



Maisons-Alfort, 26 March 2010

OPINION

of the French Food Safety Agency regarding the SuperCycle™ recycling process to produce recycled polyethylene terephthalate (PET) intended to be used for manufacture of materials and articles in contact with food and drinking water

THE DIRECTOR GENERAL

1. REVIEW OF THE REQUEST

On 9 October 2009 the French Food Safety Agency (AFSSA) received a request from the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) for an Opinion regarding the SuperCycle™ recycling process to produce recycled polyethylene terephthalate (PET) intended to be used for manufacture of materials and articles in contact with food and drinking water.

2. BACKGROUND

The DGCCRF received an application to renew and extend authorisation of the SuperCycle™ process to produce recycled PET resin intended to come into contact with foodstuffs.

This request fell within the transitional period for the implementation of Commission Regulation (EC) no. 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods. Pending evaluation by the European Food Safety Authority (EFSA) and their inclusion in the register provided for by the above-referenced regulation, existing recycling processes are still subject to national rules up to 31 December 2009, whereas new processes can be submitted at any time.

The extension concerns:

- the use of 1 to 100% recycled PET resin instead of the current 25%, and
- the use of SuperCycle™ recycled PET resin in contact with drinking water.

Moreover, the applicant has developed a second SuperCycle™ recycled PET resin production line and is asking AFSSA to verify its compliance with AFSSA's guidelines concerning the assessment of recycling processes for plastics intended for food contact, published in its Opinion of 27 November 2006 (Request 2001-SA-0315).

SuperCycle™ resin is currently used in mixture of 25% recycled PET and 75% virgin PET for the manufacture of food contact materials. The use of this resin received a favourable Opinion from AFSSA (related Request 2000-SA-0072) regarding its suitability for food contact. This Opinion specifies that the applicant cannot claim the right to use this resin in drinking water contact material without a specific assessment being conducted beforehand.

In May 2008, following a public consultation, EFSA published 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 (EFSA, 2008). This guide drew upon AFSSA's guidelines, among others.

3. ASSESSMENT METHOD

This assessment method was based on analysis of the dossier submitted by the applicant and on AFSSA's guidelines on the assessment of processes for recycling PET intended for food contact.

The collective expert assessment was conducted by the Scientific Panel on 'Food Contact Materials' (CES MCDA), which met on 16 March 2010.

4. DISCUSSION

AFSSA's analysis is based on the opinion of the CES MCDA, which includes the key points presented below:

This application concerns two production lines for recycled PET resin. The collecting and sorting operations are identical for both lines, whereas the regeneration processes differ: intermittent or batch processing is used for one and continuous processing for the other.

With respect to the overall process

The applicant has detailed the steps to which it applies quality control using specifications and ISO 9001 certification. Inspections are conducted regularly to ensure that the quality of recycled PET remains comparable to that of virgin PET. Corrective measures are planned in the event of non-conformities.

With respect to the collection, sorting and regeneration steps

The regeneration phase (crushing and washing) is described, concerning the elimination of potential contaminants in particular. After this step, the PET flakes contain less than 100 mg/kg of materials other than PET.

The products used (detergent and anti-foaming agent) during the cleaning steps comply with the national regulations in force; their constituent substances are listed in the Order of 8 September 1999.

With respect to the recycling process

To evaluate the recycling process in the case of this application, virgin PET flakes were contaminated by model substances. The method used to impregnate PET flakes, as well as the choice of model contaminants (limonene, toluene, phenol, chlorobenzene and benzophenone), are acceptable. The initial concentrations obtained after drying the PET flakes were still slightly below (for toluene and chlorobenzene) or above (for phenol) the limits recommended by the guidelines (i.e., concentration between 500 and 1000 mg/kg for each substance). The sum of the concentrations of these model substances was always below 5000 mg/kg.

The flakes contaminated in this way underwent the entire decontamination process but not the entire recycling process. The basis for these choices is acceptable.

The concentrations of the model substances were measured after PET extraction at each stage of the decontamination process. The extraction and assay methods were specified. Under these conditions, decontamination performance was above 99% for the model substances and 90% for the benzophenone, whose molecular weight is higher and coefficient of diffusion lower. Moreover, the contaminant concentrations after decontamination were consistent with the migration model followed in the AFSSA guidelines for aqueous and acid foods.

With respect to monitoring of recycled PET production

To ensure that the quality of the recycled PET continues to be comparable to that of virgin PET, and to enable detection of any potential drift in the recycling process, the applicant has established a

system for managing manufacturing processes that relies upon physico-chemical controls and controls of contaminant concentrations in recycled PET. An action plan in the event of non-conformity has also been established (downgrade, recall of material). However, the CES MCDA emphasised that assessment of the HACCP¹ study is not within its field of expertise.

5. CONCLUSION

Based on the data presented, the French Food Safety Agency is issuing a favourable Opinion on the use of the SuperCycle™ recycling process for the production of recycled PET at an incorporation rate of up to 100%, according to the two production lines, for use in contact with acid and aqueous foods (including drinking water). It will be the responsibility of the professionals to ensure its suitability for contact with other types of food (containing alcohol or fat).

AFSSA stipulates that a favourable Opinion regarding the use of recycled PET does not exempt the users from ensuring that their finished products comply with Regulation (EC) no. 1935/2004 and Directive 2002/72/EC.

These are the points of analysis that AFSSA is able to provide in response to the DGCCRF request for an Opinion regarding the SuperCycle™ recycling process to produce recycled polyethylene terephthalate (PET) intended to be used for manufacture of materials and articles in contact with food and drinking water.

The Director General

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KEYWORDS

Recycled polyethylene terephthalate, PET, recycling process.

¹ HACCP: Hazard Analysis Critical Control Point

REFERENCES

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AFSSA (2006). *Avis du 27 novembre 2006 relatif à l'évaluation des risques sanitaires liés à l'emploi de matériaux en poly(éthylène téréphtalate) recyclé destinés ou mis au contact des denrées alimentaires et des eaux de boisson (Saisine 2001-SA-0315)* [Opinion of 27 November 2006 on the assessment of health risks associated with the use of materials made from recycled polyethylene terephthalate intended for or placed in contact with foodstuffs and drinking water (Request 2001-SA-0315), available in English at www.afssa.fr].

Arrêté du 8 septembre 1999 pris pour l'application de l'article 11 du décret n°73-138 du 12 février 1973 modifié portant application de la loi du 1er août 1905 sur les fraudes et falsifications en ce qui concerne les procédés et les produits utilisés pour le nettoyage des matériaux et objets destinés à entrer en contact avec des denrées, produits et boissons pour l'alimentation de l'homme et des animaux [Order of 8 September 1999 issued for the application of Article 11 of Decree no. 73-138 of 12 February 1973 modified to support application of the Act of 1 August 1905 on fraud and misrepresentation concerning the processes and products used for the cleaning of articles and materials intended to come into contact with foodstuffs, products and beverages for human and animal consumption].

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EFSA (2008). 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. Question number EFSA-Q-2004-168.

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 foodstuffs.

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.