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Draft

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COMMISSION REGULATION

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

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(Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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Having regard to the Treaty establishing the European Union,

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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 in particular Article 5(1) thereof,

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

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Whereas:

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(1) [RECITALS OMITTED]

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[GREEN: sections amended/added to bring all recycled plastics into the scope]

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

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[GRAY: updates to the text for other reasons; mostly outdated references – not consistently
applied in this version!]

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**[NOTE: THE DRAFT AMENDMENTS IN THIS DOCUMENT CANNOT BE APPLIED
AS 'AMENDMENTS' BECAUSE OF CHANGES IN PARTICULAR TO THE SCOPE OF
THE PRESENT REGULATION; A NEW REGULATION – WITH UPDATED ARTICLE
NUMBERING – WOULD NEED TO BE ADOPTED INSTEAD ('RECAST'). THE
PROCEDURE (PRAC) HOWEVER IS THE SAME, THE RESULT WILL JUST BE THAT
REGULATION (EU) No 282/2008 WILL CEASE AND BE REPLACED]**

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26 HAS ADOPTED THIS REGULATION:

27 *Article 1*

28 *Subject matter and Scope*

- 29 1. This Regulation shall apply to the plastic materials and articles and parts thereof
30 intended to come into contact with foodstuffs as referred to in Article 1 of Regulation
31 (EU) No 10/2011 which contain recycled plastic (hereafter "recycled plastic
32 materials and articles").
- 33 2. **To be deleted in its entirety:**
- 34 3. The plastic materials and articles that fall within the scope of this Regulation remain
35 subject to Regulation (EU) No 10/2011.

36 *Article 2*

37 *Definitions*

- 38 1. For the purposes of this Regulation, the definitions laid down in Regulation (EC)
39 No 1935/2004 and Regulation (EU) No 10/2011 shall apply.
- 40 2. The following definitions shall also apply:
- 41 (a) "recycling process" means a process in which plastic waste is recycled
42 pursuant to the definition of recycling in point 7 of Article 3 of Directive
43 94/62/EC on packaging and packaging waste; for the purpose of this
44 Regulation, this term is limited to processes, in which a recycled plastic is
45 produced;
- 46 (b) "plastic input" means collected and sorted post-use plastic materials and
47 articles used as input into a recycling process;
- 48 (c) "product loops which are in a closed and controlled chain" means manufacture
49 and distribution cycles in which products circulate with a controlled reuse and
50 distribution system, and in which the recycled material originates only from
51 these entities in the chain, so that the unintentional introduction of external
52 material is just the minimum technically feasible;
- 53 (d) "challenge test" means a demonstration of the effectiveness of a recycling
54 process to remove chemical contamination from plastic materials or articles;
- 55 (e) "converter" means the natural or legal person responsible for ensuring that the
56 requirements of this Regulation, as regards the recycled plastic materials and
57 articles are met within the business under their control;
- 58 (f) "recycler" means the natural or legal person responsible for ensuring that the
59 requirements of this Regulation, as regards the recycling process are met within
60 the business under their control.
- 61 (a) **"feedstock recycling": means the conversion of waste plastics into a light fuel
62 like mixture (e.g. 'naphtha'), light alkenes, and/or synthesis gas in a thermal
63 cracking process by means of pyrolysis; the substances thus obtained are after
64 further processing used as feedstock for traditional monomer production**

Article 3

Requirements for recycled plastic materials and articles

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained only from a recycling process, authorised in accordance with this Regulation.

However, the following recycled plastic materials and articles may be placed on the market if obtained from a recycling process without authorisation, if recycled subject to the material specific rules in Annex A:

(a) recycled plastic materials and articles made from unused and unprinted production offcuts and/or process scraps from plastic materials;

(b) recycled plastic materials and articles made with plastic input originating from a product loop which is in a closed and controlled chain ensuring that only materials and articles which have been intended for food contact are used and any contamination can be ruled out;

(c) recycled plastic materials and articles in which the recycled plastic is used behind a plastic functional barrier, used in accordance with Article 13 of Regulation (EU) No 10/2011

(d) plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011 using starting substances obtained from feedstock recycling;

(e) recycled plastic materials and articles manufactured with recycling processes for which the Authority recommended no further authorisation is necessary and for which the Commission has included material specific rules in Annex A.

[Article 4 would be deleted in its entirety; point (c) will depend on the specific scientific approach]

Article 4

Conditions for the authorisation of recycling processes

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

(a) the quality of plastic input must be characterised and controlled in accordance with pre-established criteria that ensure compliance of the final recycled plastic material and article with Article 3 of Regulation (EC) No 1935/2004;

(b) the plastic input must originate from plastic materials and articles that have been manufactured in accordance with Union legislation on plastic food contact materials and articles, in particular Council Directive 78/142/EEC¹ of 30 January 1978 on the approximation of laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs and Directive 2002/72/EC;

(c) (i) either the plastic input must originate from a product loop which is in a closed and controlled chain ensuring that only materials and articles which have been intended for food contact are used and any contamination can be ruled out; or

¹ OJ L 44, 15.2.1978, p. 15.

(ii) — it must be demonstrated in a challenge test, or by other appropriate scientific evidence that the process is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health;

(d) — the quality of the recycled plastic must be characterised and controlled in accordance with pre-established criteria that ensure compliance of the final recycled plastic material and article with Article 3 of Regulation (EC) No 1935/2004;

(e) — there must be established conditions of use of the recycled plastic whereby it can be ensured that the recycled plastic materials and articles comply with Article 3 of Regulation (EC) No 1935/2004;

Article 5

Application for authorisation of recycling processes and opinion of the Authority

1. The procedure for authorisation laid down in Articles 9 to 10 of Regulation No (EC) 1935/2004 shall apply mutatis mutandis for the authorisation of recycling processes, subject to the specific provisions laid down in paragraphs 2 to 4 of this Article, and Article 5b.

2. The technical dossier shall contain all necessary information to support the evaluation of the scientific criteria the Authority applies to evaluate the recycling process for the specific recycled plastic material, based on an opinion referenced in Annex D to this Regulation.

In case the Authority did not publish any criteria suitable to evaluate that type of recycling process, these may be established in accordance with the procedure set out in Article 5b prior to the submission of the technical dossier.

The technical dossier and additional administrative information must be submitted in accordance with procedures and requirements the Authority may publish in additional administrative guidance.

3. The Authority shall give an opinion based on the scientific criteria that the applicant indicated based on Annex D as to whether or not recycled plastic produced with the recycling process for which the applicant seeks authorisation meets the requirements of Article 3 of Regulation (EU) No 1935/2004 provided the recycling process is operated in accordance with Article 3a. [See the new Article 'general conditions for the operation of recycling processes' in the other text]

4. In the event of an opinion in favour of authorising the evaluated recycling process, the opinion of the Authority shall include the following:

- (a) a short description of the recycling process;
- (b) where appropriate, any recommendations on conditions or restrictions concerning the plastic input;
- (c) where appropriate, any recommendations on conditions or restrictions concerning the recycling process;
- (d) where appropriate, any criteria to characterise the recycled plastic;
- (e) where appropriate, any recommendations concerning conditions in the field of application of the recycled plastic;
- (f) where appropriate, any recommendations concerning monitoring compliance of the recycling process with the conditions of the authorisation.

Article 5b

Establishment of evaluation criteria for specific recycled plastic materials

1. In case no appropriate criteria to evaluate the recycling of a specific type of plastic material are referenced in Annex D to this Regulation, a stakeholder association or a consortium in which at least three independent business operators participate, may submit an expression of interest for the establishment of such scientific evaluation criteria to the Commission.
2. The expression of interest shall clearly describe why the association or consortium considers the specific recycled plastic material complies with Article 3 of Regulation (EU) no 1935/2004, if manufactured using the specific type of recycling process that it proposes. Hereto it shall include a self-assessment of the safety of the process that includes at least:
 - (a) A characterisation of the input materials and their sources;
 - (b) A conservative estimate of the amount and characterisation of any incidental contamination in the input materials
 - (c) A description of the recycling process and of the conditions under which it is operated, including of the principle by which it removes the unavoidable contamination to a safe level, a description of the resulting contaminated waste stream, including a mass balance;
 - (d) The criteria and approach it used to verify and demonstrate that the process can in practice remove the incidental contamination in the input material to a concentration low enough to comply with Article 3 of Regulation (EU) No 1935/2004, such as a challenge test.
 - (e) The identification and characterisation of any pilot facilities the participating recyclers intend to operate to establish the economic and technical viability the recycling process and the recycled plastic, including an estimate of the amount of recycled plastic material manufactured with these facilities and which will be placed on the market prior to the final authorisation of the process. These facilities shall be operated at a scale no larger than necessary for this purpose. [NOTE: the material will be allowed on the market before authorisation, as otherwise we risk the whole safety assessment is theoretical only, and the development of the process will become impossible]
 - (f) A proposed system by which competent authorities can audit and verify compliance of the process with any foreseen specifications and restrictions following its envisaged authorisation.
3. The Commission shall after consultation with the Member States, competent authorities on whose territory the pilot facilities will be operated, and the Authority decide whether to provide the participating recyclers with a temporary authorisation to place recycled plastic on the market for a non-extensible period of five years.
4. In case of a favourable decision the Commission shall enter the process into the Union register of recycling processes with a temporary status, and provide the authority with a mandate to establish scientific evaluation criteria appropriate for the plastic material that is being recycled on the basis of the information contained in the expression of interest.
5. The temporary authorisation shall contain the information required in accordance with Article 6. It shall authorise the placing on the market of recycled plastic,

recycled with the new type of process at a scale no larger than the scale indicated in point 2(e) of this paragraph, or smaller when this is considered necessary to protect human health.

6. Following the acceptance of the mandate, the Authority shall publish an opinion with evaluation criteria for the type of process without delay and within three years. This time shall include, where necessary, any time required to establish a working group of experts and/or time to obtain any further additional data or information from the association or consortium required to develop the evaluation criteria.

7. The published opinion of the Authority establishing the criteria for evaluating individual recycling processes shall clearly specify what information on such a process would be required in an application under Article 5. The published evaluation criteria shall not be specific or proprietary to the association or consortium or to any other individual private parties.

Where the Authority considers that individual authorisations are not necessary because any process correctly applying the technology would be safe, it may recommend to the Commission that individual authorisations are not necessary, and provide the Commission with all information required in Article 5(4).

In this case the Commission shall enter material specific criteria in Annex A to this Regulation.

When the Authority considers it impossible to determine adequate evaluation criteria, or if it considers that under no circumstances it would be possible to produce a material meeting the requirements of Article 3 of Regulation (EU) No 1935/2004 it shall instead publish an opinion refusing the establishment of evaluation criteria. This shall clearly explain the reasons and the information the applicant would need to provide if it would again apply for the establishment of criteria, if any.

8. Immediately following the publication of a favourable opinion by the Authority any business operator may apply for the authorisation of a plastic recycling process based on the criteria set out in the opinion in accordance with Article 5, unless the opinion would require the establishment of material specific rules.

9. The temporary authorisation granted in point 3 shall expire:

(a) after five years from the date it was notified to the consortium or association, even if criteria and/or final authorisation have not yet been established; or,

(b) from the date of publication of an opinion refusing the establishment of criteria in accordance with point 7, last sub-paragraph; or,

(c) when the Commission decides on other grounds that the process does not produce a material that meets the requirements of Article 3 of Regulation (EU) No 1935/2004 and notifies the association or consortium thereof; that notification shall include the grounds for the revocation of the temporary authorisation; or,

(d) when a recycler placing recycled plastic on the market based on the temporary authorisation, does not apply for a definite authorisation under Article 5 within 6 months after publication of the opinion published in accordance with paragraph 6. In this case the temporary authorisation shall continue to apply for those recyclers that did apply; or,

(e) when the Commission adopts a final decision accepting or refusing authorisation of the process in accordance with Article 6 on the process.

There shall be no transition period during which recycled plastics subject to the expired authorisation may remain on the market. Any cost, lost investments or other burden forthcoming from the end of the temporary authorisation shall be borne by the association, consortium or its participants.

Article 6

Authorisation of recycling processes

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

Article 11(3) of Regulation (EC) No 1935/2004 shall apply.

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

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

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

- (a) the name of the recycling process;
- (b) the name and address of the authorisation holder(s);
- (c) a short description of the recycling process;
- (d) any conditions or restrictions concerning the plastic input;
- (e) any conditions or restrictions concerning the recycling process;
- (f) any characterisation of the recycled plastic;
- (g) any conditions in the field of application of the recycled plastic that has been manufactured by the recycling process;
- (h) any requirements concerning monitoring and/or verification of the compliance of the recycling process with the conditions of the authorisation;
- (i) the date from which the authorisation is effective.

4. The Decision granting or refusing the authorisation shall be published in the *Official Journal of the European Union*.

5. The *authorisation* issued to the authorisation holder shall be valid throughout the Community.

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

Article 7

Obligations arising from the authorisation

After the authorisation of a recycling process in accordance with this Regulation, the authorisation holder or any other business operator using the authorised recycling process under licence shall comply with any conditions or restrictions attached to such authorisation.

Any converter using recycled plastic from the authorised recycling process or any business operator using materials or articles containing recycled plastic from the authorised recycling process shall comply with any condition or restriction attached to such authorisation.

2. The authorisation holder or any other business operator using the authorised recycling process under licence shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the recycling process in relation to human health.

If necessary, the Authority shall then review the assessment.

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

Article 8

Modification, suspension and revocation of authorisation of a recycling process

1. The authorisation holder may, in accordance with the procedure laid down in Article 5(1) apply for a modification of the existing authorisation.
2. The application referred to in paragraph 1 shall be accompanied by the following:
 - (a) a reference to the original application;
 - (b) a technical dossier containing the new information in accordance with the guidelines referred to in Article 5(2);
 - (c) a new complete summary of the technical dossier in a standardised form.
3. On its own initiative or following a request from a Member State or the Commission, the Authority shall evaluate whether the opinion or the authorisation is still in accordance with this Regulation, in accordance with the procedure laid down in Article 5, where applicable.
4. The Commission shall examine the opinion of the Authority without delay and if necessary prepare a draft Decision to be taken.
5. A draft Decision modifying an authorisation shall specify any necessary changes in the conditions of use and, if any, in the restrictions attached to that authorisation.
6. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 6.

Article 9

Community Register

1. The Commission shall establish and maintain a Community Register of authorised recycling processes.
2. The Register shall be made available to the public.
3. Each entry in the Register shall include the information referred to in Article 6 (3).

Article 10

Official Control

1. The official control of a recycling plant and converter shall be performed in accordance with the rules laid down in Regulation (EC) No 882/2004 and shall include in particular audits as control technique as specified in Article 10 of Regulation (EC) No 882/2004.
 2. The official control shall verify that the recycling process corresponds to the authorised process and that an effective quality assurance system in accordance with Regulation (EC) No 2023/2006 is in place.
 3. The authorisation holder shall notify the competent authority in the Member State about the recycling or manufacturing site in which the authorised recycling process is being applied. Member States shall forward that information to the Commission.
 4. Manufacturing or recycling sites in third countries shall be notified to the Commission.
- The Commission shall make available and keep updated a register of recycling sites in the Community and third countries.

Article 11

Labelling of recycled plastic materials and articles

- Voluntary self-declaration of the recycled content in recycled plastic materials and articles shall follow the rules laid down in ISO 14021:1999 or equivalent.

Article 12

Declaration of Compliance and Record Keeping

1. In addition to the requirements of Article 9 of Directive 2002/72/EC, the declaration of compliance of recycled plastic materials and articles shall contain the information laid down in Part A of Annex I to this Regulation.
2. In addition to the requirements of Article 9 of Directive 2002/72/EC, the declaration of compliance of recycled plastic shall contain the information laid down in Part B of Annex I to this Regulation.

Article 13

Transitional measures for the authorisation of recycling processes

1. For the initial authorisation phase of recycling processes, the procedure provided for in Articles 5, 6 and 7 shall apply subject to paragraphs 2 to 6 of this Article.
2. During the 18 months following the publication of the guidelines for the safety assessment of a recycling process of the Authority as provided for in Article 5(2), business operators seeking authorisation shall submit an application in accordance with Article 5.
3. The Commission shall make available to the public a register of recycling processes for which a valid application has been submitted in accordance with paragraph 2.
4. The Authority shall issue an opinion on each recycling process for which a valid application has been submitted during the period referred to in paragraph 2 of this

Article. The deadline of six month for issuing the opinion, as referred to in Article 5(3), shall not apply.

5. Applications for which the Authority could not issue an opinion owing to the applicant's failure to comply with the time limits specified for submission of supplementary information in accordance with Article 10(2) of Regulation (EC) No 1935/2004 shall be excluded from consideration for the initial authorisation.
6. Within six months of receiving all the opinions referred to in paragraph 4, the Commission shall submit for opinion to the Standing Committee on the Food Chain and Animal Health draft Decisions granting or refusing authorisation of the recycling processes referred to in paragraph 1.

Article 14

Transitional Measures for the trade in and use of recycled plastic

1. Trade in and use of recycled plastic from a recycling process already in place on the date of entry into force of this Regulation, for which authorisation is refused or for which no valid application has been submitted in accordance with Article 13 shall be permitted until six months after the date of adoption of the Decisions referred to in Article 13(6).
2. Trade in and use of recycled plastic materials and articles containing recycled plastic from a recycling process already in place on the date of entry into force of this Regulation, for which authorisation is refused or for which no valid application has been submitted in accordance with Article 13 shall be permitted until exhaustion of stocks.

Article 15

Amendment to Regulation (EC) No 2023/2006

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

Article

Amendment of Regulation (EU) No 10/2011

Article 8 of Regulation (EU) No 10/2011 shall be replaced by the following:

"Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request. Substances originating from plastic recycling shall be manufactured in accordance with Regulation (EC) No 282/2008"

Article 16

Entry into force

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

However, Articles 3, 9, 10 and 12 shall apply from the date of the adoption of the Decisions referred to in Article 13(6). Until that date, national provisions in force concerning recycled

397 plastic materials and articles and recycled plastic shall continue to apply in the Member
398 States.

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

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ANNEX A

Material Specific Rules

[THE MATERIAL SPECIFIC RULES IN THIS ANNEX ARE FOR EXAMPLE ONLY – THEY WOULD REQUIRE FURTHER DISCUSSION AND DEVELOPMENT]

A: PRODUCTION SCRAPS AND OFF-CUTS

Plastic production scraps and off-cuts can be recycled within the same manufacturing site or at another operate by the same operator, or may be returned for recycling to the manufacturer of these plastic materials, provided this whole production chain is under control of good manufacturing practices, as laid down in Regulation (EC) No 2023/2006. This control shall be specifically organised to exclude the introduction of any contaminants into or onto the scraps or off-cuts including those originating from food or processing equipment.

B: RECYCLED MATERIAL PRODUCED FROM MATERIAL OBTAINED IN A CLOSED LOOP

Processes which are meant to only recycle products obtained from product loops which are in a closed and controlled chain and which meet the definition given in Article 1(c) can be operated without authorisation in accordance with the following rules:

(1) The closed loop process only applies a plastic that is listed below as suitable for recycling; when the material is not included in this list it can be added on the basis of an opinion of the Authority confirming its suitability for repeat recycling; the Authorisation procedure set out in Article 5 and 6 shall apply mutatis mutandis.

[this is an important provision/condition which will require further drafting – and may affect point 4 as well]

(a) Plastic based mainly on High Density Poly-Ethylene ('HDPE');

(b) Plastic based mainly on PolyPropylene ('PP')

(2) Any article used in a closed loop shall be clearly and indelibly labelled with the symbol preferably by means of embossing or engraving:

[one symbol for all materials used in closed loop processes – all food business operators shall manage containers labelled with this symbol in accordance with a quality management system / HACCP]

(3) Closed loop recycling processes for which an application was received prior to [enter date of application of this amendment], and for which a favourable EFSA opinion was published can operate in accordance with the description in that opinion, or in accordance with the rules below.

(4) General rules under which the recycling of material originating from the closed and controlled product chain is permitted:

(a) The closed and controlled product loop from which the material originates was used only to either transport, process or package food products; and,

(b) all steps in the controlled the closed and controlled product loop were fully controlled in accordance with practices laid down in Regulation (EC) No 2023/2006 and/or Regulation (EC) No 852/2004, as appropriate, including with

a specific control objective to prevent any contamination with substances or materials foreign to the product loop as to prevent incidental contamination with unknown substances or materials; and,

(c) the material originating from the closed and controlled product chain shall be selected for recycling only after all necessary conventional cleaning steps prior to render it suitable for re-use in contact with foods in the controlled product loop; the criteria for selection for recycling shall be damage or age rendering the material or article unsuitable for re-use, but not the presence of contamination or dirt that failed to clean; and,

(d) prior to the recycling step the materials or articles shall be further cleaned if necessary to remove any remaining surface contamination, including contamination caused by labels and their remains applied during the useful life of the material in the controlled chain, including contamination on non-food contact surfaces; and,

(e) the recycling step shall include the heating of the plastic material above its melting temperature and a temperature high enough to ensure any microbiological contamination cannot survive; and,

(f) with the objective to exclude accumulation of potential remaining contaminants, a minimum of 25% of primary (virgin) material, material obtained in a chemical recycling process, or material obtained in an authorised mechanical process shall be added during recycling; and,

(g) the recycled materials shall not be used in contact with other foods than in the closed loop system from which they originated; and,

(h) any material excluded in one of these steps shall be discarded as waste or be recycled with other techniques.

By derogation from rule (c), the materials and articles may leave the controlled chain if containing food sold to consumers and returned by those consumers in a way suitable for their subsequent re-use without recycling and prior to the selection step described in rule (d).

C: RECYCLED MATERIAL USED BEHIND A FUNCTIONAL BARRIER

Recycled materials may be used behind a plastic functional barrier, in accordance with Article 13 of Regulation (EU) No 10/2011, however Article 13(4) of that Regulation shall not apply.

To achieve the same objective as set out in Article 13(4) of Regulation 10/2011, the following rules shall apply to this type of material:

(1) the final material manufactured with this technique shall only be used as food packaging and,

(2) the plastic input shall only originate from food packaging use; and,

(3) a challenge test shall be used to determine the period during which the material can be expected to remain safe according to the following laboratory test:

(a) in the laboratory primary material shall be contaminated with known substances ('surrogate substances') as set out in the EFSA guidelines for mechanical recycling processes;

(b) the concentration of each surrogate substance in the thus contaminated plastic material shall after rinsing and drying not be below 400 mg/kg plastic;

(c) the contaminated plastic material shall be used to manufacture the final material by combining it with a functional barrier to form exactly the same material as will be used in the final application;

(d) this material shall be shaped and formed into a final shape that can contain food representative for a worst case shape used in the final application capable to pack food, where worst case means the highest expected surface to volume ratio, and the thinnest obtained barrier layer, for example in certain corners after thermoforming;

(e) a migration test shall be done in accordance with Article 18 of Regulation (EU) No 10/2011 with food simulants A, B, and D2, at temperature conditions similar to the real temperatures achieved in the intended application of the material, taking account of point 2.1.4 of Annex V to that Regulation in particular;

(f) the period during which the material can be expected to remain safe shall be set at the maximum time during which the migration of all of the surrogate substances remains undetected in all three simulants using a suitable analytical method with a limit of detection of 10 ppb

and,

(4) on the basis of the established period, each batch of the material shall be labelled with an expiry date; and,

(5) food business operators shall only use a batch of this packaging material, whether or not shaped into its final shape or form, if the expiry date of the material does not exceed:

(a) the indicated use-by date of the packaged food, or,

(b) the date obtained by the number of days until the indicated best before date of the packaged food, multiplied by two.

D: MATERIAL MANUFACTURED WITH STARTING SUBSTANCES ORIGINATING FROM FEEDSTOCK RECYCLING

No further material specific rules specified

E: OTHER MATERIAL SPECIFIC RULES FOR PROCESSES FOR WHICH EFSA RECOMMENDED NO INDIVIDUAL AUTHORISATION IS NECESSARY

(No such processes are existing)

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ANNEX D

Published opinions with criteria for the scientific evaluation of plastic materials

Material	Title of opinion	DOI + link	date
Mechanically recycled PET	Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food	10.2903/j.efsa.2011.2184 https://www.efsa.europa.eu/en/efsajournal/pub/2184	6 July 2011

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