Commission Regulation (EU) No 202/2014 of 3 March 2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

COMMISSION REGULATION (EU) No 202/2014

of 3 March 2014

amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[(1)], and in particular Article 5(1), Article 11(3) and Article 12(6) thereof,

Whereas:

(1) Annex I to Commission Regulation (EU) No 10/2011[(2)] establishes a Union list of substances which may be used in the manufacture of plastic materials and articles ('Union list of authorised substances').

(2) On 24 July 2012 the European Food Safety Authority issued favourable scientific evaluations for two additional substances, namely 2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine[(3)] and 1,3-bis(isocyanatomethyl)benzene[(4)]. Those substances should now be added to the Union list of authorised substances as food contact material (FCM) substances Nos 872 and 988.

(3) From the scientific evaluation of FCM substance No 988 it follows that migration of its hydrolysis product, 1,3-benzenedimethanamine should be controlled. 1,3-benzenedimethanamine is already authorised as FCM substance No 421. As the migration of FCM substances Nos 421 and 988 is controlled on the basis of the migration of FCM substance No 421, a group restriction including both substances should be introduced. Therefore, the authorisation of FCM substance No 421 should be amended and the group restriction introduced in Table 2 of Annex I to Regulation (EU) No 10/2011.

(4) FCM substance No 340 (dicyanodiamide) is authorised as an additive in plastics in Table 1 of Annex I to Regulation (EU) No 10/2011 without a specific migration limit. The Opinion reported in the 33rd series of the Scientific Committee for Food[(5)] established a tolerable daily intake (TDI) of 1 mg/kg body weight resulting in a specific migration limit (SML) of 60 mg/kg food. This limit coincides with the generic specific migration limit established in Article 11(2) of Regulation (EU) No 10/2011. However,

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 202/2014. (See end of Document for details)*

since the SML of 60 mg/kg is derived from a toxicological threshold such as the TDI, the SML should be specifically mentioned in Annex I to Regulation (EU) No 10/2011.

(5) In order to limit the administrative burden to business operators, plastic materials and articles which have been lawfully placed on the market based on the requirements set out in Regulation (EU) No 10/2011 and which do not comply with this Regulation should be able to be placed on the market until 24 March 2015. They should be able to remain on the market until exhaustion of stocks.

(6) Regulation (EU) No 10/2011 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Plastic materials and articles which have been lawfully placed on the market before 24 March 2014 and which do not comply with this Regulation may be placed on the market until 24 March 2015. Those plastic materials and articles may remain on the market after that date until the exhaustion of stocks.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annex I to Regulation (EU) No 10/2011 is amended as follows:

(1) Table 1 is amended as follows:

(a) the entry concerning FCM substance No 340 (dicyanodiamide) is replaced by the following:

340	47440	000046	dicyanodiamide	461-58-5	No	No	60			

(b) the entry concerning FCM substance No 421 (1,3-benzenedimethanamine) is replaced by the following:

421	13000	000147	1,3-benzenedimethanamine	1477-55-0	No	Yes	No		(34)		

(c) the following entry is inserted in accordance with the numerical order:

872		000660	2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine	77-41-6	No	Yes	No	0,05		To be used only as a co-monomer in polycarbonate copolymers	(20)

(d) the following entry is added:

988		3634-83-1	1,3-bis(isocyanatomethyl)benzene		No	Yes	No		(34)	SML(T) applies to the migration of its hydrolysis product, 1,3-benzenedimethanamine To be used only as co-monomer in the manufacture of a