



Maisons-Alfort, 14 May 2010

## OPINION

### of the French Food Safety Agency regarding the LPR recycling process (Velize, France) 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 30 November 2009 the French Food Safety Agency (AFSSA) received a request from the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) regarding the LPR recycling process (Velize, France) to produce recycled polyethylene terephthalate (PET) intended to be used for manufacture of materials and articles in contact with food and drinking water.

#### 2. CONTEXT

The DGCCRF received an application to assess the LPR recycling process (Velize, France) to produce recycled PET resin intended to come into contact with foodstuffs.

This request fell within the transitional period 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.

The request concerned the use of 1 to 100% recycled PET resin in articles intended to come into contact with food and drinking water.

AFSSA was requested to determine whether this process complies with its guidelines on the assessment of recycling processes for plastics intended for food contact, published in its Opinion of 27 November 2006 (Request 2001-SA-0315).

In May 2008, following a public consultation, EFSA published guidelines for applicants requesting a safety assessment of recycled plastic materials intended to come into contact with food (EFSA, 2008). This guide drew upon AFSSA's guidelines, among others.

#### 3. ASSESSMENT METHOD

The assessment method was based on an analysis of the dossier submitted by the applicant (dated on 18 November 2009) and on AFSSA's guidelines on the assessment of processes for recycled PET intended for food contact.

The collective expert assessment was conducted by the Scientific Panel on 'Food Contact Materials' (CES MCDA), which met on 4 May 2010.

#### 4. DISCUSSION

AFSSA's analysis is based on the opinion of the CES MCDA, which includes the key points based on the line « EREMA ADVANCE et COLORTONIC SSP » presented below:

##### ***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 (washing, crushing) is described, concerning the elimination of potential contaminants in particular. The application does not mention whether the flakes contain less than 0.05% of matter other than PET at the end of this step, but the applicant regularly undertakes impurity investigations with the goal of rejecting non-compliant batches.

The products (detergents) used in the cleaning phases are not specified. The application does not state whether they are compliant with the French Order of 8 September 1999.

##### ***With respect to the recycling process***

AFSSA's guidelines stipulate that the assessment of PET recycling processes must examine several steps: collection, sorting, regeneration, efficiency characterisation and quality control of the recycling process. If the decontamination efficiency is strictly lower than 99%, the process is deemed unacceptable. In the event that the efficiency is equal to or greater than 99%, two scenarios are possible. In the case of contact with aqueous or acidic foods, there is a migration forecasting model that can be used to assess whether or not the PET recycling process is acceptable. In the case of contact with alcoholic or fatty foods, there is no migration forecasting model. Substance migration tests are then performed on the finished article (with model substances incorporated) in order to determine the maximum concentration in PET that is compatible with a migration rate lower than 1.5 µg/kg of alcoholic or fatty food, simulated using 10% ethanol and substances simulating fat. If the measurements show that this maximum concentration is not exceeded, then the process is deemed acceptable.

In the case of this application, the assessment was conducted by the applicant after a laboratory optimisation phase which defined conditions for impregnating new PET flakes with model substances. The method that was used to impregnate PET flakes and the choice of model substances (limonene, toluene, phenol, chlorobenzene and benzophenone) are acceptable. The contaminated flakes underwent all phases of the recycling process.

The initial concentrations that were obtained after drying the PET flakes were however slightly lower (for chlorobenzene) or higher (for benzophenone and phenol) than the limits recommended in the guidelines (concentration ranging from 500 to 1,000 mg/kg for each substance). The total concentrations of these model substances were always less than 5,000 mg/kg.

Concentrations of the model substances were measured after PET extraction in each step of the decontamination process. The extraction and assaying methods are specified.

Given that, for technical reasons, efficiencies were measured for a batch that did not correspond to the batch with the highest concentration but that assay reproducibility was satisfactory; the efficiencies can be considered acceptable.

Under these conditions, the decontamination efficiency was, as stipulated in the AFSSA guidelines, greater than 99% for toluene, phenol and chlorobenzene and greater than 90% for benzophenone (which has a higher molar mass and a lower diffusion coefficient). Only limonene had a decontamination efficiency that was slightly lower than 99% (98.40%).

##### ***With respect to the monitoring of recycled PET production***

To ensure that the quality of recycled PET is equal to that of virgin PET and to enable detection of any potential drift in the recycling process, the applicant 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).

AFSSA notes that residual levels of phenol, limonene and benzophenone after decontamination were higher than the threshold concentrations compatible with the nomogram (Figure 3 of 27 November 2006 opinion) on which AFSSA's guidelines are based (8, 16 and 124 mg/kg vs 4, 4 and 10 mg/kg respectively). In the context of production monitoring, such a batch would be considered unacceptable for food contact use. However, AFSSA considers that the initial concentrations greatly exceeded the expected concentrations in realistic conditions for the 3 model substances used.

## **5. CONCLUSION**

The French Food Safety Agency is issuing a favourable opinion on the use of recycled PET produced with LPR recycling process (Velize, France) at an incorporation rate of up to 100%. The data that were submitted for use in contact with aqueous (including drinking water) and acidic foods comply with AFSSA's guidelines. If recycled PET were to be used in contact with alcoholic or fatty foods, it would be the responsibility of the professionals to ensure its suitability for contact with these food types, since the information required for their assessment was not submitted in the application.

Moreover, AFSSA considers that the applicant should check with its sub-contractors to ensure that the cleaning products it uses comply with the French Order of 8 September 1999.

Lastly, 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.

This is the points of analysis that AFSSA able to provide in response to the DGCCRF's request for an Opinion regarding the LPR recycling process (Velize, France) 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**

**Marc MORTUREUX**

## **KEYWORDS**

Recycled polyethylene terephthalate, PET, recycling process.

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- 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.