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)

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(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)

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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

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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

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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.

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(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: