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Feedback
[...] (2024) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, amending Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008, and amending Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food.

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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COMMISSION REGULATION (EU) .../...

3

of **XXX**

4 **amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come**
5 **into contact with food, amending Regulation (EU) 2022/1616 on recycled plastic**
6 **materials and articles intended to come into contact with foods, and repealing**
7 **Regulation (EC) No 282/2008, and amending Regulation (EC) No 2023/2006 on good**
8 **manufacturing practice for materials and articles intended to come into contact with**
9 **food as regards recycled plastic and other matters related to quality control and**
10 **manufacturing of plastic materials and articles intended to come into contact with food.**

11

(Text with EEA relevance)

12

THE EUROPEAN COMMISSION,

13

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

14

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the
15 Council of 27 October 2004 on materials and articles intended to come into contact with food
16 and repealing Directives 80/590/EEC and 89/109/EEC¹, and in particular Article 5(1), points
17 (a), (c), (d), (e), (h), (i) and (j) thereof,

18

Whereas:

19

(1)

20

(2) The measures provided for in this Regulation are in accordance with the opinion of the
21 Standing Committee on Plants, Animals, Food and Feed.

22

HAS ADOPTED THIS REGULATION:

23

Article 1

24

Amendments to Regulation (EU) No 10/2011

25

(1) Article 2, paragraph 3 is replaced by the following:

26

‘3 This Regulation shall be without prejudice to the Union or national provisions
27 applicable to printing inks, adhesives or coating on substances that may be
28 used in the manufacture of adhesives, coatings and printing inks and applied on
29 or incorporated in plastic materials and articles.’

30

(2) Article 3 is amended as follows:

31

(1) Point (7) is replaced by the following:

32

‘(7) ‘additive’ means a substance which is intentionally added to the
33 polymeric matrix to achieve a physical or chemical effect during
34 processing of the plastic or in the final material or article and it is
35 intended to be present in the final material or article, including

—

¹ 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 (OJ L 338, 13.11.2004, p. 4, ELI: <http://data.europa.eu/eli/reg/2004/1935/oj>).

36 substances in a solid state of which the surface becomes bonded to the
37 polymer that constitute the plastic.’

38 (2) The following points are added:

39 ‘(20) ‘reprocessing of plastic’ means the remelting, mixing, reacting or
40 otherwise processing of plastic materials resulting as a by-product from
41 an intermediate or final manufacturing operation with the intent to use
42 them again in the manufacture of plastic materials and articles alone or
43 combined with material originating from other manufacturing operations,
44 by applying, if necessary, operations to make possible the use again of
45 these by-products.

46 (21) ‘UVCB substance’ means a substance of unknown or variable
47 composition, complex reaction products or a material of a biological or
48 other natural origin used as a substance.

49

50 (3) A new Article 3a is added:

51

52

‘Article 3a

High degree of purity

53 A substance used in the manufacture of plastic materials and articles shall be
54 considered as having a high degree of purity where all of its constituents correspond
55 to its identity, and it otherwise contains only a minor amount of non-intentionally
56 added substances that individually fulfil one of the following conditions:

57 (i) they comply with the specifications or restrictions specified in the authorisation
58 of the substance in table 1 of Annex I, if any;

59 (ii) they have been subject to a risk assessment in accordance with Article 19 and
60 considered compliant;

61 (iii) they have been subject to an toxicological assessment in accordance with the
62 relevant guidance adopted by the Authority, which concludes that genotoxicity
63 is ruled out, and which concludes on the basis of documented analysis
64 concerning their foreseeable use, characteristics and fate during subsequent
65 manufacturing stages, that it can be reasonably assumed that they are present at
66 a level in the final plastic material that cannot give rise to a migration resulting
67 in their individual presence in food exceeding 0.05 mg/kg;

68 (iv) they have not been subject to an assessment specified in points (ii) or (iii), but
69 to a risk assessment which concludes on the basis of documented analysis
70 concerning their foreseeable use, characteristics and fate during subsequent
71 manufacturing stages, that it can be reasonably assumed that they cannot be
72 present at a level in the final plastic material that can give rise to a migration
73 into food resulting in their individual presence in food exceeding 0.00015
74 mg/kg.

75 For the purpose of point (iii), the individual assessment of genotoxicity may be
76 substituted with a group assessment of genotoxicity, if the assessed substances are
77 chemically related and belong to the same or similar functional groups that could
78 give rise to toxicity, or if the substances are obtained as a mixture representative for
79 migration into food and this mixture is assessed through appropriate methods.’

80 (4) In Article 4, the following paragraph is added:

81 ‘(f) comply with Commission Regulation (EU) 2022/1616* if they fall within the
82 scope of that Regulation.’

83 * Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials
84 and articles intended to come into contact with foods, and repealing Regulation (EC) No
85 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: <http://data.europa.eu/eli/reg/2022/1616/oj>).

86 (5) In Article 5, paragraph 1 is replaced by the following:

87 ‘1. Only the substances included in the Union list of authorised substances
88 (hereinafter referred to as the Union list) set out in Annex I may be used in the
89 manufacture of plastic materials and articles.’

90 (6) In Article 5, the following paragraph is added:

91 ‘4. In case of doubt over the resulting designated identity of a substance, a
92 Member State or the Commission may consult the Authority.’

93 (7) Article 6 is amended as follows:

94 (1) in paragraphs 1 and 2, the phrase ‘plastic layers in’ is deleted;

95 (2) in paragraph 4 the phrase ‘the plastic layers of’ is deleted;

96 (3) paragraph 5 is replaced by the following:

97 ‘5. By way of derogation from Article 5, substances with a biocidal function
98 used in biocidal products that can be made available on the Union market
99 in accordance with Regulation (EU) No 528/2012** for product-type 4
100 for use that covers incorporation into plastic materials and articles which
101 may enter into contact with food, may be used as additives in the
102 manufacturing of plastic materials and articles.

103 **Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May
104 2012 concerning the making available on the market and use of biocidal products (OJ L
105 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).

106 (8) Article 7 is deleted.

107 (9) Article 8 is replaced by the following:

108 *Article 8*

109 **General requirements on substances**

110 1. Substances used in the manufacture of plastic materials and articles that may be
111 present in the final plastic material, including those manufactured from waste,
112 shall be of a high degree of purity and shall be of a technical quality suitable
113 for the intended and foreseeable use of the materials or articles.

114 The composition shall be known to the manufacturer of the substance and
115 made available to the competent authorities on request, together with any
116 documentation regarding their degree of purity.

117 2. By derogation from paragraph 1, as regards purity, for UVCB substances that
118 are identified by a name in this Regulation that refers to a natural multi
119 constituent material where the source is biological or mineral, that substance
120 may be used as obtained from its natural origin, provided it does not contain
121 substances or materials that do not correspond to its identity as designated by
122 that name. Any additional specifications or requirements applicable to a

123 substance or material of natural origin set out in Table 1 of Annex I, applicable
124 to the substance or material, shall apply.

125 3. Manufacturers of plastic materials and articles, and of products from
126 intermediate stages of their manufacturing, shall ensure that documentation
127 showing compliance with paragraphs 1 to 2 is part of the documentation
128 referred to in Article 16.

129 4. Manufacturers of plastic materials and articles, and of products from
130 intermediate stages of their manufacturing, shall ensure that competent
131 authorities can take samples to verify their degree of purity and their
132 composition, including that of the substances and materials used for their
133 manufacture.’

134 (10) In Article 9, paragraph 1, the phrase ‘plastic layers in’ is deleted.

135 (11) Article 10 is replaced by the following:

136 *‘Article 10*

137 **General restrictions and requirements concerning the composition of plastic materials**
138 **and articles**

139 1. The plastic materials and articles shall meet the restrictions on plastic materials
140 and articles laid down in Annex II.

141 2. Plastic materials and articles may contain reprocessed plastic if such
142 reprocessed plastic meets the following conditions:

143 (a) it can be considered to be a by-product in accordance with Article 5 of
144 Directive 2008/98/EC of the European Parliament and of the Council²;

145 (b) it is collected and used in accordance with section C of the Annex to
146 Regulation (EC) No 2023/2006;

147 (c) it originates only from off-cuts and scraps from plastic materials and
148 articles referred to in point (a) of Article 2(1) that meet the compositional
149 requirements set out in chapter II of this Regulation;

150 (d) it does not contain substances in an amount which could:

151 (i) exceed migration limits applicable for the substance as specified in
152 Regulation (EU) No 10/2011; or,

153 (ii) cause any other non-compliance of those plastic materials and
154 articles with Article 3 of Regulation (EC) No 1935/2004;

155 (e) by derogation to point (c), it may originate from off-cuts and scraps from
156 plastic materials and articles referred to points (b) and (c) of Article 2(1),
157 and does not contain a layer which functions as a functional barrier and
158 all of its individual constituents either meet the compositional
159 requirements set out in Chapter II of this Regulation, or have been
160 subject to risk assessment on the basis of Article 19 taking into account
161 the conditions of reprocessing and their presence in the reprocessed
162 material.

² Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: <http://data.europa.eu/eli/dir/2008/98/oj>).

163 3. Where intended for repeated use in contact with food, the composition of and
164 the design of final food contact articles shall be such, so as to guarantee that no
165 increase in the migration of constituents of the material or article to the food
166 would occur when subjected to subsequent use cycles of the materials and
167 articles in accordance with the instructions for intended use as described in
168 documentation or labelling. ’

169 (12) Article 13 is amended as follows:

170 (1) in point (b) of paragraph 2, the phrase ‘in the provisional list’ is deleted;

171 (2) in paragraph 4 the phrase ‘or provisional list’ is deleted;

172 (13) The title of Chapter IV is replaced by the following:

173 **‘LABELLING, DECLARATION OF COMPLIANCE AND**
174 **DOCUMENTATION’**

175 (14) A new Article 14a is added:

176 *‘Article 14a*
177 **Labelling**

178 1. The manufacturer or other operator responsible for placing on the market a
179 final plastic food contact article intended for repeated use, shall provide
180 information to its users by means of labelling or instructions, including
181 appropriate instructions designed to slow down deterioration of the material or
182 article, as well as a description of observable changes of the article or material
183 that may indicate the deterioration of the article or material. Information shall
184 warn in case specific damage or foreseeable misuse would cause increased
185 migration or would cause the material or article to become otherwise
186 unsuitable for further use in contact with food.

187 2. Plastic materials and articles intended to be brought into contact with food but
188 are not yet in contact with food shall be accompanied with instructions of use,
189 in accordance with Article 15(7) of Regulation (EC) No 1935/2004, directed at
190 the consumer of that final food contact article at the moment of their sale or
191 supply to consumers, where they are manufactured with substances included in
192 the Union list of authorised substances, for which column 10 of table 1 of
193 Annex I sets out restrictions related to one or more of the following elements:

- 194 – specific foods or groups of foods,
195 – contact time and/or temperature, and/or,
196 – to heating conditions such as oven and microwave use,

197 The instructions of use shall mention the restrictions and provide the consumer
198 with adequate information to prevent using the material or article under
199 conditions not complying with them.’

200 (15) Article 14 is amended as follows: in paragraphs 2 and 3, the phrase ‘or the provisional
201 list’ is deleted.

202

203 (16) In Article 14, paragraph 4 is replaced by the following:

204 '4. Articles 11 and 12 apply to multi-material multi-layer materials and articles
205 when the surface layer that is in contact with food is made of a material falling
206 within the scope of this Regulation.'

207 (17) Article 14, paragraph 6 is replaced by the following:

208 '6. If the surface layer that is in contact with food is made of a material falling not
209 within the scope of this Regulation, specific and overall migration limits for
210 plastic layers and for the final material or article may be established by national
211 law.'

212 (18) Article 17(2) is replaced with the following:

213 '2. By derogation from paragraph 1 for:

214 (a) containers and other articles of a volume of less than 100 ml, a surface to
215 volume ratio of 12 dm² per kg of food may be applied,

216 (b) a material or article for which, due to their form it is impracticable to
217 estimate the relationship between the surface area of such
218 materials or articles and the quantity of food in contact therewith, a
219 surface to volume ratio of 12 dm² per kg of food may be applied,

220 (c) sheets and films that are not yet in contact with food, a surface to volume
221 ratio of 12dm² per kg of food may be applied.

222 This paragraph does not apply to plastic materials and articles intended to be brought
223 into contact with or already in contact with food for infants and young children, as
224 defined by Directives 2006/141/EC and 2006/125/EC.'

225

226 (19) Annexes III to V are amended in accordance with Annex I to this Regulation.

227

Article 2

228

Amendment to Regulation (EC) No 2022/1616

229

230 Article 4, paragraph 2 of Regulation (EC) No 2022/1616 is replaced by the following:

231

232 '2. The requirements set out in Chapters II and III and Chapter V of Regulation (EU) No
233 10/2011 shall apply to recycled plastic materials and articles. By derogation from Article 8(1)
234 thereof, the quality and purity of plastic input and the output of a decontamination processes
235 shall be in accordance with this Regulation.'

236

237

Article 3

238

Amendments to Regulation (EC) No 2023/2006

239 The Annex to Regulation (EC) No 2023/2006 is amended in accordance with Annex II to this
240 Regulation.

241

Article 4

242

Transitional measures

243 1. Plastic materials and articles complying with Regulation (EU) No 10/2011 as
244 applicable before the entry into force of this Regulation, which were first placed on
245 the market before *[enter date 18 months after the date of entry into force of this*
246 *Regulation]* may continue to be placed on the market until the exhaustion of stocks.

247 2. In case a product from an intermediate stage of the manufacturing of plastic materials
248 and articles or a substance intended for the manufacturing of such a product, material
249 or article, which complies with Regulation (EU) No 10/2011 as applicable before the
250 entry into force of this Regulation and which is first placed on the market after *[enter*
251 *date 9 months after the date of entry into force of this Regulation]* does not comply
252 with this Regulation, the declaration of compliance accompanying that substance or
253 product shall indicate that it does not comply with this Regulation, and that it can
254 only be used in the manufacture of plastic materials and articles to be placed on the
255 market before *[enter date 18 months after the date of entry into force of this*
256 *Regulation]*.

257

Article 5

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

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

261 Done at Brussels,

262

For the Commission

263

The President

264

Ursula VON DER LEYEN