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Draft

COMMISSION REGULATION

on recycled plastic materials and articles intended to come into contact with foods and amending Commission Regulation (EC) No 2023/2006

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing 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 food¹, and in particular Article 5(1) thereof,

After consulting the European Food Safety Authority ("the Authority"),

Whereas:

(1) [RECAPITULATED]

[GREEN: sections amended/added to ensure appropriate transition period]

[CYAN: sections amended/added to ensure correct implementation of individual decisions]

[YELLOW: remarks to guide the present reader that will be deleted]

[GRAY: updates to the text for other reasons; mostly outdated references]

OJ L 338, 13.11.2004, p. 4.

19 HAS ADOPTED THIS REGULATION:

20 *Article 1*
21 *Subject matter and Scope*

- 22 1. This Regulation shall apply to the plastic materials and articles and parts thereof
23 intended to come into contact with foodstuffs as referred to in Article 1 of Regulation
24 (EU) No 10/2011 which contain recycled plastic (hereafter "recycled plastic
25 materials and articles").
- 26 2. This Regulation shall not apply to the following recycled plastic materials and
27 articles, provided that they have been manufactured according to good manufacturing
28 practice, as laid down in Regulation (EC) No 2023/2006, :
- 29 (a) recycled plastic materials and articles made with monomers and starting
30 substances, derived from chemical depolymerization of plastic materials and
31 articles;
- 32 (b) recycled plastic materials and articles made from unused plastic production
33 offcuts and/or process scraps in compliance with Regulation (EU) No 10/2011,
34 that are recycled within the manufacturing site or are used at another site;
- 35 (c) recycled plastic materials and articles in which the recycled plastic is used
36 behind a plastic functional barrier, as specified in Regulation (EU) No 10/2011.
- 37 3. The plastic materials and articles that fall within the scope of this Regulation remain
38 subject to Regulation (EU) No 10/2011.

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Article 2
Definitions

41 1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No
42 1935/2004, Regulation (EC) No 10/2011, and Regulation (EU) 2017/625 shall apply.

43 2. The following definitions shall also apply:

44 (a) “recycling process” means a process in which plastic waste can be recycled
45 pursuant to the definition of recycling in point 7 of Article 3 of Directive
46 94/62/EC on packaging and packaging waste; for the purpose of this
47 Regulation, this term is limited to processes, in which a recycled plastic is
48 produced;

49 (b) “plastic input” means collected and sorted post-use plastic materials and
50 articles used as input into a recycling process;

51 (c) “product loops which are in a closed and controlled chain” means manufacture
52 and distribution cycles in which products circulate with a controlled reuse and
53 distribution system, and in which the recycled material originates only from
54 these entities in the chain, so that the unintentional introduction of external
55 material is just the minimum technically feasible;

56 (d) “challenge test” means a demonstration of the effectiveness of a recycling
57 process to remove chemical contamination from plastic materials or articles;

58 (e) “converter” means the natural or legal person responsible for ensuring that the
59 requirements of this Regulation, as regards the recycled plastic materials and
60 articles are met within the business under their control;

61 (f) “recycler” means the natural or legal person who applies a recycling process to
62 manufacture recycled plastics, including the authorisation holder where he does
63 so.

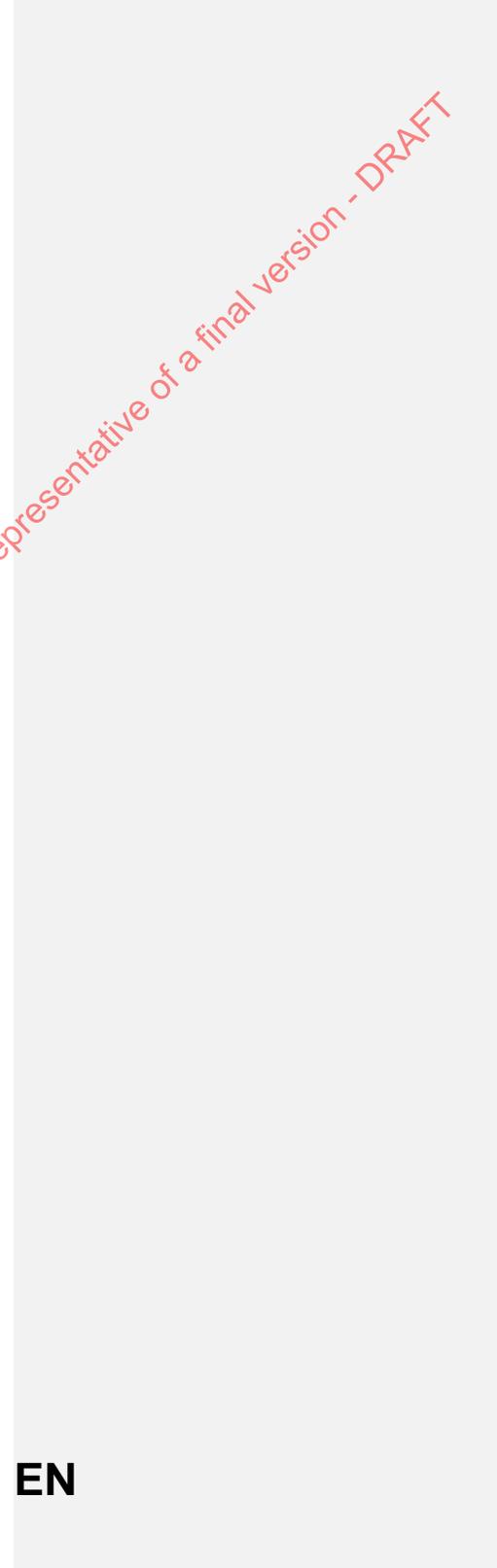
64 (g) “authorisation” means the permission to operate a defined recycling process on
65 the basis of a Commission Decision following an authorisation procedure
66 concluded with a favourable authorisation decision

67 (g) “authorisation holder” means the natural or legal person to whom the
68 authorisation decision is addressed, and who is the owner of the application
69 dossier and authorisation.

70 (h) “incidental contamination” means any contamination of a material with
71 substances without a technical function in that material, and which are
72 introduced during the manufacture, converting, use, waste or recycling stages
73 of the material, including substances originating from misuse, cross
74 contamination or from the presence of materials that were intended or used for
75 non-food purposes.

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- 76 (i) "recycling facility" means a part of a manufacturing site at which one recycling
77 process is operated.
- 78 (j) "PET" means polyethylene terephthalate based plastics

79 *Article 3*

80 *Requirements for recycled plastic materials and articles*

81 Plastic materials and articles containing recycled plastic shall only be placed on the market if
82 that recycled plastic is manufactured at a recycling facility with a recycling process authorised
83 and operated in accordance with this Regulation, and which is not subject to suspension or
84 revocation of the authorisation or the use thereof.

85 Business operators participating in the supply chain of recycled plastics are responsible for
86 ensuring the requirements of this Regulation, where these requirements are met within the
87 business under their control. They shall ensure adequate communication in the supply chain to
88 ensure the different actors along the supply chain can meet their respective roles.

89 *Article 3a*

90 *General conditions for the operation of recycling processes*

91 The operation of a recycling process shall comply with the conditions set out below:

92 1. Conditions on quality assurance

93 (a) the process shall be managed by an appropriate quality assurance system that
94 ensures that the recycled plastic complies with:

- 95 – the general requirements set out in this Regulation; and,
- 96 – in case an authorisation applies to the recycling process, with any
97 specific restrictions and specifications on the process set out in that
98 authorisation.

99 That quality assurance system shall comply with Regulation (EC) No
100 2023/2006, and in particular to the detailed rules laid down in Annex B thereto.

101 (b) the plastic input to the recycling process shall meet the following quality
102 criteria:

- 103 (i) it shall originate only from plastic materials and articles that previously
104 have been recycled in accordance with this Regulation or which have
105 been manufactured in accordance with Regulation (EU) No 10/2011;
106 and,
- 107 (ii) it shall originate only from plastic used by consumers or food business
108 operators and their supply chain; and,
- 109 (iii) it shall be collected with a waste collection system that is designed and
110 organised to minimise incidental contamination with plastics used for

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111 purposes other than for contact with food, and with chemicals and
112 plastics from other waste streams.

113 Plastic materials from a non-food and/or industrial origin and incidental
114 contaminants shall only be present in minor and unavoidable amounts. If an
115 authorisation is applicable to a process, the maximum level of incidental
116 contamination and the composition of the input materials shall be in
117 accordance with that authorisation.

118 (c) For the purpose of point (b) the collection of the input materials shall be
119 controlled by means of a certified quality assurance system throughout the
120 whole collection chain. Article 3, 4, 5, 6, and 7 of Regulation (EC) No
121 2023/2006 shall apply mutatis mutandis to all stages of the collection chain of
122 plastic input

123 (d) where a monitoring programme in accordance with Article 12b is in place, the
124 data that is required under that programme is collected.

125 2. Conditions on the technical suitability of the recycling process:

126 a) it is demonstrated by appropriate scientific evidence that the process can be
127 operated in a way that reduces the unavoidable contamination of the plastic
128 input to a concentration that ensures the conditions of Article 3 of Regulation
129 (EC) No 1935/2004 can be met;

130 b) there are pre-established criteria by which the quality of the recycled plastic is
131 characterised and can be controlled to ensure compliance of the final recycled
132 plastic material with Article 3 of Regulation (EC) No 1935/2004;

133 c) there are pre-established conditions of use of the recycled plastic whereby it
134 can be ensured that the recycled plastic materials and articles comply with
135 Article 3 of Regulation (EC) No 1935/2004.

136 d) there are defined instructions and procedures regarding the operation of the
137 recycling process which ensure compliance with Article 3 of Regulation (EC)
138 No 1935/2004 and with the conditions set out in this Regulation and with the
139 applicable authorisation, if any;

140 e) the evidence, criteria, conditions and instructions and procedures in point (a) to
141 (d) can be implemented in a mutually coherent way that ensures the process
142 overall can produce recycled plastic that meets the requirements of Article 3 of
143 Regulation (EC) No 1935/2004;

144 f) the recycling process does not add any substances to the recycled plastic that
145 are not listed in Annex I to Regulation (EU) No 10/2011, unless in accordance
146 with a derogation set out in Article 6 to that Regulation.

147 3. Administrative conditions:

148 (a) The recycler, recycling facility and, if any, the authorisation holder are
149 registered in the Union register of recycling processes for food contact
150 materials and the listed information is up to date;

- 151 (b) a compliance monitoring summary sheet is established in accordance with
152 Article 9a; if no authorisation is applicable to a recycling process, the recycler
153 shall establish an equivalent document;
- 154 (c) information on the compliance of each manufactured batch is kept for a period
155 of at least 3 years; this information shall be in accordance with the summary
156 sheet referred to in point (b);
- 157 (d) the conditions of use of the recycled plastic in accordance with paragraph 2(d)
158 and, if applicable, those set out in the authorisation, are communicated to users
159 of recycled plastic by means of appropriate labelling and documentation, and a
160 Declaration of Compliance in accordance with Article 12.
- 161 (e) for the purpose of point (a), information equivalent to the information required
162 under Article 6(3) has been submitted to the Commission if the process is not
163 subject to an authorisation in accordance with this Regulation.
- 164 The general conditions for the operation of recycling processes set out in this Article may be
165 amended or overridden with specific derogations set out in an authorisation.

166 *Article* 4
167 **Conditions for the authorisation of recycling processes**

168 In order to be authorised, a recycling process shall comply with the following conditions:

- 169 (a) the process can meet the conditions on the technical suitability of the process set out
170 in Article 3a (2);
- 171 (b) (other provisions previously contained in Article 4 are moved to Article 3a)
- 172 (c) (i) either the plastic input must originate from a product loop which is in a closed
173 and controlled chain ensuring that only materials and articles which have been
174 intended for food contact are used and any contamination can be ruled out; or
- 175 (ii) it must be demonstrated in a challenge test, or by other appropriate scientific
176 evidence that the process is able to reduce any contamination of the plastic
177 input to a concentration that does not pose a risk to human health;

178 *Article 5*
179 **Application for authorisation of recycling processes and opinion of the Authority**

- 180 1. The procedure for authorisation laid down in Articles 9 to 10 of Regulation No (EC)
181 1935/2004 shall apply mutatis mutandis for the authorisation of recycling processes,
182 subject to the specific provisions laid down in paragraphs 2 to 4 of this Article.
- 183 2. The technical dossier shall contain the information specified in the guidelines for the
184 safety assessment of a recycling process to be published by the Authority at the latest
185 six months after the date of publication of this Regulation.
- 186 3. The Authority shall give an opinion within six months of receipt of a valid
187 application as to whether or not the recycling process complies with the conditions
188 laid down in Article 4.
- 189 4. In the event of an opinion in favour of authorising the evaluated recycling process,
190 the opinion of the Authority shall include the following:
- 191 (aa) the identification and the address of the applicant;
- 192 (a) a short description of the recycling process, including a process flow diagram
193 in accordance with section 4.3 of ISO 10628-1:2014 and the name of the
194 process;
- 195 (b) where appropriate, any recommendations on conditions or restrictions
196 concerning the plastic input;
- 197 (c) where appropriate, any recommendations on conditions or restrictions
198 concerning the recycling process;
- 199 (d) where appropriate, any criteria to characterise the recycled plastic;

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- 200 (e) where appropriate, any recommendations concerning conditions in the field of
201 application of the recycled plastic;
- 202 (f) where appropriate, any recommendations concerning monitoring compliance of
203 the recycling process with the conditions of the authorisation.

204 *Article 5a*

205 **Confidential information**

206 Where the information received in an application dossier submitted under this Regulation,
207 including information relevant for point 5(a)-(f) is subject to a request accepted by the
208 Authority to treat certain parts of the information as confidential in accordance with Article
209 20 of Regulation (EU) No 1935/2004, it shall be part of an Annex to the opinion that shall not
210 be published. The complete opinion including the confidential Annex shall be provided to the
211 applicant, the Member States and the Commission.

212 This information may include:

- 213 – the process flow diagram required under point (a), provided a simplified diagram is
214 included in the public part of the opinion and which clearly shows all relevant process
215 steps;
- 216 – details of equipment, such as precise drawings, internals, and control equipment;
- 217 – values of parameters by which the process is controlled;
- 218 – details of the quality assurance system including procedures, forms, labels, and contracts
219 with third parties;
- 220 – Any other information contained in the dossier that is not directly relevant to the safety of
221 the plastic manufactured with the process.

222 Information received under point 5(aa) shall not be confidential, even if this information
223 includes personal information.

224 *Article 6*

225 **Authorisation of recycling processes**

226 1. The Commission shall adopt a Decision addressed to the applicant granting or refusing
227 authorisation of the recycling process.

228 Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the
229 Council³ shall apply.

230 The Commission shall be assisted by the Standing Committee on Plants,
231 Animals, Food and Feed established by Article 58(1) of Regulation (EC) No

³ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

232 178/2002 of the European Parliament and of the Council³). That Committee
233 shall be a committee within the meaning of Regulation (EU) No 182/2011.

234 2. The Decision shall take into account the opinion of the Authority, relevant provisions
235 of Union law, and other legitimate factors relevant to the matter under consideration.

236 Where the Decision is not in accordance with the opinion of the Authority, the
237 Commission shall provide an explanation for the reasons for the differences.

238 3. The Decision granting the authorisation shall include the following:

239 (a) the name of the recycling process;

240 (b) the name and address of the authorisation holder(s);

241 (c) a short description of the recycling process;

242 (d) any conditions or restrictions concerning the plastic input;

243 (e) any conditions or restrictions concerning the recycling process;

244 (f) any characterisation of the recycled plastic;

245 (g) any conditions in the field of application of the recycled plastic that has been
246 manufactured by the recycling process;

247 (h) any requirements concerning monitoring and/or verification of the compliance
248 of the recycling process with the conditions of the authorisation;

249 (i) any specific derogations to the general conditions for the operation of recycling
250 processes set out in Article 3a

251 (j) the date from which the authorisation is effective.

252 4. The Decision granting or refusing the authorisation shall be notified to the applicant.

253 5. The authorisation thus issued to the authorisation holder shall be valid
254 throughout the Union.

255 The authorisation holder may provide the right to operate the authorised process to
256 recyclers in accordance with Article 7.

257 6. The authorised recycling process shall be entered in the Register referred to in
258 Article 9(1).

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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Article 7

General Obligations arising from the authorisation

261 1. After the authorisation of a recycling process in accordance with this Regulation, the
262 authorisation holder or a **recycler** using the authorised recycling process shall comply
263 with any conditions or restrictions attached to such authorisation.

264 **A** converter using recycled plastic from the authorised recycling process or **a**
265 business operator using materials or articles containing recycled plastic from the
266 authorised recycling process shall comply with any condition or restriction attached
267 to such authorisation.

268 2. The authorisation holder or **a recycler** using the authorised recycling process **under**
269 **Article 6** shall immediately inform the Commission of **new** scientific or technical
270 information, which might affect the safety assessment of the recycling process in
271 relation to human health.

272 If necessary, the Authority shall then review the assessment.

273 3. **The authorisation holder shall apply good administrative practices with respect to the**
274 **administration of its ownership of the authorisation and the application dossier. It shall**
275 **communicate any relevant modifications to the Member State in which it is located**
276 **and to the Commission, including changes to its points of contact, its trade and**
277 **company names, and other information relevant to the authorisation.**

278 **In case the authorisation holder intends to transfer its rights and obligations**
279 **forthcoming from the authorisation to a third party, it shall notify the Commission**
280 **before the transfer, indicating the name, address and contact information of that third**
281 **party. At the time of the transfer it shall provide the application dossier and all**
282 **documents included therein to the party acquiring those rights and obligations. That**
283 **party shall contact the Commission without delay by registered letter, stating that it**
284 **accepts the transfer, has received all documents, and is able to meet all the obligations**
285 **arising from the authorisation. It shall then be considered the Authorisation holder.**

286 **The Commission shall update the Union register of recycling processes for food**
287 **contact materials without delay when the Authorisation holder notifies it of changes. If**
288 **necessary, the Commission shall then amend the Authorisation Decision in accordance**
289 **with the procedure set out in Article 6(1). The Commission shall not be required to**
290 **seek the opinion of the Authority if the updates in question are not liable to have an**
291 **effect on human health.**

292 4. **The authorisation holder shall immediately inform the competent authority in which**
293 **territory it is located and the Commission of a situation under which it can or will no**
294 **longer assume its responsibilities as authorisation holder, including:**

295 **– A situation under which a natural or legal person received this authorisation as**
296 **part of a bankruptcy estate, but is not able to assume the responsibilities set out**
297 **in this Regulation; or,**

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298 – when the authorisation holder decides that for technical or commercial reasons
299 the authorised process becomes obsolete or will not be operated for more than
300 1 year; or,

301 – when the authorisation holder modifies the process in such a way that its
302 operation no longer corresponds to the authorised process or if the conditions
303 in Article 3a can no longer be met.

304 The Authorisation holder shall provide all necessary information to allow the
305 Commission to determine whether the authorisation should be modified suspended,
306 or revoked.

307 5. The granting of an authorisation shall not affect the general civil and criminal
308 liability of any business operator in respect of the authorised recycling process, the
309 material or article containing recycled plastic from the authorised recycling process,
310 and the food that is in contact with such material or article.

311 *Article 8*

312 *Modification, suspension and revocation of authorisation of a recycling process*

313 1. The authorisation holder may, in accordance with the procedure laid down in
314 Article 5(1) apply for a modification or revocation of the existing authorisation.

315 2. In case it concerns a modification, the application referred to in paragraph 1 shall be
316 accompanied by the following:

317 (a) a reference to the original application;

318 (b) a technical dossier containing the new information in accordance with the
319 guidelines referred to in Article 5(2);

320 (c) a new complete summary of the technical dossier in a standardised form.

321 3. In case of doubt over the ability of the recycling process to meet the conditions on
322 the technical suitability set out in Article 3a(2), on its own initiative or following a
323 request from a Member State or the Commission, the Authority shall evaluate
324 whether the opinion or the authorisation is still in accordance with this Regulation, in
325 accordance with the procedure laid down in Article 5, where applicable.

326 4. The Commission shall examine the opinion of the Authority without delay and if
327 necessary prepare a draft Decision to be taken.

328 5. A draft Decision modifying an authorisation shall specify any necessary changes in
329 the conditions of use and, if any, in the restrictions attached to that authorisation.

330 6. If appropriate, the authorisation shall be modified, suspended or revoked in
331 accordance with the procedure referred to in Article 6(1), and this shall be indicated
332 in the Union Register in accordance with Article 9.

333 7. Where it has been suspended for a continuous period of two years, the authorisation
334 shall be revoked automatically.

335 8. Revocation shall be definite; the reference to the process shall be removed from the
336 Union Register after three years.

337 *Article 9*

338 **Union Register of recycling processes for food contact materials**

- 339 1. The Commission shall establish and maintain a Union Register of recycling
340 processes. This register shall list authorisation holders, recyclers and recycling
341 facilities.
- 342 2. The Register shall be made available to the public on the website of the Commission.
343 The Commission shall thereafter regularly update the register to facilitate the
344 communication to the public of status changes regarding authorisation and facilities
345 appearing on the register.
- 346 3. Each entry in the Register shall include the information referred to in Article 6 (3),
347 the type of recycling process, and its authorisation status.

Commented [BS1]: This will go into a recital explaining 'regularly'

348 *Article 9a*

349 **Compliance monitoring summary sheet**

350 1. A recycler shall ensure the presence of a summary sheet in accordance with Annex
351 III at the start of the operation of a new recycling facility.

352 It shall be compiled and agreed with the competent authority in accordance with the
353 following procedure:

354 (i) the recycler shall compile the information required in the compliance
355 monitoring summary sheet designed to meet the conditions and obligations set
356 out in the Authorisation, this Regulation, and Regulation (EC) No 2023/2006.
357 The recycler shall use the template provided in Annex III to this Regulation
358 ('the summary sheet');

359 In that summary the recycler shall clearly describe the process, its operation,
360 and relevant procedures and documents designed to meet the general
361 conditions for the operation of a recycling process defined in this Regulation
362 and any specific conditions set out in the Authorisation in accordance with
363 Article 6(3); and

364 (ii) the recycler shall notify the responsible competent authority and the
365 Commission of the date at which the operation of the recycling facility will
366 start at least 10 working days prior to that date;

367 (iii) the recycler shall provide the compiled summary sheet to the responsible
368 competent authority within one month from the start date;

369 (iv) the competent authority of a Member State that receives the compiled summary
370 sheet shall without delay verify whether the information provided in the
371 summary sheet complies with this Regulation and with the requirements of

Commented [BS2]: Recital will explain this month, the summary sheet should correctly describe the actual operation, and can therefore only be provided after the start of operation to adequately reflect it.

372 Annex III; as part of this verification the competent authority shall perform an
373 audit of the recycling facility;

374 (v) when the competent authority concludes that the information indicated in the
375 summary sheet is not correct or the operation of the recycling facility is not in
376 agreement with this Regulation and the authorisation, the recycler shall without
377 delay update the submitted summary sheet, and/or change the process or its
378 operating conditions; step (iii) of this procedure shall than be repeated;

379 (vi) when the competent authority concludes that the operation of the recycling
380 facility is in compliance it will notify the recycler and the Commission thereof;
381 when this conclusion is not reached within 6 months following the first
382 reception of the summary sheet, the competent authority may suspend the
383 operation of that facility. In this case, the use of the authorisation by the
384 recycler of an authorised process shall also be suspended in accordance with
385 Article 10b, and the competent authority shall request the Commission to
386 indicate the suspension of the operation in the Union Register.

387 (vii) upon receiving the notification of compliance from a competent authority, the
388 Commission shall indicate the validation date in the entry in the Union Register
389 applicable to the recycling facility.

390 (viii) If the competent authority did not notify the Commission of compliant
391 operation within one year after the start of the operation of the facility the use
392 of the authorisation at that recycling facility shall be suspended automatically.

393 2. The compiled and agreed summary sheet shall be kept at the recycling facility, and
394 the recycler shall present it without delay to the competent authority upon its request;

395 *Article 10*
396 **Official Control**

397 1. The official control of a recycling facility and converter shall be performed in
398 accordance with the rules laid down in Regulation (EC) No 882/2004 and shall
399 include in particular audits as control technique as specified in Article 14 of
400 Regulation (EU) 2017/625. During such controls, a competent authority shall:

401 - apply the agreed summary sheet established in accordance with Article 9 as the
402 starting point for its audits or other control techniques to verify whether the
403 operation of the recycling facility and the application of good manufacturing
404 practices is still in accordance with the information provided in the summary
405 sheet; but,

406 - omit physical or chemical verification of the quality of recycled plastic such as
407 with laboratory techniques. When poor quality of a batch of recycled plastic
408 is observed or suspected, audit techniques or inspections of the operation of
409 the process shall be prioritized with a purpose to establish or identify the
410 cause of the poor quality of the batch and to take remedial action.

411 2. A recycler shall notify the competent authority about a recycling facility in the
412 territory in which it operates it. Member States shall forward that information to the
413 Commission.

414 3. The Commission shall audit competent authorities in third countries on whose
415 territory a recycling facility is operated with respect to the tasks conferred upon them
416 by this Regulation, and in accordance with Article 120-123 of Regulation (EU)
417 2017/625.

418 The Commission shall invite those competent authorities to participate in relevant
419 trainings it organises.

420 If such a competent authority refuses an audit, or fails to provide evidence that the
421 recommendations forthcoming from an audit are adequately implemented, the use of
422 authorisations by recyclers operating in the territory of that competent authority shall
423 be suspended.

424 *Article 10a*
425 ***non-compliance of recycled plastic***

426 1. If, during an audit or other control activity in accordance with Article 10(1) a
427 recycler cannot demonstrate that a batch of recycled plastic placed on the market in
428 accordance with Article 3 was manufactured in compliance with this Regulation
429 and/or with the authorisation, that batch shall be considered as not being obtained
430 from an authorised process and therefore be considered non-compliant.

431 In the case a batch is considered non-compliant, the recycler shall without delay
432 produce evidence for all other batches produced during the last six months,
433 demonstrating they are manufactured in compliance with this Regulation. Batches for
434 which such evidence cannot be produced during the audit shall also be considered as
435 not being obtained from an authorised process.

436 2. The operation of a recycling facility shall be considered non-compliant to this
437 Regulation if:

438 (a) During the audit done in accordance with paragraph 1 the competent authority
439 determined the non-compliance of more than two batches; or,

440 (b) the competent authority determines on other grounds that the process or its
441 operation is not in conformity with Article 3a and/or its authorisation; or,

442 (c) no summary of the quality assurance system has been agreed with the
443 competent authority in accordance with Article 9a; or,

444 (d) the recycler does not participate in notified monitoring activities as referred to
445 in Article 12a.

446 If the operation at the recycling facility is considered non-compliant with this
447 Regulation, any plastic manufactured with it shall be considered as not being
448 obtained from an authorised process. In case the process operates subject to a

Commented [BAS3]: This is left unchanged (the alternative would be to require the recycler to notify also the Commission), as it allows for verification by the competent authority and member state also against other applicable legislation, and ensures that the Commission will receive only one and verified set of data for the register. It will also establish the point of contact responsible for this facility in the MS.

449 transition period or derogation under which authorisation is not required, that
450 transition period or derogation shall not apply to this situation.

451 3. Batches that cannot be considered as being obtained from an authorised process and
452 have already been placed on the market in accordance with Article 3 shall be
453 recalled.

454 4. The recycler shall remedy the non-compliance of its operations without delay, and
455 report the changes in its operation of the process without delay to the Competent
456 Authority.

457 5. If the recycler applying the non-compliant process is not the authorisation holder, it
458 shall provide the authorisation holder with the details of the non-compliance without
459 delay.

460 *Article 10b*

461 *Suspension of the use of the authorisation of a recycling process*

462 1. If evidence obtained in subsequent official controls of a recycling facility
463 demonstrates repeat failure to comply with the conditions and obligations set out in
464 this Regulation or in the authorisation, a competent authority may suspend the use of
465 the authorisation at the recycling facility or by a specific recycler. In this case the
466 competent Authority shall inform the Commission. The Commission shall then
467 indicate the suspension status on the register pursuant to Article 9(3) for the
468 recycling facility and/or recycler in case the suspension involves all recycling
469 facilities the recycler operates.

470 2. However, where the ground for the suspension relates to the technical suitability of
471 the process in accordance with Article 3a(2), the Commission shall upon receiving
472 the request consult the Authority on the need to evaluate the technical suitability of
473 the process in accordance with Article 8(3). If the Authority confirms the need, the
474 Commission shall provide the authority with a mandate to re-evaluate the process
475 and inform the authorisation holder thereof. In case the Authority indicates more
476 than six months will be needed to evaluate the suitability of the process, the
477 Commission shall suspend the authorisation in accordance with Article 8(6). The
478 authorisation holder shall provide all information the Authority requests.

479 3. When the use of the authorisation is suspended the process shall not be applied to
480 manufacture recycled plastic in accordance with this Regulation at each recycling
481 facility where the suspension applies until the suspension ends.

482 The Competent Authority shall notify the recyclers to which it applies of the
483 suspension of the use of the authorisation, which is immediately applicable, and shall
484 end when the condition leading to it no longer exists.

485 The authorisation holder and/or any recycler to which the suspension applies shall
486 ensure the condition leading to the suspension is resolved, and communicate the
487 resolution to the Competent Authority once it is fully implemented. The requesting
488 competent authority shall inform the Commission that the suspension has ended if it
489 is satisfied that the conditions leading to the suspension no longer exist.

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490 4. The Commission shall indicate the suspension of the use of the authorisation in the
491 Union Register of recycling processes for each recycling facility to which it applies.

492

493 *Article 11*
494 **Labelling of recycled plastic materials and articles**

495 Recycled plastic shall be labelled in accordance with Annex IV of this Regulation.

496 Voluntary self-declaration of the recycled content in recycled plastic materials and articles
497 shall follow the rules laid down in ISO 14021:2016 or equivalent.

498 *Article 12*
499 **Declaration of Compliance**

500 1. In addition to the requirements of Article 9 of Regulation (EU) No 10/2011, the
501 declaration of compliance of recycled plastic materials and articles shall contain the
502 information laid down in Part A of Annex I to this Regulation.

503 2. In addition to the requirements of Article 9 of Regulation (EU) No 10/2011, the
504 declaration of compliance of recycled plastic shall contain the information laid down
505 in Part B of Annex I to this Regulation.

506 *Article 12a*
507 **Analytical Monitoring programmes**

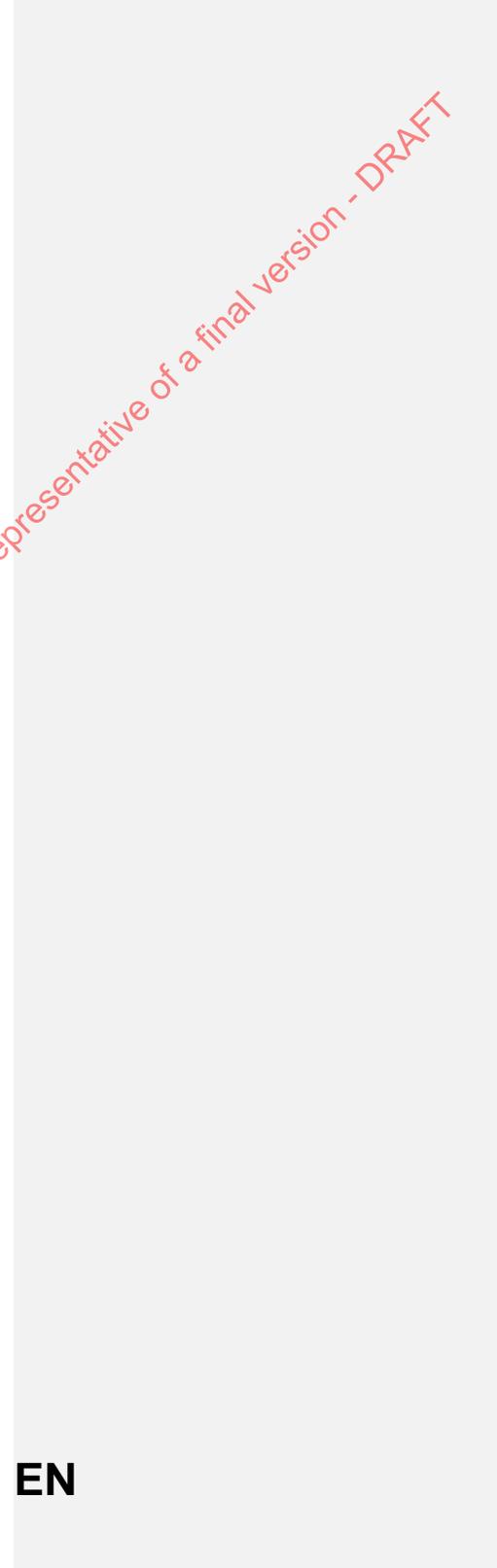
508 1. To verify whether recycled plastics meet Article 3 of Regulation (EC) No 1935/2004
509 in practice, the Commission or Member States may adopt programmes to monitor the
510 level of contaminants both in input materials, and in recycled materials.

511 2. Such a monitoring programme shall clearly describe its objectives, scope, and the
512 period during which it is active.

513 3. It may require recyclers to perform the necessary analytical activities to determine
514 the level of contaminants in the input and output materials that are processed at their
515 facility. It may also require metadata on the plastic that is being analysed, including
516 on the waste stream from which the material is originating.

517 4. The monitoring programme shall be notified by letter to the recyclers to which it
518 applies at least 3 months in advance of its start. The Commission or the Member
519 State organising it shall provide adequate guidance, support, and a system to submit
520 the results in advance of its start.

521 5. Within 6 months following the completion of the programme, the Commission or the
522 Member State organising it shall provide a summary report of the results of the
523 monitoring project containing only aggregated data. The data submitted by individual
524 recyclers shall remain confidential but may be used for statistical purposes.



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526

Article 13
Transitional measures for the authorisation of recycling processes

527 **[Note: the actual text will be an amending text. This text will delete Article 13 and 14**
528 **presently in Regulation (EC) No 282/2008. The transitional provisions below (in green) will**
529 **be set out in the main text of the amending act – the structure of these provisions may**
530 **change somewhat therefore, not the contents or the sequence of events]**

531 After entry into force of this Regulation the Commission shall submit to the Standing
532 Committee on Plants, Animals, Food and Feed for opinion all draft decisions granting or
533 refusing authorisation of the processes concerning the recycling of PET on which the
534 Authority published its opinion before [enter date of publication of this Regulation]. These
535 draft decisions shall be submitted in a single meeting. If the Standing Committee provides a
536 negative opinion on one or more draft decisions, all decisions shall be re-submitted during a
537 next session of the Standing Committee following amendments to take account of the views
538 of the Standing Committee. Once the Standing Committee provides a positive opinion on all
539 draft decisions, the Commission shall consider to adopt these decisions and notify them to the
540 applicants during a period of at most 21 working days.

541 The procedure set out in Article 6 shall apply mutatis mutandis.

542 When all notifications are sent, the Commission shall publish the register required under
543 Article 9 in the Official Journal of the European Union and on its website.

544 Recyclers not subject to authorisation shall send equivalent information in accordance with
545 Article 9(4) within one month after the publication of the register in the Official Journal.

546
547

Article 14
Transitional Measures for the trade in and use of recycled plastic

548 1. Article 3 shall apply 6 months after the publication of the register required under
549 Article 9.

550 2. Notwithstanding Article 3 of this Regulation, processes for which the Authority
551 received a valid application at the latest 6 months after the publication of the Register
552 may continue to be used for the placing on the market of recycled plastic materials and
553 articles produced from PET by mechanical recycling processes also after the six
554 months period allowed by that paragraph, until:

555 a. the adoption of an opinion by the Authority identifying, on the basis of the
556 scientific evidence available, safety concerns to the health of the consumers related
557 to plastic manufactured with the process; or

558 b. the adoption of an opinion by the Authority considering that the scientific evidence
559 available is insufficient to conclude that there is no safety concern the health of the
560 consumers related to plastic manufactured with the process; or

561 c. adoption by the Commission of a decision granting or refusing authorisation of the
562 recycling process; or

563 d. the withdrawal of the application by the applicant.
564 until one of these conditions is true, the Commission shall indicate in the register
565 pursuant to Article 9 that the process is permitted in accordance with this paragraph.

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566 3. In case the Authority considers the application received in accordance with paragraph
567 2 is not valid, the applicant may re-submit an updated application within three months
568 after being notified of its non-validity. Thereafter the procedure set out in paragraph 2
569 shall continue to apply.

570 4. Notwithstanding Article 3 of this Regulation, the placing on the market of recycled
571 plastic materials and articles other than recycled plastic materials and articles
572 produced from PET by mechanical recycling processes shall be allowed to
573 continue subject to Articles 3a, 9, 9a, 11 and 12 of this Regulation, and other
574 applicable legislation, until the Commission establishes rules for the manufacture
575 of such recycled plastics.

576

577 *Article 15*
578 *Amendment to Regulation (EC) No 2023/2006*

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

581 *Article 16*
582 *Entry into force*

583 This Regulation shall enter into force on the 20th day following that of its publication in the
584 *Official Journal of the European Union*.

585 However, Articles 3a, 10 and 12 shall apply from the date of the publication in the Official
586 Journal of the European Union of the Union Register on Authorised substances referenced in
587 Article 9. Until that date, national provisions in force concerning recycled plastic materials
588 and articles and recycled plastic shall continue to apply in the Member States.

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

590 Done at Brussels,

591 *For the Commission*
592

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593

ANNEX I

594

PART A

595

**ADDITIONAL INFORMATION IN THE DECLARATION OF COMPLIANCE
FOR RECYCLED PLASTIC MATERIALS AND ARTICLES**

596

597 The written declaration referred to in Article 12(1) shall contain the following additional
598 information:

599 1. One of the following declarations, as applicable:

600 (a) A declaration that only recycled plastic from an authorised recycling process
601 has been used listing the EC Register number of the authorised recycling
602 process.

603 (b) A declaration that a percentage recycled plastic from an authorised recycling
604 process has been used listing the EC Register number of the authorised
605 recycling process.

606 (c) A declaration that a percentage recycled plastic from a recycling process not
607 subject to authorisation has been used

608 2. Any specifications and conditions of use under which the material or article shall be
609 used to ensure that it meets the requirements of this Regulation and Regulation (EC)
610 No 1935/2004

611

PART B

**ADDITIONAL INFORMATION IN THE DECLARATION OF COMPLIANCE FOR
RECYCLED PLASTIC**

612
613

614 1. The written declaration referred to in Article 12(2) shall contain the following
615 additional information: confirmation that the recycled plastic was manufactured in
616 compliance with Article 3 and 3a of this Regulation, including the EU registry
617 number of the Recycling process.

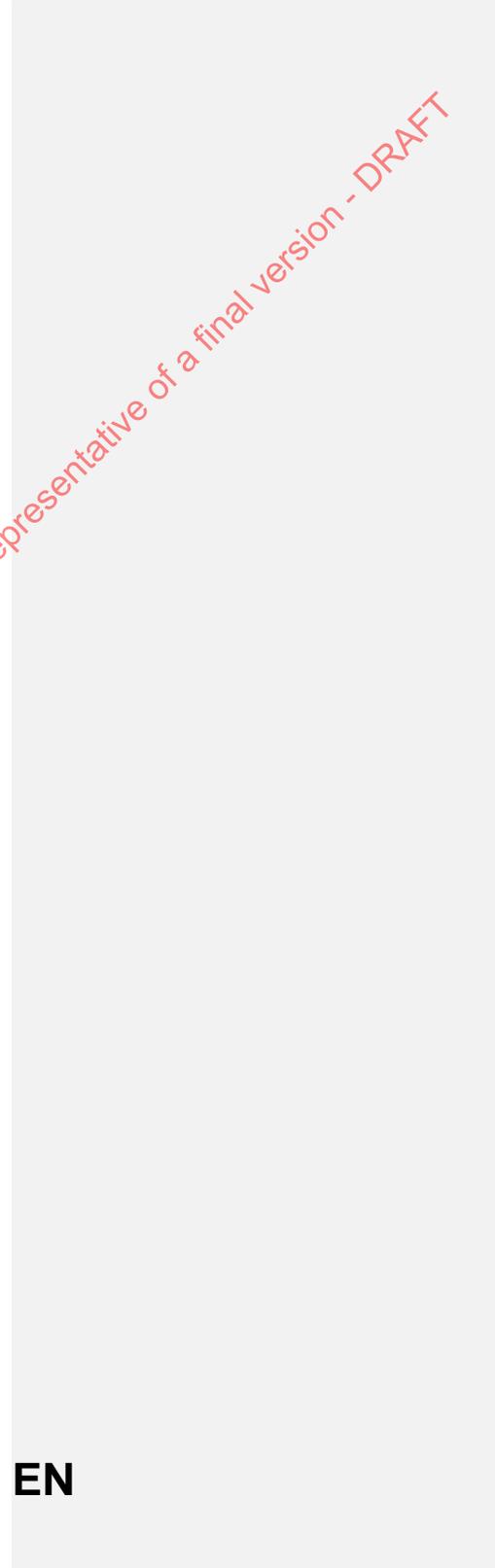
618 2. Any specifications and conditions of use under which the recycled plastic shall be
619 used to ensure that it meets the requirements of this Regulation and Regulation (EC)
620 No 1935/2004.

621 3. Any labelling in compliance with Article 11, or instructions for such labelling
622 directed at the manufacturers of recycled plastic materials and articles.

623 3. The declaration that a quality assurance system according to Section B of Annex to
624 Regulation 2023/2006 is in place.

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ANNEX II

626 The Annex to Regulation (EC) No 2023/2006 is amended as follows:

627 (1) The following section title is inserted after the title:

628

'A. PRINTING INKS'

629 (2) The following section is added:

630

**'B. QUALITY ASSURANCE SYSTEM FOR PLASTIC RECYCLING PROCESSES
COVERED BY REGULATION (EC) NO [.../2008] ON RECYCLED PLASTIC
MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH
FOODS AND AMENDING COMMISSION REGULATION (EC) NO 2023/2006**

631

632

633

634 1. The Quality Assurance System implemented by the recycler must give adequate
635 confidence in the capability of the recycling process to ensure the recycled plastic
636 meets the requirements in the authorisation.

637 2. All the elements, requirements and provisions adopted by the recycler for his quality
638 assurance system must be documented in a systematic and orderly manner in the
639 form of written policy statements and procedures.

640 That quality system documentation must permit uniform interpretation of the quality policy
641 and procedures, such as quality programmes, plans, manuals, records and measures
642 taken to ensure traceability.

643 It must include, in particular:

644 (a) a quality policy manual, containing a clear definition of the recycler's quality
645 objectives, the organisation of the business and in particular the organisational
646 structures, the responsibilities of the managerial staff and their organisational
647 authority where manufacture of the recycled plastic is concerned;

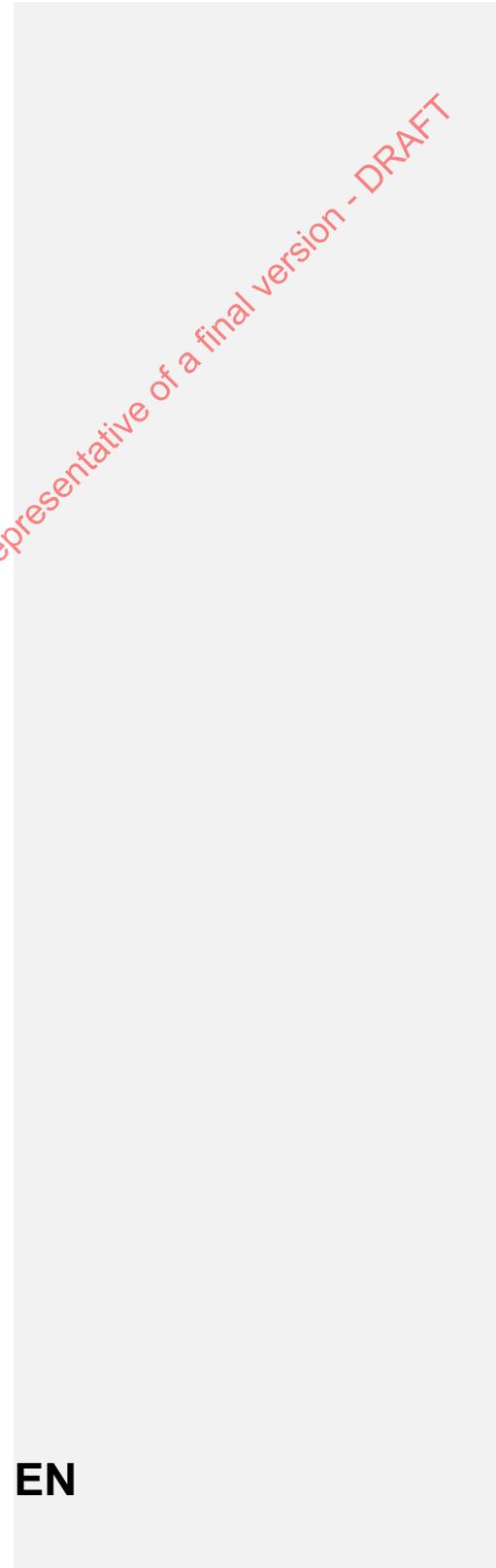
648 (b) the quality control plans, including those for input and recycled plastic
649 characterisation, suppliers' qualification, sorting processes, washing processes, deep
650 cleansing processes, heating processes, or any other part of the process relevant for
651 the quality of the recycled plastic including the choice of points which are critical for
652 the quality control of the recycled plastics;

653 (c) the managing and operative procedures implemented to monitor and control the
654 whole recycling process, including the inspection and quality assurance techniques at
655 all the manufacturing stages, especially the establishment of critical limits at the
656 points which are critical for the quality of the recycled plastics;

657 (d) the methods of monitoring the efficient operation of the quality system and in
658 particular its ability to achieve the desired recycled plastic quality, including control
659 of products which fail to conform;

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- 660 (e) the tests and analytical protocols or any other scientific evidence applied before,
661 during and after recycled plastic production, the frequency with which they will take
662 place, and the test equipment used; it must be adequately possible to trace back the
663 calibration of the test equipment;
- 664 (f) the recording documents adopted.
665

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ANNEX III:

667

Compliance Monitoring Summary Sheet

668 *The parts in yellow will be left empty in the individual Decision. A guidance document will be*
669 *produced to help operators/authorisation holders/competent authorities to fill these parts.*
670 *Parts in magenta are fields which will be pre-filled.*

671 **1. SECTION 1: GENERAL INFORMATION**

672 **1.1. Plant information**

Process name	Name (This name should agree with the name in the register, but should include also the name used by a recycler)
Address	Address

673 **1.2. EFSA Documents**

EFSA Question Number	Number
EFSA Application Date	Application Date
EFSA Publication Number	Publication Number (e.g. ON1234)
EFSA Publication Date	Publication Date

674 **1.3. Commission Documents**

Commission Authorisation Decision Number and Process name	RECYC001, Name
Commission Authorisation Decision Date	dd/mm/yyyy
Name and address of Authorisation Holder	XXXX (same as in body of Decision)

675 **1.4. Internal Documents**

Good Manufacturing Practices	Annex 1 organisation name, reference, dd/mm/yyyy
Standard Operating Procedures	Annex 2 company name, reference, dd/mm/yyyy
Equipment manuals	companynames, machinetype xxxx references, dd/mm/yyyy
Quality assurance system according to Annex II of 282/2008	EN ISO 9001-2008, Last audit dd/mm/yyyy Valid until dd/mm/yyyy
Other relevant documents	

676 **1.5. Responsible person**

Contact details	Name Ms/Mr firstname+ surname
-----------------	-------------------------------

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Position/Role	Director
---------------	----------

677 **2. SECTION 2: PROCESS**

678 **2.1. Written Statements**

679 *2.1.1. Recyclers statement explaining principle to achieve safety for health*

680 Describe in a maximum of 300 words how the process ensures compliance of final
 681 recycled material with the applicable legislation; the description shall be complete
 682 without references to other sources such as publications, the EFSA opinion or the
 683 Commission Decision. This statement shall in particular demonstrate that obligations
 684 under Article 3a(2) are correctly implemented. The authorisation holder shall not
 685 provide this statement. **For example:**

686 “The process ensures that the final recycled material does not contain substances at a
 687 level that could be hazardous to health because it uses only flakes as input from post-
 688 consumer origin with a non-food content of less than 5%, and which have been
 689 caustic washed and flaked. In during preheating (step 1) and crystallisation (step 2)
 690 the possible contaminants are reduced and these steps are thereto operated in a
 691 accordance with the critical parameters. For step 1 this is only temperature, for step 2
 692 this is temperature, inert gas flow, and residence time.

693 The operator in charge controls these parameters in accordance with standard
 694 operating procedures, and documents corrective actions in accordance with GMP.
 695 We only approve batches if all critical parameters were according to specification
 696 during the specified residence time, these batches are labelled ‘for food contact’.
 697 Rejected batches sold for use other than in contact with food, or are re-processed
 698 according to the needs of the business. The output material can be used for all foods
 699 in all conditions.”

700 *2.1.2. Recyclers Statement explaining correspondence to the authorised process*

701 This section is applicable only to authorised processes.

702 Describe in a maximum of 300 words why the process as operated fully corresponds
 703 to the process as evaluated by the European Food Safety Authority in the assessment
 704 on which basis the authorisation has been granted. Explain why the present
 705 equipment can be regarded as equivalent to the equipment used in the challenge test,
 706 the ability to operate in accordance with the critical parameters, and explain why
 707 apparent differences, if any, are not relevant to the authorisation. **For example:**

708 “The equipment in present use operates according to the same principles as the
 709 equipment on which the application was based. The challenge test was performed in
 710 a laboratory, and the conditions in the challenge test are the same as the conditions in
 711 the commercial equipment. Therefore, the process is also operated according to the
 712 same critical parameters. However, the capacity of the main crystalliser has been
 713 increased by 30%. Apart from a change in its length, which was not subject to the
 714 evaluation by the EFSA, no further changes have been made. Due to its lengthening
 715 the minimum residence time required in accordance with the critical parameter table
 716 can be met”

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717 **2.2. Process Schematic**

718 Add a piping and instrumentation diagram shall be included in the CMSS; the
719 following rules shall apply:

720 (d) The drawing and information provided with the drawing shall be in accordance
721 with section 4.4 of ISO 10628-1:2014, where ISO 10628-2 does not provide a
722 suitable symbol for certain specific equipment, an alternative symbol that
723 clearly represents that equipment may be used;

724 steps deemed critical by the EFSA shall be clearly marked, for instance by encircling the
725 equipment that is part of such a step by a line of a different colour;

726 all instrumentation used to control the critical parameters shall be included in the diagram,
727 other instrumentation may be left out if it is clear that that instrumentation is not relevant to
728 the control purposes of this Regulation, and cannot be confused with equipment that is
729 relevant;

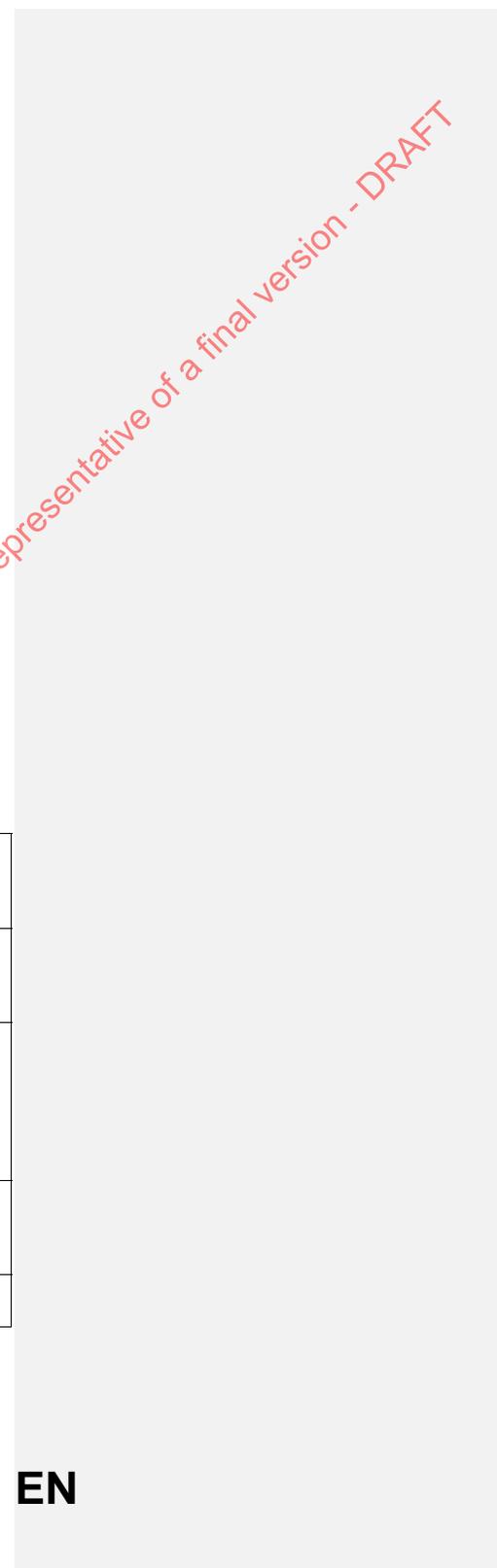
730 the physical numbering in the manufacturing facility, and the indication in the control and/or
731 SCADA⁴ system shall correspond to the numbering in the diagram.

732 On the next page an example is given to explain these rules; this example is purely
733 imaginative and any resemblance to a real process Therefore, is a coincidence. Note
734 that the instrumentation used to control the critical parameters is explicitly marked.
735 Not all information required under section 4.4 of ISO 10628-1:2014 has been
736 included in this example.

737 **2.3. Process Critical steps**

Critical item	Control rule (critical parameters)*	Measuring or Control Device (as in 2.2)	Corrective Action	SOP code
Step 1; pre-heater	T >200°C	I-5	During Normal operation controlled by a PI controller; when 20°C or more below set-point for 5 minutes the batch will be rejected.	SOP-xxxx
Step 2; crystalliser	t residence > 20 min.	I-3; calculated from I-9 and I-8	During Normal operation controlled by a computer controller; when residence time is 18-20 minutes for more than 2 minutes the batch will be rejected, when below 18 minutes for the batch will always be rejected.	SOP-xxxx
	T >220°C	I-4	During Normal operation controlled by a PI controller; when 10°C or more below set-point for 2 minutes the batch will be rejected.	SOP-xxxx
	Inert gas flow > 60 NI/s	I-1		SOP-xxxx

SCADA: Supervisory control and data acquisition system; the computer system that retains all data on the processing of the material.



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738 * In case the rule is evaluated against a non-constant parameter, e.g. a temperature
 739 ramp, screenshots with added control rules shall be given.

740 **2.4. Batch definitions**

741 Definition of input and output batches, and any other intermediate batches if
 742 relevant:

743 Explanation + example: a batch may not have the same meaning throughout the
 744 process. Therefore, it is important to clearly define the different type of batches an
 745 operator may be using – for the sake of this example, the table has been made
 746 complex on purpose:

Batch type	Definition/Description	Typical size range	Traceability rule
Input bottles	Bales of bottles procured on the market as one consignment, subject to the same paperwork;	24-32 bales	DoCs received from suppliers are entered in database and receive batch number
Input flakes	Big-bags with conventionally recycled flakes (i.e. caustic washed, dried and sorted) procured on the market as one consignment, subject to the same paperwork	12-28 big bags	DoCs received from suppliers are entered in database and receive batch number
Intermediate washed and flaked (IWF-batch)	On-site conventionally recycled and sorted material	80 tons (one silo)	Input batch numbers contained in the intermediate batch receive and IWF batch number in database system
Intermediate recycled material (IRM-batch)	The process is continuous. Batches are defined according to run-length in accordance with a given set of parameters, which are kept constant during the run. Once a new run with different parameters has started or the processes did not meet specifications, a new IRM batch is automatically created.	1-100 tons (max one silo)	IWF batch numbers contained in the IRM batch run receive an IRM batch number in database system.
Silo batch	Several IRM batches of the same grade may be contained in the same silo	1-100 tons (max one silo)	IRM batch numbers contained in the silo batch run receive an silo batch number in database system.
Output Batch	Batch of recycled material as placed on the market, with single DoC document	1-100 tons (big bags) 30 tons (bulk)	Single silo batch number

747 **2.5. Process restrictions**

748 *2.5.1. Input to the process*

Allowed collection system	Deposit	Kerbside	Other?	SOP code Short description
Accepted input (yes/no)	Yes/no	Yes/no	Yes/no	
Limitations	<5 % non food post consumer PET applications	<5 % non food post consumer PET applications	<5 % non food post consumer PET	Document Description QA doc xxxx Process description zzzz1

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			applications	Description zzzz1 Formular aaaa1 Description aaaa1
Allowed flake input	EFSA input spec		SOP code Short description	
Flake spec			Checklist xxxx2 Description xxxx2	Formular aaaa2 Description aaa2

749 2.5.2. Output applications

Description according to EFSA	Limitations	Labelling procedure
Food grade bottles* up to 5% alcohol content	x%	Art nr xxx Art nr yy Art nr zz
Food grade bottles above 5% alcohol content	y%	Art nr wz
Food grade bottles* hot fill	W%	Art nr wy
Food grade bottles fatty products	WW%	Art nr wx
Food grade trays all foodstuff except water	z%	Art nr za Art nr az
Food grade trays all foodstuff incl. waters	ZZ%	Art nr rz
All other applications need specif labeling	U%	Art nr tt

750 * contains mineral water, soft drinks, ice teas, fruit syrup, syrup with aromas, fruit
751 juices

752 3. SECTION 3: BATCH VALIDATION

753 3.1. Relevant SOP

754

SOP List of relevant SOP	Applicable Batch types (as listed in section 2.4)	SOP code	Short description
Sampling output		Checklist xxxx1, Checklist xxxx2	Description xxxx1, Description xxxx2
Determination of IV and other technical tests		Checklist xxxa1, Checklist xxxa2	Description xxxa1, Description xxxa2
COA		Checklist xxxb1, Checklist xxxb2	Description xxxb1, Description xxxb2
Labelling		Checklist xxxc1, Checklist xxxc2	Description xxxc1, Description xxxc2
Batch validation		Checklist xxxd1, Checklist xxxd2	Description xxxd1, Description xxxd2

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755 4. SECTION 4: RECORD LIBRARY

Procedure	Documentation
Transport	<p>CoA in computer database</p> <p>packaging list</p> <p>Delivery note</p> <p>Int. Transport papers(CMR etx)</p> <p>Cleaning certificate</p> <p>Transport order</p> <p>Export papers</p> <p>Export invoice</p> <p>Weighing ticket</p> <p>Formular xxxx1 :</p> <p>Loading truck with granulate</p>
Contact person	Frist name, sure name
Position/Role	Internal sales

756

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ANNEX IV:

760

Labelling:

761 Any conditions in the field of application of recycled plastic and other information relevant to
762 converters and/or food business operators through the subsequent supply value chain, and
763 who are using the recycled plastic, shall be clearly and succinctly indicated on each packaging
764 containing recycled materials or articles provided. This information in the label shall be
765 consistent with the information provided in the declaration of compliance. It shall also be
766 provided to end-users if relevant for the storage and preparation of packaged food.

767 The minimum font size of labels shall be 9 points if the labels are applied to articles of which
768 the largest dimension is at or below 30 centimetres. The minimum point size ('ps') for articles
769 of which the largest dimension ('ld') is greater than 30 centimeters shall be determined
770 according to the following formula: $ps = 1.643 * ld$, ps in points, and ld in cm.

771 Any symbols used to the same purpose shall be at least twice the required font size.

772 The labels shall at all times be clearly legible and be located at a visible place on the
773 packaging.