



# Plastic materials and articles intended to come into contact with food

## European Commission published the Regulation (EU) 1245/2020

On Sept. 2, 2020, the European Commission (EC) published the Regulation (EU) 1245/2020 amending the Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food.

### What is new?

Regulation (EU) 1245/2020 introduces relevant changes for plastic articles designed to contact food substances.

- The list of nine metals (Annex II of this regulation) for which the specific migration must be evaluated is extended to four lanthanides and includes other elements such as antimony, arsenic, cadmium, chromium, lead and mercury, that must not be detectable in transfer simulants or in food.
- The limitation for certain PAA (Primary Aromatic Amines) listed in entry 43 to Appendix 8 of Annex XVII to Regulation European Commission (EC) 1907/2006 of the European Parliament and of the Council is lowered to 0.002 milligrams per kilograms (mg/kg).
- For articles intended for repeated use, the concept of stability is introduced: overall and specific migration shall be evaluated on each of three contacts with food simulant. The migration in the second test shall be lower than in the first test, and the migration in the third test shall be lower than in the second test.
- New substances have been added to the positive list.
- New Overall Migration (OM) condition for determining OM for specific articles.





## When will Regulation (EU) 1245/2020 enter into force?

Plastic materials and articles complying with Regulation (EU) No. 10/2011 as applicable before the entry into force of Regulation (EU) 1245/2020, which were first placed on the market before March 23, 2021, may continue to be placed on the market until Sept. 23, 2022, and remain on the market until the exhaustion of stocks.

## PAA limitation

What was tested before Reg. (EU) 1245/2020?	What is tested now with Reg. (EU) 1245/2020?
Sum of PPA (Primary Aromatic Amines): <0.01 mg/kg	<ul style="list-style-type: none"> <li>• Single PAA (listed in entry 43 to Appendix 8 of Annex XVII to Regulation 1907/2006 of the European Parliament and of the Council): &lt;0.002 mg/kg</li> <li>• Sum of other PAA: &lt;0.01 mg/kg</li> </ul>

SOURCES: COMMISSION REGULATION (EU) 2020/1245: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32020R1245>, COMMISSION REGULATION (EU) No 10/2011 (consolidated): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0010-20200923>



## The list of metals — Annex II of the Regulation (EU) 1245/2020

What was tested before Reg. (EU) 1245/2020?		What is tested now with Reg. (EU) 1245/2020?		
	Element	SML*	Element	SML*
1	Aluminium	1 mg/kg	Aluminium	1 mg/kg
2	Barium	1 mg/kg	Barium	1 mg/kg
3	Cobalt	0.05 mg/kg	Cobalt	0.05 mg/kg
4	Copper	5 mg/kg	Copper	5 mg/kg
5	Iron	48 mg/kg	Iron	48 mg/kg
6	Lithium	0.6 mg/kg	Lithium	0.6 mg/kg
7	Manganese	0.6 mg/kg	Manganese	0.6 mg/kg
8	Nickel	0.02 mg/kg	Nickel	0.02 mg/kg
9	Zinc	5 mg/kg	Zinc	5 mg/kg
10			Antimony	0.04 mg/kg
11			Arsenic	Non-detectable (ND) (0.01 mg/kg)
12			Cadmium	ND (0.002 mg/kg)
13			Chromium	ND (0.01 mg/kg)
14			Europium	0.05 mg/kg
15			Gadolinium	0.05 mg/kg
16			Lanthanum	0.05 mg/kg
17			Lead	ND (0.01 mg/kg)
18			Mercury	ND (0.01 mg/kg)
19			Terbium	0.05 mg/kg

\* SML = Specific Migration Limit

For ammonium, calcium, potassium, magnesium and sodium the migration is subject to Article 11(3) and Article 12 so they shall be evaluated through overall migration (limitation 60 mg/kg).

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