European Food Safety Authority

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Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on

Guidelines on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food

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INTRODUCTION

According to the Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods (European Commission, 2008), hereafter referred to as "the Regulation", recycled plastics used to manufacture materials and articles intended for food contact shall be obtained only from processes authorised by the Commission following a safety assessment performed by the European Food Safety Authority (EFSA). The Regulation also states that the recycling process shall be managed by a quality assurance system (QAS) that has to meet the requirements laid down in the Annex of Regulation (EC) No 2023/2006 (European Commission, 2006).

The purpose of these guidelines is to give guidance to applicants wishing to obtain authorization for production processes of recycled plastics according to the "Regulation". It gives guidance on the administrative and technical data required and on the format of applications for the evaluation by the EFSA.

These guidelines apply to processes using mechanical recycling, whereby the collected plastics are ground into small pieces and decontaminated before being processed to new food contact materials. Chemical recycling processes, whereby the plastic is completely depolymerised into monomers and starting substances which are then reused in a polymerisation reaction are not in the scope of the Regulation and are not covered by these guidelines. Processes where the mechanical recycling is the main part of the whole process are in the scope of these guidelines provided that the plastic is not subsequently depolymerised.
In addition, these guidelines do not apply to the following materials which are not in the scope of the Regulation:

(i) recycled plastics used behind a plastic functional barrier, as specified in Directive 2002/72/EC[1,] (European Commission, 2002)

(ii) offcuts and scraps from the production of plastic food contact materials that have not yet been in contact with food and which are recycled within the manufacturing site or at another site where an audited quality assurance system is in place, that meets the requirements laid down in the Annex of Regulation (EC) No 2023/2006 (European Commission, 2006).

[1] According to the Commission Directive 2002/72/EC (European Commission, 2002), a plastic functional barrier means a barrier, consisting of one or more layers of plastic which ensures that the finished materials or articles are compliant with Regulation (EC) No 1935/2004, Art. 3 (European Commission, 2004), i.e. they do not transfer their constituents to food in amounts which could endanger human health or bring about unacceptable changes in the composition of the food or of its organoleptic properties.

GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD

The risks associated to the use of recycled plastic materials and articles in contact with foods come from the possible migration of chemicals such as:

- **Contaminants of the input**
    - **contaminants which may be introduced in the input stream by materials which are not suitable for food contact applications.** According to the Regulation, the plastic input shall originate from plastic materials manufactured in accordance with Community legislation on plastic food contact materials and articles. However if the sorting system is not completely efficient, the input stream may contain plastics manufactured from substances which have not been authorised for food contact applications (AFSSA 2007),
    - **incidental contaminants from previous uses including possible misuse.** Plastic containers designed for food may be misused by consumers who could use them to store chemicals which may be toxic and which may be present in the input (Begley *et al.*, 2002; FDA, 2002; FDA, 2006; Franz *et al.*, 2004a; Komolprasert and Lawson, 1994; Welle, 2005).
- **Chemicals used in the recycling process**, e.g. detergents, which may not be completely eliminated from the recycled plastic (AFSSA, 2007, Begley *et al.*, 2002, Welle, 2005).
- **Degradation products of the polymer or of plastic additives**. During the various steps of the recycling process, e.g. high temperature treatments, the polymeric chain may break down to smaller molecules and the additives may react and be converted into new compounds (Vilaplana *et al.*, 2007).

Chemicals are of concern if they are present in the recycled plastic and if they migrate into the food in amounts which could endanger human health (AFFSA, 2007; FDA, 2007, Pennarun *et al.*, 2005). The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are all crucial points for the risk assessment. Taking into account all potential sources of contamination of the input, it has to be demonstrated that the process is able to reduce it to levels not posing a risk to human health for the intended use of the final product (Franz *et al.*, 2004a; Komolprasert and Lawson, 1994; AFSSA, 2007; Coulier *et al.*, 2007; FDA, 2006).

The dossier submitted by the applicant shall include all the relevant information enabling the EFSA to perform a safety assessment. The EFSA will, where appropriate, issue opinions, recommendations, specifications or restrictions on the input, on the recycling process or on the use of the recycled plastic.

According to the Regulation, the QAS evaluation and audit will be performed by Member States and not by the EFSA. However, these guidelines do include a requirement for the QAS documentation to be provided when the applicant considers it relevant for the safety assessment.

It should be noted that these guidelines do not cover environmental aspects such as persistence in the environment, ecological impact of food contact materials constituents and their fate after the food contact material has been submitted to waste disposal treatment.

SUBMISSION OF AN APPLICATION

Applicants should note that competent authorities in Member States will get full access to any dossier submitted to the EFSA (Art. 9 of the Regulation (EC) No1935/2004) (European Commission, 2004). It should also be noted that there will be public access to applications except for the parts which are clearly marked as confidential. Information of direct relevance to the safety evaluation cannot be confidential. Only information which might significantly harm the competitive position of the applicant can be treated as confidential. In such a case verifiable justification must be provided (Art. 19 and 20 of Regulation (EC) No 1935/2004**)** (European Commission, 2004)**.**

Applications shall be submitted in accordance with Article 5 of the "Regulation". The applicant shall provide all available data relevant for the evaluation by the EFSA. For the purposes of the current guidelines, the definitions laid down in the "Regulation" shall apply.

The applicant should submit a dossier with the full information, both on paper and in electronic format on standard physical media (CD-ROM). It has to be declared by letter that the electronic and the paper versions are identical.

In addition to the complete version with the full information, applicants are requested to provide a second version of the CD- ROM without the confidential information. This version will be made available to anyone who might submit a request to the EFSA, according to Regulation (EC) No 1935/2004, Art. 19 (European Commission, 2004).

Any specific literature reference (such as scientific papers) mentioned and used to support the petition must be supplied in the dossier as full length paper. When reference is made to a book or to extensive publications, only the relevant parts need be supplied.

Applicants may deviate from the guidelines, provided valid and documented scientific reasons are given in the dossier. In all cases the EFSA may request additional data.

INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR THE AUTHORISATION OF A RECYCLING PROCESS

The dossier shall be composed of three sections: the summary document, the administrative part and the technical dossier. To allow a complete safety assessment, information is required in all the sections 1 to 3.

1) Summary document

The summary document shall summarise the information provided in the technical dossier and the safety evaluation of the process, including possible recommendations on restrictions of use and special applications. The summary document should follow the same order as described for the technical dossier. This document shall be a stand alone document.
If a reference is made to other documents, a summary of the relevant information in these documents shall also be given.

Applicants should also present their own conclusions, drawing attention to any unusual features in the data presented and their own evaluation of the process, including possible restrictions of use on special applications.

2) Administrative part

The data supplied shall identify the legal entities and the business involved, as well as the person in charge of the application.[2]

1) Name of the applicant (company, organisation, etc), address and other means of communication, e.g. telephone, telefax, e-mail.
2) Name of the business operator intended to be the authorisation holder (if different from above), address and other means of communication, e.g. telephone, telefax, e-mail.
3) Name of the person responsible for the application, address and other means of communication, e.g. telephone, telefax, e-mail.
4) Date of submission of the application.
5) Table of contents of the application.

[2] For conditions of authorisation of a recycling process, interested parties should refer to article 4 of Regulation (EC) No 282/2008 (European Commission, 2008) and to DG SANCO http://ec.europa.eu/dgs/health_consumer/index_en.htm

3) Technical Dossier

3. 1 General information

3.1.1 General description

This information is destined to be published in the Register of authorised recycling processes by the Commission services.
The subject of the application should be described clearly, with a description of the type of plastic and, in general terms, of the main key steps of the process, especially those contributing to removal of potential contaminants. Information on the intended use of the recycled plastic such as percentage in the final article, single-use or repeated-use applications, food types and contact conditions should also be provided. This part should not contain any data which cannot be disclosed to the public**.**

3.1.2 Existing authorisations

Any information concerning existing legislation and/or authorisations in EU Member States and other countries should be included.
It should be indicated whether the process has been already authorised as such (the same process, for the same plant), for the same company (e.g. on another plant) or a similar process (e.g. a process having similar characteristics and key steps). If available, the internet address for the authorisation should be supplied; a copy of an authorisation letter can be annexed. Any other useful and relevant information on the existing authorisations should be supplied.

In this section the applicant should provide information on the status of the recycling process, that is, if the process is already running or if it is going to be set up.

3. 2 Specific information

3. 2. 1 Recycling process

In this section, the recycling process, that is the process to obtain the recycled plastic, starting from the input, should be described in detail.
A flow chart diagram showing the relevant key steps in the process should be included, accompanied by a short written description (1-2 pages) of the reported process steps.
Then, a more detailed description of all the relevant steps of the process, starting from the input and ending with the recycled plastic, or articles made of it, should be given. In accordance with the flow chart, the objective of each step should be indicated: e.g. input control, sorting, cleaning, drying, grinding or flake production, distribution, recollection.
The applicant should identify and describe the steps within the process that are applied to reduce the level of any contaminant possibly present in the input. In addition the issue of the chemicals used in the cleaning steps and of the possible degradation products of the polymer or of plastics additives should be addressed.
This section should be detailed enough to allow the EFSA to evaluate any possible risks to human health.

The applicant should highlight the parameters that are relevant to characterise the process and the relevant steps (e.g. temperatures, pressures, times, operative details, special devices).
The applicant should demonstrate that the critical parameters related to the safety assessment are well controlled.

3. 2. 2 Characterisation of the input

In this section the applicant should demonstrate how it is ensured that the input does not contain chemicals which could survive the recycling process and migrate into food from the final food contact materials and articles in amounts which would be of concern for public health.
The applicant should describe the specifications for the input with regard to possible contaminants and the plan for evaluation and qualification of the suppliers based on their ability to meet specific requirements. Relevant information on the origin of the input should be provided (e.g. kerbside collection, deposit system, bins, bells, closed loop circuit etc.) with particular emphasis on the aspects of traceability and on the actions to prevent entry into the input stream of materials and articles not suitable for food contact applications.
Identify the steps that are critical for the safety assessment.

3.2.3 Determination of the decontamination efficiency of the recycling process

Chemical contaminants of concern are those which are not eliminated during the process, e.g. by washing or evaporation and which may migrate into food at levels which may be of concern for human health. This is related to the physical and chemical properties of the contaminants, mainly their polarity and their molecular weight. These two parameters influence the affinity to the polymer, to the washing media and to the food, the migration rate and the volatility.

To demonstrate the decontamination efficiency of the recycling process, specially designed tests are performed, called challenge tests in which sets of surrogate contaminants are used. These surrogates are substances with different molecular weight and polarity representative of all possible contaminants of concern (FDA, 1992; Pennarun *et al.*, 2005). The yield of decontamination (reduction of each surrogate level) of a recycling process should be determined by means of plastics spiked with surrogates, then submitted to all the steps of the recycling process. In these challenge tests, the surrogates shall be used at concentrations in the plastic allowing their easy analytical detection at the relevant stages of the process. Spike levels may be several orders of magnitude higher than realistic concentrations of contaminants. Sets of surrogates have been proposed in the literature, depending on the polymer and on its intended uses (Begley *et al.*, 2002; FDA, 1992; FDA, 2006; Pennarun *et al.* 2005; Franz *et al.*, 2004a; Vilaplana *et al.*, 2007).

All relevant experimental data shall be provided. The procedure and the results of challenge test(s) to determine the yield of decontamination after the relevant steps of the process should be described in detail. Experimental or theoretical considerations on the possible migration into the foods destined to come into contact should be laid out with clarity. Relevant scientific evidence supported by adequate documentation and / or scientific literature should be provided.

In many cases, the use of some machinery may have a strong impact on the yield of decontamination. Therefore it is acceptable that the challenge test is done by the producer of such a machinery.

3. 2. 4 Characterisation of the recycled plastic

In this section, the applicant should provide relevant data showing that the recycled plastic produced (e. g. flakes, resins, materials etc.) is suitable for the manufacture of food contact materials and articles.
The applicant should identify the parameters that are important in characterising the recycled plastic and report their specifications (e.g. melt flow index, glass transition temperatures). If several grades of recycled plastics are characterised, the intended use of each grade should be indicated as it is described in the section 3.2.5.

3. 2. 5 Intended application in contact with food

Detailed information on the type(s) of food intended to come in contact, along with the duration and temperature of the contact, the surface of plastic/volume of food ratio, single-use or repeated-use applications shall be provided to enable an evaluation of the possible migration (AFSSA, 2007; FDA, 2006; Franz *et al.*, 2004b; Welle, 2005).

3. 2. 6 Compliance with the relevant provisions on food contact materials and articles

Any evidence to demonstrate that recycled plastic and/or the final materials and articles produced from it meet the requirements of the relevant provisions on food contact materials and articles should be provided.

3. 2. 7 Process analysis and evaluation

Applicants shall perform their own risk analysis and give their own conclusions taking into account all the data above (AFSSA, 2007).

A justified identification of the critical steps should be provided. An analysis of the possible consequences of an incidental failure of compliance of some critical parameters with pre-established values, e.g. sorting efficiency, temperature range during washing or decontamination should be provided.

RE-EVALUATION OF A PROCESS

Authorisation holders should note that any significant modification to the process could lead to a request for a re-evaluation of the process by the EFSA. Depending on the importance of the changes, the request for re-evaluation can range from a simple notification by letter to a complete dossier. A complete dossier shall be submitted when the parameter(s) modified is (are) critical for the safety assessment.

QUALITY ASSURANCE SYSTEM (QAS)

Where appropriate, information on those parts of the Quality Assurance System (QAS) that are relevant for the safety assessment shall be submitted together with the technical dossier.
The provided information should highlight only the key points of the QAS that ensure the recycled plastic meets pre-established criteria fundamental for compliance of the final material and articles with the relevant provisions on food contact materials.
Certification of the QAS conformity to a relevant norm (e.g. ISO 9000) is not required by the Community provisions. However, when the QAS conformity to any relevant norm has been certified, the certification documents could be enclosed with the petition.

REFERENCES

Note: The references cited below are those used by the EFSA to draft the guidelines. The reference section is not aimed to be an exhaustive bibliography.

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