

SAFEGUARDS

SGS CONSUMER TESTING SERVICES

HARDLINES

NO. 017/11 JANUARY 2011

NEW REGULATION ON PLASTIC MATERIALS FOR FOOD CONTACT PUBLISHED IN EUROPE

The new regulation on food contact plastics for the European Union (EU) market has been published on 15 January, 2011 and revealed a number of changes in requirements. The new regulation includes a large number of provisions and enters into force on 4 February, 2011. Earliest applications will start on 1 May, 2011. Due to the nature of a regulation it is not necessary for EU member states to transpose it into national laws.

In December 2010, the proposed Plastics Implementation Measures (PIM) was accepted by the EU Council of Ministers¹. This proposal has been adopted and has recently been published in the Official Journal of the European Union (OJEU). The new regulation will bring all EU legislation on food contact plastics under one umbrella².

There are a number of transitional provisions from 1 May, 2011 to 31 December, 2015. The provisions for specific migrations and overall migrations shall apply from 31 December, 2012. Some highlights on this new regulation are summarised in Table 1.



¹ [Press Release, 3061st Council Meeting](#), Council of the European Union, Brussels, 20 December 2010

² [Plastic materials and Articles intended to come into contact with food](#), Commission Regulation (EU) No 10/2011 of 14 January 2011, L 12/1 – L12/89, 15 January 2011, Official Journal of the European Union

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NO.	ITEM	HIGHLIGHT
1	Scope	<ul style="list-style-type: none"> Materials, articles and parts thereof consisting exclusively of plastics. Plastic multi-layer materials and articles held together by adhesives or by other means. Materials and articles referred to in first two points that are printed and/or covered by a coating. 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. Plastic layers in multi-material multi-layer materials and articles.
2	Exemption	Ion exchange resins, rubber and silicones
3	Union list of authorised substances (Annex I)	<ul style="list-style-type: none"> Contains 885 items Only these substances may be used for manufacturing. Substances not on the Union list (or provisional list) may be used but allowance is subject to national law. Substances classified as CMRs (carcinogenic, mutagenic or reprotoxic) should not be used. Substances not authorised may be used behind a functional barrier providing a maximum migration level of 0.01 mg/kg in food. Nanomaterials should not be covered by the functional barrier concept
4	Substance composition	<ul style="list-style-type: none"> Shall be of a quality suitable for the use of the material Known to the manufacturer Made available to competent authorities on request
5	Food simulants for specific migration test (ANNEX III)	<ul style="list-style-type: none"> 3 % acetic acid Ethanol (10%, 20% or 50%) Vegetable oil Poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm
6	Overall Migration Limit (OML)	<ul style="list-style-type: none"> $\leq 10 \text{ mg/dm}^2$ $\leq 60 \text{ mg/kg}$ for food contact plastics for infants and young children (Directives 2006/141/EC and 2006/125/EC)
7	Specific Migration Limits ³ (SML, ANNEX I)	<p>Non-exhaustive examples for certain substances:</p> <ul style="list-style-type: none"> $\leq 0.6 \text{ mg/kg}$ (bisphenol A (BPA)) <p>PHTHALATES</p> <ul style="list-style-type: none"> $\leq 0.3 \text{ mg/kg}$ (Dibutyl phthalate (DBP)) $\leq 30 \text{ mg/kg}$ (Benzylbutyl phthalate (BBP)) $\leq 1.5 \text{ mg/kg}$ (Bis(2-ethylhexyl) phthalate (DEHP)) Not detected (diallyl phthalate) $\leq 60 \text{ mg/kg}$ for substances with no SML or other restrictions

³ Expressed in mg/kg of food or food simulant

(To be cont'd)

Table 1

(Cont'd) NO.	ITEM	HIGHLIGHT
8	Specific migration limits ³ (SML, ANNEX II)	<p>HEAVY METALS</p> <ul style="list-style-type: none"> • ≤ 1 mg/kg (barium (Ba)) • ≤ 0.05 mg/kg (cobalt (Co)) • ≤ 5 mg/kg (copper (Cu)) • ≤ 48 mg/kg (iron (Fe)) • ≤ 0.6 mg/kg (lithium (Li)) • ≤ 0.6 mg/kg (manganese (Mn)) • ≤ 25 mg/kg (zinc (Zn)) <p>PRIMARY AROMATIC AMINES (PAA)</p> <ul style="list-style-type: none"> • ≤ 0.01 mg/kg
9	Declaration of Compliance	Shall be available to permit easy identification of materials, articles or products from intermediate stages of manufacture or substances.
10	Supporting Documents	Demonstration that materials and articles, products from intermediate stages of their manufacturing as well as substances intended for the manufacturing of those materials and articles made available to business operators and competent authorities on request.

SGS will follow up and keep you informed about developments on regulations or policies in consumer products as a complimentary service.

Throughout our global network of laboratories, we are able to provide a wide range of services, including analytical testing and consultancy, for restricted substances in food contact plastics and similar products for the EU and international markets. Please do not hesitate to contact us for further information.

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