

EU Plans to Change Regulation of Plastic FCM by the End of 2015

Date : 2015-05-07

According to information of Chemical Watch on 7 May 2015, the European Commission notifies WTO that it plans to make several amendments to (EU) Regulation No 10/2011 on plastic materials and articles intended to come into contact with food in December.

1. Eight substances are to be added to the list of approved substances, under Annex I to the Regulation. These are:

- dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α -hydro- ω -hydroxypoly (oxy-1,2-ethanediyl) and 1-propene;
- furan-2,5-dicarboxylic acid;
- 1,7-octadiene;
- perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt;
- ethylene glycol dipalmitate;
- n,n'-bis(2,2,6,6-tetramethyl-4-piperidiny) Isophthalamide;
- 2,4,8,10-tetraoxaspiro[5.5] undecane-3,9-diethanol, β 3, β 3, β 9, β 9-tetramethyl- ('SPG'); and
- fatty acids, C16–18 saturated, esters with dipentaerythritol.

All the above substances prove to be safe for use by the European Food Safety Authority (Efsa).

Note: Annex I includes: 1. Monomers or other starting substances 2. Additives, exclusive of colorant 3.

Polymer production aids excluding solvents 4. Macromolecules obtained by microbial fermentation 5. 885 authorised substances

2. In the meanwhile, the amendments will further clarify the scope of regulations concerning rubber food contact materials, the salts of authorised acids, phenols or alcohols, and testing methods for oligomer migration.

3. Migration limits for aluminium and nickel are added on plastic materials and articles, intended to come into contact with food. In addition, the migration limit for zinc is amended from 25mg/kg to 5mg/kg. After such amendment, the standard controls migration of nine heavy metals in total. See the table below for limits before and after amendment:

Annex II -General restriction on materials & Articles		
Element	Before	After
Aluminium	/	1 mg/kg food or food simulant
Barium	1 mg/kg food or food simulant.	1 mg/kg food or food simulant.
Cobalt	0,05 mg/kg food or food simulant.	0,05 mg/kg food or food simulant.
Copper	5 mg/kg food or food simulant	5 mg/kg food or food simulant
Iron	48 mg/kg food or food simulant	48 mg/kg food or food simulant
Lithium	0,6 mg/kg food or food simulant	0,6 mg/kg food or food simulant
Manganese	0,6 mg/kg food or food simulant	0,6 mg/kg food or food simulant
Nickel	/	0,02 mg/kg food or simulant
Zinc	25 mg/kg food or food simulant	5 mg/kg food or food simulant

4. Introduction of two new test temperatures: two new temperatures are added as stimulant temperature recommendations during

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the test procedures to Annex V. Previously testing temperature for products with their use temperatures over 175°C depends on their actual use temperatures; however, after amendment, the testing temperature for products with use temperatures between 175°C-200°C is 200°C and the testing temperature for those higher than 200°C is 225°C.

Refer to the original text for more amendments

The aforesaid amendments will be published by Official Journal of the European Union. Related clauses will take into force after such publishing and products that not conforming to regulations may fail to be sold on the EU market normally.

C&K Testing hereby reminds related parties to follow the regulations, complete review of products combined with such regulations, and send the products to the 3rd-party organ if necessary. C&K Testing will keep a close eye on the latest news of the regulation. Please feel free to contact us in case of any questions.

Further information

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