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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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[(1)], and in particular Article 5(1) thereof,

After consulting the European Food Safety Authority (‘the Authority’),

Whereas:

(1) Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste[(2)] promotes the recovery and incineration at waste incineration plants with energy recovery and recycling of packaging waste.

(2) Regulation (EC) No 1935/2004 sets out the general principles for eliminating the differences between the laws of Member States as regards materials and articles in contact with food and provides in Article 5(1) for the adoption of specific measures for groups of materials and articles. That Regulation identifies that harmonisation of rules on recycled plastic materials and articles should be given priority.

(3) Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs[(3)] sets out rules for plastic materials and articles which are intended to come into contact with foodstuffs.

(4) Plastic packaging waste may contain residues from previous use, contaminants from misuse and contaminants from non-authorised substances. Therefore it is necessary to lay down special requirements to ensure that materials and articles produced from recycled plastics and intended for food contact respect the requirements of Article 3 of Regulation (EC) No 1935/2004.

(5) 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[(4)] lays down rules on good manufacturing practice for groups of materials and articles intended to come into contact with food listed in Annex I to Regulation (EC)

No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.

(6) Plastic waste can be treated mechanically to produce recycled materials and articles or it can be broken down to monomers and oligomers by chemical depolymerisation. Monomers and oligomers resulting from chemical depolymerisation should not be treated differently from monomers manufactured by chemical synthesis. Therefore, they are covered by the authorisation of monomers and additives in Directive 2002/72/EC and they should comply with the specifications and purity criteria established therein. Therefore, they should not be covered by this Regulation.

(7) Offcuts and scraps from the production of plastic food contact materials, that has not been in contact with food or otherwise contaminated and is re-melted on the premises into new products or sold to a third party as part of a quality control system in compliance with the rules for good manufacturing practice laid down in Regulation (EC) No 2023/2006 would be considered as suitable for food contact applications and should not fall under the scope of this Regulation. All other offcuts and scraps from the production of plastic food contact materials should fall within the scope of the present Regulation.

(8) Recycled plastic used behind a plastic functional barrier as defined by Directive 2002/72/EC should not be covered by the authorisation procedure in this Regulation. The rules set out in Directive 2002/72/EC for substances used behind a plastic functional barrier are regarded as sufficient to ensure the safety also of recycled plastics used behind a functional barrier.

(9) Directive 2002/72/EC lays down lists of substances authorised to be used in the manufacture of plastic food contact materials or articles. These substances have been evaluated for their safety and migration limits have been set for their safe use. To ensure the same level of safety of recycled plastic materials and articles only authorised monomers and additives should be added to the recycled plastics and their migration limits should also be respected by recycled plastic food contact materials.

(10) Directive 2002/72/EC provides for a declaration of compliance and record keeping to ensure that relevant information on the safe use of the plastic material is passed on between business operators and to the competent authorities. Those general rules are also valid for recycled plastics; therefore, they should apply also to recycled plastic food contact materials and articles.

(11) Only the combination of characteristic of the input, sorting efficiency, and the effectiveness of the process to reduce contamination together with the defined use of recycled plastic ensure the safety of the recycled plastic material and article. They are specific to the type of plastic and the recycling process applied. It is only feasible to evaluate all these aspects together in individual evaluations of the recycling processes followed by individual authorisations.

(12) The safety of the recycled plastics can only be ensured if the recycling process is able to produce a reproducible quality of the recycled plastics. This can be controlled if an effective quality assurance system is applied. Therefore, only recycled plastics from a

recycling process managed by an effective quality assurance system should be placed on the market.

(13) Directive 2002/72/EC lays down the list of monomers and starting substance authorised to the exclusion of all others (positive list) to be used in the manufacture of plastic food contact materials or articles and, therefore, only materials and articles complying with the provisions laid down in Directive 2002/72/EC should be used as input for the recycling process. This can be achieved by sorting the plastic articles before recycling. For certain materials, such as polyolefines, due to their physico-chemical properties, 100 % sorting efficiency may be necessary to ensure recycled plastic that complies with the requirements of Article 3 of Regulation (EC) No 1935/2004. This sorting efficiency can be achieved in product loops which are in a closed and controlled chain. For other materials, for example, PET the safety of the recycled plastic can be ensured with a lower sorting efficiency as regards to its former use in food contact which is realistically achievable from kerbside collection systems. The sorting efficiency necessary for each material should be identified on a case by case basis.

(14) Plastic waste may be contaminated by substances from the previous use or incidental misuse of the plastics or by substances originating from non-food contact grade plastic. As it is not possible to know all possible types of contamination and as different types of plastics have different capacities to retain and release contaminants it is not possible to set defined characteristics for the final product applicable to all types of recycled plastics. Therefore a combination of input characterisation together with an adequate process to remove possible contamination is necessary to control the safety of the final product.

(15) In the mechanical treatment, in which the plastic waste is ground into small pieces and cleaned, special care has to be taken to remove these contaminations. The recycling process must demonstrate that it can efficiently reduce potential contamination to a level that does not pose a risk to human health. The contaminants should only migrate in levels comparable to or well below levels demonstrated in the challenge tests of that recycling process or in other appropriate analytical test and should comply with the requirements of Article 3 of Regulation (EC) No 1935/2004. A safety assessment should verify that the recycling process fulfils these conditions. Alternatively, for non-fillable materials and articles, such as crates and pallets that are handled in product loops in a closed and controlled chain in which all steps of manufacture, distribution and use are controlled, it may be sufficient to prove that contamination can be excluded when they are only used in contact with dry food such as fruits and vegetables.

(16) Certain types of plastic materials and articles manufactured with recycled plastics may only be suitable for contact with specified types of food under certain conditions. A safety assessment should identify these materials and articles and appropriate contact conditions.

(17) Differences between national laws, regulations and administrative provisions concerning the safety assessment and the authorisation of recycling processes, used in the manufacture of materials and articles intended to come into contact with food, may hinder the free movement of these materials and articles, creating conditions of unequal

and unfair competition. An authorisation procedure should therefore be established at Community level on the basis of the authorisation procedure provided for in Articles 9 to 12 of Regulation (EC) No 1935/2004.

(18) The authorisation procedure provided for in Article 9 to 12 of Regulation (EC) No 1935/2004 is intended for the authorisation of substances. Changes to that procedure should be introduced in the present Regulation to adapt the authorisation procedure to the authorisation of recycling processes. These changes are specific procedural rules as referred to in Article 5(1)(n) of Regulation (EC) No 1935/2004.

(19) A safety assessment of the recycling process should be carried out by the European Food Safety Authority (‘the Authority’). In order to inform the applicant of the data to be provided for the safety assessment, the Authority should publish detailed guidance concerning the preparation and the submission of the application.

(20) The safety assessment of the recycling process should be followed by a risk management decision as to whether this recycling process should be authorised. That decision should be adopted in accordance with the regulatory procedure described in Article 23(2) of Regulation (EC) No 1935/2004 so as to ensure close cooperation between the Commission and the Member States.

(21) The recycling process is company specific as regards technology and process parameters used. Therefore, only process specific authorisations should be granted. The authorisation procedure provided for in Articles 9 to 12 of Regulation (EC) No 1935/2004 should be adapted accordingly.

(22) It should be possible to apply the process in different production sites as long as technology and process parameters as described in the application and authorisation are adhered to.

(23) The public should be informed on the authorised recycling processes. For that purpose, a Community register, as referred to in Article 5(1)(m) of Regulation (EC) No 1935/2004, of recycling processes authorised under this Regulation should be established including the description of the field of application for the recycled plastic of the authorised process.

(24) The recycling and the converting plant should be subject to inspection and control by the Member State. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules[(5)] also covers official control on food contact materials. The most efficient way to control if the recycling process is applied as specified in the authorisation and to control if an effective quality assurance system is in place is the auditing of the recycling plant by the competent authorities. Therefore official controls performed to ensure compliance with this Regulation should include audits as specified in Article 10 of Regulation (EC) No 882/2004. The audits should be made in the most cost effective manner possible to keep to a minimum the administrative and economic burden to competent authorities and small and medium enterprises.

(25) To ensure an efficient control Member States and the Commission should be informed about the recycling or manufacturing sites in which the authorised recycling process is being applied.

(26) Industry should be enabled to label that their packaging contains recycled plastics. However, consumers should not be misled by labelling as regards recycled content. Rules for labelling of recycled plastics in relation to the content of recycled plastics have been laid down in EN ISO 14021. To ensure adequate information of the consumer when recycled plastics are labelled, they should follow transparent rules as those laid down in EN ISO 14021 or equivalent.

(27) Article 16 of Regulation (EC) No 1935/2004 requires a declaration of compliance for materials and articles. The converter of recycled plastic material and articles should declare that he is using only recycled plastic from an authorised process and that the final product respects Community and national provisions applicable to it, in particular Regulation (EC) No 1935/2004 and Directive 2002/72/EC. The recycler should provide the converter with the information that the recycled plastic is produced by an authorised process and specify its field of application. Therefore, both the finished recycled plastic materials and articles and the recycled plastic should be accompanied by a declaration of compliance. General information to be provided in the declaration is already laid down in Directive 2002/72/EC. Therefore, this Regulation should only specify the additional information in relation to the content of recycled plastics in the recycled plastic materials and articles.

(28) Since recycled materials and articles are already on the market in the Member States, provision should be made to ensure that the transition to a Community authorisation procedure is smooth and does not disturb the existing recycled plastic materials and articles market. Sufficient time should be allowed for applicants to make available to the Authority the information necessary for the safety assessment of the recycled plastic used in such products. Therefore, a certain time period, (the ‘initial authorisation phase’), should be fixed during which time the information for existing recycling processes should be submitted by the applicants to the Authority. Applications for authorisations of new recycling processes may also be submitted during the initial authorisation phase. The Authority should evaluate without delay all applications for existing, as well as new recycling processes for which sufficient information has been submitted during the initial authorisation phase.

(29) Specific requirements need to be set on the quality assurance system applied in recycling processes. As the quality assurance is part of the good manufacturing practice which is covered by Regulation (EC) No 2023/2006 the specific requirements on the quality assurance system should be included in the Annex to that Regulation.

(30) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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Article 1

Subject matter and scope

1 This Regulation shall apply to the plastic materials and articles and parts thereof intended to come into contact with foodstuffs as referred to in Article 1 of Directive 2002/72/EC which contain recycled plastic (hereafter 'recycled plastic materials and articles').

2 This Regulation shall not apply to the following recycled plastic materials and articles, provided that they have been manufactured according to good manufacturing practice, as laid down in Regulation (EC) No 2023/2006:

a recycled plastic materials and articles made with monomers and starting substances, derived from chemical depolymerization of plastic materials and articles;

b recycled plastic materials and articles made from unused plastic production offcuts and/or process scraps in compliance with Directive 2002/72/EC, that are recycled within the manufacturing site or are used at another site;

c recycled plastic materials and articles in which the recycled plastic is used behind a plastic functional barrier, as specified in Directive 2002/72/EC.

3 The plastic materials and articles that fall within the scope of this Regulation remain subject to Directive 2002/72/EC.

Article 2

Definitions

1 For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 1935/2004 and Directive 2002/72/EC shall apply.

2 The following definitions shall also apply:

a 'recycling process' means a process in which plastic waste is recycled pursuant to the definition of recycling in point 7 of Article 3 of Directive 94/62/EC on packaging and packaging waste; for the purpose of this Regulation, this term is limited to processes, in which a recycled plastic is produced;

b 'plastic input' means collected and sorted post-use plastic materials and articles used as input into a recycling process;

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

d 'challenge test' means a demonstration of the effectiveness of a recycling process to remove chemical contamination from plastic materials or articles;

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

f 'recycler' means the natural or legal person responsible for ensuring that the requirements of this Regulation, as regards the recycling process are met within the business under their control.

Article 3

Requirements for recycled plastic materials and articles

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

2 The authorised recycling process, referred to in paragraph 1 of this Article, shall be managed by an appropriate quality assurance system that ensures that the recycled plastic complies with the requirements set out in the authorisation.

That quality assurance system shall comply with the detailed rules laid down in the Annex to Regulation (EC) No 2023/2006.

Article 4

Conditions for the authorisation of recycling processes

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

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

(b) the plastic input must originate from plastic materials and articles that have been manufactured in accordance with Community legislation on plastic food contact materials and articles, in particular Council Directive 78/142/EEC of 30 January 1978 on the approximation of laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs[(6)] and Directive 2002/72/EC;

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

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

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

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

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Article 5

Application for authorisation of recycling processes and opinion of the Authority

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

2 The technical dossier shall contain the information specified in the guidelines for the safety assessment of a recycling process to be published by the Authority at the latest six months after the date of publication of this Regulation.

3 The Authority shall give an opinion within six months of receipt of a valid application as to whether or not the recycling process complies with the conditions laid down in Article 4.

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

a a short description of the recycling process;

b where appropriate, any recommendations on conditions or restrictions concerning the plastic input;

c where appropriate, any recommendations on conditions or restrictions concerning the recycling process;

d where appropriate, any criteria to characterise the recycled plastic;

e where appropriate, any recommendations concerning conditions in the field of application of the recycled plastic;

f where appropriate, any recommendations concerning monitoring compliance of the recycling process with the conditions of the authorisation.

Article 6

Authorisation of recycling processes

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

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

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

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

3 The Decision granting the authorisation shall include the following:

a the name of the recycling process;

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

c a short description of the recycling process;

d any conditions or restrictions concerning the plastic input;

e any conditions or restrictions concerning the recycling process;

f any characterisation of the recycled plastic;

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

h any requirements concerning monitoring of the compliance of the recycling process with the conditions of the authorisation;

i the date from which the authorisation is effective.

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

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

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

Article 7

Obligations arising from the authorisation

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

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

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

If necessary, the Authority shall then review the assessment.

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

Article 8

Modification, suspension and revocation of authorisation of a recycling process

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

2 The application referred to in paragraph 1 shall be accompanied by the following:

a a reference to the original application;

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

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

3 On its own initiative or following a request from a Member State or the Commission, the Authority shall evaluate whether the opinion or the authorisation is still in accordance with this Regulation, in accordance with the procedure laid down in Article 5, where applicable.

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

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

6 If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 6.

Article 9

Community register

1 The Commission shall establish and maintain a Community register of authorised recycling processes.

2 The register shall be made available to the public.

3 Each entry in the register shall include the information referred to in Article 6(3).

Article 10

Official control

1 The official control of a recycling plant and converter shall be performed in accordance with the rules laid down in Regulation (EC) No 882/2004 and shall include in particular audits as *control technique* as specified in Article 10 of Regulation (EC) No 882/2004.

2 The official control shall verify that the recycling process corresponds to the authorised process and that an effective quality assurance system in accordance with Regulation (EC) No 2023/2006 is in place.

3 The authorisation holder shall notify the competent authority in the Member State about the recycling or manufacturing site in which the authorised recycling process is being applied. Member States shall forward that information to the Commission.

Manufacturing or recycling sites in third countries shall be notified to the Commission.

The Commission shall make available and keep updated a register of recycling sites in the Community and third countries.

Article 11

Labelling of recycled plastic materials and articles

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

Article 12

Declaration of compliance and record keeping

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

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

Article 13

Transitional measures for the authorisation of recycling processes

1 For the initial authorisation phase of recycling processes, the procedure provided for in Articles 5, 6 and 7 shall apply subject to paragraphs 2 to 6 of this Article.

2 During the 18 months following the publication of the guidelines for the safety assessment of a recycling process of the Authority as provided for in Article 5(2), business operators seeking authorisation shall submit an application in accordance with Article 5.

3 The Commission shall make available to the public a register of recycling processes for which a valid application has been submitted in accordance with paragraph 2.

4 The Authority shall issue an opinion on each recycling process for which a valid application has been submitted during the period referred to in paragraph 2 of this Article. The deadline of six months for issuing the opinion, as referred to in Article 5(3), shall not apply.

5 Applications for which the Authority could not issue an opinion owing to the applicant's failure to comply with the time limits specified for submission of supplementary information in accordance with Article 10(2) of Regulation (EC) No 1935/2004 shall be excluded from consideration for the initial authorisation.

6 Within six months of receiving all the opinions referred to in paragraph 4, the Commission shall submit for opinion to the Standing Committee on the Food Chain and Animal Health draft decisions granting or refusing authorisation of the recycling processes referred to in paragraph 1.

Article 14

Transitional measures for the trade in and use of recycled plastic

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

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

Article 15

Amendment to Regulation (EC) No 2023/2006

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

Article 16

Entry into force

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

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

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

Done at Brussels, 27 March 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX I

PART A

Additional information in the declaration of compliance for recycled plastic materials and articles

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

A declaration that only recycled plastic from an authorised recycling process has been used listing the EC Register number of the authorised recycling process.

PART B

Additional information in the declaration of compliance for recycled plastic

The written declaration referred to in Article 12(2) shall contain the following additional information:

1. The declaration that the recycling process has been authorised listing the EC Register number of the authorised recycling process;
2. The declaration that the plastic input, the recycling process and the recycled plastic meet the specifications for which the authorisation has been granted;
3. The declaration that a quality assurance system according to Section B of Annex to Regulation (EC) No 2023/2006 is in place.

ANNEX II

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

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

A. Printing inks

(2) The following section is added:

B. Quality assurance system for plastic recycling processes covered by Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006

1. The quality assurance system implemented by the recycler must give adequate confidence in the capability of the recycling process to ensure the recycled plastic meets the requirements in the authorisation.
2. All the elements, requirements and provisions adopted by the recycler for his quality assurance system must be documented in a systematic and orderly manner in the form of written policy statements and procedures.

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

It must include, in particular:

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

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

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

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

(e) the tests and analytical protocols or any other scientific evidence applied before, during and after recycled plastic production, the frequency with which they will take place, and the test equipment used; it must be adequately possible to trace back the calibration of the test equipment;

(f) the recording documents adopted.

(**1**) OJ L 338, 13.11.2004, p. 4.

(**2**) OJ L 365, 31.12.1994, p. 10. Directive as last amended by Directive 2005/20/EC (OJ L 70, 16.3.2005, p. 17).

(**3**) OJ L 220, 15.8.2002, p. 18. Directive as last amended by Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17).

(**4**) OJ L 384, 29.12.2006, p. 75.

(**5**) OJ L 165, 30.4.2004, p. 1; corrected version (OJ L 191, 28.5.2004, p. 1). Regulation as last amended by Commission Regulation (EC) No 180/2008 (OJ L 56, 29.2.2008, p. 4).

(**6**) OJ L 44, 15.2.1978, p. 15.