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)

Article 1

Subject matter and scope

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

Article 2

Definitions

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

- 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⁽¹⁾ and Directive 2002/72/EC;
- (c) 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.

Article 5

Application for authorisation of recycling processes and opinion of the Authority

- 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.
- 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.

- 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.

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

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

- 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

- 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.
- 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.
- 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

- 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).
- 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

(1) OJ L 44, 15.2.1978, p. 15.