



Brussels, **XXX**  
SANTE/10932/2021 CIS  
(POOL/E2/2021/10932/10932-EN  
CIS.docx)  
[...](2021) **XXX** draft

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

**of **XXX****

**on recycled plastic materials and articles intended to come into contact with foods, and  
repealing Regulation (EC) No 282/2008**

(Text with EEA relevance)

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

of **XXX**

## **on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC<sup>1</sup>, and in particular Article 5(1), second subparagraph, points (h), (i), (k) and (n), thereof,

Whereas:

- (1) As part of the 2015 circular economy action plan<sup>2</sup>, the Commission identified the increase in plastic recycling as an essential prerequisite for the transition to a circular economy and committed to address this sector in a targeted way. The Commission therefore adopted in 2018 a European strategy for plastics in a circular economy<sup>3</sup> which presents key commitments for action at Union level in order to curb adverse impacts of plastic pollution. It strives to extend the plastic recycling capacity in the Union, and to increase recycled content in plastic products and packaging. As a large proportion of plastic packaging materials are used as food packaging, the policy can only achieve its objectives if also the recycled plastic content in food packaging increases.
- (2) A pre-requisite to any increase in recycled content in food packaging and other food contact materials remains the need to secure a high level of protection of human health. However, wasted plastic materials and articles originating from food use may contain contaminants incidental to that use, which potentially compromises the safety and quality of recycled plastic food contact materials and articles. While such plastic waste should not be contaminated with a relatively high amount of specific substances known to be hazardous to human health, as could be the case for instance in plastics originating from industrial purposes, the identity and level of incidental contaminants that could be present in collected food packaging is undetermined, random, depend on the source and collection method of the plastic waste, and may vary between collections. Therefore, the plastic should always be decontaminated during its recycling to a level at which it is certain that remaining contaminants cannot endanger human health or affect the food otherwise, if used for the production of recycled plastic food contact materials and articles. To ensure that food consumers and food

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<sup>1</sup> OJ L 338, 13.11.2004, p. 4.

<sup>2</sup> COM/2015/0614 final

<sup>3</sup> COM(2018) 28 final

business operators can trust decontaminated materials, and that there is a uniform interpretation of the extent of decontamination that is regarded as sufficient, the decontamination of recycled plastic materials and articles intended for contact with food should be subject to a uniform set of rules.

- (3) Commission Regulation (EC) No 282/2008<sup>4</sup> already established specific requirements for recycling processes to ensure that recycled plastic materials and articles intended for food contact comply with Article 3 of Regulation (EC) No 1935/2004. Regulation (EC) No 282/2008 did however not apply to all recycling technologies. At the time of its adoption, only a few recycling technologies existed, particularly the mechanical recycling of polyethylene terephthalate ('PET') and chemical depolymerisation applied by feedstock recycling, as well as plastic materials originating from product loops which are in a closed and controlled chain. Also scraps and off-cuts were being recycled, and functional barriers were used to contain contaminated recycled plastic. While Regulation (EC) No 282/2008 set out rules for plastic recycled with certain of these recycling technologies, the use of other materials was subject to Commission Regulation (EU) No 10/2011<sup>5</sup>. That Regulation however does not define rules for partially depolymerised substances or oligomers, does not allow the presence of contaminants classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' when used behind a functional barrier, and requires that impurities are identified and subject to risk assessment in all cases. In addition, innovative novel technologies are constantly being developed. It is, therefore, appropriate to replace Regulation (EC) No 282/2008 with new rules covering all those existing recycling technologies which cannot adequately be regulated by Regulation (EU) No 10/2011 as well as capable of covering future recycling technologies.
- (4) In natural language widely and loosely used terminology, such as 'technology', 'process', 'equipment' and 'installation', may depending on context and user refer to the same or to similar concepts and the meaning may overlap. In order to make clear the scope and subject of the obligations laid down under this Regulation, it is appropriate to clearly define these concepts for the purpose of this Regulation. In particular, it is necessary to distinguish 'recycling technology', which covers the general concepts and principles by which contaminants are removed from waste plastic, from the 'recycling process', which refers to the description of a specific sequence of operations and equipment designed using a specific recycling technology, and from the 'recycling installation', which should refer to the actual physical equipment used to operate the recycling process to manufacture recycled plastic materials and articles.
- (5) Recycling processes may consist of many sequential basic operations applying a single transformation ('unit operations'), but only some of these operations achieve decontamination. As plastic waste should always be decontaminated, and there should be clear rules applicable to decontamination, recycling operations that together ensure decontamination should be referred to as the decontamination process and should be distinguished from operations carried out before and after decontamination.

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<sup>4</sup> Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006 (OJ L 86, 28.3.2008, p. 9).

<sup>5</sup> Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

- (6) Given the relevance of quality control of the material that is being recycled to the eventual quality and safety of recycled plastic materials and articles, and to traceability, it is appropriate to define precisely the notion of ‘batches’ to which quality control rules apply.
- (7) Experience with the evaluation of processes under Regulation (EU) No 282/2008 shows that scientific criteria and understanding specific to a certain recycling technology should be established prior to the evaluation of individual recycling processes using that technology, as insufficient scientific understanding of contaminant levels in the input as well as on of the functioning of the technology may otherwise leave too many uncertainties to allow the European Food Safety Authority (‘the Authority’) to conclude on the safety of those individual recycling processes. Experience has also shown that other recycling technologies can ensure with certainty that any recycling process applying them results in safe recycled plastic, and that, therefore, the evaluation of each recycling process using these technologies brings little benefit in comparison with the burden it represents for both business operators and the Authority. Therefore, it is appropriate to provide that recycled plastic materials and articles may, in principle, only be placed on the market where they have been produced using a technology which is sufficiently well understood as to allow the Commission to decide on whether it allows in principle to recycle waste plastic into plastic meeting the requirements of Article 3 of Regulation (EC) No 1935/2004, and on whether its use should be subject to specific requirements, including whether recycling processes applying that technology sufficiently differ among them regarding the parameters of the decontamination treatment or the configuration of the process, as to require an individual authorisation of each of them in order to ensure the safety and quality of the recycled plastic manufactured with them.
- (8) On the basis of the evaluations done by the Authority of the applications for authorisation submitted in accordance with Regulation (EC) No 282/2008, for mechanical PET recycling and product loops in a closed and controlled chain (‘closed-loop recycling’) may be considered as suitable technologies to recycle waste plastic into plastic meeting the requirements of Article 3 of Regulation (EC) No 1935/2004 and the specific conditions concerning their use should be laid down. In particular, mechanical PET recycling processes should be subject to individual authorisation as the severity and duration of the treatment of the plastic input applied in the decontamination operations, and thus their capacity to decontaminate, depend on the specific configuration of those processes, and, therefore, requires a case-by-case evaluation on based on established criteria. Conversely, it is not necessary to require the authorisation of individual recycling processes applying the closed-loop recycling technology as for all those processes the introduction of contaminants in the chain is sufficiently controlled to ensure that the only contamination of the plastic input can be removed with the simple washing and heating processes needed in any case for the remoulding of the materials.
- (9) In order to ensure the safety and quality of recycled plastic materials and articles, rules on the placing on the market of those products should be laid down.
- (10) Regulation (EU) No 10/2011 sets out compositional requirements that ensure the safe use of plastic food contact materials, including which substances are authorised for the manufacture and migration limits. To ensure the same level of safety of recycled plastic materials and articles, they should be of the same composition as plastics manufactured in accordance with Regulation (EU) No 10/2011, and comply with the restrictions and specifications, such as migration limits, laid down that Regulation.

However, as residual incidental contamination in plastic input is to be removed to a safe level in accordance with this Regulation, the rules on compliance set out in Regulation (EU) No 10/2011 should not apply to residual incidental contamination.

- (11) To ensure transparency and to facilitate quality control and traceability, a public register should be established that holds information on recyclers, recycling installations and recycling processes and registration in that register should be a requirement to place recycled plastic materials and articles on the market.
- (12) While Regulation (EC) No 1935/2004 lays down specific rules for the labelling of materials and articles to inform users on their appropriate use, such rules do not exist regarding the post-processing of decontaminated plastic. However, based on the extent of the decontamination certain instructions may apply to the further processing and use of recycled plastic, such as mixing requirements to achieve a maximum recycled content, or limitations on their use. While such instructions should be transferred via documentation, plastic materials may not be easily recognisable as requiring a special treatment. To prevent mistakes and to facilitate controls, recycled plastic should therefore be labelled in a clearly legible way to ensure it is correctly used during post-processing in accordance with the instructions from the recycler.
- (13) To ensure that plastic materials and articles are subject to conditions throughout the recycling process that ensure their safety and quality, and to facilitate enforcement and the functioning of the supply chain, rules should be established on the operation of all recycling stages, from pre-processing to decontamination and to post processing. In particular, as the plastic input to the decontamination process should be of a reliable quality to allow for sufficient decontamination, it is appropriate to provide that the rules laid down in Commission Regulation (EC) No 2023/2006<sup>6</sup> on good manufacturing practices apply, as appropriate, also to waste management operations taking place before the decontamination process and that a quality assurance system is applied.
- (14) However, given the diversity of recycling technologies and of recycling processes there should be a possibility for adopting specific rules complementing or derogating from some of those general rules to take into account of the specific capabilities of a recycling technology or process. Furthermore, those general rules should not apply in relation to those recycling technologies that rely on the establishment of a special scheme for using and collecting plastic materials and articles in which recyclers, food business operators and other business operators participate and which aims at keeping the contamination of the collected plastic waste to a minimum and, therefore, at reducing the requirements for decontamination. However, in order to ensure that decontamination is always sufficient, it is appropriate that this Regulation sets out rules on the functioning such schemes. In particular, to ensure clarity and uniform application of a recycling scheme, only one entity should be responsible for managing its overall functioning and it should be responsible to provide all participating operators with binding directions. It should also be ensured that participants, third parties and control authorities can easily recognise the plastic materials and articles which must be used according to a specific recycling scheme.
- (15) Even if the rule should be that only recycled plastic materials and articles produced using technologies that have been demonstrated to be suitable may be placed on the

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<sup>6</sup> Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, p. 75).

market, it is appropriate, in order to allow for, and encourage, the development of such technologies, to authorise, under strict conditions and for a limited time, the placing on the market of recycled plastic materials and articles produced using new technologies. This should allow developers to gather the data on a large and representative number of samples which is necessary to minimise the uncertainty as to the characterisation of the plastic input and of recycled plastic materials and articles and which is, therefore, necessary to assess the suitability of a novel technology and to lay down the specific requirements, where appropriate.

- (16) However, rules should be laid down to ensure that recycled plastic materials and articles produced with new technologies are of minimal risk and that the possibility to place such materials and articles on the market is effectively used to collect the information and experience allowing for the evaluation of the technology. In particular, given the importance for the safety of recycled plastic materials and articles and for the understanding of a technology of the level of contamination in the input materials, as well as of the contaminant levels in the final materials and articles and the potential of their transfer to food, rules should be laid down concerning, in particular, the analytical monitoring of recycled plastic materials and articles produced with recycling technologies under development and the potential presence of hazardous substances. Moreover, to ensure trust, public knowledge and scrutiny on technologies that are being developed, it is important that the reports of such monitoring are made public regularly.
- (17) In order to ensure that the possibility to place on the market recycled plastic materials and articles produced with new technologies remains limited to the time necessary to collect the information and experience necessary for the assessment of the technology, rules should be laid down regarding the initiation of that assessment. However, since it is not unlikely that several developers may simultaneously and independently be using similar installations based, in substance, on the same technology, a level of flexibility should exist regarding the start and the scope of the assessment of a novel technology so that that assessment may be informed with information originating from all concerned technology developers,.
- (18) In case there is evidence or indications showing that recycled plastic materials and articles recycled with a suitable recycling technology or with a novel technology may endanger the health of consumers, it should be possible for the Commission to analyse the technology and the safety of the recycled plastic materials and articles it produces, and to take appropriate and immediate action on it.
- (19) Since this Regulation requires the individual authorisation of recycling processes in certain cases, a procedure should be laid down to this end. This procedure should be similar to the procedure for authorisation of a new substance laid down in Regulation (EC) No 1935/2004, adapted as necessary for the individual authorisation of recycling processes. In particular, since preparing an application for authorisation requires of the applicant an intricate knowledge of the recycling process concerned, and in order to avoid that several applications for the same recycling process are submitted, it is appropriate to lay down that only the business operator who developed the recycling process, and not any recycler using it, may apply for authorisation. Furthermore, as authorised recycling processes may be subject to minor and major technical and administrative changes over their life-cycle, this Regulation should ensure clarity over the procedures applicable to changes to authorised recycling processes.

- (20) Since recycling installations are complex and their configuration and operation may be subject to many parameters and procedures, it is appropriate, in order to facilitate compliance monitoring by the recyclers themselves and efficient audits as part of official controls, to require that recyclers operating a decontamination installation keep available a document summarising in a standardised way the operation, control and monitoring of that installation as well as of the recycling installation of which it is part in a way that shows compliance with this Regulation,.
- (21) The decontamination of recycled plastic should be subject to inspection and control by competent authorities. Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law also covers official control on food contact materials and, therefore, includes decontamination installations. However, while that Regulation provides for general rules for official controls, it does not set out any specific procedures to control decontamination installations. To ensure uniform application of official controls of decontamination installations independent of where they are located, it is therefore appropriate to define appropriate control techniques, as well as rules that define when recycled plastic should be considered to be not in compliance with this Regulation.
- (22) To ensure that recycled plastic and recycled plastic materials and articles are used appropriately and in a traceable manner by converters and food business operators, a declaration of compliance should be provided to accompany batches of recycled plastic, in order to establish the identity of the recycler, the recycled origin of the plastic, and to provide instructions to the converters and final users regarding its use. To ensure that that document can be understood in a uniform manner by anyone who receives it, operators should be required to use a pre-defined template
- (23) Recycled materials and articles are presently placed on the market subject to national rules. Therefore, provisions should be laid down to ensure that the transition to this Regulation is smooth and does not disturb the existing recycled plastic materials and articles market. In particular, it should be possible for a limited time to apply for authorisation of existing recycling processes subject to individual authorisation in accordance with this Regulation, and to continue placing on the market recycled plastic, and recycled plastic materials and articles, produced through those recycling processes until the authorisation procedure is finalised. Applications submitted in accordance with Regulation (EC) No 282/2008 concerning such recycling processes should be considered as applications submitted under this Regulation. Applications submitted in accordance with Regulation (EC) No 282/2008 concerning recycling processes not subject to individual authorisation in accordance with this Regulation should be terminated as there is no basis for authorisation of the concerned processes under this Regulation.
- (24) Recyclers operating recycling processes based on technologies that are not listed as suitable technologies should be allowed sufficient time to consider whether they want to develop that technology further in order to allow the listing of the technology as suitable or otherwise to terminate the concerned recycling operations. Therefore, the placing on the market of recycled plastic, and recycled plastic materials and articles, produced through recycling processes based on those technologies and in accordance with current existing national rules should be allowed for a limited time
- (25) This Regulation requires that certain waste management operators involved in the collection of plastic, as well as those involved in further operations as part of pre-processing, set up a certified quality assurance system to ensure the quality and

traceability of the plastic input. As those operators need time to fully prepare for such certification, sufficient time should be granted for those operators to adapt to that requirement.

- (26) Regulation (EC) No 282/2008 should be repealed.
- (27) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

## **Chapter I – Subject matter, scope and definitions**

### *Article 1*

#### *Subject matter and scope*

1. This Regulation lays down rules for:
  - (a) the placing on the market of plastic food contact materials and articles, containing plastic originating from plastic waste;
  - (b) the development and operation of recycling processes to produce recycled plastic for use in those plastic materials and articles;
  - (c) the use in contact with food of recycled plastic materials and articles and of plastic materials and articles which are intended to be recycled.
2. This Regulation shall not apply to the use of plastic waste to manufacture substances included in the Union list of authorised substances in accordance with Article 5 of Regulation (EU) No 10/2011 when intended for subsequent use in accordance with that Regulation.

### *Article 2*

#### *Definitions*

1. For the purposes of this Regulation, the definitions in Article 3 of Regulation (EU) No 10/2011 and the definitions in Article 3 of Regulation (EC) No 2023/2006, shall apply.
2. For the purposes of this Regulation, the following definitions also apply:
  - (1) ‘waste’, ‘municipal waste’, ‘waste management’, ‘collection’, ‘re-use’, and ‘recycling’, as laid down in Article 3 of Directive 2008/98/EC of the European Parliament and of the Council<sup>7</sup>;
  - (2) ‘food business’ and ‘food business operator’, as laid down in Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>8</sup>;
  - (3) ‘competent authorities’, and ‘audit’, as laid down in Article 3 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

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<sup>7</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

<sup>8</sup> 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).



3. The following definitions also apply:

- (1) 'recycling technology' means a specific combination of physical and chemical concepts, principles, and practices to recycle a waste stream of a certain type and collected in a certain way into recycled plastic materials and articles of a specific type and with a specific intended use, and includes a decontamination technology;
- (2) 'decontamination technology' means a specific combination of physical and chemical concepts, principles, and practices part of a recycling technology which have as primary purpose to remove contamination;
- (3) 'recycling process' means a sequence of unit operations that is intended to manufacture recycled plastic materials and articles through pre-processing, a decontamination process, and post-processing, and which is based on a specific recycling technology;
- (4) 'recycled plastic' means plastic resulting from the decontamination process of a recycling process and plastic resulting from subsequent post-processing operations and that is not yet transformed into recycled plastic materials and articles;
- (5) 'recycled plastic materials and articles' means food contact materials and articles in their finished state that contain recycled plastic;
- (6) 'pre-processing' means all waste management operations carried out to sort, shred, wash, mix or otherwise treat plastic waste in order to make it suitable for the decontamination process;
- (7) 'plastic input' means the plastic materials resulting from pre-processing which are entered into a decontamination process;
- (8) 'decontamination process' means a specific sequence of unit operations which together have as primary purpose to remove contamination from plastic input in order to make it suitable for contact with food, using a specific decontamination technology;
- (9) 'incidental contamination' means contamination present in plastic input originating from food, from plastic materials and articles intended and used for contact with food, from their use or misuse for non-food purposes, and from the unintentional presence of other substances, materials and articles due to waste management;
- (10) 'post-processing' means all unit operations by which recycled plastic is converted into recycled plastic materials and articles in their finished state;
- (11) 'recycling installation' means the equipment operating at least a part of a recycling process;
- (12) 'decontamination installation' means specific equipment operating a decontamination process;
- (13) 'recycling facility' means a location where waste management operations take place and where at least one decontamination installation is located;
- (14) 'recycling scheme' means a single system that manages the use and separate collection of plastic materials and articles with the objective to limit or prevent

their contamination in order to reduce decontamination requirements during their recycling;

- (15) ‘recycler’ means any natural or legal person who applies a decontamination process;
- (16) ‘converter’ means any natural or legal person that carries out one or more post-processing unit operations;
- (17) ‘unit operation’ means a basic operation that is part of a process, and applies a single transformation to its input, or more transformations if they occur in conjunction;
- (18) ‘manufacturing stage’ means one or more sequential unit operations and which are followed by a quality assessment of the material resulting from that stage;
- (19) ‘batch’ means a quantity of plastic of the same quality, and produced using uniform production parameters at a certain manufacturing stage, stored and contained to exclude mixing with other materials or contamination, and designated as such by a single production number.

### *Article 3*

#### *Suitable recycling technologies*

1. A recycling technology shall be considered suitable if it is shown to be capable of recycling waste into recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004.
2. A suitable recycling technology shall be distinguished from other recycling technologies based on the following properties:
  - (a) the type, mode of collection and origin of the input material;
  - (b) the specific combination of physical and chemical concepts, principles and practices used to decontaminate that input material;
  - (c) the type and the intended use of the recycled plastic materials and articles;
  - (d) the need or absence thereof for the evaluation and authorisation of recycling processes applying that technology, and the criteria therefore.
3. Where a suitable recycling technology may be implemented through different recycling processes and that the capacity of each of those processes to recycle waste into recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 may vary, each recycling process shall be individually authorised by the Commission in accordance with Article 19(1) (‘the authorisation’).
4. Suitable recycling technologies are listed in Annex I. Annex I may be amended in accordance with Articles 15 and 16.

## **Chapter II – Placing on the market of recycled plastic and recycled plastic materials and articles**

### *Article 4*

#### *Requirements for recycled plastic materials and articles*

1. Recycled plastic materials and articles shall only be placed on the market where the requirements set out in paragraphs 2 to 7 are met during their manufacture.
2. The compositional requirements and requirements on compliance set out in Chapter II and Chapter V of Regulation (EU) No 10/2011 shall apply to recycled plastic materials and articles. Those rules shall not apply to potential residual incidental contamination present in recycled plastic materials and articles.
3. The recycled materials and articles are manufactured using one of the following:
  - (a) a suitable recycling technology; or,
  - (b) a novel technology as referred to in Chapter IV.
4. Where the recycled plastic materials and articles are manufactured using a suitable recycling technology, the following requirements are met:
  - (a) where relevant, the recycling process used to manufacture the recycled plastic materials and articles has been granted an authorisation.
  - (b) the recycling and use of the recycled plastic materials and articles comply with the general requirements laid down in Articles 6, 7 and 8, and, where relevant, with the specific rules for the technology set out in Annex I and with the specific rules for the recycling process set out in the authorisation.
  - (c) by derogation to point (b), where the suitable technology is to be implemented through a recycling scheme, the recycling and use of the recycled plastic materials and articles comply with the general requirements laid down in Article 9, and, where relevant, with the specific rules for the technology set out in Annex I.
5. Where the recycled plastic materials and articles are manufactured using a novel technology, the requirements laid down in Articles 10 to 13 are met.
6. The Union register established in Article 24 includes the following information regarding the manufacture of recycled plastic:
  - (a) on the basis of a notification in accordance with Article 25, the used decontamination installation, the recycling facility where that is located, and the identity of the recycler operating it;
  - (b) the applied recycling process, if the applied suitable recycling technology requires the authorisation of recycling processes;
  - (c) the used recycling scheme, if the applied recycling technology requires the use of a recycling scheme;
  - (d) and/or the novel technology, if the manufacture of the recycled plastic uses a novel recycling technology.
7. Where relevant, the status in the Register established in Article 24 of the authorised recycling process used for the manufacturing is not ‘suspended’ or ‘revoked’.
8. The status in the Register established in Article 24 of the decontamination installation used for the manufacturing is not ‘suspended’.

#### *Article 5*

#### *Requirements for documentation, instructions and labelling*

1. Individual batches of recycled plastic or recycled materials and articles shall be subject to a single document or record regarding their quality, and shall be identified by a unique number and the name of the manufacturing stage from which they originate.
2. Recycled plastic placed on the market shall be accompanied by compliance documentation in accordance with Article 29.
3. Containers with recycled plastic delivered to converters shall be labelled. The label shall indicate:
  - (a) the registry number of the recycling installation where the recycled plastic was manufactured, and the batch number;
  - (b) the percentage by weight of the plastic content that originates from recycling; and,
  - (c) the maximum percentage by weight of the recycled plastic that final recycled plastic materials and articles containing the recycled plastic may contain, if this is less than 100%; and,
  - (d) a brief summary of any other instructions provided in the documentation in accordance with paragraph 2.
4. The labels referred to in paragraph 3 shall be at all times clearly legible and be located at a visible place on the packaging.

The minimum font size on the labels shall be 17 points (6 mm) for containers of which the largest dimension is 75 centimetres or smaller. The minimum point size ('ps') for containers of which the largest dimension ('ld') is larger than 75 centimetres shall be determined according to the following formula:  $ps = 2 \cdot \sqrt{ld}$ , ps in points, and ld in cm.
5. Restrictions and specifications laid down in Annex I concerning the use of recycled material or articles manufactured with a suitable technology, and, where relevant, restrictions and specifications laid down in the authorisation concerning the use of recycled material or articles manufactured with a recycling process shall be included in the labelling required by Article 15 of Regulation (EC) No 1935/2004 of recycled material or articles provided to food business operators or to final consumers.

### **Chapter III – General requirements for plastic recycling and the use of recycled plastic**

#### *Article 6*

##### *Requirements for collection and pre-processing*

1. Waste management operators that participate in the supply chain of plastic input shall ensure that the collected plastic waste meets the following requirements:
  - (a) the plastic waste originates only from municipal waste, or from food retail or other food businesses if it was only intended and used for contact with food;
  - (b) the plastic waste originates only from plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011 or recycled plastic materials and articles manufactured in accordance with this Regulation;
  - (c) the plastic waste is subject to separate collection;

- (d) the presence of plastic materials and articles that are different from the plastic for which the decontamination process is intended, including caps, labels and adhesives, other materials and substances, and remaining food is reduced to a level specified in the requirements for the plastic input provided by the recycler and which shall not compromise the achieved level of decontamination.
2. For the purposes of paragraph 1, point (c), the plastic waste shall be considered as collected separately when one of the following conditions is fulfilled:
    - (a) it consists only of plastic materials and articles meeting the requirements of paragraph 1, points (a) and (b), and which have been collected separately for recycling from any other waste;
    - (b) it is collected together with other waste packaging fractions of municipal waste or with other non-packaging plastic, metal, paper or glass fractions of municipal waste collected separately for recycling and the following requirements are met:
      - (i) the collection system does not collect waste likely to contain hazardous substances;
      - (ii) the collection of waste and the subsequent sorting are designed and carried out to minimise contamination of collected plastic waste from any plastic waste not meeting the requirements of paragraph 1, points (a) and (b), or other waste;
      - (iii) quality assurance systems are set up by the waste management operators in order to verify that the conditions set out in points (i) and (ii) are fulfilled.
  3. The plastic waste shall be controlled throughout collection and pre-processing by means of quality assurance systems. The quality assurance systems shall:
    - (a) ensure traceability of each batch up to the point of the first sorting of collected plastic waste; and,
    - (b) be certified by an independent third party.

Articles 4, 5, 6 and 7 of Commission Regulation (EC) No 2023/2006 as well as point B of the Annex to that Regulation shall apply *mutatis mutandis* as regards good manufacturing practice, quality control and assurance systems and the relevant documentation.

#### *Article 7*

##### *Requirements for decontamination*

1. The plastic input and output of the applied decontamination process shall meet the specifications set out in column 3, 5, and 6 of table 1 of Annex I for the relevant recycling technology and, as applicable, the specific criteria set out in the authorisation.
2. Decontamination shall be carried out in accordance with good manufacturing practices. Recyclers shall ensure compliance with Regulation (EC) No 2023/2006.
3. The decontamination installation shall meet the following requirements:

- (a) it is located at a single recycling facility, which is organised so as to ensure that no new contamination of recycled plastic or recycled plastic materials and articles can occur;
  - (b) its configuration and operation corresponds to that of the recycling process it applies;
  - (c) it is operated as described in the compliance monitoring summary sheet established in accordance with Article 26.
4. A repository of records used to record information on the quality of individual batches as defined in section 4.1 of the compliance monitoring summary sheet referred to in paragraph 3(c) shall be maintained. Records stored in that repository shall be retained for a period of at least three years.

#### *Article 8*

##### *Post-processing and use of recycled plastic materials and articles*

1. Converters shall comply with the following requirements:
  - (a) post-process recycled plastic in accordance with the instructions provided by the recycler or other converter in accordance with Article 5(3);
  - (b) where relevant, provide to subsequent converters instructions in accordance with Article 5, paragraphs (3), (4) and (5), and
  - (c) where relevant, provide instructions to the users of the recycled plastic materials and articles in accordance with Article 5(5).
2. Food business operators shall use recycled plastic materials and articles in accordance with the instructions received in accordance with Article 5(5).

They shall communicate relevant instructions to consumers of food packed in such materials and articles, and/or to other food business operators, where relevant.
3. Retailers of recycled plastic materials and articles not yet in contact with food shall communicate relevant instructions to the users of such materials and articles, where relevant.

#### *Article 9*

##### *Requirements for the operation of recycling schemes*

1. A single legal entity shall act as the manager of a recycling scheme, and shall be responsible for the overall functioning of the recycling scheme.

At least 15 working days prior to the start of the operation of a recycling scheme the manager of the recycling scheme shall inform the competent authority in the territory where it is located and the Commission for the purpose of its registration in the Union register established in accordance with Article 24.

The manager shall provide its name, address, contact persons, the name of the scheme, a summary of the scheme not exceeding 300 words, the marking referred to in paragraph 5, a list of Member States where business operators participating in the scheme are located, and references to any recycling installations used by the scheme. Thereafter, the manager shall ensure this information is kept up to date.

2. By derogation to the registration procedure referred to in Article 4(6)(a), Article 25(1)(c), and Article 26 shall not apply when recyclers notify the production of recycled plastic as part of a recycling scheme, unless in case of the used technology column 8 of table 1 to Annex I or table 4 thereof specifies this derogation shall not apply, or sets out alternative requirements. When this derogation applies, the registration status in accordance with paragraph 2, point (g) of Article 24, as referred to in Article 25(2), shall be ‘active’.
3. The manager of the recycling scheme shall provide a single document to all participating business operators and other participating organisations. This document shall set out the objectives of the scheme, explain how it functions, provide instructions, and set out the detailed obligations it places on the participants. The explanation shall include a description of the recycling operations.
4. Recycling schemes shall be set up in accordance with the specific requirements applicable to the applied suitable recycling technology as laid down in table 1 in Annex I and, where applicable, with the authorisation of the applied recycling process.

A waste collection system shall be part of a recycling scheme and shall be dedicated to the scheme so as to ensure that only materials and articles that were used subject to the scheme are collected.

5. All materials and articles used subject to a recycling scheme shall bear a marking registered in the Union register established in Article 24. That marking shall be clearly visible, indelible and unique to the recycling scheme.
6. Any food business operator using materials and articles bearing a marking provided for in paragraph 5 shall ensure that those materials and articles meet the following requirements:
  - (a) they are labelled, used and cleaned in accordance with instructions obtained from the manager of the recycling scheme;
  - (b) they are used only for the purpose of distribution, storage, display and sale of the foods which they are intended for;
  - (c) they are not contaminated with materials or substances other than those permitted by the recycling scheme.

Where any of the requirements set out in the first subparagraph is not fulfilled, the materials or articles shall be excluded from the recycling scheme and be discarded.

7. Where a scheme permits collection from consumers, collection shall take place separately from other waste at designated collection points suitable for ensuring that the collection of waste is compliant with the scheme.
8. Recycled plastic materials and articles produced in accordance with the scheme may not be placed on the market for use outside of the scheme.
9. Business operators and other organisations that participate in a recycling scheme shall:
  - (a) operate a quality assurance system in accordance with Regulation (EU) No 2023/2006, designed to ensure compliance with the requirements of the scheme; or,

- (b) alternatively, small food business operators, may implement the requirements of the scheme as part of their permanent procedures based on the ‘hazard analysis and critical control points’ (HACCP) principles, as referred to in Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council<sup>9</sup>.

## Chapter IV – Development and listing of novel technologies

### Article 10

#### *Requirements for the development of a novel technology*

1. Several developers may independently develop novel technologies at the same time, even if these technologies may be regarded as similar or the same.

Where business operators or other organisations collaborate on the development of a novel technology, a single legal entity shall represent these operators or organisations, and act as the developer of the novel technology.

2. At least four months prior to the start of the operation of the first decontamination installation operated on the basis of Article 4(2)(b), the developer shall notify the competent authority in the territory where the developer is located and the Commission of the novel technology.

For the purpose of the registration of the novel technology in the Union register established in Article 24, the developer shall include in this notification its name, address, contact persons, the name of the novel technology, a summary of the novel technology not exceeding 300 words, an Uniform Resource Locator (‘URL’) locating the reports to be published in accordance with Article 13(3), and the names and addresses or numbers of any recycling facilities at which the development of the technology is foreseen to take place. It shall ensure this information is kept up to date thereafter.

3. The notification by the developer shall also provide detailed information concerning the following:
  - (a) a characterisation of the novel technology based on the properties of recycling technologies set out in Article 3(3);
  - (b) an explanation of any applied deviations from the requirements set out in Articles 6, 7 and 8, or whether the novel technology applies a recycling scheme.
  - (c) reasoning and scientific evidence compiled by the developer demonstrating that the novel technology can manufacture recycled plastic materials and articles that meet the requirements of Article 3 of Regulation (EC) No 1935/2004, including a characterisation of expected contaminant levels in the plastic input and in the recycled plastic, and the expected transfer of these contaminants from the recycled plastic materials and articles to the food.
  - (d) a description of one or more typical recycling processes using the technology, including a block diagram of the main manufacturing stages, and, if relevant,

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<sup>9</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).



an explanation of the recycling scheme and of the rules governing its functioning.

- (e) an explanation based on point (a) describing why the technology is to be considered different from existing suitable technologies and is to be considered novel;
- (f) a summary proposing evaluation criteria for evaluating recycling processes that apply the novel technology on which the installation is based in accordance with Article 20(2)
- (g) an estimate of the expected number of decontamination installations that will be operated to develop the novel technology, and the foreseen addresses of the recycling facilities where they will be located.

The information referred to in the first subparagraph shall be available to the Member States, and to the Authority. The developer shall also provide it to all recyclers using the novel technology. It shall be updated without delay on the basis of new information forthcoming from development activities. The information shall be considered of commercial relevance to the developer, and shall not be made public prior to a request of the Commission to the Authority to assess the recycling technology in accordance with Article 12.

- 4. The developer shall adapt the template of the compliance monitoring summary sheet provided for in Annex II to the extent necessary to reflect the particularities of the novel technology. It shall provide this adapted template to compliance monitoring summary sheet to all recyclers using the novel technology.
- 5. The developer shall ensure an on-going dialogue with all recyclers using the novel technology to exchange knowledge about its functioning and capacity to decontaminate the plastic input. It shall keep records thereof, setting out the matters discussed and conclusions on the functioning and decontamination capacity of the technology, which shall be made available upon request to any competent authority in a territory where the developer and/or recyclers are located.
- 6. Where a technology applies a recycling scheme, it shall be operated in accordance with Article 9. The developer shall act as the manager of the recycling scheme referred to in Article 9(1). Articles 6, 7 and 8, and Article 9(2) shall not apply.

### *Article 11*

#### *Conditions on the operation of recycling installations applying novel technologies*

- 1. A recycling installation applying a novel recycling technology shall be based on a novel technology notified in accordance with Article 10(2).
- 2. By derogation to Articles 6, 7, and 8, a recycling installation used to develop a novel technology may be operated in a way that deviates from one or more of the specific requirements set out in those Articles, or apply a recycling scheme, provided the deviation or the operation of the scheme is in accordance with Article 10;
- 3. The recycler shall have documented supplementary information available in accordance with Article 12 demonstrating that the recycled plastic produced with the recycling installation meets the requirements of Article 3 of Regulation (EC) No 1935/2004.

4. The recycler shall have a completed compliance monitoring summary sheet on the basis of the template provided by the developer in accordance with Article 10(4).
5. The supplementary information referred to in paragraph 3 including any supporting documentation, and the compliance monitoring summary sheet referred to in paragraph 4 shall be provided to the developer and to the competent authorities on their request.

### *Article 12*

#### *Supplementary information requirements on recycling installations using novel technology*

1. A recycler shall keep available at the decontamination installation the following supplementary information:
  - (a) a summary of the novel technology not exceeding 250 words;
  - (b) a summary describing the complete recycling installation and the process it applies, not exceeding 1 500 words. This summary shall demonstrate the safety of the recycled plastic manufactured with the installation, and shall be based on the information provided by the developer in accordance with Article 10(3), as well as the evaluation criteria referred to in point (f) of Article 10(3);
  - (c) a detailed block diagram showing the sequence of the main manufacturing stages of the recycling installation, including all individual unit operations operated at the recycling facility;
  - (d) a piping and instrumentation diagram of the decontamination process in accordance with section 4.4 of ISO 10628:2014, showing only the instrumentation relevant for decontamination;
  - (e) an URL providing the location on the website of the developer where the reports published in accordance with Article 13(3) are or will be located.
2. The supplementary information in paragraph 1 shall be updated without delay as a result of on-going dialogue between the developer and the recyclers, when new information becomes available either as a result of the operation and development of the installation, or of the monitoring in accordance with Article 13, or where the developer changes the technology or collects new measurements on the performance or functioning of the novel technology. The recycler shall then provide the developer with the updated information and supporting documentation.
3. For the purpose of paragraph 1, point (b), the supporting documentation shall include at least the following elements:
  - (a) information on the level of incidental contamination present in the plastic input;
  - (b) information on the amount or percentage of the contamination that the decontamination process can remove ('the decontamination efficiency');
  - (c) information on estimated residual incidental contamination present in the output of the decontamination process taking the decontamination efficiency into account, including that of potentially remaining genotoxic and endocrine disrupting substances and substances referred to in Article 13(4)(a) of Regulation (EU) No 10/2011, even if their occurrence is below the limit of their detection of the applied analytical techniques;

- (d) information on the fate of contaminants removed in the decontamination process;
- (e) information on the migration to food of the residual contamination present in the recycled plastic material or article, post-processed in accordance with the requirements of the recycling process, and taking into account the conditions of use defined for the concerned materials and articles;
- (f) an overall reasoning, discussion and conclusion on the safety of the recycled plastic materials and articles based on the information set out in points (a) to (e).

The information referred to in this paragraph shall be kept up to date and be based on the latest information relevant to these elements, including information provided by the suppliers of the plastic input and the users of the recycled plastic, and information forthcoming from the monitoring in accordance with Article 13 and the dialogue referred to in Article 10(5).

### *Article 13*

#### *Monitoring and reporting of contamination levels*

1. A recycler operating a decontamination installation in accordance with Article 11 shall monitor the average contaminant level by sampling each batch of plastic input and the corresponding decontaminated output batch.

The sampling strategy shall be designed to obtain the best possible estimate of the average contaminant level in a batch, particularly by the sampling of shredded and mixed material. In case the input batch sizes exceed 30 tonnes, at least every 30 tonnes of material shall be subject to sampling for the purpose of this Article.

Where determining the sampling frequency based on plastic input batches is impractical due to the particularities of the recycling process, the frequency shall be determined on the basis of batches used at the closest pre-processing operation for which such determination is practical.

2. Recyclers shall provide the developer at least every six months with the data forthcoming from the monitoring and their updated reasoning in accordance with Article 12 (3)(f) if that has changed on the basis of the data.
3. The developer shall publish every six months a report on its website, based on the latest information from all installations using the novel technology received in accordance with paragraph 2.
4. The report shall contain at least:
  - (a) a brief description of the novel technology on the basis of the information referred to in Article 10(3);
  - (b) a summary of the reasoning on the capability of the novel technology and the recycling process(es) to manufacture recycled plastic materials and articles that meet the requirements of Article 3 of Regulation (EC) No 1935/2004 on the basis of the information included in points (a) to (e) of Article 10(3), and the information received in accordance with paragraph 2;
  - (c) a list of all chemical contaminants found in the plastic inputs to each of the decontamination installations and in the recycled plastic output thereof, sorted in descending order by their relative occurrence and of which at least the first

20 detected substances have been identified), and their amounts specified as weight fraction of the input and output;

- (d) a list of other contaminants, including different polymer types, plastics not intended for contact with food, and other materials that are found in the inputs and outputs referred to in point (c), and their amounts specified as weight fraction of the input and output;
- (e) an analysis of the most likely origin of the identified contaminants referred to in points (c) and (d), and of whether those origins could give rise to the simultaneous presence of other more toxic substances that are either undetected or unidentified with the applied analytical techniques;
- (f) a measurement or estimation of the migration levels to food of contaminants present in the recycled plastic materials and articles;
- (g) a detailed description of the analytical procedures and methods used, including sampling procedures and limits of detection and quantification;
- (h) an analysis and explanation of any discrepancies observed between contaminant levels expected in the input plastic and in the output of the installation and its decontamination efficiency based on the reasoning provided under point (b) and the actual results under point (c).
- (i) a discussion of the differences with the previous report published in accordance with this paragraph, if any.

#### *Article 14*

##### *Assessment of novel technologies*

1. When the Commission considers there is sufficient data available on a novel technology, it may on its own initiative request the Authority to assess that technology, and include other novel technologies in that request, provided these technologies are substantially similar or the same.
2. A developer may request the Commission to initiate the assessment referred to in paragraph 1 once it published at least four consecutive reports in accordance with Article 13(3) concerning a decontamination installation.

In case the developer requests the assessment of the novel technology, the Commission may delay the request to the Authority by up to two years in case it considers that the available knowledge on the novel technology is still insufficient, or when other operators are developing the same or similar novel technologies.

3. The Authority shall assess the suitability of the decontamination technology that the novel technology applies taking into account the recycling technology as a whole.

The suitability assessment shall thereto include the capacity of the employed chemical and/or physical principles to remove contamination from a specified plastic input to a level sufficiently low so that plastic materials and articles manufactured with the novel technology meet Article 3 of Regulation (EU) No 1935/2004, based on a characterisation of the contaminant level in the plastic input and the intended use of the plastic output.

Within one year after receiving the request for assessing the novel technology, the Authority shall publish an opinion concerning the outcome of its assessment. That opinion shall contain:

- (a) a characterisation of the recycling technology based on the properties defined in Article 3(3);
  - (b) a discussion and conclusion on its assessment of the capacity of the novel technology to recycle plastic waste in accordance with paragraph 3, including specific observations or concerns the Authority has on the technology, and on processes and installations using it, and a definition and justification of any restrictions and specifications deemed necessary;
  - (c) a conclusion on whether individual recycling processes applying that recycling technology require further individual evaluation in accordance with Articles 17 to 20;
  - (d) if the Authority concludes that individual evaluation of the recycling processes is necessary, specific guidance as referred to in Article 20(2);
  - (e) in case that the Authority concludes that individual evaluation of the recycling processes is not necessary, information equivalent to the information required in Article 18(4), points (c) to (g).
4. Where the Authority considers that it needs to involve new experts to assess a novel technology accordingly, it may extend the period provided for in paragraph 4 by up to one year.
5. Where needed for completing its assessment, the Authority may request the developers of the novel technologies under assessment to supplement the information available to it with information compiled in accordance with Articles 10 and 12, as well as with other information or explanations that it deems necessary for that purpose, and within time limits it specifies, which shall not exceed 1 year in total. Where the Authority requests such supplementary information, the time limit laid down in paragraph 4 is suspended until the requested information is received, from at least one, several, or all developers as appropriate for the purposes of the assessment.
6. Articles 39 to 39e of Regulation (EC) No 178/2004 and Article 20 of Regulation (EC) No 1935/2004 shall apply *mutatis mutandis* to the supplementary information requested in accordance with paragraph 6; for this purpose, the developer or developers of the novel technologies in the scope of the assessment shall be regarded as the applicant.

For the purpose of assessing technologies, the Authority shall provide confidential treatment to supplementary information it requests on aspects specific to individual recycling processes and installations used by a recycler. Information referred to in Article 12(1)(b) and (e), and Article 12(3) shall not be treated as confidential.

Information considered confidential in accordance with this paragraph shall not be shared with or between other developers, recyclers, or third parties without the consent of the owner of that information.
7. When developers of other novel technologies not included in the scope of the assessment publish new information relevant for the assessment, the Authority may take this information into account.

#### *Article 15*

#### *Decision on the suitability of a novel technology*

1. Taking into account the opinion of the Authority, relevant provisions of Union law and other legitimate factors relevant to the matter under consideration, the Commission shall decide whether the novel technology is a new suitable recycling technology in accordance with Article 3(1) or be included in an existent suitable recycling technology.

Where the Commission considers a novel technology is a suitable recycling technology, it shall set out, as necessary, the specific requirements applicable to that technology and decide whether recycling processes applying it shall be subject to authorisation and whether a recycling scheme shall be used to apply the technology.

2. Where the Commission considers that recycling processes applying a technology shall be subject to authorisation, it shall set out provisions concerning the operation of recycling installations notified in accordance with Article 10(2).
3. A technology that was not considered suitable in accordance with paragraph 1 shall no longer be considered a novel technology. Developers may use that technology as a basis to start the development of another novel technology, provided it is substantially changed so as to address the concerns of the Authority and/or the Commission.

#### *Article 16*

##### *Safeguard clause concerning the placing on the market of recycled plastic materials and articles manufactured with a novel or suitable technology*

1. On the request of a Member State or on its own initiative the Commission may analyse whether there are grounds to change the conditions of the placing on the market of recycled plastic materials and articles manufactured with a specific recycling technology, or fully prevent their placing on the market, even if that technology has been considered suitable.
2. For the purpose of the analysis referred to in paragraph 1, the developer of the technology, developers, manufacturers or providers of recycling processes or installations using the technology such as those referred to in Article 17(1), recyclers, converters and Member States shall provide the Commission with all the information they have obtained on the recycling technology. Where necessary, the Commission may consult the Authority.
3. The Commission may call upon the actors referred to in paragraph 2 to carry out a specific monitoring programme or migration testing. The Commission may specify deadlines before which those actors shall provide the required information or reports.
4. On basis of the outcome of its analysis, the Commission may:
  - (a) lay down restrictions and specifications regarding the technology, as necessary;
  - (b) consider the recycling technology as unsuitable.

## **Chapter V – Procedure for the authorisation of individual recycling processes**

#### *Article 17*

##### *Application for the authorisation of individual recycling processes*

1. To obtain authorisation of an individual recycling process, the natural person or legal entity that developed the decontamination process of the recycling process, either exclusively for its own purposes as a recycler or for the sale or licensing of recycling or decontamination installations to recyclers, 'the applicant', shall submit an application in accordance with paragraph 2.
2. The applicant shall submit the application to the competent authority of a Member State accompanied by the following:
  - (a) the name and address of the applicant;
  - (b) a technical dossier containing the information specified in paragraph 5;
  - (c) a summary of the technical dossier.
3. The competent authority referred to in paragraph (2) shall:
  - (a) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt, stating the date of the receipt ;
  - (b) inform the Authority without delay;
  - (c) make the application and any supplementary information supplied by the applicant available to the Authority.
4. The Authority shall without delay:
  - (a) inform the Commission and the other Member States of the application and make the application and any supplementary information supplied by the applicant available to them;
  - (b) make public the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 19 and 20 of Regulation (EC) No 1935/2004, unless otherwise provided for in paragraph 6 of this Article.
5. The technical dossier shall contain the following information:
  - (a) any information required in the detailed guidance published by the Authority in accordance with Article 20(2);
  - (b) a description of the pre-processing carried out to produce plastic input suitable for being entered into the decontamination process and of the specific quality control procedures applied during collection and pre-processing, including a detailed specification of the pre-processed plastic input;
  - (c) a description of any required post-processing of the recycled plastic and of the intended use of the resulting plastic materials and articles and of uses for which it would not be suitable, including relevant instructions and labelling to be provided to convertors and to end-users of the recycled plastic materials and articles;
  - (d) a simple block diagram of all unit operations used in the decontamination process, that provides a reference to the input, output and quality control procedures applied by each operation;
  - (e) a piping and instrumentation diagram of the decontamination process in accordance with section 4.4 of ISO 10628:2014, showing only the instrumentation relevant for decontamination;

- (f) a description of the quality control procedures applied at each unit operation of the decontamination process, including:
  - (i) the values of monitored parameters such as operating temperatures, pressures, flowrates and concentrations, and acceptable ranges thereof;
  - (ii) laboratory analysis and its frequency; if any,
  - (iii) correction and record keeping procedures; and
  - (iv) any other information the applicant deems relevant to fully describe its quality control procedures.
- 6. Information provided in accordance with paragraph 5, points (e) and (f), and equivalent information submitted in accordance with paragraph 5, point (a), may be kept confidential pursuant to Article 20(2) of Regulation (EC) No 1935/2004.

### *Article 18*

#### *Opinion of the Authority*

1. The Authority shall publish an opinion within a time limit of six months from the receipt of a valid application as to whether the recycling process is capable of applying the suitable recycling technology it uses so that plastic materials and articles manufactured with it meet Article 3 of Regulation (EU) No 1935/2004.

The Authority may extend the time limit provided for in the first subparagraph by a maximum period of a further six months. In such a case, it shall provide an explanation for the extension to the applicant, the Commission and the Member States.
2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time, whether in writing or by oral explanation. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 is suspended until that information has been provided.
3. The Authority shall:
  - (a) verify that the information and documents submitted by the applicant are in accordance with Article 17(5), in which case the application shall be regarded as valid;
  - (b) inform the applicant, the Commission and the Member States if the application is not valid.
4. The opinion of the Authority shall include the following information:
  - (a) the identification and address of the applicant;
  - (b) the number of the suitable recycling technology the process uses;
  - (c) a short description of the recycling process including a short description of the required pre-processing and post-processing stages, a characterisation of the plastic input, and conditions and limitations of use of the output;
  - (d) a process flow diagram of the decontamination process that discerns the order of the distinct unit operations that the Authority has evaluated together with a description of each of these operations and how any parameters critical to their operation are controlled;



- (e) a scientific evaluation of the decontamination efficiency in accordance with the guidance set out in Article 20(2);
- (f) a discussion and conclusion on whether the recycling process can manufacture recycled plastic materials and articles that meet the requirements of Article 3 of Regulation (EC) No 1935/2004, including a reasoning justifying restrictions and specifications that should in the opinion of the Authority apply to the plastic input, the configuration and operation of the decontamination process and the use of the recycled plastic and recycled plastic materials and articles;
- (g) where appropriate, any recommendations concerning monitoring of the compliance of the recycling process with the conditions of the authorisation.

### *Article 19*

#### *Authorisation of an individual recycling process*

1. Taking into account the opinion of the Authority, relevant provisions of Union law and other legitimate factors relevant to the matter under consideration, the Commission shall consider whether the individual recycling process complies with the conditions of use of the suitable technology it applies and produces recycled plastic that meets the requirements of Article 3 of Regulation (EC) No 1935/2004.

The Commission shall then adopt a decision addressed to the applicant granting or refusing the authorisation of the recycling process. Article 23(1) of Regulation (EC) No 1935/2004 and Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>10</sup> shall apply.

Where the decision is not in accordance with the opinion of the Authority, the Commission shall explain the reasons for its decision.

2. A decision granting the authorisation shall include the following:
  - (a) a recycling process authorisation number ('RAN');
  - (b) the name of the recycling process;
  - (c) the recycling technology, as listed in Annex I, for which the process is authorised;
  - (d) the name and address of the authorisation holder;
  - (e) a reference to the opinion of the Authority on which the decision is based;
  - (f) any specific requirements for the operation of the decontamination process, pre-processing and post-processing complementing or derogating from the general requirements set out in Articles 6, 7 and 8, or Article 9;
  - (g) any specific requirements concerning monitoring and verification of the compliance of the recycling process with the conditions of the authorisation;
  - (h) any conditions, specifications, and specific labelling requirements concerning the use of the plastic with recycled content originating from the process;

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<sup>10</sup> 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).

## Article 20

### *Guidelines published by the Authority*

1. The Authority shall publish detailed guidelines, following the agreement with the Commission, concerning the preparation and the submission of the application, taking into account standard data formats, where they exist in accordance with Article 39(f) of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.
2. For each suitable technology for which the authorisation of individual recycling processes is required, the Authority shall publish scientific guidelines describing the evaluation criteria and the scientific evaluation approach it will use to evaluate the decontamination capability of those recycling processes. These guidelines shall specify the information required to be included in an application dossier for the authorisation of a recycling process applying that specific technology.

## Article 21

### *General obligations arising from the authorisation of a recycling process*

1. The granting of an authorisation of a recycling process shall not affect the civil and criminal liability of any business operator in respect of the authorised recycling process, a recycling installation applying the process, recycled plastic and recycled plastic materials and articles obtained with such a recycling installation, and the food that is in contact with such material or article.
2. The authorisation holder or any recycler shall immediately inform the Commission of any new scientific or technical information which might affect the evaluation on which the authorisation is based.
3. An authorisation holder may permit third parties to operate a decontamination installation under its licence as recyclers. The authorisation holder shall ensure that those recyclers receive all necessary information, instructions and support required to ensure that the operation of the installation and the resulting recycled plastic complies with this Regulation.
4. The authorisation holder shall communicate without delay to the competent authority in the territory where it is established and to the Commission, any changes to its points of contact, its trade and company names, and other information relevant to the authorisation of a recycling process.
5. The authorisation holder shall immediately inform the competent authority in the territory where it is established and the Commission of a situation under which it can or will no longer assume its responsibilities as authorisation holder in accordance with this Article. The authorisation holder shall provide all necessary information to allow the Commission to determine whether the authorisation of a recycling process should be modified or revoked.

## Article 22

### *Request for the modification of an authorisation by the authorisation holder*

1. The authorisation holder may apply for a modification of the authorisation of a recycling process.
2. The modification referred to in paragraph 1 shall be subject to the procedure laid down in Articles 17 to 20, unless otherwise provided for in this Article.

3. The application referred to in paragraph 1 shall be accompanied by the following:
  - (a) the reference to the original application;
  - (b) a technical dossier containing the information required in Article 17(5) in so far as that information is different from the information included in the technical dossier already submitted during the original application in accordance with Article 17(5) and Article 18(2);
  - (c) a new complete summary of the technical dossier in a standardised form;
  - (d) at least one complete compliance monitoring summary sheet related to a decontamination installation operating the authorised process as submitted to a competent authority in accordance with Article 26, and an updated version which includes all changes, if any, expected to be forthcoming from the requested change.
4. In case the modification concerns a transfer of the authorisation of a recycling process to a third party, the authorisation holder shall notify the Commission before the transfer, indicating the name, address and contact information of that third party. At the time of the transfer, it shall provide the notified authorisation, the technical dossier and all documents included therein to the third party. That third party shall contact the Commission without delay by a registered letter, stating that it accepts the transfer, has received all documents and accepts to meet all the obligations arising from this Regulation and the authorisation.

#### *Article 23*

##### *Modification, suspension and revocation of the authorisation of a recycling process on the initiative of the competent authorities, the Authority or the Commission*

1. On its own initiative or following a request from a Member State or the Commission, the Authority shall evaluate whether the opinion, authorisation of a recycling process and/or the recycling process is still in accordance with this Regulation, in accordance with the procedure laid down in Article 18, which shall apply *mutatis mutandis*. The Authority may, where necessary, consult the authorisation holder.
2. Prior to submitting a request in accordance with paragraph 1, the Commission or a Member State shall consult the Authority on whether a new evaluation or the authorised process is necessary based on the particulars of the request. The Authority shall provide the Commission and, where appropriate, the requesting Member State with its views within a period of 20 working days. In particular where the Authority considers that an evaluation is not necessary, it shall provide a written explanation to the Commission and, if applicable, to the requesting Member State.
3. Based on the opinion of the Authority published in accordance with Article 18(1), the Commission may decide to amend or revoke the authorisation. Where needed, the recycling process or the operation of specific decontamination installations may be suspended until these amendments are implemented in the recycling installations based on the process. The status of the registration in the Union register shall change accordingly.

## Chapter VI – Registration of information necessary for controls

### Article 24

#### *Union register of technologies, recyclers, recycling processes, recycling schemes, and decontamination installations*

1. A public Union register of novel technologies, recyclers, recycling processes, recycling schemes and decontamination installations ('the Register') is established.
2. The Register shall contain:
  - (a) the names of novel technologies and the names and addresses of the developers and the development status;
  - (b) the names of authorised recycling processes and the names and addresses of the authorisation holders;
  - (c) the authorisation status of each registered recycling processes, including whether its authorisation is suspended, revoked, or subject to transitional provisions, and the latest date of change of the authorisation status;
  - (d) the company name and the address of the head office of recyclers operating a decontamination installation;
  - (e) the addresses of recycling facilities;
  - (f) decontamination installations, the technology they use, the facility at which they are located, and the authorised process it applies, if any;
  - (g) the registration status of decontamination installations, including whether the installation is newly registered, being established, active or suspended, and the latest date of change of that status;
  - (h) names of recycling schemes, and names and addresses of the entity managing the scheme;
  - (i) the markings required in accordance with Article 9(5);
  - (j) where relevant, the information required in accordance with Article 19(2);
  - (k) cross-references between technologies, processes, schemes, recyclers, and installations and schemes;
3. The Register shall maintain the above information in tables. It shall assign the following entities with unique numbers, as follows:
  - authorised recycling processes are assigned a recycling authorisation number ('RAN');
  - recyclers are assigned a recycler operator number ('RON');
  - recycling installations are assigned a recycling installation number ('RIN');
  - recycling schemes are assigned a recycling scheme number ('RSN');
  - recycling facilities are assigned a recycling facility number ('RFN');
  - novel recycling technologies are assigned a novel technology number ('NTN').
4. The Register shall be made available to the public.

## Article 25

### *Registration of recyclers and decontamination installations*

1. Recyclers shall comply with the following administrative requirements:
  - (a) at least 15 working days prior to the start date of the production of recycled plastic in a decontamination installation, the recycler shall notify the installation and either the address of the facility where it is located or the facility number to the Commission and to the competent authority in the territory where the installation is located, as well as its own registration number if the recycler is already registered, the recycling authorisation number if it applies an authorised process, and the number of the suitable or novel technology, as applicable;
  - (b) upon notification of its first decontamination installation in accordance with point (a), the recycler shall notify its company name, contact persons, and the address of its head office to the Commission and to the competent authority in the territory where the head office is located;
  - (c) the recycler shall have a completed compliance monitoring summary sheet in accordance with Annex II available at the recycling installation and have submitted it to the competent authority in accordance with Article 26;
2. Following the notification in accordance with paragraph 1, point (a), the installation shall be registered in the Union register and the registration status in accordance with paragraph 2, point (g), of Article 24 shall be ‘newly registered’.
3. The notification referred to in paragraph 1, point (a), shall include a reference to the authorised recycling process on which basis the decontamination installation is operated, if any, to the suitable or novel technology that it applies, and, if applicable, to the recycling scheme it is subject to.
4. The recycler shall notify any changes to the information for registration provided in accordance with this Article to the Commission and the competent authority in the territory where the decontamination installation or the recycler, as relevant, is located.

## Article 26

### *Compliance monitoring summary sheet and verification of the operation of a decontamination installation*

1. Recyclers shall draw up the compliance monitoring summary sheet for each decontamination installation under their control using the template provided in Annex II, or in case of a novel technology, the template provided by the developer, if different.

The compliance monitoring summary sheet shall provide a summary clearly describing the recycling installation, its operation, the relevant procedures and documents in a way demonstrating compliance with this Regulation.

Recyclers shall take into account the applicable guidelines published by the Commission concerning the compliance monitoring summary sheet, as well as the particular situation at the concerned recycling facility where the installation is located.

2. Recyclers shall submit the compliance monitoring summary sheet to the competent authority in the territory where the decontamination installation is located within one month from the start date of the production of recycled plastic with that installation. The status of the registration in accordance with Article 24(2), point (g), shall change to ‘being established’.

3. The competent authority shall verify whether the information provided in the compliance monitoring summary sheet complies with this Regulation and perform a control of the recycling installation to this purpose in accordance with Article 27.

When compliance cannot be established, the competent authority shall request the recycler to update the information in the compliance monitoring summary sheet, the operation of the recycling installation, or both, as appropriate.

When compliance is established, the competent authority shall inform the Commission thereof. The status of the registration in accordance with Article 24(2), point (f), shall change to ‘active’.

4. If the competent authority does not inform the Commission that compliance is established within one year from the start date of the production of recycled plastic in the decontamination installation, the status of the registration in accordance with Article 24(2), point (g), shall be changed to ‘suspended’.

If the status of a decontamination installation is ‘suspended’ for one year, the entry concerning the installation shall be removed from the Register.

## **Chapter VII – Official controls**

### *Article 27*

#### *Official controls of recycling installations*

Official controls of recycling installations and recyclers shall include in particular audits in accordance with Article 14, point (i), of Regulation (EU) 2017/625.

These audits shall be complemented by:

- (a) an assessment of procedures on good manufacturing practices in accordance with Article 14, point (d), of Regulation (EU) 2017/625;
- (b) an examination in accordance with Article 14, points (a) and (e), of Regulation (EU) 2017/625, of the compliance monitoring summary sheet established in accordance with Article 26, and, on the basis of that summary sheet, of the controls that operators have put in place and of documents and records referred to in that summary sheet.

### *Article 28*

#### *Non-compliance of recycled plastic*

- 1. A competent authority shall establish that a batch of recycled plastic is non-compliant if it finds during official controls that:
  - (a) a recycler has placed it on the market without appropriate documentation or labelling;
  - (b) a recycler cannot demonstrate on the basis of its records and other documentation that it was manufactured in accordance with this Regulation;

- (c) the batch was manufactured at a recycling installation that was not operated in accordance with this Regulation during a period established in accordance with paragraph 3.
- 2. When one or more batches are established as non-compliant, the competent authority shall take appropriate action in accordance with Article 138 of Regulation (EU) 2017/625.
- 3. The operation of a recycling installation shall be considered not in accordance with this Regulation when the competent authority establishes that:
  - (a) two batches are non-compliant on the basis of paragraph 1, point (b), due to deficiencies in the operation of the recycling installation, and that these deficiencies due to their nature are likely to affect other batches;
  - (b) the manufacturing of recycled plastic at the recycling installation is not in accordance with the general requirements laid down in this Regulation and, where relevant, the specific requirements applicable to the suitable technology applied and the recycling process used, or with the requirements applicable to the novel technology applied;
  - (c) where relevant, it could not verify the compliance monitoring summary sheet in accordance with Article 24(3) within one year from the start date of the production of recycled plastic in the decontamination installation.

When the competent authority establishes that the operation of a recycling installation is not in accordance with this Regulation, the competent authority shall establish the period during which it was the case, taking account of any available evidence or the lack thereof. In case of the first subparagraph, point (c), this shall be the entire period of operation of the recycling installation.

- 4. In case the competent authority considers changes are necessary to the recycling installation, the use of a decontamination installation part thereof may be suspended. If this suspension is expected to be longer than two months, the suspension shall be indicated in the Union Register in accordance with Article 24(2)(f).

## **Chapter VIII – Compliance documentation**

### *Article 29*

#### *Specific requirements for declarations of compliance for recyclers and converters*

- 1. Recyclers shall provide a declaration of compliance in accordance with the description and template set out in Part A of Annex III.
- 2. The declaration of compliance shall include instructions to converters that are sufficient for ensuring that converters can further process the recycled plastic into recycled plastic materials and articles that are in compliance with Article 3 of Regulation (EC) 1935/2004. These instructions shall be based on the specifications, requirements or restrictions set out for the recycling technology applied and, where applicable, the recycling process used.
- 3. Converters shall provide a declaration of compliance in accordance with the description and the template set out in Part B of Annex III;

## Chapter IX – Final provisions

### *Article 30*

#### *Repeal*

Regulation (EU) No 282/2008 is repealed.

### *Article 31*

#### *Transitional provisions*

1. Recycled plastic materials and articles obtained by means of a recycling process based on a recycling technology for which this Regulation requires the individual authorisation of recycling processes and for which a valid application has been submitted to the competent authority in accordance with Article 5 of Regulation (EC) No 282/2008, or for which an application is submitted in accordance with Articles 17(1) or 22(1) of this Regulation at the latest on ... [*enter date 6 months after entry into force of this Regulation*], may be placed on the market until the applicant withdraws its application, or until the Commission adopts a decision granting or refusing authorisation of the recycling process pursuant to Article 19(1).
2. Recycled plastic materials and articles obtained by means of recycling processes based on a recycling technology that is not considered suitable by this Regulation may continue to be placed on the market only until ... [*6 months after entry into force of this Regulation*], unless manufactured with a recycling installation that is operated for the purpose of development of a novel technology in accordance with Chapter IV.
3. Applications submitted in accordance with Regulation (EC) No 282/2008 for the authorisation of recycling processes based on a recycling technology that is not considered suitable by this Regulation and for product loops which are in a closed and controlled chain, shall be deemed terminated.
4. For the purposes of this Regulation, the start date of a decontamination installation that was used to produce recycled plastic before ... [*enter date of entry into force of this Regulation*] shall be ... [*enter date 1 month after entry into force of this Regulation*].

### *Article 30*

#### *Entry into force*

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

Article 6(3)(b) shall apply from ... [*enter date 24 months after entry into force of this Regulation*].

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



Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*