

**COMMISSION REGULATION (EU) 2022/1616****of 15 September 2022****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, even when originating from food use, may contain contaminants incidental to that use which potentially compromise the safety and quality of recycled plastic food contact materials and articles. While such plastic waste is unlikely to 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 otherwise affect the food, if used for the production of recycled plastic food contact materials and articles. To ensure that food consumers and food 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, as it excluded chemical depolymerisation, the use of offcuts and scraps, and the use of barrier layers from its scope. The use of recycled plastic materials in contact with food manufactured with excluded technologies it considered subject to Commission Regulation (EU) No 10/2011 <sup>(5)</sup> on plastic materials and articles. Regulation (EU) No 10/2011 however does not provide clear support of the excluded technologies, as it does not define rules for partially depolymerised substances or oligomers, offcuts, and process scraps, and limits the substances that can be used behind a functional barrier.

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

<sup>(2)</sup> COM(2015) 614 final.

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

<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 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

- (4) The European Food Safety Authority ('the Authority') observed that it is impossible to predict the identity of contaminants potentially present in post-consumer PET used as input of a recycling process and therefore to ensure that they are not genotoxic <sup>(6)</sup>. As the reasoning that the Authority applied can be extended to other plastic waste, it cannot be generally assumed that such other waste streams are free of certain groups of contaminants without additional scientific data. Therefore, it also cannot be assumed that it is possible to risk assess contaminants in the same way as impurities are assessed under Regulation (EU) No 10/2011, or that mixtures of chemically depolymerised materials are free of such contaminants, or that plastic functional barriers may fully contain them. Consequently, recycled plastics manufactured with technologies that are excluded from the application of Regulation (EC) No 282/2008 also cannot be used subject to Regulation (EU) No 10/2011.
- (5) Consequently, Regulation (EC) No 282/2008 and Regulation (EU) No 10/2011 together do not apply to all plastic recycling technologies and recycled plastic materials and articles. As further innovative novel plastic recycling technologies are being developed, and the market of recycled plastics is growing, the lack of clearly applicable and suitable rules creates a potential risk to human health and inhibits innovation. To establish clear rules and to address the risk of incidental contaminants, it is therefore appropriate to replace Regulation (EC) No 282/2008 with new rules covering all existing and future plastic recycling technologies.
- (6) Regulation (EU) No 10/2011 requires that substances used to manufacture plastic materials and articles are of a suitable purity, and that remaining impurities can be identified so that they can be subject to risk assessment. As single substances can be purified to a level suitable to this purpose, it does not generally limit production methods for the substances on the Union list of authorised substances. It is thus also possible to manufacture those substances from any source, including therefore from waste materials. Moreover, substances produced from waste and that are obtained at a high level of purity are indistinguishable from the same substances produced otherwise. Therefore the manufacture of plastic materials and articles with substances obtained at a high level of purity from waste materials, and that are included in the Union list established by Regulation (EU) No 10/2011, or subject to certain derogations, should be subject to that Regulation, whereas other substances in which incidental contaminants cannot be assumed a priori to be absent or be easily excluded, including mixtures, oligomers, and polymers produced from waste should be subject to this Regulation. To avoid uncertainty over which Regulation applies to a certain recycling technology that results in substances at an intermediate recycling stage, substances subject to Regulation (EU) No 10/2011 should be clearly excluded from the scope of this Regulation.
- (7) In natural language widely and loosely used terminology, such as 'technology', 'process', 'equipment' and 'installation', may refer to the same or to similar concepts and the meaning may overlap, depending on context and user. 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.
- (8) This Regulation requires the decontamination of plastics by means of a suitable recycling technology, and includes the use of chemical recycling technologies in its scope. However, when referring to the removal of contaminants from substances or mixtures rather than from materials, purification is often used, instead of decontamination. When chemical recycling technologies are applied with the purpose to remove contaminants from mixtures or substances these could therefore be considered to achieve purification rather than decontamination. However, as, in that case, the decontamination of the plastic is achieved by means of purification, it should however be clarified that decontamination also includes purification of substances or mixtures.

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<sup>(6)</sup> Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food, EFSA Journal 2011;9(7):2184.

- (9) 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.
- (10) Decontamination distinguishes a recycled plastic that is not suitable for contact with food from a recycled plastic made suitable for such contact, even if limited to only microbiological decontamination. This stage should therefore be the main focus of official controls done in the context of this Regulation. Depending on the applied technology and/or on the organisation thereof, decontamination may take place at facilities that would traditionally be regarded as waste management facilities, recycling facilities, or facilities where plastic conversion takes place. To ensure uniformity and clarity over the role of a facility where decontamination takes place under this Regulation, such a facility should be consistently referred to as a recycling facility.
- (11) 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.
- (12) The principle underlying Regulation (EC) No 1935/2004 is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. This principle therefore also applies to recycled food contact materials. However, that Regulation also explains that the use of recycled materials and articles should only be favoured provided strict requirements are established concerning food safety. Ensuring food safety includes not only the transfer of substances that may affect human health, or which could affect the quality of the food, but it also includes microbiological safety. As the input to recycling processes originates from waste, it is much more likely to be microbiologically contaminated than materials and articles that have been newly manufactured from starting substances. Therefore, this Regulation should ensure that recycled plastic materials and articles are not only sufficiently inert but also microbiologically safe.
- (13) Experience with the evaluation of processes under Regulation (EC) 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 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 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.
- (14) On the basis of the evaluations done by the Authority of the applications for authorisation submitted in accordance with Regulation (EC) No 282/2008, mechanical PET recycling and product loops in a closed and controlled chain may be considered as suitable recycling 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 based on established criteria. Conversely, it is not necessary to require the authorisation of individual recycling processes obtaining only plastic from a closed and controlled chain that prevents contamination, as the introduction of contaminants in the chain is then sufficiently controlled to ensure that the only contamination of the plastic input can be removed with the simple cleaning and heating processes needed in any case for the remoulding of the materials.

- (15) 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.
- (16) 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 in that Regulation.
- (17) 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.
- (18) 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, depending 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 its use. While such instructions are to 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 also be labelled in a clearly legible way to ensure it is correctly used during post-processing in accordance with the instructions from the recycler.
- (19) 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, the contamination level in the plastic input to the decontamination process should never exceed the maximum levels at which the process can ensure sufficient decontamination and, therefore, it should be assured that the input quality consistently meets the relevant specifications. Therefore the rules laid down in Commission Regulation (EC) No 2023/2006 <sup>(7)</sup> on good manufacturing practices should apply, as appropriate, also to the waste management operations that take place before the decontamination process and ensure that a quality assurance system is applied. 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.
- (20) Furthermore, those general rules on the operation of all recycling stages should not apply in relation to 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 plastic input to a minimum and, therefore, at reducing the requirements for the applied decontamination process. As the safety of the recycled plastic therefore depends on preventing contamination and consequently on the correct functioning of such recycling schemes, rather than on the processing of waste and its subsequent decontamination, it is appropriate that this Regulation sets out rules on their functioning. 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.

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<sup>(7)</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).

- (21) 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 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 novel 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.
- (22) However, rules should be laid down to ensure that recycled plastic materials and articles produced with novel 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. Therefore, prior to the placing on the market of these recycled material and articles, all available information on the principles, concepts and practices used by the novel technology should be used to minimise risks, and data on the decontamination efficiency of the technology should be available. Where this data would be insufficient to verify the adequate functioning of the technology, particularly when decontamination is not the main or only principle used to achieve safety, complementary tests should be designed based on the specifics of the novel technology. Furthermore, to establish the level of contamination in the input materials, as well as of the residual 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. To characterise exposure risk, such monitoring should not only focus on average levels, but also assess matters such as whether certain contaminants are frequently occur in different batches or are linked to a particular source. Moreover, to ensure trust, public knowledge and regulatory scrutiny of technologies that are being developed, it is important that the reports on the safety of the materials and of such monitoring are made public.
- (23) In order to ensure that the possibility to place on the market recycled plastic materials and articles produced with novel 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.
- (24) 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.
- (25) 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.
- (26) 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.

- (27) The decontamination of recycled plastic should be subject to inspection and control by competent authorities. Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law <sup>(8)</sup> 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.
- (28) 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.
- (29) Recycled plastic 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.
- (30) Recyclers applying technologies in their present recycling operations that are not listed as suitable recycling 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 their use of those recycling operations for the manufacture of plastic materials and articles. Therefore, the placing on the market of recycled plastic, and recycled plastic materials and articles, produced through recycling processes and installations based on those technologies and in accordance with current existing national rules should continue to be allowed for a limited time.
- (31) In case operators decide to develop the technology further in order to allow the listing of the technology as suitable, this Regulation requires the notification of the technology and the designation of a developer. The notification procedure however would require at the time of the notification extensive reasoning on the safety of those recycled plastic materials and articles, and the publication of a report based thereon. While operators already using these technologies should have information on the safety of the recycled plastic materials and articles manufactured therewith, the requirements that this Regulation sets out for such reports are extensive. Since it may take significant time to obtain the required additional information, it is therefore appropriate to allow those developers to provide this information in the months after the notification.

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<sup>(8)</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

- (32) Pursuant to this Regulation, it may no longer be possible after a certain date to legally place recycled plastic materials and articles on the market manufactured with a certain recycling installation. However, food business operators may still have stocks of such recycled plastic material and articles, or may have already used these to pack food. As this situation is not due to immediate safety concerns and those recycled plastics materials and articles were placed on the market subject to the control of national authorities, food waste and burden to food business operators should be avoided, and they should be allowed to use those recycled plastic material and articles to pack food and place them on the market, until that stock is exhausted.
- (33) Among those recycling technologies that fall within the scope of this Regulation and that are not listed as suitable recycling technologies, the manufacture of recycled plastic materials and articles in which the recycled plastic is used behind a plastic functional barrier, requires special consideration because several hundred recycling installations would presently already manufacture recycled plastic materials and articles with this technology. Recycled plastic materials and articles manufactured with this technology have been so far placed on the market assuming compliance with Regulation (EC) No 10/2011, and subject to the control of national competent authorities. The present information on these materials does not dispel doubts over their actual compliance with that Regulation. In particular there is insufficient information available on the ability of the applied functional barriers to prevent migration to food of contaminants contained in the recycled plastic over an extended period of time. Therefore, this technology should not be established as a suitable recycling technology yet. However, unlike other technologies to be considered as novel for the purposes of this Regulation, the main principles of this technology are already understood. This allows to lay down specific adaptations to the rules on novel technologies concerning the use of this technology until a decision is taken on its suitability, and in particular to add a requirement to verify the effectiveness of the barrier principle. Therefore, while on the one hand, given the number of existing installations, it does not appear necessary to require the monitoring of all these recycling installations in order to obtain sufficient data on contamination levels, on the other hand, given that, on the basis of the already available knowledge, there are doubts as to the ability of the functional barriers to prevent migration of contaminants on the long term, it is appropriate to subject the placing on the market of recycled plastic materials and articles manufactured with this technology to the condition that additional testing has been carried out to guarantee that ability.
- (34) This Regulation requires that certain waste management operators involved in the collection of plastic, as well as operators 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.
- (35) To ensure uniform and adequate application of analytical methods, this Regulation requires that recyclers that monitor contaminant levels as part of their activities on the development of novel technologies participate in proficiency tests. As this Regulation sets out this requirement for the first time, those proficiency tests require further adaptation to the provisions of this Regulation, and laboratories need time to organise their participation. Therefore, sufficient time should be allowed so that such proficiency tests can be adapted and organised.
- (36) Regulation (EC) No 282/2008 should be repealed.
- (37) 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 is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.

2. This Regulation lays down rules for:
  - (a) the placing on the market of plastic materials and articles falling within the scope of Article 1(2) of Regulation (EC) No 1935/2004, containing plastic originating from waste or manufactured therefrom;
  - (b) the development and operation of recycling technologies, processes and installations, 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.
3. This Regulation shall not apply to the use of waste to manufacture substances included in the Union list of authorised substances in accordance with Article 5 of Regulation (EU) No 10/2011, and to manufacture substances subject to Article 6(1), (2), and (3)(a) thereof, 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', 'recycling', and 'non-hazardous waste', as laid down in Article 3 of Directive 2008/98/EC of the European Parliament and of the Council <sup>(9)</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>(10)</sup>;
  - (3) 'competent authorities', and 'audit', as laid down in Article 3 of Regulation (EU) 2017/625.
3. The following definitions shall also apply for the purpose of this Regulation:
  - (1) 'recycling technology' means a specific combination of physical or 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 or chemical concepts, principles, and practices part of a recycling technology which have as primary purpose to remove contamination or to purify;
  - (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, and that are made either fully or partly of recycled plastic;
  - (6) 'recycled content' refers to the amount of recycled plastic directly resulting from the decontamination process of a recycling process contained either in further post-processed recycled plastic or recycled plastic materials and articles manufactured therefrom.

<sup>(9)</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>(10)</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).



- (7) '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;
- (8) 'plastic input' means the plastic materials resulting from pre-processing which are entered into a decontamination process;
- (9) '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;
- (10) '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;
- (11) 'post-processing' means all unit operations subsequent to the decontamination process by which its output is further polymerised, otherwise treated, and/or converted, resulting in recycled plastic materials and articles in their finished state;
- (12) 'recycling installation' means the equipment operating at least a part of a recycling process;
- (13) 'decontamination installation' means specific equipment operating a decontamination process;
- (14) 'recycling facility' means a location where at least one decontamination installation is located;
- (15) 'recycling scheme' means an arrangement between legal entities to manage the use, separate collection and recycling of plastic materials and articles with the objective to limit or prevent their contamination in order to facilitate their recycling;
- (16) 'recycler' means any natural or legal person who applies a decontamination process;
- (17) 'converter' means any natural or legal person that carries out one or more post-processing unit operations;
- (18) '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;
- (19) 'manufacturing stage' means one or more sequential unit operations and which are followed by a quality assessment of the material resulting from that stage;
- (20) 'batch' means a quantity of material 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 and are microbiologically safe.
2. Recycling technologies shall be distinguished 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. Suitable recycling technologies are listed in Annex I. Annex I may be amended in accordance with Articles 15 and 16.
4. Where the capacity to achieve sufficient decontamination of recycling processes that use a certain recycling technology depends on the precise specification of the input, the detailed configuration of those processes or on the applied operating conditions, and when that specification, configuration or those conditions cannot be laid down in simple rules at the time that technology is established as suitable, each recycling process using that technology shall be individually authorised by the Commission in accordance with the procedure laid down in Chapter V, and in particular Article 19(1) thereof ('the authorisation').
5. Annex I shall specify whether for a recycling technology individual recycling processes are to be authorised.
6. Any recycling technology that has not been subject to a decision on its suitability in accordance with Article 15 or 16 shall be regarded as a novel technology for the purpose of this Regulation.

## 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 requirements set out in Chapters II and III and Chapter V of Regulation (EU) No 10/2011 shall apply to recycled plastic materials and articles.
3. The recycled plastic materials and articles are manufactured using one of the following:
  - (a) a suitable recycling technology listed in Annex I; or,
  - (b) a novel technology as referred to in Article 3(6) and developed in accordance with 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 recycled plastic to manufacture the recycled plastic materials and articles complies with the general requirements laid down in Articles 6, 7 and 8, as supplemented by the specifications and requirements for the technology set out in column 8 of Table 1 of Annex I and those laid down in the authorisation, and subject to the specific derogations specified in column 9 of Table 1 of Annex I, and in the authorisation.
  - (c) by derogation to point (b), where the suitable recycling 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 the recycled plastic:
  - (a) the decontamination installation where the recycled plastic was manufactured, the address of the recycling facility, and the identity of the recycler operating it;
  - (b) the applied authorised recycling process, if the applied suitable recycling technology requires the authorisation of recycling processes;
  - (c) the name of the recycling scheme used, the identity of the entity managing it, and the applied markings, if the applied recycling technology requires the use of a recycling scheme;
  - (d) the name of 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 and of recycled plastic 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 a declaration of compliance in accordance with Article 29.
3. Containers of recycled plastic delivered to converters shall be labelled. The label shall show the symbol defined in Annex II to Regulation (EC) No 1935/2004, followed by:
  - (a) the symbol **RIN** and the registry number of the decontamination installation where the recycled plastic was manufactured in accordance with Article 24,
  - (b) the symbol **Batch No** followed by the batch number,
  - (c) the percentage by weight of the recycled content,
  - (d) the maximum percentage by weight of the recycled content that final recycled plastic materials and articles containing the recycled plastic may contain, if this is less than 100 %, and,
  - (e) when the declaration referred to in paragraph 2 provides additional instructions, the symbol defined in ISO 7000 with reference number 1641.
4. The labels referred to in paragraph 3 shall be at all times clearly legible, be located at a visible place, and be firmly attached.

The minimum font size on the labels shall be at least 17 points (6 mm) on containers of which the largest dimension is smaller than 75 centimetres, 23 points on containers of which the largest dimension is in between 75 centimetres and 125 centimetres, and 30 points on containers where the largest dimension exceeds 125 centimetres.

5. By derogation to paragraph 4, labelling may be omitted from fixed containers mounted in installations or on vehicles.

6. Restrictions and specifications laid down in Annex I concerning the use of recycled plastic materials or articles manufactured with a suitable recycling technology, and, where relevant, restrictions and specifications laid down in the authorisation concerning the use of recycled materials 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 materials 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, including waste discarded from a recycling scheme in accordance with Article 9(6);
- (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 packaging waste fractions of municipal waste or with other non-packaging plastic, metal, paper or glass fractions of municipal waste collected separately from residual waste for recycling, and the following requirements are met:
  - (i) the collection system collects only non-hazardous waste;
  - (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;

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 the conditions and requirements set out in paragraph 1 and 2 are met;
- (b) ensure traceability of each batch up to the point of the first sorting of collected plastic waste; and,
- (c) 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 the 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, if applicable, the specific criteria set out in the authorisation.
2. The decontamination process shall be carried out in accordance with the relevant specifications and requirements laid out in column 8 of table 1 of Annex I and, if applicable, the specific criteria set out in the authorisation. 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 5 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 the supplying 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(6).
2. Food business operators shall use recycled plastic materials and articles in accordance with the instructions received in accordance with Article 5(6).

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 such instructions are not apparent from labelling already applied to those materials and articles.

#### 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 established 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 schemes are located, and references to any decontamination installations used by the scheme. Thereafter, the manager shall ensure this information is kept up to date.

2. A compliance monitoring summary sheet shall not be established, and 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 column 8 of Table 1 of Annex I requires to establish it. In case Article 25(1)(c), and Article 26 do not apply, 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. At use stages during which their contact with food is intended or foreseeable, all materials and articles used subject to a recycling scheme shall be labelled with 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 these requirements 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, unless column 9 of Annex I provides for derogation to this requirement.

9. Business operators and other organisations that participate in a recycling scheme:

- (a) shall 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>(1)</sup>, applying these procedures *mutatis mutandis* to contamination hazards of the plastic.

#### CHAPTER IV

### DEVELOPMENT AND LISTING OF RECYCLING 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 6 months prior to the start of the operation of the first decontamination installation operated on the basis of Article 4(3)(b), the developer shall notify the competent authority in the territory where the developer is established 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 paragraph 4 and Article 13(4), and the names and addresses or numbers of any recycling facilities at which the development of the technology is foreseen to take place.

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(2);
  - (b) an explanation of any deviations from the requirements set out in Articles 6, 7 and 8, or whether the novel technology applies a recycling scheme;
  - (c) extensive reasoning, and scientific evidence and studies, compiled by the developer, demonstrating that the novel technology can manufacture recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 ensuring also their microbiological safety, including a characterisation of contaminant levels in the plastic input and in the recycled plastic, a determination of the decontamination efficiency, and of the transfer of these contaminants from the recycled plastic materials and articles to the food, and reasoning on why the applied concepts, principles, and practices are sufficient for meeting those requirements;
  - (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, an explanation of the used 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 technologies and is to be considered novel;
  - (f) a summary proposing evaluation criteria to the Authority for its potential future evaluation of recycling processes that apply the novel technology on which the installation is based as required in Article 20(2);

<sup>(1)</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).

- (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.

For the purposes of point (c), the data used to determine the decontamination efficiency shall be obtained either by the operation of a pilot installation, or originate from commercial production of recycled plastics not intended for contact with food. Where needed to fully establish the safety of the plastic materials and articles, the data shall be complemented by tests designed to assess the concepts, principles, and practices specific to the technology. Where the plastic input may contain plastics not produced in compliance with Regulation (EU) No 10/2011, the evidence required shall demonstrate that the technology removes substances that were used in the manufacture of those plastics to the extent necessary to ensure the requirement in Article 4(2) is met.

The information referred to in the first and second 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 14.

4. At the time of the notification, the recycler shall also publish a detailed initial report on its website using the URL provided in accordance with paragraph 2, concerning the safety of the manufactured plastic based on the information provided in paragraph 3. That report may omit details of recycling processes and installations that use the novel technology as far as these details are justifiably of commercial relevance, and shall provide a robust summary containing all information necessary to make an independent assessment of the technology without the need to consult the information contained in more detailed reports and studies;

5. 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.

6. Where a technology applies a recycling scheme 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.

7. 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.

8. A competent authority that was notified in accordance with paragraph 2 shall verify within 5 months from the notification whether the requirements set out in paragraphs 1 to 7 are met, and verify the requirements forthcoming from paragraph 8 regularly thereafter.

In case the competent authority considers these requirements are not met, it shall notify its concerns to the developer, and it may instruct the developer to delay the start of the operation of the first decontamination installation in accordance with paragraph 2 until the developer addressed those concerns.

The developer shall inform the competent authority of the way it addressed the concerns or clarify why it considers that no action is necessary.

In case the competent authority has serious concerns over the safety of the recycled plastic materials and articles, the competent authority shall notify the Commission.



*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. The recycler shall comply with the administrative requirements set out in Article 25.
3. 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 Article 6, 7 and 8, or use a recycling scheme in accordance with Article 9, provided each deviation or the use of that scheme is justified by the explanation provided in accordance with Article 10(3)(b).
4. 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 and is microbiologically safe.
5. 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(5).
6. 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 10628-1:2014, showing only the instrumentation relevant for decontamination; .
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, and information on other kinds of contamination and the levels thereof, in particular where on the basis of Article 11(3) the plastic input does not meet one or more of the requirements set out in Article 6;
  - (b) information on the amount or percentage of the contamination that the decontamination process can remove ('the decontamination efficiency');

- (c) information on estimated residual 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(7).

#### Article 13

### Monitoring and reporting of contamination levels

1. A recycler operating a decontamination installation in accordance with Article 11 shall monitor the average contamination level on the basis of a robust sampling strategy which samples the plastic input batches and the corresponding decontaminated output batches. The sampling strategy shall take account of all factors potentially affecting the composition of the plastic input, and particularly address variations in the origin thereof, whether geographic or otherwise.

The sampling shall initially include all input batches and corresponding output batches, but the sampling frequency may be reduced once stable averages are obtained. The sampling frequency shall in any case be maintained at a suitable level to detect trends and/or other changes in the contamination levels of the input batches, and to identify whether the presence of contaminants is reoccurring.

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.

Residual contaminant levels in the output shall be determined before any dilution of the output material by addition of other material. Where contaminant levels in the output are below the level of quantification of the applied analytical methods for monitoring, the monitoring of the output may be replaced with one or more studies that determine the residual contaminant level in a limited number of output batches with analytical methods with a limit of quantification sufficiently low for determining the real decontamination efficiency obtained in the decontamination installation. In case residual contamination in the output is so low that quantification thereof is not possible, the level of detection of those methods shall be sufficiently low to support reasoning on whether the decontamination efficiency is sufficient to ensure that recycled plastic materials and articles comply with Article 3 of Regulation (EC) No 1935/2004.

2. For the analyses and tests required to determine the contamination level in accordance with paragraph 1, laboratories performing these activities shall take part regularly and with satisfactory performance in proficiency tests appropriate for this purpose. The first time a laboratory participates in such a proficiency test shall be before the start of the operation of the recycling facility.

3. Recyclers shall provide the developer at least every 6 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.

4. The developer shall publish every 6 months a report on its website, based on the latest information from all installations using the novel technology received in accordance with paragraph 3.
5. 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), including the information required under points (a), (b), (d) and (f) thereof;
  - (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 comply with Article 3 of Regulation (EC) No 1935/2004 and that are microbiologically safe on the basis of the information included in points (a) to (f) of Article 10(3), and taking into account the information received in accordance with paragraph 3;
  - (c) a list of all substances with a molecular weight below 1 000 Dalton 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 incidental contaminants in the input have been identified, and their amounts specified as weight fraction of the input and output;
  - (d) a list of contaminating materials regularly present in the plastic input, including polymer types that differ from that in the intended plastic input, 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 substances of concern 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 applied sampling strategy;
  - (h) a detailed description of the analytical procedures and methods used, including sampling procedures and limits of detection and quantification, as well as validation data and reasoning on their suitability;
  - (i) 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).
  - (j) a discussion of the differences with previous reports 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(4) 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 2 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 include the efficiency of the employed chemical and/or physical principles to decontaminate a specified plastic input so that the plastic materials and articles manufactured from recycled plastic obtained from the novel technology comply with Article 3 of Regulation (EC) No 1935/2004. It shall also include the microbiological safety.

4. Within 1 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(2);
- (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).

5. Where the Authority considers that it needs to involve new experts to assess a novel technology, it may extend the period provided for in paragraph 3 by up to 1 year.

6. 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 one, several, or all developers as appropriate for the purposes of the assessment.

7. The Commission may decide to adjust the time limits referred to in paragraph 3, 4 and 5 for the assessment of a specific novel technology, after consultation of the Authority and of the developers of that technology.

8. Articles 39 to 39e of Regulation (EC) No 178/2002 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.

9. 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 whether it shall be included in an existing 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 it shall include the use of a recycling scheme.

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 recycling 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.

5. Where the Commission decides that a recycling technology is unsuitable, Article 15(3) shall apply.

## 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 converters 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 10628-1:2014, 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 6 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 (EC) No 1935/2004 and are microbiologically safe.

The Authority may extend the time limit provided for in the first subparagraph by a maximum period of a further 6 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 assigned in table 1 of Annex I 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 comply with Article 3 of Regulation (EC) No 1935/2004 and are microbiologically safe, 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 recycling technology it applies and produces recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 and are microbiologically safe.

The Commission shall prepare a draft decision to be 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>(12)</sup> shall apply.

Where the draft 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 recycled plastic originating from the process.

#### Article 20

### Guidance published by the Authority

1. The Authority shall publish detailed guidance, 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 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.

2. For each suitable recycling technology for which the authorisation of individual recycling processes is required, the Authority shall publish scientific guidance describing the evaluation criteria and the scientific evaluation approach it will use to evaluate the decontamination capability of those recycling processes. The guidance 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 the recycling process, 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.

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<sup>(12)</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).



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, or to other information included in the register established in accordance with Article 24, 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), including the information of the technical dossier already submitted during the original application in accordance with Article 17(5) and Article 18(2), updated with the modifications. All modifications (deletions and additions) shall be clearly marked and visible in the technical dossier;
  - (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 of 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. 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 URL referred to in Article 10(2);
- (b) the names of authorised recycling processes and the names and addresses of the authorisation holders, and on which technology each process is based;
- (c) the authorisation status of each registered recycling process, 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 they apply, if any;
- (g) the registration status of decontamination installations, including whether the status 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');
- decontamination 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 30 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 is located or the recycler, as relevant, is established.

#### 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 1 month from the start date of the production of recycled plastic with that installation. The competent authority shall notify the reception of the compliance monitoring summary sheet without delay to the Commission. 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 (g), shall change to 'active'.

4. If the competent authority does not inform the Commission that compliance is established within 1 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 1 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) at least 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 recycling technology applied and the recycling process used, or with the requirements applicable to the novel technology applied, or,
  - (c) where relevant, it could not verify the compliance monitoring summary sheet in accordance with Article 24(3) within 1 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 2 months, the suspension shall be indicated in the Union Register in accordance with Article 24(2)(g).

## 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 (EC) 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 suitable 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 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. Applications submitted in accordance with Regulation (EC) No 282/2008 for the authorisation of recycling processes based on a recycling technology that is not included as a suitable recycling technology in Annex I at the time of entry into force of this Regulation and for product loops which are in a closed and controlled chain shall be deemed terminated.
3. 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 10 July 2023, unless manufactured with a recycling installation that is operated for the purpose of development of a novel technology in accordance with Chapter IV.
4. For the purposes of this Regulation, the start date of a decontamination installation that was used to produce recycled plastic before 10 October 2022 shall be 10 December 2022 for a decontamination installation which is based on a suitable recycling technology, or 10 June 2023 for a decontamination installation that is operated for the purpose of development of a novel technology in accordance with Chapter IV.
5. By derogation to the time limit specified in Article 10(2), developers of technologies already in use to manufacture recycled plastic materials and articles before 10 October 2022 shall provide the information required in accordance with Article 10(3) and publish the report required in accordance with Article 10(4) before 10 April 2023. The time limit of 5 months referred to in the first subparagraph of Article 10(8) shall apply from the date on which the competent authority receives the information in accordance with Article 10(3). The possibility for a competent authority to delay the start of the operation of the first decontamination installation set out in the second sub-paragraph of Article 10(8) shall not apply.
6. Food business operators may use recycled plastic materials and articles legally placed on the market to pack food and place that on the market until exhaustion of stocks.

*Article 32***Specific transitional provisions applicable to the manufacture of materials and articles in which the recycled plastic is used behind a functional barrier**

1. The following additional requirements shall apply to the operation of recycling installations that already manufactured recycled plastic materials and articles in which the recycled plastic is used behind a plastic functional barrier before 10 October 2022:
  - (i) the decontamination installation manufacturing the recycled plastic as well as any post-processing installation adding the functional barrier is included in a list of installations submitted by a developer notifying the specific recycling technology applied by all the installations on the list in accordance with Article 10(2); and,
  - (ii) results from migration tests, challenge tests, and/or migration modelling, as appropriate and applicable to the notified recycling technology and to the specifics of the process that the recycling installation applies, unequivocally show that the functional barrier is capable, taking into account the contamination level of the recycled plastic, of acting as a functional barrier in accordance with Regulation (EU) No 10/2011 during the foreseeable shelf-life of the manufactured recycled plastic materials and articles, which comprises the time from their manufacture onwards, and the maximum shelf-life of the packaged food, if any.

The developer shall communicate the list referred to in point (i) and a study report incorporating the test results required under point (ii) to the competent authority and to the Commission before 10 April 2023. A robust summary of the study shall be part of the initial report published in accordance with Article 10(4).

2. Individual recyclers, converters or other operators participating in the manufacture of the materials referred to in paragraph 1 shall not act as developer in accordance with point (i) thereof. In case the developer of a specific technology is the individual recycler, converter or other operator using the installation or part thereof, or may not be identified, does no longer exist or is not willing to assume the obligations laid down in this Regulation, at least one of the operators using the installation shall join a consortium or association that can act as developer on its behalf, or ask an independent third party to act as developer. Where a consortium, association or third party receives multiple requests from such operators, it shall group these requests on the basis of the technical equivalence of the applied recycling installations and processes with the purpose to minimise the number of technologies it notifies.

3. By derogation to Article 13(1), recyclers operating decontamination installations notified by the same developer may agree to monitor the contamination levels in only a third of the installations included in the list provided in accordance with point (i) of paragraph 1, provided that the installations where the monitoring is carried out are designated on that list, monitoring is carried out at all recycling facilities, and the robustness of the overall sampling strategy is not reduced.

#### *Article 33*

#### **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)(c) and 13(2) shall apply from 10 October 2024.

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

Done at Brussels, 15 September 2022.

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

**Suitable Recycling technologies as referred to in Article 3**

Table 1 contains the following information:

Column 1: number assigned to the recycling technology;

Column 2: name of the recycling technology;

Column 3: types of polymer that the recycling technology allow to recycle;

Column 4: short description of the recycling technology and reference to a detailed description in Table 3;

Column 5: the type of input that the recycling technology can decontaminate, where

— PCW: 'post-consumer waste' means plastic waste collected in accordance with Article 6;

— FG: 'food-grade' means plastic that was as primary material compliant with Regulation (EU) No 10/2011;

— 'Non-food PCW' means packaging that was not used to package food and may not have been manufactured in full compliance with Regulation (EU) No 10/2011 and other post-consumer plastic materials which were not intended for contact with food;

— 'Non-food %' (% w/w) means the maximum amount of non-food PCW present in the input;

Column 6: the type of output manufactured with the recycling technology;

Column 7: if 'yes' is indicated in column 7, individual recycling processes shall be authorised in accordance with Articles 17 to 19;

Column 8: reference to Table 4 on specifications and requirements applicable to the use of the technology in accordance with Article 4(4)(b), supplementing the requirements in Article 6 to 8;

Column 9: derogations from Articles 6 to 8 in accordance with Article 4(4)(b), and derogations from Article 9(8);

Column 10: if 'yes' is indicated in column 10, the recycling technology shall only be used as part of a recycling scheme in accordance with Article 9



Table 1

## List of suitable recycling technologies

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Recycling technology number	Technology name	Polymer type (detailed specification in Table 2)	Short description of the recycling technology (detailed specification in Table 3)	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes	Specifications and requirements (reference to Table 4)	Derogations (reference to Table 5)	Recycling scheme applies
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances.	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	Yes	-	-	No
2	Recycling from product loops which are in a closed and controlled chain	All polymers manufactured as primary materials in compliance with Regulation (EU) No 10/2011	Basic cleaning and microbiological decontamination during remoulding (3.2)	Chemically uncontaminated plastic materials and articles produced from a single polymer or from compatible polymers which were used or intended for use under the same conditions of use and solely obtained from a product loop which is in a closed and controlled chain, and excludes collection from consumers	Remoulded materials and articles intended to be used for the same purpose and under the same conditions of use as the materials and articles circulated in the recycling scheme from which the plastic input was obtained.	No	4.1	-	Yes

Table 2

**Detailed specification of polymers**

Reference number	Acronym	Resin number and/or Recycling symbol, if any <sup>(1)</sup>	Detailed specification for the purposes of this Regulation
2.1	PET	1	polyethylene terephthalate polymer made by the polycondensation of the comonomers ethylene glycol and terephthalic acid or dimethyl terephthalate, of which the polymeric backbone contains up to 10 % w/w other comonomers listed in Table 1 of Annex I to Regulation (EU) No 10/2011, such as isophthalic acid and diethyleneglycol

<sup>(1)</sup> As defined in Decision 97/129/EC, ASTM D7611 or GB/T 16288-2008.

Table 3

**Detailed description of the decontamination technology**

Reference number	Name	Detailed description
3.1	Mechanical recycling	<p>This recycling technology recovers collected plastics via mechanical and physical processes, typically sorting, grinding, washing, separating materials, drying, and re-crystallisation to produce plastic input which retains the chemical identity of the collected plastic.</p> <p>The critical stage of this recycling technology is the decontamination during which the plastic input is subjected for at least a minimum time to heat, and a vacuum or flowing gas, in order to remove incidental contamination down to a level that is without health concern. This stage may be followed by further recycling and conversion stages, such as filtration, re-granulation, compounding, extrusion and moulding stages.</p> <p>The use of this recycling technology retains the polymeric chains that constitute the plastic, and may increase their molecular weight. A small unintentional decrease in molecular weight may also occur.</p>
3.2	Recycling from product loops which are in a closed and controlled chain	<p>A recycling technology that recycles plastic input only originating from entities participating in closed cycles consisting of manufacturing, distribution or catering stages, and which participate in a recycling scheme in accordance with Article 9.</p> <p>Plastic input originates only from materials and articles that are intended and used for food contact, and any contamination other than surface residues from food and labelling, can be ruled out. The plastic input may contain shredded materials and articles, as well as off-cuts and scraps from the production of plastic materials and articles. The scheme excludes the collection of materials and articles as plastic input if these have been provided to consumers for use outside of the premises and/or control of the entities participating in the recycling scheme.</p> <p>The decontamination technology applied as part of this recycling technology provides for microbiological decontamination by high temperature during remoulding preceded by basic surface cleaning by washing or other means suitable for preparing the material for remoulding. In addition it may add new plastic to prevent quality loss of the recycled plastic that would make it unsuitable for the use that it was intended for.</p> <p>The recycled plastic is used only for manufacturing plastic materials and articles for contact with the same foods and under the same conditions as the collected materials and articles were intended for, and for which compliance to Regulation (EU) No 10/2011 was initially verified.</p>

Table 4

**Specifications and requirements applicable to the use of the technology in accordance with Article 4(4)**

Reference number	Specifications/requirements
4.1	<p>(a) the technology and its operation shall fully correspond with the description provided in point 3.2 of Table 3;</p> <p>(b) where materials are subject to re-use within the distribution chain, without recycling operations, they shall be cleaned regularly and sufficiently to prevent the build-up of residues originating from food, usage and labelling;</p> <p>(c) the use, re-use, cleaning in accordance with point (b), and recycling shall be implemented in a way designed to prevent incidental contamination of the plastic input that cannot be removed with surface cleaning;</p> <p>(d) the use of any labelling or printing on the plastic materials and articles which cannot be fully removed with the cleaning applied before remoulding shall be excluded;</p> <p>(e) the document provided in accordance with article 9(3) shall provide explicit instructions and procedures to food business operators participating in the recycling scheme to prevent the introduction of external material and incidental contamination;</p> <p>(f) the plastic input and the recycled plastic shall at all times fully comply with Regulation (EU) No 10/2011; accumulation of constituents of the plastic material, present due to repeated recycling, such as residues of additives, or degeneration products, shall be considered non-intentionally added substances in accordance with Article 6(4)(a) of Regulation (EU) No 10/2011. Their presence shall not exceed a level that is regarded as unsafe in a risk assessment in accordance with article 19 of that Regulation. Where needed to ensure the quality of the recycled plastic materials and articles, new plastic manufactured in accordance with that Regulation shall be added;</p> <p>(g) there is documented scientific evidence demonstrating that the plastic materials and articles recycled as part of the scheme do not pose a risk to human health due to:</p> <ul style="list-style-type: none"> <li>— accumulation of constituents of the plastic material, such as residues of additives, or degeneration products resulting from repeated recycling; or</li> <li>— the presence of common residues from other sources such as food, detergents and labelling</li> </ul>

Table 5

**Derogations applicable to the use of the technology in accordance with Article 4(5)**

Reference number	Specifications/requirements

## ANNEX II

**Template for the Compliance Monitoring Summary Sheet in accordance with Article 26 of Regulation (EU) 2022/1616**

The template shall be completed taking account of the definitions set out in Regulation (EC) No 2023/2006 on good manufacturing practices, and Annex B thereto.

Abbreviations used in this document in accordance with Regulation (EC) No 2023/2006:

QA: Quality Assessment

SOP: Standard Operating Procedure

SOP code: a SOP code is comprised of two numbers, the number of the SOP and the number of the document in which it is described in the format SOPNr – DocNr; the document number shall correspond to the document number listed in Section 2.3, the SOP number to the numbering system of the recycler.

1. SECTION 1: IDENTIFICATION

The numbers (RIN, RFN, RON, RAN, NTN) referred to in this section shall correspond to the numbers in the Union Register laid down in accordance with Article 24 of Regulation (EU) 2022/1616.

1.1 **Identification of the recycling installation**

Installation name	
Applied recycling technology in accordance with Annex I	
EU Register number (recycling installation number, 'RIN')	
Facility Address	
Recycling Facility Number ('RFN')	
Contact details	
Position/Role of contact persons	
Relevant national register numbers, if any	
Notification date (Article 25(1)(a))	

1.2. **Identification of the recycler**

Company Name	
EU Register number (Recycler Operator Number, 'RON')	
Address of the head office	
Contact details	
Position/Role of main contact person	
Relevant national register numbers, if any	
Authorisation holder? (Yes/No/Not applicable)	

### 1.3. Recycling process authorisation Decision or novel technology

A: identification of the authorisation Decision or novel technology used by the process that the installation applies:

EU Register number, i.e. Recycling Process Authorisation Number ('RAN'), Novel Technology Number ('NTN')	
--	--

B: authorisation holder or novel technology developer

Name of authorisation holder (*)/ of the technology developer (**) as applicable	
Address	
Contact details	
Position/Role	

(\*) The name of the authorisation holder and its address must be the same as on the authorisation Decision.

(\*\*) The technology developer that notified the novel technology used by the process which the installation applies, in accordance with Article 10(2).

### 1.4. Document references used by the European Food Safety Authority ('EFSA')

EFSA Question number	
EFSA Publication date of the opinion	
EFSA Publication number (output number)	
Confidentiality Decision number	
Confidentiality Decision date	

### 1.5. Additional responsible person(s) for the operation of the recycling installation

Name	Position/Role	Contact details

## 2. SECTION 2: OPERATION OF THE RECYCLING INSTALLATION

### 2.1. Written Statements

A maximum of 3 000 characters including spaces shall apply both to Sections 2.1.1 and 2.1.2

#### 2.1.1 Recyclers' statement explaining the production and quality of the recycled plastic

#### 2.1.2. Recycler's statement explaining correspondence to the authorised process

This section is applicable only to authorised processes.

## 2.2 Recycling operations at the recycling facility

The following information shall be provided in this section:

- A diagram of the main manufacturing stages that are part of the recycling process and which are carried out at the recycling facility ('site diagram');
- A table describing those manufacturing stages and the material streams connecting them carried out at the recycling facility and corresponding to that diagram.

### 2.2.1. Diagram of the main manufacturing stages carried out at the recycling facility (site diagram)

### 2.2.2. Description of the main manufacturing stages carried out at the recycling facility and the streams connecting them

Stage Number	Name	Description	Average Processed Tonnage per year
Stream Number	Name	Description	Average Stream size

## 2.3. Internal Documents

Provide a comprehensive list of documents relevant to the operation of the process and quality management and other administrative procedures related thereto, as well as documents related to the authorisation. The documents shall be numbered and these numbers shall be used in Section 3 to refer to these documents. The recycler may apply its own numbering system.

Document type	Document Number	Related production stage	Title	Description	Date, version, author

## 2.4. Batch definitions

The following batches shall be defined in accordance with the table below:

- Entry Batch: the unprocessed plastic entering the recycling facility from suppliers;
- Input Batch: input plastic processed at the facility entered at the decontamination stage;
- Output Batch: the recycled plastic resulting from the decontamination stage; and,
- Exit Batch: the recycled plastic (or recycled plastic materials and articles) leaving the facility for further processing or use.
- Any other intermediate batches corresponding to a QA check.

Where either the entry or input batch is the same because no further QA checks take place, only the input batch shall be defined. The same approach shall be used for the output and exit batches. Where there are different types of entry and or exit batches, these shall be defined separately, and be given a meaningful name.

The QA shall be numbered in the same way as in the site diagram (Section 2.2.1)

Batch type	Internal Batch name	Stream/QA No	Definition/Description	Typical size range	Traceability rule

**2.5. Process diagram of the decontamination installation**

Add a piping and instrumentation diagram in accordance with Section 4.4 of ISO 10628-1:2014, taking account of ISO 10628-2.

**2.6. Control of critical decontamination operations**

The table below shall include a reference to steps, stages, or operations that EFSA identified as critical, a control criterion for each critical parameter, the involved control instruments, and the description of corrective actions in case the control criterion fails. Further information of the evaluation of complex control rules shall be added if relevant.

Critical operation (and ref to EFSA opinion)	Control criterion	Measuring or Control Instrument (reference to 2.5)	Short description of corrective actions if control rule is not met	SOP code (SOPNr – DocNr)

*2.6.1. Further information on complex control rules, where relevant*

**2.7. Relevant standard operating procedure for Operation**

The table below shall provide a reference to each SOP used for the operation of the installation, provide a short description thereof, and indicate the location where it is carried out.

SOP code	Short description	Location)

**3. SECTION 3: QUALITY ASSESSMENT**

**3.1. List of quality assessment stages**

Each QA stage shall be described using the table below:

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code (SOPNr – DocNr)

There shall be at least four stages (unless there is no difference between entry and input or output and exit – see Section 2.4):

- entry stage (the first QA stage where the material enters the facility),
- input stage (where the plastic input enters the decontamination process)
- output stage (where the material leaves the decontamination process)
- exit stage (where the recycled plastic or the recycled plastic materials and articles leave the facility)

Additional intermediate stages shall be added where relevant for the quality of the material in other stages. Those intermediate stages shall be given a meaningful name.

### 3.2. Relevant standard operating procedures applied at QA stages

The table below shall provide a reference to each standard operating procedure used at QA stages, provide a short description thereof, and indicate the location where it is carried out.

Quality Assessment (QA) No (ref 3.1)	SOP code (SOPNr – DocNr)	Short description	Location (of QA)

## 4. SECTION 4: RECORD REPOSITORY

### 4.1 Quality assessment recording systems

Quality Assessment No (ref 3.1)	Name	Definition/Description	Location	Backup	SOP Code (SOPNr – DocNr)	Modification prevention

### 4.2. List of standard operating procedures codes for recording system

Quality Assessment No (ref 3.1)	SOP code (SOPNr – DocNr)	Short description	Location (of entry into recording system)

### 4.3. Other relevant records/systems

Procedure	Description/Documentation



ANNEX III

**Templates for declaration of compliance**

PART A

**Declaration of compliance to be used by recyclers**

RECYCLERS DECLARATION of COMPLIANCE with REGULATION (EU) 2022/1616

I, the undersigned, declare in name of [ADD NAME OF RECYCLER] as identified in Section 1.1, that the recycled plastic material identified in Section 1.2 was produced in accordance with Regulation (EU) 2022/1616. The recycled material to which this declaration applies is suitable for use in contact with food, provided it is used in accordance with the restrictions set out Section 3 of this declaration, and with the instructions in this declaration and with the labelling on the product.

Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) 2022/1616.

Section 1: Identification

1.1 Recycler		1.2 Recycled product		1.3 Competent authority	
1.1.1 Name		1.2.1 Tradename / designation		1.3.1 Name	
1.1.2 FCM-RON *		1.2.2 Batch No		1.3.2 Address	
1.1.3 Country		1.2.3 FCM-RIN *		1.3.3 Country/region	
1.1.4 FCM-RFN *		1.2.4 Other information		1.3.4 assigned Registration Number	

Section 2: Compliance

2.1 Basis for authorisation or permission to operate (tick one box only)

2.1.1	<input type="checkbox"/>	Authorisation Decision	RAN *
2.1.2	<input type="checkbox"/>	Recycling scheme	RSN *
2.1.3	<input type="checkbox"/>	No authorisation or recycling scheme required	
2.1.4	<input type="checkbox"/>	Novel technology	NTN *

2.2 Results of compliance assessment as listed in the compulsory quality assessment stages in Table 3.1 of Annex II; compulsory only if 2.1.1 ticked

Important: Fields 2.2.2 to 2.2.4 may be left blank, provided field 2.2.5 is ticked

Stage **	Decision criteria and outcome(s)	Batch Number(s)
2.2.1 Exit		
2.2.2 Entry		
2.2.3 Input		
2.2.4 Output		
2.2.5	The undersigned confirms that the information required in fields 2.2.2 to 2.2.4 will be made available to competent authority upon its request, within 3 working days	<input type="checkbox"/>

### Section 3: Instructions and information to users of the product

3.1	Instructions to converters	
3.1.1	Maximum recycled content (w/w %)	%
3.1.2	Present recycled content (w/w %)	%
3.1.3	Restrictions of use **	
3.1.4	Other instructions	
3.2	Instructions to users further down the supply chain, including end users	
3.2.1	Restrictions of use **	
3.2.2	Summary of labelling	
3.2.3	Other instructions	

### Section 4: Signature

4.1	Signature and company stamp
4.2	Name of person signing
4.3	Role/position of person signing
4.4	Date and place

- \* RAN – recycling authorisation number; RON – recycling operator number (recyclers); RIN – recycling installation number; RSN – recycling scheme number; NTN – novel technology number; RFN – Recycling facility number.
- \*\* Filling out the fields for the exit stage (the batch that is placed on the market and which is accompanied by this declaration) is compulsory. The completion of the other fields is voluntary, but in case this information is not provided by means of this declaration, it shall be made available to a competent authority, upon its request, within 3 working days.
- \*\*\* Restrictions of use shall correspond to any applicable conditions in the field of application of the recycled plastic, in accordance with Annex I for the applied technology, Article 7, 8, or 9, the Authorisation of the recycling process, if any, or any other restriction the recycler deems necessary.

PART B

**Declaration of compliance to be used by converters if the converted plastic material contains recycled plastic**

CONVERTERS DECLARATION of COMPLIANCE with REGULATION (EU) 2022/1616

I, the undersigned, declare in name of [ADD NAME OF CONVERTER] as identified in Section 1.1, that the recycled plastic material identified in Section 1.2 was produced in accordance with Regulation (EU) 2022/1616. The recycled material to which this declaration applies is suitable for use in contact with food, provided it is used in accordance with the restrictions set out Section 3 of this declaration, and with the instructions in this declaration and with the labelling on the product.

Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) 2022/1616.

Section 1: Identification

1.1 Converter		1.2 Product with recycled plastic		1.3 Competent authority	
1.1.1 Name		1.2.1 Tradename/ designation		1.3.1 Name	
1.1.2 Address		1.2.2 Batch No		1.3.2 Address	
1.1.3 Country		1.2.4 Other info		1.3.3 Country/ region	
				1.3.4 Reg. number	

Section 2: Compliance

2.1

2.1.1	Origin of recycled plastic; RIN numbers	
2.1.2	Batch numbers recycled plastic from decontamination installation	
2.1.3	Maximum recycled content indicated by recycler (Part A, 3.1.1)	% w/w
2.1.4	Actual recycled content of this product	% w/w
2.1.5	Restrictions provided in the Declaration of compliance received from the recycler are met	<input type="checkbox"/>

2.1.6	Addition of additives or starting substances	<input type="checkbox"/> Added additives or starting substances comply with Regulation (EU) No 10/2011	<input type="checkbox"/> No additions
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## Section 3: Instructions and information to users of the product

3.2	Instructions to users further down the supply chain, including end users			
3.2.1	The product identified in Section 1.2 is a: (tick as applicable; both may apply)	(A) a recycled plastic for further conversion stages	<input type="checkbox"/>	
		(B) a final plastic material or article suitable for contact with food without further processing.	<input type="checkbox"/>	
3.2.2	Type or types of food with which it is intended to be put in contact			
3.2.3	Time and temperature of treatment and storage in contact with the food			
3.2.4	The highest food contact surface area to volume ratio for which compliance has been verified			
3.2.5	List of added substances with migration limits; add rows as required. (note: FCM Number and specific migration limit ('SML') may not exist for certain substances)	FCM No*	Other designation (CAS No, chemical name)	SML* (mg/kg food)
3.2.6	Other relevant information and instructions, including in accordance with points 7 and 9 of Annex IV to Commission Regulation (EU) No 10/2011 <sup>(1)</sup>			
3.2.7	The recycled plastic to which this declaration applies is contained in a layer in a multi-layer material or article subject respectively to Articles 13 or 14 of Regulation (EU) No 10/2011 that contains plastic manufactured in accordance with that Regulation in another layer or layers. A separate declaration of compliance in accordance with Article 15 of that Regulation regarding that layer or those layers is available and must be taken into account.	<input type="checkbox"/>		

## Section 4: Signature

4.1	Signature and company stamp	
4.2	Name of person signing	
4.3	Role/position of person signing	
4.4	Date and place	

<sup>(1)</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance (OJ L 12, 15.1.2011, p. 1).