



Brussels, **XXX**
[...](2013) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

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

(Text with EEA relevance)

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

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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/EEC¹, and in particular points (a) and (e) of Article 5(1), Article 11(3) and Article 12 (6) thereof,

Whereas:

- (1) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food² establishes a Union list of monomers, other starting substances and additives which may be used in the manufacture of plastic materials and articles. Recently the European Food Safety Authority ('the Authority') issued favourable scientific evaluations for additional substances which should now be added to the current list
- (2) Annex I to Regulation (EU) No 10/2011 should therefore be amended accordingly.
- (3) From the scientific evaluation of the substance 1,3-bis(isocyanatomethyl)benzene with FCM number 988 it follows that migration of its hydrolysis product, 1,3-benzenedimethanamine should be controlled. 1,3-benzenedimethanamine is already an authorised starting substance with FCM number 421. As the migration of substance 421 and 988 is controlled in the same manner a group restriction which includes both substances should be introduced. Therefore the authorisation of substance 421 should be amended and the group restriction introduced to table 2 of Annex I.
- (4) The substance with FCM Substance Number 340 and the name dicyanodiamide is authorised to be used 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 Food³ established a TDI of 1 mg/kg b.w. resulting in an 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 if 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, which should therefore be corrected accordingly.

¹ OJ L 338, 13.11.2004, p. 4

² OJ L 12, 15.1.2011, p. 1

³ Reports of the Scientific Committee for Food, 33rd series, p. 31, Office for Official publications of the European Communities, Luxembourg, 1995, ISBN 92-826-9275-2

- (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 one year after entry into force of this Regulation. They should be able to remain on the market until exhaustion of stocks.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them.

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 first placed on the market before {estimated date of entry into force + 1 year} and which do not comply with this Regulation may remain on the market after that date until the exhaustion of stocks.

Article

This Regulation shall enter into force on the 20th 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.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels,

For the Commission
The President

On behalf of the President

[Position]

ANNEX

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

- (1) In Table 1 the following lines are inserted in numerical order of the FCM Substance numbers:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
872		0006607-41-6	2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine	No	Yes	No	0.05		To be used only as a co-monomer in polycarbonate copolymers	20
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 middle layer coating on a poly(ethylene terephthalate) polymer film in a multilayer film	

- (2) In Table 1 for the following substance, the content of the column (8) is replaced by the following:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
340	47440	0000461-58-5	dicyanodiamide	Yes	No	No	60			

- (3) In Table 1 for the following substance, the content of the column (8) is deleted and to column (9) "(34)" is added:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
421	13000	0001477-55-0	1,3-benzenedimethanamine	No	Yes	No		(34)		

- (4) in Table 2 the following line is inserted in numerical order of the group restriction numbers:

(1)	(2)	(3)	(4)
Group Restriction No	FCM substance No	SML (T) [mg/kg]	Group restriction specification

(1)	(2)	(3)	(4)
34	421 988	0.05	Expressed as 1,3-benzenedimethanamine

(5) In Table 3 the following line is inserted in numerical order of the notes on verification of compliance:

(1)	(2)
Note No.	Note on verification of compliance
20	The substance contains aniline as an impurity; verification of compliance with the restriction set for primary aromatic amines in Annex II (2) is necessary.