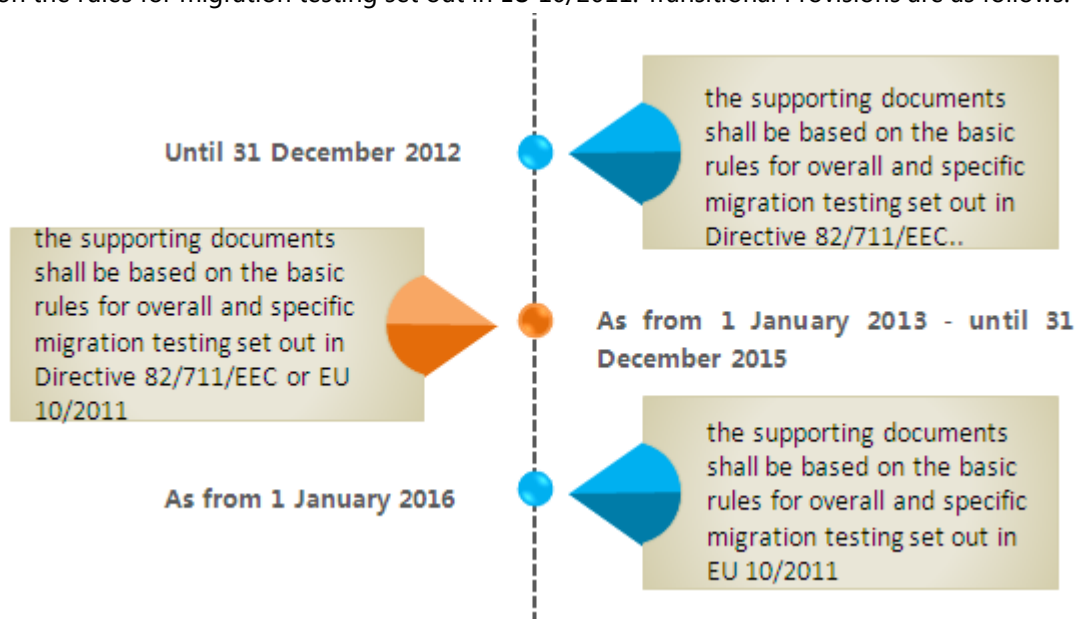




(EU) No 10/2011 will be fully implemented from January 1st 2016

EU Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food was published on 15th Jan. 2011, and started to on effect on 15th May 2011. It repeals Commission Directive 2002/72/EC, 80/766/EEC and 81/432/EEC, and set the transitional provisions between 82/711/EEC.

According to the transitional provisions, as from 1st Jan. 2016, the supporting documents shall be based on the rules for migration testing set out in EU 10/2011. Transitional Provisions are as follows:



The concentration and the types of the food simulant solution were modified in 10/2011 EU, especially for the simulant of dry food. The test conditions for the overall migration and the special migration were set up respectively, and the conditions of the test were also significantly changed compared with 82/711/EEC. Details are as follows:

(1) Food Simulants

Food Simulants	Abbreviation	Type of Food
Ethanol 10 % (v/v)	Food Simulant A	Food with hydrophilic character
Acetic acid 3 % (w/v)	Food Simulant B	Acidic food (pH < 4.5)
Ethanol 10 % (v/v)	Food Simulant C	Alcohol content ≤20%
Ethanol 50 % (v/v)	Food Simulant D1	Alcohol content ≥20%
Vegetable oil	Food Simulant D2	Oil in water emulsions, such as milk
poly(2,6-diphenyl-p-phenylene oxide)	Food Simulant E	Fatty food
		Dry food

(2) Testing conditions for overall migration

For repeated use articles, the migration test(s) shall be carried out three times on a single sample using



another portion of food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.

No.	Contact time at contact temperature	Food contact conditions
OM 1	10 d at 20°C	Any food contact at frozen and refrigerated conditions.
OM 2	10 d at 40°C	Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
OM 3	2 h at 70°C	Any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.
OM 4	1 h at 100°C	High temperature applications for all food simulants at temperature up to 100 °C.
OM 5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C
OM 6	4 h at 100 °C or at reflux	Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C
OM 7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5
In case technically NOT feasible to perform OM7 with food simulant D2		
OM 8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only
OM 9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature

(3) Testing conditions for specific migration

For repeated use articles, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.

Testing conditions for specific migration---temperature

Contact temperature	Test temperature
$T \leq 5 \text{ } ^\circ\text{C}$	5 °C
$5 \text{ } ^\circ\text{C} < T \leq 20 \text{ } ^\circ\text{C}$	20 °C
$20 \text{ } ^\circ\text{C} < T \leq 40 \text{ } ^\circ\text{C}$	40 °C
$40 \text{ } ^\circ\text{C} < T \leq 70 \text{ } ^\circ\text{C}$	70 °C
$70 \text{ } ^\circ\text{C} < T \leq 100 \text{ } ^\circ\text{C}$	100 °C or reflux temperature
$100 \text{ } ^\circ\text{C} < T \leq 121 \text{ } ^\circ\text{C}$	121 °C (*)
$121 \text{ } ^\circ\text{C} < T \leq 130 \text{ } ^\circ\text{C}$	130 °C (*)
$130 \text{ } ^\circ\text{C} < T \leq 150 \text{ } ^\circ\text{C}$	150 °C (*)
$150 \text{ } ^\circ\text{C} < T \leq 175 \text{ } ^\circ\text{C}$	175 °C (*)
$T > 175 \text{ } ^\circ\text{C}$	Adjust the temperature to the real



	temperature at the interface with the food (*)
(*)This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 7.	

Testing conditions for specific migration---time

Contact time	Test time
t ≤ 5 min	5 min
5 min < t ≤ 0,5 hours	0,5 hours
0,5 h < t ≤ 1 hour	1 hours
1 h < t ≤ 2 hours	2 hours
2 h < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours
1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
> 30 days	See specific conditions
Specific conditions	
20°C 10 days	all storage times at frozen condition
40°C 10 days	all storage times at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes
50°C 10 days	all storage time at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes and storage times of up to 6 months at room temperature.
60°C 10 days	long term storage above 6 months at room temperature and below including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

HCT Solutions :

As compared to 82/711/EEC, the requirements for migration testing in 10/2011 are more stringent. FCM related enterprises need to improve the production process in order to meet the testing rules. HCT can provide one-stop service for consumer products and ensure quality throughout the whole production process to remove trade barrier.



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