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Scientific Opinion on the safety assessment of the process LPR based on EREMA Advanced and Colortronic SSP ® technology used to recycle post-consumer PET into food contact materials

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Panel Members

Acknowledgment

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Contact

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On request from: Direction Générale De la Concurrence, de la Consommation et de la Répression des Fraudes, France

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Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety assessment of the recycling process LPR (EU register No RECYC061) which is based on the EREMA advanced and Colortronic SSP ® technologies. The input to the process is hot caustic washed and dried PET flakes originating from collected post-consumer PET bottles and containing no more than 5 % of PET from non-food consumer applications. In this process, washed and dried PET flakes are heated successively in two continuous reactors under vacuum before being extruded into pellets. After extrusion they are crystallised and solid state polymerized. Having examined the results of the challenge test provided, the Panel concluded that the four steps, the decontamination in two continuous reactors, extrusion, crystallisation and solid state polymerization are the critical steps that determine the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature, pressure, gas flow and residence time. Under these conditions, it was demonstrated that the recycling process is able to ensure that the level of migration of potential unknown contaminants into food is below the modelled migration of 0.1 µg/kg food derived from exposure scenario for infants and 0.15 µg/kg food derived from the exposure scenario for toddlers. The Panel concluded that recycled PET obtained from LPR process is not of safety concern when used to manufacture articles intended for food contact materials applications in compliance with the conditions as specified in the conclusion of the opinion.

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Summary

According to Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is requested to evaluate recycling processes in which plastic waste is recycled. In this context, the CEF Panel evaluated the process “LPR”.

The Direction Générale De la Concurrence de la Consommation et de la Répression des Fraudes, France, requested the evaluation of the recycling process LPR submitted by Lorraine Plast Recycling company. The recycling process has been allocated the European Union register No RECYC061. It is deemed to recycle poly(ethylene terephthalate)(PET) from PET bottles collected through post-consumer collection systems. According to the applicant, the recycled PET obtained from the process is intended to be used at a percentage: i) up to 50 % in mixtures with virgin PET, in the manufacture of bottles, intended for contact with all type of foodstuffs and ii) up to 85 % in mixtures with virgin PET, in the manufacture of thermoformed trays and containers, intended for contact with all type of foodstuffs except packaged water. These recycled articles are intended to be used for long term storage at room temperature, with or without hotfill.

The process comprises five steps. First the post-consumer collected PET bottles are processed into washed and dried flakes which are used as input to the LPR® decontamination technology. Dried flakes are heated in a continuous reactor under vacuum (step 2) and then heated in a second continuous reactor under vacuum (step 3) before being extruded (step 4). Finally, they are crystallised and solid state polymerised (step 5).

Detailed specifications for the input materials are provided and the proportion of non-food containers is reported to be below 5 %.

A challenge test was conducted with surrogate contaminants in a small production plant on the process steps from 2 to 5 (continuous first reactor, continuous second reactor, extrusion, crystallization and SSP respectively) to measure the decontamination efficiency.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 90.7 % to above 99.9 %, have been used to calculate the residual concentrations of potential unknown contaminants in pellets (Cres) according to the evaluation procedure described in the Scientific Opinion on “the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food” (EFSA CEF Panel, 2011). According to these criteria and the intended uses (up to 50 % for manufacture of bottles intended for contact with all types of foodstuffs and up to 85 % for manufacture of thermoformed trays and containers, intended for contact with all types of foodstuffs except packaged water), the recycling process under evaluation is able to ensure that the level of unknown contaminants in recycled PET is below a calculated concentration (Cmod) corresponding to a modelled migration of 0.1 µg/kg food (derived from the exposure scenario for infants) and 0.15 µg/kg food (derived from the exposure scenario for toddlers).

The Panel considered that the process is well characterised and the main steps used to recycle the PET flakes into decontaminated PET pellets are identified. Having examined the results of the challenge test provided, the Panel concluded that the four steps, the decontamination in two continuous reactors (steps 2 and 3) extrusion (step 4) and the crystallisation and SSP (step 5) are the critical steps for the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are

temperature, pressure, gas flow and residence time. Therefore, the Panel considered that the recycling process LPR is able to reduce any foreseeable accidental contamination of post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

- i. it is operated under conditions that are at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the processes and,
 - ii. the input to the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the Community legislation on food contact materials and contain no more than 5 % PET from non-food consumer applications and,
 - iii. the final bottles manufactured with the recycled pellets do not contain more than 50 % recycled post-consumer PET and,
 - iv. the final thermoformed trays and containers manufactured with the recycled pellets and not used for packaging water do not contain more than 85 % recycled post-consumer PET.
- Therefore, the recycled PET obtained from the process LPR, intended to be used for the manufacture of bottles for contact with all types of foodstuffs and for the manufacture of thermoformed trays and containers for contact with all types of foodstuffs except packaged water for long term storage at room temperature with or without hotfill, is not considered of safety concern when final articles are manufactured with no more than the percentage of recycled post-consumer PET specified above. The trays made of recycled PET are not intended to be used and should not be used in microwaves and ovens.

The Panel recommended that it should be verified periodically, as part of the good manufacturing practice (GMP), that as foreseen in Regulation (EC) No 282/2008, art. 4b, the input originates from materials and articles that have been manufactured in accordance with the Community legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5 % in the input to be recycled. Critical steps should be monitored and kept under control; supporting documentation describing how it will be ensured that the critical steps are operated under conditions at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the process should be available.

Keywords

EREMA Advanced, Colortronic SSP, food contact materials, plastic, poly(ethylene terephthalate)(PET), recycling process, safety evaluation