

Use of mechanically recycled plastic made from polyethylene terephthalate (PET) for the manufacture of articles coming into contact with food

The Expert Group on Plastic Material for Food Contact of the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) has dealt with the use of mechanically recycled plastic made from polyethylene terephthalate (PET) for the manufacture of articles coming into contact with food. As a result, the following opinion is stated:

1 Legal situation and introduction

According to § 5 para 1 no. 1 of the German Act on Foods and Commodities (LMBG), mechanically recycled polyethylene terephthalate for food contact use must meet the same requirements as virgin PET as given in §§ 30 and 31 (1) of LMBG as well as those of the German Regulations on Commodities (Bedarfsgegenständeverordnung). No PET constituents are allowed to migrate into the food except they are considered to be safe with regard to consumers' health and acceptable with regard to affecting food odour and taste and only in such amounts which are technically unavoidable.

Manufacturers and distributors of such commodities coming into contact with food made from PET are fully responsible for the safety to health within the scope of the principles of good manufacturing practice and due diligence.

The Committee on Plastic Material for Food Contact of the Federal Institute for Health Protection of Consumers and Veterinary Medicine had already issued earlier an opinion on plastic articles for multiple use and on recycled plastics for the manufacture of articles for food contact [1].

The starting material for mechanical recycling is generally divided into three quality classes:

Class 1:

Materials remaining from production by the manufacturing or converting industry (primary recyclate) where their past history is known and which have always been under the control of the processor. If contamination can be excluded, this material is as suitable for direct contact with foodstuffs as new material.

Class 2:

Pure-grade but contaminated material (secondary recyclate) which had been used for food packaging for known applications and re-collected pure-grade by the utilizer, for instance via a deposit system or material collection. The utilizer does not usually have complete control of the plastic materials over the time period from its first use up to its return.

Class 3:

Non pure-grade and contaminated material (secondary recyclate) which had been used like class 2 material for certain applications also outside of the food packaging area and enters the recycling system via mixed plastics collection, for example such ones as operated by 'Duales System Deutschland' (DSD).

In the past years, essential technological progress has been made in the area of decontamination of "post-consumer" plastics, in particular from the PET beverage bottle market. The development of modern recycling procedures increasingly allows cleaning and reconditioning of "post-consumer" recycled PET for being reused in direct food contact applications. In parallel, research carried out in connection with this technological development has provided an enormous increase in knowledge which allows today to assess with sufficient confidence and safety the extent of interaction processes of possible recycle-specific contaminants between PET bottles and the infilled foodstuff [2].

In order to take account of these developments and in the absence of regulations in this new area of food packaging applications at a European level, guidelines have been elaborated as a supplement to the general opinion of the Plastics Committee from 1995. These guidelines shall assist the relevant industry implementing R&D developments in the field of PET recycling.

2 Guidelines for the use of recycled PET

State of the art

In the manufacture of articles from primary plastics there is normally perfect control of the starting raw materials used. For secondary recycle materials as in categories 2 and 3, complete control of the material is not possible. Here, it can be expected that substances are introduced which are untypical of polymers, above all components from the filled product from the first use but also from misuse by the consumer and that corresponding contamination of the secondary recycle material occurs.

As is generally known, plastics can interact with organic chemicals. The extent of this interaction depends on the diffusion behaviour specific to polymers and the sorption properties of the plastic. These properties ultimately determine the potential risk of food contamination due to recycling. In relation to this aspect, PET possesses much more favourable material properties in comparison to other packaging plastics, such as polyolefins or polystyrene and is, therefore, much better suited for mechanical recycling for being reused in the commodity sector.

Recycling processes for the manufacture of recycled PET as a final product, which is safe from the angle of food legislation, must include processing steps which efficiently clean the plastic and eliminate substances which originate from the first use or possible misuse. It is therefore imperative in this highly sensitive field that the utilizer of secondary recycle material demonstrates in a worst-case scenario that, even under the most unfavourable conditions, conformity with the Act on Foods and Commodities (LMBG) is ensured for the articles partially or completely manufactured from recycled material.

For the safe manufacture and use of commodities made from recycled PET the following points must be taken into consideration:

- I. Control of material recovery logistics***
- II. Testing and evaluation of the efficiency of cleaning steps in the recycling process***
- III. Analytical quality assurance***

Ad I:

The first use of the returned material and the proportion of foreign polymers is controlled by *material recovery logistics*. Only original food-grade PET shall be used as the raw material source for the recycling process. A deposit system for drink bottles or a controlled, pure-grade re-collection system normally fulfils the mentioned requirements for recovery control. If other re-collection systems are used, the sorting process must ensure the corresponding purity grade. Experience has shown that maximum fractions of foreign polymers of 1% are technologically attained when good manufacturing practices are adhered to. Under foreign polymers also pure-grade PET material which has not been used in its first application in contact with food is understood. Sufficient sorting efficiency is to be guaranteed by corresponding control measures.

Guideline 1: *Use only food-grade PET quality as a raw material source. Ensure a sorting efficiency to provide purities of at least 99% excluding other PET qualities and foreign polymer fractions.*

Ad II:

The efficiency of the cleaning steps in the recycling process is checked and assured by a so-called "challenge test"[3]. For this test, organic chemicals with varying chemical and physical properties are introduced into the sorted (see above) returned PET material which is then recycled by the process to be assessed. The organic substances serve as model contaminants or so-called surrogates. A model food contact article is then manufactured using the regranulate contaminated in this way which is subjected to migration testing. Recommended chemicals are listed below which should be used as surrogates.

Recommended model contaminants: *Toluene, chlorobenzene, phenyl cyclohexane, benzophenone, methyl stearate.*

The contamination must be carried out in such a way that sufficient amounts of chemicals can diffuse into the plastic material. It is recommended to work with a mixture of all chemicals. The initial concentration of the model contaminants to be used must be sufficiently high to establish a worst-case scenario with respect to the recycling system to be assessed or, if necessary, the modular cleaning step which is to be checked. With pure-grade re-collected PET, for example, a concentration in the range of 500 ppm (mg/kg) to 1000 ppm per model contaminant used is a sufficient initial condition for checking the entire process. An addition of too high initial concentrations can have a negative effect on the processability of the contaminated material within the challenge test and may lead to technical difficulties during the manufacture of the regranulate and the model food contact article. According to the present state of knowledge, initial concentrations of 500 ppm to 1000 ppm include a safety factor in the range of 100 to 1000 with respect to really occurring maximum initial concentrations of foreign substances in recycled PET which are PET untypical and do not originate from the previously filled foodstuff. By mixing single misused bottles, which may occur sporadically, with large amounts of fully uncontaminated returned PET material, there results an extremely high dilution effect as a rule.

The recycling process to be assessed by the challenge test must be able to remove the recycling-related substances introduced so efficiently that the finished product (regranulate) meets the requirements of food legislation. To guarantee this, the model article coming into contact with food that has been produced in the challenge test shall undergo migration testing. It should be noted that the conditions of the envisaged use of the article containing recycled material influence the extent of possible migration into food. The migration-determining parameters are contact time and temperature as well as the nature of the real filling product, in addition to the corresponding test conditions according to EU Directive 97/48/EC and EU Directive 85/572/EEC, respectively. With regard to the conditions of use it

also has to be considered whether the recycled PET is in direct contact with the foodstuff or separated by a functional barrier. In case of doubt, it must be guaranteed that migration testing is carried out under worst-case conditions.

As an assessment criterion for sufficient cleaning efficiency of the recycling process a maximum migration of 10 ppb ($\mu\text{g}/\text{kg}$) is to be applied for the surrogates used. This level must not be exceeded in the migration test including the analytical tolerance (repeatability 'r').

Instead of verification of the assessment criterion by migration testing this requirement can be checked via determination of the residual surrogate content in the regranulate or in the model article, in connection with a scientifically recognised method for migration modelling [2, 4].

A given recycling process shall at least be systematically checked and evaluated once by a challenge test. When the checked process parameters are adhered to, the same cleaning efficiency can be assumed for other equipments constructed in the same way. However, if technical changes to the recycling process are made, it has to be proved that the cleaning efficiency of the recycling process has not deteriorated. This can also be done via a modular test of the respective process step and by means of reduced-scale testing. If necessary, the test should be repeated.

Guideline II: Check the cleaning efficiency of a recycling process by means of a challenge test on the basis of model contaminants (surrogates) introduced artificially in sufficient quantities. Recommended model contaminants are: Toluene, chlorobenzene, phenyl cyclohexane, benzophenone, methyl stearate. For pure-grade re-collected PET, an initial concentration of 500 ppm to 1000 ppm per surrogate is sufficient. For the assessment of the cleaning efficiency, carry out migration testing under suitable testing conditions according to the envisaged use on a model article coming into contact with food which has been manufactured from the contaminated recycling product (recyclate-granulate) resulting from the challenge test. As a result of migration testing, the surrogates used must not exceed a level of 10 ppb [$\mu\text{g}/\text{kg}$] including analytical tolerance. This test has to be carried out only once for the same technological process.

Ad III:

Irrespective of the successful result of the challenge test carried out once, the cleaning efficiency of the recycling process has to be checked by adequate controls. It is therefore recommended to establish an efficient analytical quality assurance in the production process. A suitable approach for example offers gas chromatographical headspace analysis of the incoming raw material and/or the regranulate (finished product) with which migration-relevant foreign compounds in PET, such as organic substances from previous use or misuse can be quantitatively determined [5]. Experience has shown that recycled PET, which has been manufactured from post-consumer PET bottles by modern procedures, can even perform more favourably with regard to components relevant to migration than new material. In any case, on the basis of the analytical result of the quality assurance measures, a recycled product shall not be disadvantageously distinguishable from virgin material.

Guideline III: In addition to the above-mentioned quality assurance criteria (recovery control, cleaning efficiency test and considering conditions of practical use), establish an adequate analytical control of recyclate production.

3 Summary

The legal requirements for commodities are also to be applied to mechanically recycled PET plastics. However, taking account of the possible misuse and, as a rule, inhomogeneous incoming material, additional quality assurance measures are necessary. The incoming material for the mechanical recycling process should be composed of at least 99% of originally food-grade PET. The applied recycling process must be capable to remove from the polymer matrix such migration-relevant substances which could be present from the first use. The necessary cleaning efficiency has to be proved once in a worst-case scenario applying model contaminants (surrogates) and including migration testing and migration assessment, respectively. To control the production process, adequate analytical quality assurance measures are imperative.

References

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