Brief Introduction of (EU) No 10/2011 on Plastic FCM

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.

I . Transitional Provisions

Table 1. Transitional provisions

Date	Implementation phase
Until 31 December 2012	the supporting documents shall be based on the basic rules for overall and specific migration testing set out in Directive 82/711/EEC.
As from 1 January 2013 – until 31 December 2015	the supporting documents shall be based on the basic rules for overall and specific migration testing set out in Directive 82/711/EEC or EU 10/2011
As from 1 January 2016	the supporting documents shall be based on the basic rules for overall and specific migration testing set out in EU 10/2011

II . Difference between 82/711/EEC and EU 10/2011

The scope of EU 10/2011 are wider, including plastics, multi-layer plastics and printed plastics and plastic coatings. And plastic articles placing on the market should comply with the relevant requirement and GMP. Restrictions of heavy metals and primary aromatic amines (PAA) are first mentioned; the food stimulants are different and the testing conditions are different as well.

III . Scope

Table 2. Scope of EU 10/2011

Apply to	a) materials and articles and parts thereof consisting exclusively of plastics; b) plastic multi-layer materials and articles held together by adhesives or by other means; c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating; d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials; e) plastic layers in multi-material multi-layer materials and articles.
Not Apply to	a) ion exchange resins; b) rubber; c) silicones.

IV . Restriction requirement

An union list of authorised substances, which containing more than 800 kinds of substances such as monomers, additives, polymer production aids and macromolecules obtained from microbial fermentation, is listed on EU 10/2011. And specific migration limit (SML) of specific substances are listed.

Moreover, the restriction of overall migration, heavy metals and PAA are required.

Table 3. Restriction requirement

Item	Restriction
Overall migration	10 mg/dm^2 (products for infants and young children: 60mg/kg)
Heavy metals and PAA (Annex II)	Ba: 1 Co: 0.05 Cu: 5 Fe: 48 Li: 0.6 Mn: 0.6 Zn: 25mg/kg
	PAA：Absent

SML on Annex I	SML on Annex I of specific substances： acrylonitrile：ND Caprolactam：15 mg/kg VCM：1 mg/kg（in final products） BPA：0.6 mg/kg Formaldehyde：15 mg/kg Melamine：2.5mg/kg Phthalates: SML（BBP30，DBP0.3，DEHP1.5，DINP+DIDP 9，nDnOP+DnDP+DnOP 5 mg/kg；DAP ND）；Totals(DBP0.05%，BBP0.1%，DEHP0.1%，DINP0.1%，DIDP0.1%）

V．Food Simulants

Table 4. List of 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% Oil in water emulsions, such as milk
Vegetable oil	Food Simulant D2	Fatty food
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food Simulant E	Dry food

VI．Testing conditions for overall migration

See Table 5. Standardised 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.

VII．Testing conditions for specific migration

See Table 6. Testing conditions for specific migration---temperature and Table 7. Testing conditions for specific migration---time.

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VIII . Repealed directives

Directives 80/766/EEC, 81/432/EEC, and 2002/72/EC are hereby repealed with effect from 1 May 2011.



Contact us

- Suzhou +86/(0)512-87661878
- Hong Kong +852/3591 1718
- Guangzhou +86/(0)20-82037973
- Nanjing +86/(0)25-84701983
- Ningbo +86/(0)574-27867981
- Technical service: TS@stq-cert.com
- Customer service: CS@stq-cert.com

Wechat

Weibo

Table 5. Standardised testing conditions for overall migration

No.	Contact time at contact temperature	Food contact conditions
OM 1	10 d at 20℃	Any food contact at frozen and refrigerated conditions.
OM 2	10 d at 40℃	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℃	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℃	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

Table 6. Testing conditions for specific migration---temperature

Contact temperature	Test temperature
T≤5 °C	5 °C
5 °C< T≤20 °C	20 °C
20 °C< T≤40 °C	40 °C
40 °C< T≤70 °C	70 °C
70 °C< T≤100 °C	100 °C or reflux temperature
100 °C< T≤121 °C	121 °C (*)
121 °C< T≤130 °C	130 °C (*)
130 °C< T≤150 °C	150 °C (*)
150 °C< T≤175 °C	175 °C (*)
T >175 °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.

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℃ 10 days	all storage times at frozen condition
40℃ 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℃ 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℃ 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.