acetic acid as simulant). 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 results, but report as much significant figures as possible. 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 evaluations. The laboratories were also requested to report some details of the test methods used.

To get comparable results a detailed report form, on which the units were prescribed as well as the reference test methods and a letter of instructions were prepared and made available on the data entry portal www.kpmd.co.uk/sgs-iis-cts/. The laboratories were requested to confirm the sample receipt on the same data entry portal.

3 RESULTS

During five weeks after sample dispatch, the 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 in the appendix 1 of this report. The laboratories are represented by the 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.

Additional or corrected test results are used for the data analysis and the original results are placed under 'Remarks' in the result tables in appendix 1. 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 organisation of this proficiency test was the one as described in the report 'iis Interlaboratory Studies, Protocol for the Organisation, Statistics and Evaluation' of April 2014 (iis-protocol, version 3.3).

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. Not all data sets proved to have a normal distribution, in which cases the statistical evaluation of the results should be used with due care.

In accordance to ISO 5725 the original test results per determination were submitted subsequently to Dixon, Grubbs and/or Rosner General ESD outlier tests. 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. 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. 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.

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

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 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 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. Also a normal Gauss curve was projected over the Kernel Density Graph for reference.

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. In case no literature reproducibility was available, other target values were used.

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 should be done in order to evaluate whether the reported test result is fit-for-use.

The z-scores were calculated according to:

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

The $z_{(\text{target})}$ scores are listed in the 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 interlaboratory study, no problems were encountered with the dispatch of the samples. No participants reported test results after the final reporting date, but three participants did not report any test results at all. Thus, 32 of the 35 participants submitted test results.

In total over 400 (intermediate) results were reported, of which 227 test results in both mg/dm² and mg/kg food simulant. From this, fifteen participants reported test results in both mg/dm² contact surface and mg/kg food simulant, a further nine participants only a test result in mg/dm² and seven only a test result in mg/kg. In total five statistical outliers were observed, which is 2.2% of the combined migration results in mg/dm² contact surface and mg/kg food simulant. In proficiency studies, outlier percentages of 3% - 7.5% are quite normal. It should be noted that twenty test results were excluded from the statistical evaluations (= 8.8%!).

For the determination of Specific Migration, several standardised test methods exist. The most relevant literature is test method EN13130 part 1. Method EN13130-1 describes how the specific migration test should be performed. Regretfully no reference test method is available with precision requirements for the migration of metals from food contact materials. Therefore, it was decided to estimate the target reproducibilities from the Horwitz equation.

Method EN13130-1 describes that the volume to surface ratio that should be used for this test (see paragraph 10.2 of EN13130-1:2004) is 100 ml for 0.6 dm². This is a volume to surface ratio of 167 ml/ dm². Surprisingly, only 48% of the reporting laboratories used a volume to surface ratio of 167 ml/dm². This is less than the 60% that used the correct ratio in last year's PT.

Only when using the volume to surface ratio of 100 ml for 0.6 dm², automatically the calculated result in mg/kg food simulant will be the same as the result obtained by the multiplication of the result in mg/dm² with the conventional conversion factor 6.

Five laboratories (2115, 2129, 2384, 2495 and 2760) were excluded from the evaluation in mg/kg food simulant, because the conventional conversion factor 6 obviously was not used to calculate the results from mg/dm² to mg/kg food simulant.

4.1 EVALUATION PER TEST

Concentration metals in simulant in mg/l final solution of simulant:

These intermediate results were not evaluated as they are in principle dependent on the amount of simulant used.

Specific migration of Barium in mg/dm² contact surface:

This determination may be problematic. One statistical outlier was observed. The calculated reproducibility after rejection of the statistical outlier is not in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Barium in mg/kg food simulant:

This migration result is obtained from the specific migration in mg/dm² by multiplication with the conventional conversion factor 6.

This determination may be problematic. No statistical outliers were observed, but five test results were excluded for not using the conventional conversion factor 6. The calculated reproducibility after rejection of the suspect data is not in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Cobalt in mg/dm² contact surface:

This determination may not be problematic. Two statistical outliers were observed. However, the calculated reproducibility after rejection of the statistical outliers is in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Cobalt in mg/kg food simulant:

This migration result is obtained from the specific migration in mg/dm² by multiplication with the conventional conversion factor 6.

This determination may be problematic. No statistical outliers were observed, but five test

results were excluded for not using the conventional conversion factor 6. The calculated reproducibility after rejection of the suspect data is not in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Copper in mg/dm² contact surface:

This determination may be problematic. One statistical outlier was observed. The calculated reproducibility after rejection of the statistical outlier is not in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Copper in mg/kg food simulant:

This migration result is obtained from the specific migration in mg/dm² by multiplication with the conventional conversion factor 6.

This determination may be problematic. No statistical outliers were observed, but five test results were excluded for not using the conventional conversion factor 6. The calculated reproducibility after rejection of the suspect data is not in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Zinc in mg/dm² contact surface:

This determination may be problematic. One statistical outlier was observed. The calculated reproducibility after rejection of the statistical outlier is not in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Copper in mg/kg food simulant:

This migration result is obtained from the specific migration in mg/dm² by multiplication with the conventional conversion factor 6.

This determination may be problematic. No statistical outliers were observed, but five test results were excluded for not using the conventional conversion factor 6. The calculated reproducibility after rejection of the suspect data is not in agreement with the estimated reproducibility using the Horwitz equation.

Specific migration of Iron, Lithium and Manganese in mg/dm² and mg/kg food simulant:

The majority of the participants did not detect these metals in the simulant solution and reported a 'smaller than' value or "not detected".

Specific migration of metals in mg/L food:

The majority of the participants reported the same test result in mg/L food as the result in mg/kg food, as is described in method EN13130-1 (see appendix 3).

4.2 EVALUATION OF THE TEST METHODS USED

Most participants reported to have used EN13130 (part 1). Eight laboratories reported to have used an in house method and one other laboratory used EN1186. EN1186 is a method to determine Overall Migration. Two laboratories reported to have used EU 10/2011. The reported details that were used by the participants (volume of simulant and contact surface) are listed in appendix 2 and 3. The actual concentrations measured in the simulant for each metal are listed in appendix 3.

4.3 PERFORMANCE EVALUATION FOR THE GROUP OF LABORATORIES

A comparison has been made between the reproducibility as declared by the relevant test method and the reproducibility as found for the group of participating laboratories. The target reproducibilities derived from literature standards are compared in the next tables.

Specific Migration	unit	n	Average	2.8 * sd	R (target)
Barium	mg/dm ²	24	0.29	0.29	0.16
Cobalt	mg/dm ²	23	0.05	0.03	0.03
Copper	mg/dm ²	24	0.33	0.26	0.17
Iron	mg/dm ²	23	<8	n.a.	n.a.
Lithium	mg/dm ²	22	<0.1	n.a.	n.a.
Manganese	mg/dm ²	22	<0.1	n.a.	n.a.
Zinc	mg/dm ²	24	0.58	0.48	0.28

Table 4: Reproducibilities of tests on sample #16620 in mg/dm²

Specific Migration	unit	n	Average	2.8 * sd	R (target)
Barium	mg/kg food	18	1.77	1.62	0.73
Cobalt	mg/kg food	18	0.30	0.23	0.16
Copper	mg/kg food	18	2.05	1.62	0.82
Iron	mg/kg food	22	<48	n.a.	n.a.
Lithium	mg/kg food	21	<0.6	n.a.	n.a.
Manganese	mg/kg food	21	<0.6	n.a.	n.a.
Zinc	mg/kg food	18	3.70	2.88	1.36

Table 5: Reproducibilities of tests on sample #16620 in mg/kg food simulant

Without further statistical calculations, it can be concluded that there is not a good compliance of the group of laboratories with the relevant target reproducibility (see for discussion paragraph 4.1).

4.4 COMPARISON WITH PREVIOUS PROFICIENCY TESTS

The evolution of the uncertainty for Specific Migration in mg/dm² and/or mg/kg as observed in this proficiency scheme and the comparison with the findings in previous rounds is visualized in table 6.

	Metals via total immersion iis16P11SM	DEHP via total immersion iis15P10SM	BPA via total immersion iis14P09SM	formaldehyde via article filling	Target (Horwitz)
2012	----	----	----	41 - 47%	14-20%
2013	----	----	----	41 – 61%	14-20%
2014	----	----	44 – 52%	----	14-20%
2015	----	34-40%	----	----	14-20%
2016	29-30%	----	----	----	14-20%

Table 6: comparison of the uncertainties in % for Specific Migration in mg/dm² and/or mg/kg in the previous and present round

From the above table it is clear that the performance of this PT shows improvement over the PTs of the last years, but is not yet meeting the strict requirements, estimated from the Horwitz equation.

When looking at the group of laboratories that used the volume to surface ratio of 167 ml/dm² as per test method EN13130-1, the uncertainties for the metals in mg/dm² vary from 15 to 24%, which meet the target requirements (see Discussion paragraph 5).

5 DISCUSSION

Before the start of this PT, it was assumed 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:

Simulant	3% acetic acid
Exposure time	2.0 hr (120 min)
Exposure temperature	100.0 °C
Migration method	Total immersion
Article use	Single use

Table 7: 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 metal concentration in the simulant. The reported metal concentrations are listed in appendix 3. Using these intermediate test results, it was possible to check the calculations done by the laboratories. This revealed that in the initially reported test results of a number of laboratories, calculation errors were present. These test results were either corrected by the participant or excluded from the statistical calculations by iis.

The majority of laboratories performed a double surface immersion test. This is the test that should be used for this symmetrical sample according to EN13130-1. Two laboratories (2375 and 2495) used a single surface test. When performing total immersion on both sides, but using only the single surface area in the calculation the test result could be twice as high. The results of both laboratories do not appear to be twice as high for all detected metals. Therefore, it is assumed that the laboratories sufficiently corrected their results for the single surface use.

Test method EN13130-1 uses for the total immersion test an area of 0.6 dm² and 100 ml simulant. This means that the volume to surface area ratio is 167 ml/dm². About 47% of the laboratories used this ratio. Surprisingly still, 34% used a ratio around 100 (1 dm² and 100 ml), as is described in the **Overall** Migration method for total immersion EN1186-3. One laboratory used a lower ratio of 50 and four laboratories used a ratio higher than 200 ml/dm².

Evaluating the test results in mg/dm² for the laboratories that used the ratio of 167 ml/dm², the uncertainties significantly decrease (from a RSD of 29-30% for all laboratories to a RSD of 15-24% for only the laboratories using a ratio of 167 ml/dm²). Unfortunately, when the same evaluation is done for the results in mg/kg food simulant, performed with a ratio of 167 ml/dm², the uncertainties do not increase (RSD 23-31%). Please note that only sixteen laboratories reported results in both mg/dm² and mg/kg food simulant, while the others reported either mg/dm² or mg/kg food simulant. Only seven reported results in both units and used a ratio of 167 ml/dm². Therefore, the difference in RSD between the results in mg/dm² and mg/kg food simulant may be a result of the fact that the participants of each group are not the same. Still, using a different volume to surface ratio than

described in method EN13130-1 may have a negative influence on the reproducibility of the group. So the precision of this test method may be improved by following the method regarding the volume to surface ratio used

Details for cleaning the sample before testing were also requested. Twenty-one participants did not clean the sample and eight participants cleaned the sample with a cloth or by purged air. Surprisingly, four participants cleaned the sample before testing with (warm) water and/or detergent/surfactant, while paragraph 15.5 of EN13130-1 explicitly states that under no circumstances the sample to be tested should be cleaned with water.

Comparing the determinations of the different metals, it can be seen that only the performance of the determination of Cobalt is close to the estimated requirements of the Horwitz equation. This determination is done in two steps, a migration step (which is the same for all metals) and a quantification step. The quantification of Cobalt appears to be less difficult than the quantification of Barium, Copper and Zinc.

From the reported details, it became clear that not all participants followed the test method that was reported to have been used. Several deviating conditions (like surface to volume ratio, calculations, preparation) were used. These deviations may be one of the main reasons for the large variation in the test results as observed.

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.

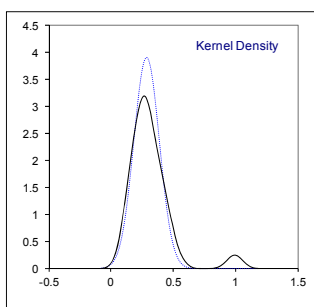
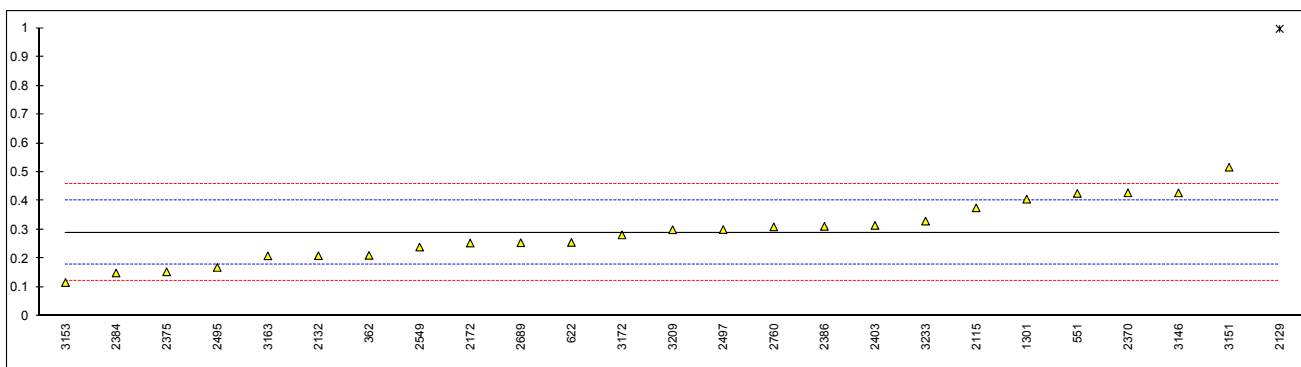
APPENDIX 1

Specific Migration of Barium as Ba per contact surface on sample #16620; results in mg/dm²

lab	method	value	mark	z(targ)	remarks
310		----		----	
330		----		----	
362		0.211		-1.41	
551	EN13130-1	0.426		2.44	
622	In house	0.256		-0.61	
1179		----		----	
1301	INH-95-1003	0.4063		2.08	
2115	In house	0.376		1.54	
2129	DIN EN 13130-1	0.9971	R(0.01)	12.66	
2132	In house	0.21		-1.43	
2172	EU 10 2011	0.254		-0.64	
2215		----		----	
2284		----		----	
2353		----		----	
2370	INH-602	0.428		2.47	
2375	In house	0.154		-2.43	
2384	BS EN13130-1	0.15	C	-2.50	first reported: 15.41
2386	DIN 13130-1	0.3117		0.39	
2403	BS/EN 13130-1	0.315		0.45	
2495	In house	0.1692		-2.16	
2497	In house	0.30078		0.20	
2549	EN13130	0.24		-0.89	
2689	EN13130	0.255		-0.62	
2747		----		----	
2753		----		----	
2760	INH-13130	0.31	C	0.36	first reported: 0.61
3146	DIN EN 13130-1	0.428		2.47	
3151	EN 13130	0.517		4.07	
3153	EN 13130-1	0.117		-3.09	
3163	EN-1186	0.209333	C	-1.44	first reported: 3.15
3172	EN 13130-1	0.282		-0.14	
3209	EN13130	0.300		0.18	
3225		----		----	
3233	INH-13130	0.33		0.72	
3237		----		----	

Only volume to surface ratio of 167 ml/dm²

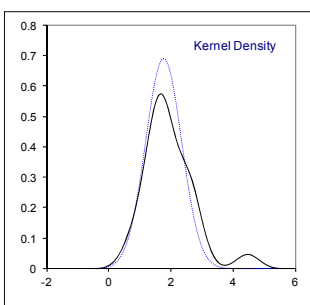
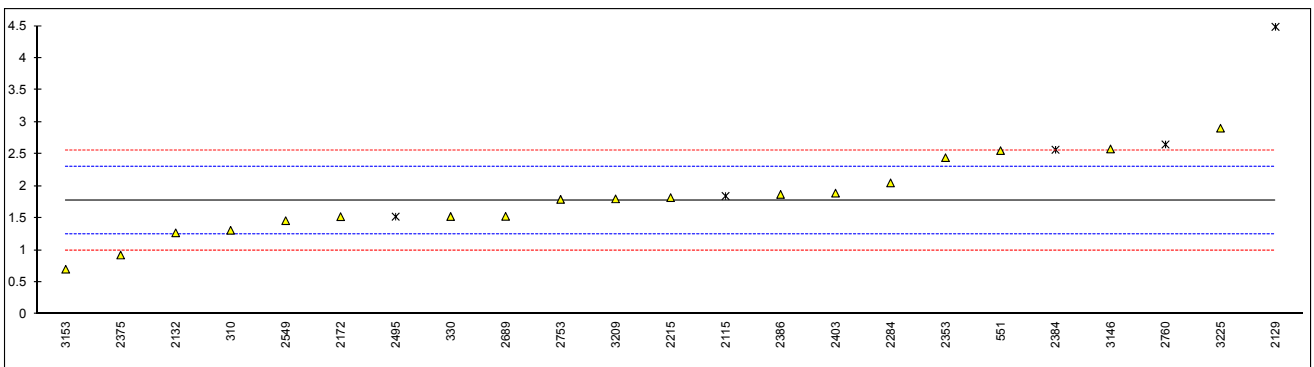
normality	OK		OK
n	24		10
outliers	1		0
mean (n)	0.2898		0.3142
st.dev. (n)	0.10223	RSD = 35%	0.06631 RSD = 21%
R(calc.)	0.2862		0.1857
R(Horwitz)	0.1565		0.1675



Specific Migration of Barium as Ba on sample #16620; results in mg/kg food simulant

lab	method	value	mark	z(targ)	remarks
310	EN 13130	1.31		-1.78	
330	NF EN 13130-1	1.526		-0.96	
362		----		----	
551	EN13130-1	2.554		2.99	
622		----		----	
1179		----		----	
1301		----		----	
2115	In house	1.845	ex	0.27	excluded for not using conventional conversion factor 6 (see §4 and 5)
2129	DIN EN 13130-1	4.487	ex	10.41	excluded for not using conventional conversion factor 6 (see §4 and 5)
2132	In house	1.27		-1.94	
2172	EU 10 2011	1.523		-0.97	
2215	(EU)NO.10/2011	1.82		0.17	
2284	EN 13130-1	2.05		1.06	
2353	EN13130-1	2.444		2.57	
2370		----		----	
2375	In house	0.924		-3.27	
2384	BS EN13130-1	2.568	ex	3.04	excluded for not using conventional conversion factor 6 (see §4 and 5)
2386	DIN 13130-1	1.87		0.36	
2403	BS/EN 13130-1	1.89		0.44	
2495	In house	1.523	ex	-0.97	excluded for not using conventional conversion factor 6 (see §4 and 5)
2497		----		----	
2549	EN13130	1.46		-1.21	
2689	EN13130	1.528		-0.95	
2747		----		----	
2753	EN 13130-1	1.793		0.07	
2760	INH-13130	2.65	ex	3.36	excluded for not using conventional conversion factor 6 (see §4 and 5)
3146	DIN EN 13130-1	2.58		3.09	
3151		----		----	
3153	EN 13130-1	0.702		-4.12	
3163		----		----	
3172		----		----	
3209	EN13130	1.801		0.10	
3225	EN13130	2.9040		4.33	
3233		----		----	
3237		----		----	

normality	OK			<u>Only volume to surface ratio of 167 ml/dm²</u>	
n	18			not OK	
outliers	0 (+5ex)			12	
mean (n)	1.7749			0	
st.dev. (n)	0.57958	RSD = 33%		1.8932	
R(calc.)	1.6228			0.43697	RSD = 23%
R(Horwitz)	0.7294			1.2235	
				0.7705	

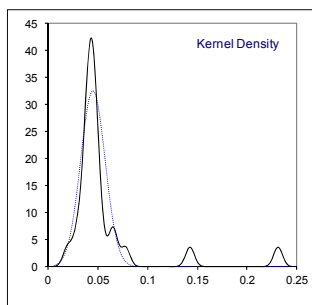
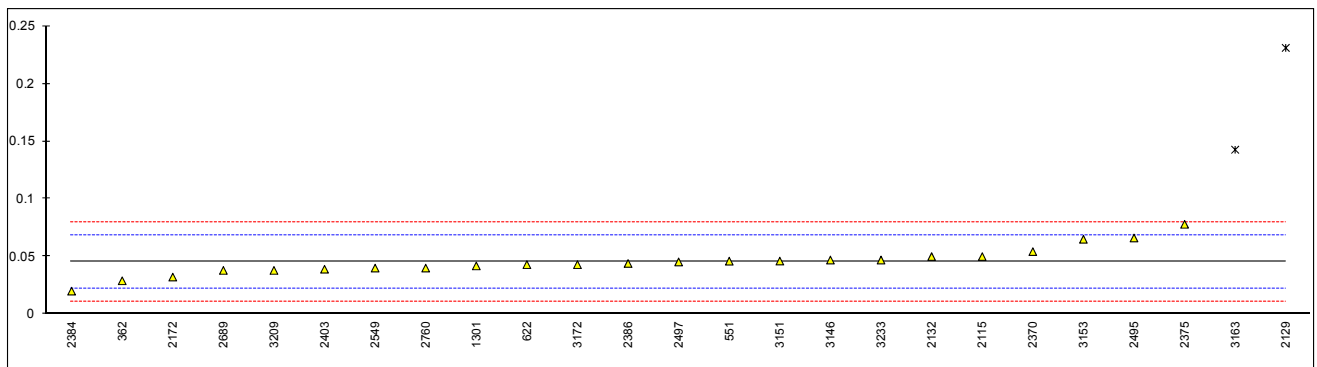


Specific Migration Cobalt as Co per contact surface on sample #16620; results in mg/dm²

lab	method	value	mark	z(targ)	remarks
310		----		----	
330		----		----	
362		0.029		-1.41	
551	EN13130-1	0.046		0.06	
622	In house	0.043		-0.20	
1179		----		----	
1301	INH-95-1003	0.0419		-0.30	
2115	In house	0.05		0.40	
2129	DIN EN 13130-1	0.231	R(0.01)	16.06	
2132	In house	0.05		0.40	
2172	EU 10 2011	0.0322		-1.14	
2215		----		----	
2284		----		----	
2353		----		----	
2370	INH-602	0.0543		0.77	
2375	In house	0.078		2.83	
2384	BS EN13130-1	0.02	C	-2.19	first reported: 2.07
2386	DIN 13130-1	0.0440		-0.12	
2403	BS/EN 13130-1	0.039		-0.55	
2495	In house	0.0661		1.80	
2497	In house	0.04531		0.00	
2549	EN13130	0.04		-0.46	
2689	EN13130	0.038		-0.64	
2747		----		----	
2753		----		----	
2760	INH-13130	0.04	C	-0.46	first reported: 0.08
3146	DIN EN 13130-1	0.047		0.14	
3151	EN 13130	0.0461		0.07	
3153	EN 13130-1	0.065		1.70	
3163	EN-1186	0.142667	C,R(0.01)	8.42	first reported: 2.06
3172	EN 13130-1	0.043		-0.20	
3209	EN13130	0.038		-0.64	
3225		----		----	
3233	INH-13130	0.047		0.14	
3237		----		----	

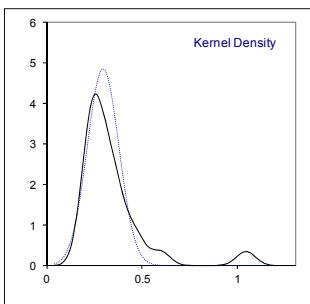
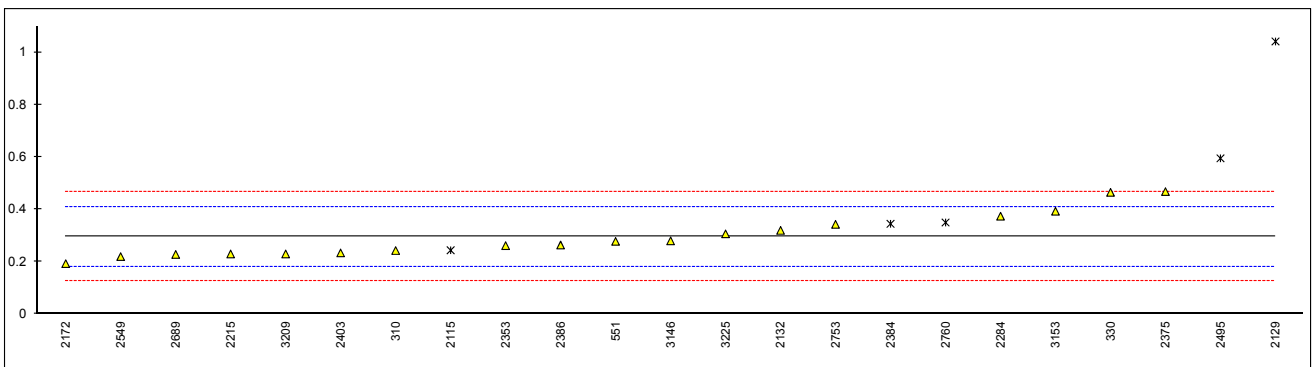
Only volume to surface ratio of 167 ml/dm²

normality	suspect		OK
n	23		10
outliers	2		0
mean (n)	0.0453		0.0422
st.dev. (n)	0.01230	RSD = 27%	0.00613 RSD = 15%
R(calc.)	0.0344		0.0172
R(Horwitz)	0.0324		0.0304



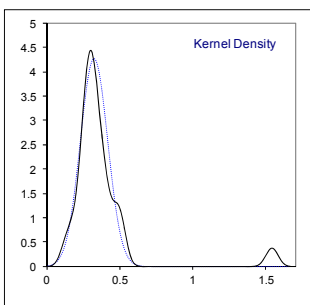
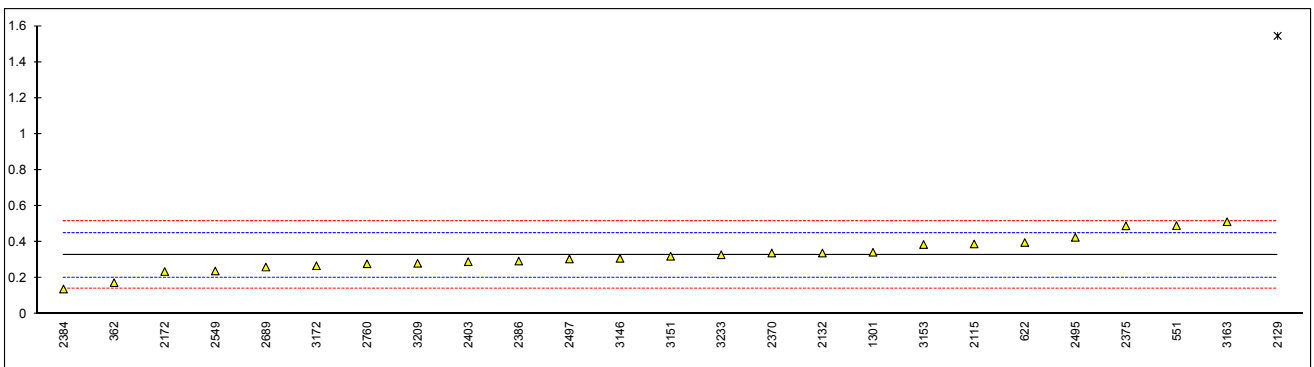
Specific Migration Cobalt as Co on sample #16620; results in mg/kg food simulant

lab	method	value	mark	z(targ)	remarks
310	EN 13130	0.243		-0.93	
330	NF EN 13130-1	0.465		2.97	
362		----		----	
551	EN13130-1	0.278		-0.32	
622		----		----	
1179		----		----	
1301		----		----	
2115	In house	0.244	ex	-0.92	excluded for not using conventional conversion factor 6 (see §4 and 5)
2129	DIN EN 13130-1	1.041	ex	13.09	excluded for not using conventional conversion factor 6 (see §4 and 5)
2132	In house	0.32		0.42	
2172	EU 10 2011	0.193		-1.81	
2215	(EU)NO.10/2011	0.23		-1.16	
2284	EN 13130-1	0.374		1.37	
2353	EN13130-1	0.2617		-0.61	
2370		----		----	
2375	In house	0.468		3.02	
2384	BS EN13130-1	0.345	ex	0.86	excluded for not using conventional conversion factor 6 (see §4 and 5)
2386	DIN 13130-1	0.264		-0.57	
2403	BS/EN 13130-1	0.234		-1.09	
2495	In house	0.595	ex	5.25	excluded for not using conventional conversion factor 6 (see §4 and 5)
2497		----		----	
2549	EN13130	0.22		-1.34	
2689	EN13130	0.228		-1.20	
2747		----		----	
2753	EN 13130-1	0.343		0.82	
2760	INH-13130	0.35	ex	0.95	excluded for not using conventional conversion factor 6 (see §4 and 5)
3146	DIN EN 13130-1	0.280		-0.28	
3151		----		----	
3153	EN 13130-1	0.393		1.70	
3163		----		----	
3172		----		----	
3209	EN13130	0.230		-1.16	
3225	EN13130	0.3067		0.18	
3233		----		----	
3237		----		----	
normality	OK				Only volume to surface ratio of 167 ml/dm ²
n	18				not OK
outliers	0 (+5ex)				12
mean (n)	0.2962				0
st.dev. (n)	0.08249	RSD = 28%			0.2805
R(calc.)	0.2310				0.07919 RSD = 28%
R(Horwitz)	0.1594				0.2217
					0.1521



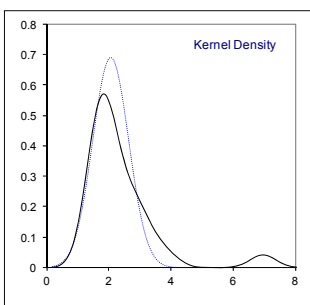
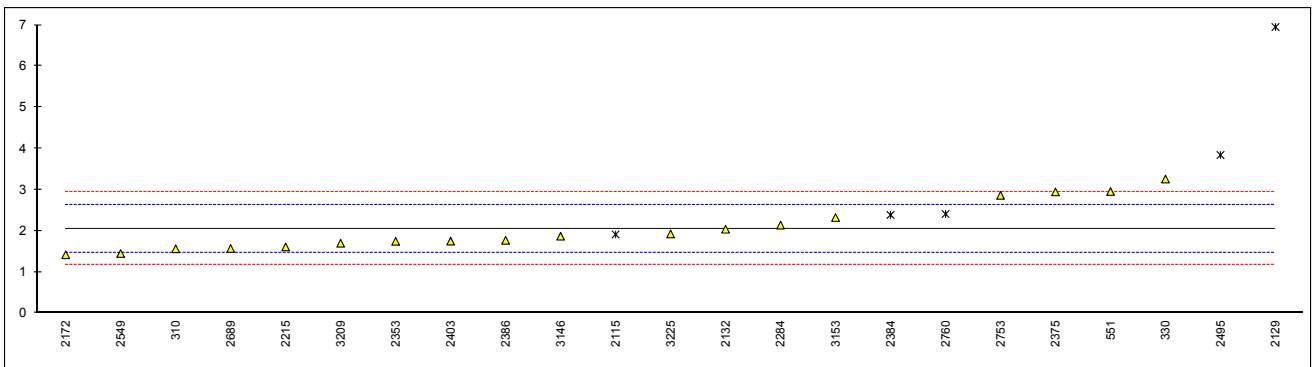
Specific Migration Copper as Cu per contact surface on sample #16620; results in mg/dm²

lab	method	value	mark	z(targ)	remarks
310		----		----	
330		----		----	
362		0.175		-2.46	
551	EN13130-1	0.492		2.65	
622	In house	0.398		1.13	
1179		----		----	
1301	INH-95-1003	0.3438		0.26	
2115	In house	0.390		1.01	
2129	DIN EN 13130-1	1.545	R(0.01)	19.63	
2132	In house	0.34		0.20	
2172	EU 10 2011	0.237		-1.46	
2215		----		----	
2284		----		----	
2353		----		----	
2370	INH-602	0.340		0.20	
2375	In house	0.491		2.63	
2384	BS EN13130-1	0.14	C	-3.03	first reported: 14.32
2386	DIN 13130-1	0.2950		-0.53	
2403	BS/EN 13130-1	0.292		-0.58	
2495	In house	0.4270		1.60	
2497	In house	0.30688		-0.34	
2549	EN13130	0.24		-1.41	
2689	EN13130	0.262		-1.06	
2747		----		----	
2753		----		----	
2760	INH-13130	0.28	C	-0.77	first reported: 0.56
3146	DIN EN 13130-1	0.310		-0.28	
3151	EN 13130	0.322		-0.09	
3153	EN 13130-1	0.387		0.96	
3163	EN-1186	0.513333	C	2.99	first reported: 8.01
3172	EN 13130-1	0.269		-0.95	
3209	EN13130	0.283		-0.72	
3225		----		----	
3233	INH-13130	0.33		0.04	
3237		----		----	
					<u>Only volume to surface ratio of 167 ml/dm²</u>
normality	OK				not OK
n	24				10
outliers	1				0
mean (n)	0.3277				0.3040
st.dev. (n)	0.09337	RSD = 28%			0.07420 RSD = 24%
R(calc.)	0.2614				0.2078
R(Horwitz)	0.1736				0.1629



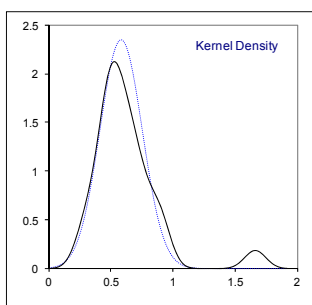
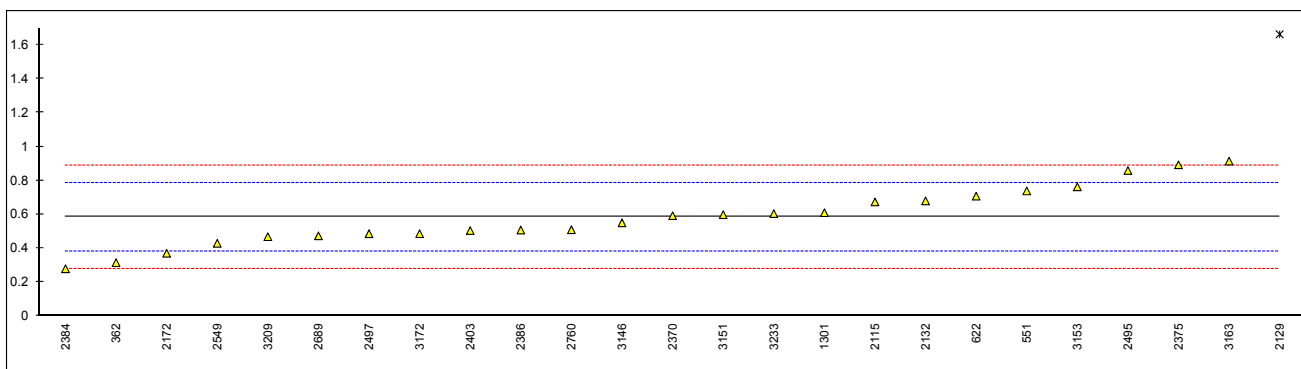
Specific Migration Copper as Cu on sample #16620; results in mg/kg food simulant

lab	method	value	mark	z(targ)	remarks
310	EN 13130	1.565		-1.65	
330	NF EN 13130-1	3.26		4.11	
362		----		----	
551	EN13130-1	2.955		3.07	
622		----		----	
1179		----		----	
1301		----		----	
2115	In house	1.913	ex	-0.47	excluded for not using conventional conversion factor 6 (see §4 and 5)
2129	DIN EN 13130-1	6.951	ex	16.64	excluded for not using conventional conversion factor 6 (see §4 and 5)
2132	In house	2.04		-0.04	
2172	EU 10 2011	1.421		-2.14	
2215	(EU)NO,10/2011	1.61		-1.50	
2284	EN 13130-1	2.14		0.30	
2353	EN13130-1	1.745		-1.04	
2370		----		----	
2375	In house	2.946		3.04	
2384	BS EN13130-1	2.387	ex	1.14	excluded for not using conventional conversion factor 6 (see §4 and 5)
2386	DIN 13130-1	1.77		-0.95	
2403	BS/EN 13130-1	1.75		-1.02	
2495	In house	3.843	ex	6.09	excluded for not using conventional conversion factor 6 (see §4 and 5)
2497		----		----	
2549	EN13130	1.45		-2.04	
2689	EN13130	1.573		-1.62	
2747		----		----	
2753	EN 13130-1	2.862		2.76	
2760	INH-13130	2.41	ex	1.22	excluded for not using conventional conversion factor 6 (see §4 and 5)
3146	DIN EN 13130-1	1.87		-0.61	
3151		----		----	
3153	EN 13130-1	2.324		0.93	
3163		----		----	
3172		----		----	
3209	EN13130	1.700		-1.19	
3225	EN13130	1.9260		-0.42	
3233		----		----	
3237		----		----	
	normality	OK			Only volume to surface ratio of 167 ml/dm ²
	n	18			suspect
	outliers	0 (+5ex)			0
	mean (n)	2.0504			2.0347
	st.dev. (n)	0.57763	RSD = 28%		0.63467 RSD = 31%
	R(calc.)	1.6174			1.7771
	R(Horwitz)	0.8245			0.8197



Specific Migration Zinc as Zn per contact surface on sample #16620; results in mg/dm²

lab	method	value	mark	z(targ)	remarks
310		----		----	
330		----		----	
362		0.316		-2.65	
551	EN13130-1	0.739		1.52	
622	In house	0.708		1.22	
1179		----		----	
1301	INH-95-1003	0.6105		0.26	
2115	In house	0.674		0.88	
2129	DIN EN 13130-1	1.663	R(0.01)	10.64	
2132	In house	0.68		0.94	
2172	EU 10 2011	0.371		-2.11	
2215		----		----	
2284		----		----	
2353		----		----	
2370	INH-602	0.593		0.08	
2375	In house	0.893		3.04	
2384	BS EN13130-1	0.28	C	-3.00	first reported: 27.84
2386	DIN 13130-1	0.5083		-0.75	
2403	BS/EN 13130-1	0.505		-0.78	
2495	In house	0.8590		2.71	
2497	In house	0.48673		-0.96	
2549	EN13130	0.43		-1.52	
2689	EN13130	0.474		-1.09	
2747		----		----	
2753		----		----	
2760	INH-13130	0.51	C	-0.73	first reported: 1.03
3146	DIN EN 13130-1	0.551		-0.33	
3151	EN 13130	0.599		0.14	
3153	EN 13130-1	0.763		1.76	
3163	EN-1186	0.914667	C	3.26	first reported: 14.21
3172	EN 13130-1	0.487		-0.96	
3209	EN13130	0.469		-1.14	
3225		----		----	
3233	INH-13130	0.605		0.20	
3237		----		----	
	normality	OK			Only volume to surface ratio of 167 ml/dm ²
	n	24			suspect
	outliers	1			10
	mean (n)	0.5844			0
	st.dev. (n)	0.17026	RSD = 29%		0.5181
	R(calc.)	0.4767			0.10379
	R(Horwitz)	0.2839			RSD = 20%
					0.2906
					0.2563

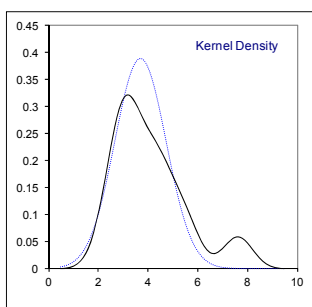
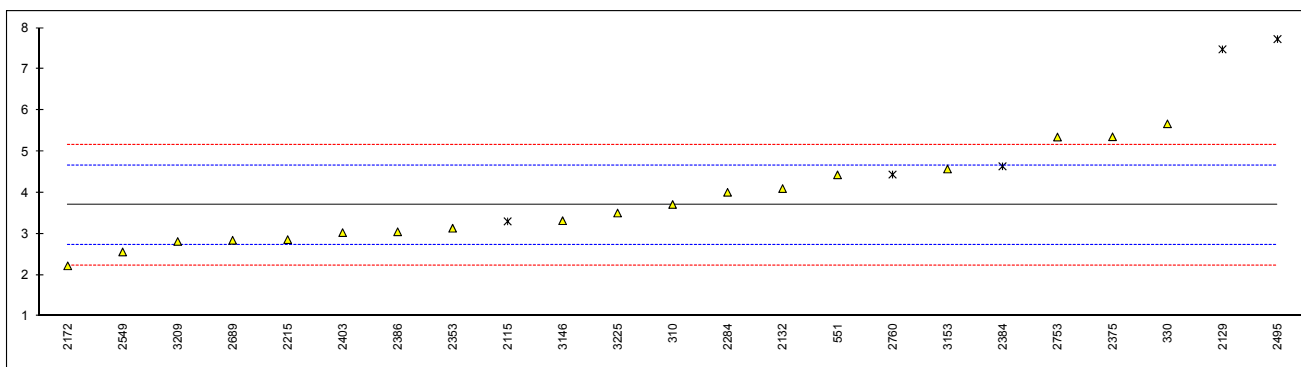


Specific Migration Zinc as Zn on sample #16620; results in mg/kg food simulat

lab	method	value	mark	z(targ)	remarks
310	EN 13130	3.714		0.03	
330	NF EN 13130-1	5.672		4.06	
362		----		----	
551	EN13130-1	4.433		1.51	
622		----		----	
1179		----		----	
1301		----		----	
2115	In house	3.303	ex	-0.81	excluded for not using conventional conversion factor 6 (see §4 and 5)
2129	DIN EN 13130-1	7.482	ex	7.79	excluded for not using conventional conversion factor 6 (see §4 and 5)
2132	In house	4.10		0.83	
2172	EU 10 2011	2.224		-3.03	
2215	(EU)NO.10/2011	2.86		-1.72	
2284	EN 13130-1	4.009		0.64	
2353	EN13130-1	3.137		-1.15	
2370		----		----	
2375	In house	5.358		3.42	
2384	BS EN13130-1	4.640	ex	1.94	excluded for not using conventional conversion factor 6 (see §4 and 5)
2386	DIN 13130-1	3.05		-1.33	
2403	BS/EN 13130-1	3.03		-1.37	
2495	In house	7.731	ex	8.30	excluded for not using conventional conversion factor 6 (see §4 and 5)
2497		----		----	
2549	EN13130	2.56		-2.34	
2689	EN13130	2.844		-1.76	
2747		----		----	
2753	EN 13130-1	5.352		3.40	
2760	INH-13130	4.44	ex	1.53	excluded for not using conventional conversion factor 6 (see §4 and 5)
3146	DIN EN 13130-1	3.32		-0.78	
3151		----		----	
3153	EN 13130-1	4.575		1.81	
3163		----		----	
3172		----		----	
3209	EN13130	2.815		-1.82	
3225	EN13130	3.5060		-0.39	
3233		----		----	
3237		----		----	

Only volume to surface ratio of 167 ml/dm²

normality	OK		OK
n	18		12
outliers	0 (+5ex)		0
mean (n)	3.6977		3.5296
st.dev. (n)	1.02886	RSD = 28%	1.10827 RSD = 31%
R(calc.)	2.8808		3.1032
R(Horwitz)	1.3606		1.3079



Specific Migration Fe, Li and Mn per contact surface on sample #16620; results in mg/dm²

lab	method	Fe	Li	Mn	Remarks
310		----	----	----	
330		----	----	----	
362		----	----	----	
551	EN13130-1	<0.05	<0.05	<0.05	
622	In house	0.006	0.000	0.000	
1179		----	----	----	
1301	INH-95-1003	0.0152	<0.001	<0.001	
2115	In house	0.005	----	----	
2129	DIN EN 13130-1	0.00987	<0.001	<0.001	
2132	In house	<0.01	<0.01	<0.01	
2172	EU 10 2011	<0.83	<0.017	<0.017	
2215		----	----	----	
2284		----	----	----	
2353		----	----	----	
2370	INH-602	0.00433	<0.004	<0.004	
2375	In house	----	----	----	
2384	BS EN13130-1	<0.1	<0.1	<0.1	
2386	DIN 13130-1	0.0022	<0.005	0.0012	
2403	BS/EN 13130-1	ND	ND	ND	
2495	In house	<0.004	<0.004	<0.004	
2497	In house	0.00715	0.00001	0.00009	
2549	EN13130	<0.005	<0.005	<0.005	
2689	EN13130	ND	ND	ND	
2747		----	----	----	
2753		----	----	----	
2760	INH-13130	0.0009	0.0008	0.0001	C fr. resp. 0.0018, 0.0016 and 0.0002
3146	DIN EN 13130-1	<0.002	<0.005	<0.002	
3151	EN 13130	0.00413	nd	nd	
3153	EN 13130-1	<0.5	<0.01	<0.01	
3163	EN-1186	0.018	0.000524	0.000041	C fr. resp. 0.224, 0.032 and 0.005
3172	EN 13130-1	n.d.	n.d.	n.d.	
3209	EN13130	ND	ND	ND	
3225		----	----	----	
3233	INH-13130	< 0.1	< 0.01	< 0.01	
3237		----	----	----	
n		23	22	22	
mean (n)		<8	<0.1	<0.1	

Specific Migration Fe, Li and Mn on sample #16620; results in mg/kg food simulant

lab	method	Fe	Li	Mn	Remarks
310	EN 13130	0.004	0	0	
330	NF EN 13130-1	0	0	0	
362		----	----	----	
551	EN13130-1	<0.05	<0.05	<0.05	
622		----	----	----	
1179		----	----	----	
1301		----	----	----	
2115	In house	0.022	----	----	
2129	DIN EN 13130-1	0.04442	<0,001	0.00268	
2132	In house	<0.03	<0.03	<0.03	
2172	EU 10 2011	<5	<0.1	<0.1	
2215	(EU)NO.10/2011	<0.03	<0.03	<0.03	
2284	EN 13130-1	nd	nd	nd	
2353	EN13130-1	< 0.25	< 0.5	< 0.25	
2370		----	----	----	
2375	In house	----	----	----	
2384	BS EN13130-1	<0.25	<0.5	<0.25	
2386	DIN 13130-1	0.013	<0.005	0.007	
2403	BS/EN 13130-1	ND	ND	ND	
2495	In house	<0.04	<0.04	<0.04	
2497		----	----	----	
2549	EN13130	<0.03	<0.03	<0.03	
2689	EN13130	ND	ND	ND	
2747		----	----	----	
2753	EN 13130-1	0.013	<0.001	0.001	
2760	INH-13130	0.008	0.007	0.001	
3146	DIN EN 13130-1	<0.014	<0.089	<0.014	
3151		----	----	----	
3153	EN 13130-1	<5	<0.1	<0.1	
3163		----	----	----	
3172		----	----	----	
3209	EN13130	ND	ND	ND	
3225	EN13130	<1.0	<0.10	<0.05	
3233		----	----	----	
3237		----	----	----	
n		22	21	21	
mean (n)		<48	<0.6	<0.6	

APPENDIX 2

Details reported by the participating laboratories

lab	sample cleaned during preparation	exposed contact surface area in dm ²	used as single or double surface	volume of simulant used in mL	simulant preheated before use	thickness of sample used for area
310	No	4.50	Double surface	450	Yes	Yes
330	No	0.60	Double surface	100	Yes	Yes
362	No	4.56	---	2000	No	---
551	Yes, with a lint free cloth	0.60	Double surface	100	Yes	Yes
622	No	1	Double surface	100	No	No
1179	---	---	---	---	---	---
1301	No	1.28	Double surface	500	---	No
2115	No	0.49	Double surface	100	Yes	No
2129	No	4.50	Double surface	500	Yes	No
2132	Yes, with lint-free cloth	1.039	Double surface	100	Yes	Yes
2172	No	0.60	Double surface	100	Yes	No
2215	No	4.53	Double surface	755	Yes	Yes
2284	No	0.60	Double surface	100	Yes	Yes
2353	Yes, with brush to remove dust	4.1909	Double surface	419	Yes	Yes
2370	Yes, purged air to remove dust.	4.52	Double surface	753	Yes	Yes
2375	No	2.19	Single surface	200	Yes	No
2384	No	0.55	Double surface	55	Yes	Yes
2386	Yes, with H ₂ O	1.20	Double surface	200	Yes	Yes
2403	No	0.78	Double surface	130	Yes	Yes
2495	Yes, with dry paper to remove dust	2.25	Single surface	250	Yes	No
2497	Yes, with non -ionic surfactant	4.3210	---	220	Yes	---
2549	No	4.54	Double surface	750	Yes	Yes
2689	No	4.56	Double surface	760	Yes	No
2747	---	---	---	---	---	---
2753	No	4.54	Double surface	757	Yes	Yes
2760	No	4.32	Double surface	500	Yes	No
3146	No	4.53	Double surface	2150	Yes	Yes
3151	Yes, with *)	0.269	Double surface	30	No	Yes
3153	Yes, with a lint-free cloth	1.00	Double surface	100	Yes	Yes
3163	No	0.375	Double surface	50	Yes	No
3172	No	4.55	Double surface	760	Yes	Yes
3209	Yes, with Distilled water	4.54	Double surface	757	Yes	Yes
3225	Yes, with a Kimwipe	4.54	Double surface	750	Yes	Yes
3233	Yes, with a lint-free cloth	0.60	Double surface	100	Yes	No
3237	No	4.50	---	---	---	---

*) Washed with household liquid detergent in water about 40°C, rinsed with tap water and then deionized

APPENDIX 3:

Other results reported by participating laboratories on Specific Migration on sample #16620

lab	actual surface area used (dm ²)	actual volume simulant used (ml)	actual volume to surface ratio (ml/dm ²)	final conc. in food simulant (mg/L) Ba	final conc. in food simulant (mg/L) Co	final conc. in food simulant (mg/L) Cu	final conc. in food simulant (mg/L) Zn	factor 6 used to calc. spec. migration in mg/kg food simulant?	result in mg/L the same as mg/kg food simulant?
310	4.50	450	100.00	2.181	0.404	2.608	6.190	Yes	----
330	0.60	100	166.67	1.526	0.465	3.26	5.672	Yes	----
362	4.56	2000	438.60	0.48	0.065	0.40	0.72	----	----
551	0.60	100	166.67	2.554	0.278	2.955	4.433	Yes	Yes
622	1	100	100.00	2.555	0.429	3.983	7.079	----	----
1179	----	----	----	----	----	----	----	----	----
1301	1.28	500	390.63	1.040	0.107	0.880	1.563	----	----
2115	0.49	100	204.08	1.845	0.244	1.91	3.303	No	Yes
2129	4.50	500	111.11	----	----	----	----	No	----
2132	1.039	100	96.25	2.20	0.56	3.54	7.10	Yes	Yes
2172	0.60	100	166.67	1.523	0.193	1.421	2.224	Yes	Yes
2215	4.53	755	166.67	----	----	----	----	Yes	----
2284	0.60	100	166.67	2.05	0.374	2.14	4.009	Yes	----
2353	4.1909	419	99.98	4.073	0.4361	2.908	5.229	Yes	Yes
2370	4.52	753	166.59	2.57	0.326	2.04	3.56	----	----
2375	2.19	200	91.32	1.68	0.85	5.37	9.77	Yes	Yes
2384	0.55	55	100.00	1.541	0.207	1.432	2.784	No	Yes
2386	1.20	200	166.67	1.87	0.264	1.77	3.05	Yes	----
2403	0.78	130	166.67	1.89	0.234	1.75	3.03	Yes	Yes
2495	2.25	250	111.11	1.523	0.595	3.843	7.731	No	Yes
2497	4.3210	220	50.91	5.908	0.890	6.028	9.560	----	----
2549	4.54	750	165.20	1.47	0.23	1.46	2.58	Yes	----
2689	4.56	760	166.67	1.528	0.228	1.573	2.844	Yes	Yes
2747	----	----	----	----	----	----	----	----	----
2753	4.54	757	166.74	----	----	----	----	Yes	----
2760	4.32	500	115.74	2.65	0.35	2.41	4.44	No	Yes
3146	4.53	2150	474.61	0.902	0.098	0.654	1.16	Yes	----
3151	0.269	30	111.52	4.637	0.0124	0.0866	0.161	----	----
3153	1.00	100	100.00	1.173	0.656	3.884	7.644	Yes	No
3163	0.375	50	133.33	1.57	1.07	3.85	6.86	----	----
3172	4.55	760	167.03	----	----	----	----	----	----
3209	4.54	757	166.74	1.801	0.230	1.700	2.815	Yes	Yes
3225	4.54	750	165.20	2.9040	0.3067	1.9260	3.5060	Yes	----
3233	0.60	100	166.67	1.99	0.28	1.98	3.63	----	----
3237	----	----	----	----	----	----	----	----	----

APPENDIX 4

Number of participating laboratories per country

1 lab in BRAZIL

1 lab in BULGARIA

2 labs in FRANCE

4 labs in GERMANY

4 labs in HONG KONG

1 lab in INDIA

1 lab in INDONESIA

4 labs in ITALY

1 lab in MALAYSIA

7 labs in P.R. of CHINA

1 lab in QATAR

1 lab in SERBIA

1 lab in TAIWAN R.O.C.

3 labs in THE NETHERLANDS

2 labs in TURKEY

1 lab in UNITED ARAB EMIRATES

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 outlier test
R(0.05)	= straggler in Rosner outlier test
n.a.	= not applicable
E	= probably an error in calculation
W	= test result withdrawn on request of the participant

Literature:

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