EUROPEAN COMMISSION

Community research

Guidance and Criteria for **Safe Recycling** of Post Consumer Polyethylene Terephthalate (PET) into New Food Packaging Applications

PROJECT REPORT

EUR 21155

Interested in European research?

RTD info is our quarterly magazine keeping you in touch with main developments (results, programmes, events, etc.). It is available in English, French and German. A free sample copy or free subscription can be obtained from:

European Commission
Directorate-General for Research
Information and Communication Unit
B-1049 Brussels
Fax (32-2) 29-58220
E-mail: research@cec.eu.int
Internet: http://europa.eu.int/comm/research/rtdinfo/index_en.html

EUROPEAN COMMISSION

Directorate-General for Research
Directorate E — Biotechnology, Agricultural and Food Research
Unit E2 — Food quality

European Commission
Office SDME 8/21
B-1049 Brussels

Fax (32-2) 29-64322

E-mail: rtd-food@cec.eu.int@cec.eu.int

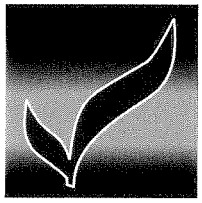
EUROPEAN COMMISSION

Guidance and Criteria for Safe Recycling of Post Consumer Polyethylene Terephthalate (PET) into New Food Packaging Applications

Authors:
Roland Franz[1], Forrest Bayer[2] and Frank Welle[1]

[1] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Freising, Germany
[2] The Coca-Cola Company, Atlanta, USA

This report has been carried out with the financial support of the Commission of the European Communities, under the Fourth Framework for RTD, specific programme FAIR (Agriculture and Fisheries including Agro-industry, Food technologies, Forestry, Aquaculture and Rural Development), contract N° FAIR-CT98-4318 : RECYCLABILITY



2004

Directorate-General for Research
FAIR – Fisheries and Agriculture

EUR 21155

Europe Direct is a service to help you find answers to your questions about the European Union

Freephone number:
00 800 6 7 8 9 10 11

A great deal of additional information on the European Union is available on the Internet.
It can be accessed through the Europa server (http://europa.eu.int).

Cataloguing data can be found at the end of this publication.

Luxembourg: Office for Official Publications of the European Communities, 2004

ISBN 92-894-6776-2

Printed in Belgium

PRINTED ON WHITE CHLORINE-FREE PAPER

EU-Project FAIR-CT98-4318 "Recyclability"

Project: "Programme on the Recyclability of Food Packaging Materials with Respect to Food Safety Considerations - Polyethylene Terephthalate (PET), Paper & Board and Plastics Covered by Functional Barriers".

Section I: PET Recyclability

Subject: # Guidance and Criteria for Safe Recycling of Post Consumer Polyethylene Terephthalate (PET) into New Food Packaging Applications

---

Authors: Roland Franz[1)], Forrest Bayer[2)] and Frank Welle[1)]

Date: February 2003

[1)]Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Freising, Germany

[2)] The Coca-Cola Company, Atlanta, USA

Foreword

Between January 1999 and April 2002, a European project, FAIR-CT98-4318 "Recyclability" was carried out to investigate into an (at this time) existing knowledge gap related to the average contamination levels of post-consumer recycled polyethylene terephthalate (PCR PET) materials. Therefore the objective of a very comprehensive study which was carried out within Section I of the mentioned EU project was to establish a statistical overview over the nature and extent of contaminants in PCR PET recovered from the European food packaging market. A co-objective was to investigate whether there is an impact of the recollecting system, the social situation and consumer behaviour in different recyclate markets on the PCR PET quality.

Typical contamination patterns and the frequency of misuse of PET bottles as well as the counteractive reduction effect due to dilution with non-contaminated bottles during recycling are crucial issues in risk assessment of PCR PET intended for bottle to bottle recycling for direct food contact applications. It can be therefore expected that the misuse of PET bottles is a very rare event. Therefore information about the average concentration of hazardous compounds in PCR PET is accessible only by screening of large amounts of samples. Within the EU project, 727 PCR PET flakes samples from commercial washing plants were collected. These materials are used as a feedstock for further deep cleansing recycling technologies, so-called super-clean processes, which produce PET recyclates suitable for direct food contact. For comparison purposes, also 142 super-clean as well as 20 virgin samples were included.

The observed patterns of compounds occurring in PCR PET flakes can be divided into substances which are PET related such as acetaldehyde or are unspecific for PET and related to the medium which was in contact. The latter group in turn can be sub-divided into food-borne substances such as flavours like limonene absorbed by the PET bottle and into external contaminants such as technologically needed substances or misuse chemicals. As a result, in PCR PET flakes average concentrations for limonene and acetaldehyde samples were found to be 2.9 ppm and 18.6 ppm, respectively, and at maximum occurring concentrations of approximately 20 ppm for limonene and 86 ppm for acetaldehyde. The impact of the recollecting system and the EU country, where the post-consumer PET bottles were collected, on the nature and extent of adventitious contaminants was not significant. In three cases samples were found with obvious hints for chemically misused PET bottles most likely by storage of household chemicals or other aggressive solvent cocktails. From a statistical evaluation it appears that 0.03 to 0.04 % of recollected PET bottles may be misused. Under consideration of the dilution of the PET flakes during washing and grinding with non-misused PET bottles maximum total concentrations of misuse chemical such as solvents up to the range of 1.4 to 2.7 ppm can be present in the PET recycling feedstream for super-clean processes which reduce these levels efficiently below the analytical detection limits.

From the study results, maximum possible migration and exposure from food contact articles made from the PCR PET feedstream can be made. As a very conservative result one can conclude that the consumer will be exposed to maximum levels which are lower than 50 ng of total misuse chemicals such as

solvents per day. As an overall conclusion from the project results and from many other findings and considerations it can be concluded that modern super-clean technologies can safely reprocess PCR PET into new materials and articles for direct food applications in the same and which are indistinguishable from virgin food grade PET.

The results from this study were the necessary and a suitable scientific basis to allow the writing of this guidance document for the safe recycling and use of PCR PET. It is the wish of the project coordinator that this document will lead to a situation in Europe which allows safe PET recycling in all European member states as well as other countries, so they wish, according to harmonised test protocols which, however, should contain sufficient flexibility to meet further technological and scientific progress in this field. Furthermore, the proposed test protocols have been designed such that to the best of our knowledge and experience also a harmonisation with US FDA requirements has been achieved.

The project coordinator, also on behalf of the co-authors, wishes to express his thanks to all involved laboratories, industries and other stakeholders inclusively the project officers from DG Research from the European Commission (for a complete list see under Chapter 9).

Roland Franz,

Coordinator of EU project FAIR-CT-98-4318

Contents

Abbreviations

BfR	(German) Bundesinstitut für Risikobewertung (the former German BgVV)
CF	consumption factor
CFR	Code of Federal Regulations (of the US FDA)
EC	European Commission
EEC	European Economic Community
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FDA	(US) Food and Drug Administration
FID	flame ionisation detector
GC	gas chromatography
HT-HSGC	high temperature headspace GC
ILSI	International Life Science Institute
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MS	mass spectrometry
MIC	maximum initial concentration
MW	molecular weight
PCA	principal component analysis
PCR	post consumer recycle
PET	polyethylene terephthalate
PEN	polyethylene naphthalate
ppm	parts per million (mg/kg)
ppb	parts per billion (µg/kg)
WHO	World Health Organisation

1. Introduction

In the past few years essential under the pressure of new ecological demands [1] enormous 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 processes increasingly allows cleansing and reconditioning of "post-consumer" recycled (PCR) 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 recycling specific contaminants between PET bottles and the filled foodstuff [2 - 12 and numerous other papers cited therein].

Current and future worldwide beverage packaging PET consumption is characterised by annual increase rates of 9%. As a consequence, this development is paralleled in Europe by industrial investments into new PET recollection and recycling capacities by at least the same increase rates [13]. The currently by far greatest application market for PCR PET which is fibres for textiles and carpets may approach saturation in the near future with the effect that food packaging applications will be of increasing economic and therefore consumer safety interest.

In the manufacture of articles from primary plastics there is normally perfect control of the starting raw materials used. For post-consumer materials complete control of the material is not possible. Here it can be expected that substances are introduced which are untypical for 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 post-consumer material occurs.

As is generally known, plastics can interact with organic chemicals. The extent of this interaction moreover depends on the diffusion behaviour specific to polymers and the sorption properties of the plastic. These physical 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 polyolefines or polystyrene and is, therefore, much better suited for mechanical recycling for being reused in the food commodity sector.

Recycling processes for the manufacture of recycled PET as a final product, which is food legally safe, must include process steps which efficiently deep cleanse 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 recycler of post-consumer material demonstrates in a worst-case scenario that even under the most unfavourable conditions conformity with the law on food and commodities is ensured for the articles partially or completely manufactured from recycled material.

One objective of this document is to summarise the state of the art in PCR PET reprocessing into new packaging applications for direct food contact from a historical/food legal point of view and with rather short notices on technology aspects. The major intention, however, is to give practical guidance and a reliable criteria for the safe recycling and use of PCR PET in this challenging market

application. Here, in particular, the control methodologies of so-called challenge tests on the deep cleansing efficiency of modern super-clean process technologies is of highest interest to assure the required high quality standards in PET reprocessing and finally ensure the food safety demands for consumer health protection.

The recommendations, guidelines and criteria presented in this document can be considered as the implementation of the results and conclusions from a large European project, FAIR-CT-98-4318 [14], which have been published elsewhere [12] and therefore do correspond to the scientific state of the art in this field.

2. Definitions

Adventitious contaminants:
Any unwanted substance that deliberately or inadvertently comes into contact with the packaging material before it is collected for recycling and that therefore may contaminate the plastic and negatively influence the quality of the product filled by a recycled packaging material.

Challenge test:
A test of the effectiveness of a super-clean recycling process to remove chemical contamination from materials or articles. The test involves introduction of exaggerated levels of surrogates and includes as an end parameter the migration evaluation of these surrogates from a model food contact article. As a safety criterion this migration must not exceed 10 µg kg^{-1} (ppb) food. This can be considered to be a purely technical cleaning efficiency criterion which demonstrates the powerfulness of a super-clean recycling process.

"Conventional" PET recycling:
A recycling procedure using the process steps grinding, washing and surface drying of recollected PET containers. The output material of conventional recycling processes are PET flakes customary used for non-food or for the core layer of multi-layer applications. Conventional recycled PET flakes are usually used as input material for so-called super-clean recycling processes.

Consumption factor (CF):
Generally, CFs are used to correct a migration test result (measured concentration in food simulant) into a exposure value (average uptake by the consumer with the diet). Specifically, the US FDA defines CF as the plastic packaging usage factor which is CF = 0.16 for virgin PET and CF = 0.05 for any recycled PET. In Europe, the system of packaging usage factors has not been established yet. However, the concept of fat consumption factors has recently been adopted with the consequence that a fat reduction factor (FRF) will be introduced into European legislation (future amendment of Directive 85/572/EC).

Extraction:
Quantitative dissolution of constituents from a plastic into a solvent and based on a strong interaction between plastic and solvent.

Feedstock/feedstream:
Post consumer PET plastics used as raw materials for recycling.

Food grade PET:
For Europe: PET plastic of a suitable standard for food applications manufactured in compliance with EU Directive 2002/72/EEC (and future amendments). For USA: the PET plastic must be compliant with 21 CFR 177.1630 and 21 CFR 177.1315. It should be noted that food grade PET is also used for non-food packaging applications.

Migration:
Diffusion-controlled mass transfer from a packaging material or article to food or simulant. Classically, migration is experimentally determined by standardised tests using food simulants. Due to the scientific progress in this field, today migration can also be mathematically modelled and conservatively predicted.

Migrations limits:
Food regulatory maximum concentrations of migrants in food simulants or foodstuffs resulting from a migration process. With respect to the sensitive area of recycled food packaging materials and articles, the legally prescribed overall migration is of much lower relevance and importance than specific migration limits as for instance defined also by a threshold of no concern.

Post consumer recycle PET (PCR PET):
PET plastic material (bottles/containers) that has been manufactured, distributed and used by the consumer. Discarded PCR PET material becomes the feedstock for recycling processes.

Post industrial recycle PET:
Industrial inhouse plant scrab generated during the manufacture process which may be reused in the production of new bottles.

"Super-clean" PET recycling:
In most instances the process uses as a source the output material from conventional recycling, for example washed and surface-dried PET flakes, and includes one or more additional cleaning steps. The output of "super-clean" processes may be used for packaging applications in direct contact to the foodstuff provided they meet the appropriate regulatory guidelines or legal requirements.

Surrogates:
Organic compounds (also known as "model contaminants") of a wide range of chemical types and physical properties representing exaggerated contamination to challenge the safety of recycled materials and articles. Possible application may be as individuals or a test mixture.

Threshold of no concern:
A concentration of a migrant in a foodstuff which, from a toxicological point of view, is considered to pose no health risk to the consumer even in case that the chemical structure of the migrant is unknown. As an example the US FDA threshold-of-regulation concept according to 21 CFR 170.39 may serve where the threshold, understood as the daily dietary intake, is set at 0.5 ppb (µg kg^{-1} food).
In Europe, this concept is under discussion but a general threshold value has not yet been adopted. However, specifically for evaluation of the safety of super-clean processes the purely technical cleaning efficiency criterion (see challenge test) is applicable. A JECFA task force of FAO/WHO has adopted the utilisation of a threshold of toxicological concern concept for the evaluation of flavouring substances in food. The proposed no concern level was 1.5 µg per person per day [15, 16].

3. Categories of PET recycling feedstocks and process technologies

In general, feedstock materials for PET recycling processes can be divided into the four quality classes [17, 18]:

Class 1: Materials remaining from production by the manufacturing or converting industry where their past history is known and which have always been under the control of the processor. Provided that good manufacturing practice is followed and contamination can be excluded, this material is as suitable for direct contact with foodstuffs as new material.

Class 1 material can be defined as "post industrial recycle PET" and corresponds to US FDA's Primary Recycling (pre-consumer scrap).

Class 2: PCR PET material which had been used for food packaging for well-known applications and recollected pure-grade by the recycler, for instance via a deposit system or material collection. Due to its post-consumer character, the recycler usually does not have complete control of the plastics material over the time period from its first use up to its return.

Class 3: Impurified PCR PET material and possibly commingled with other plastics which had been used for certain applications also outside of the food packaging area and enters the recycling feedstream via mixed plastics collection, for example such ones as operated by the "green dot" collections. The material could include also food-grade PET from non-food packaging applications.

Both, class 2 and 3 correspond to US FDA's Category "Physical reprocessing: Secondary Recycling".

Class 4: Any class 1 to 3 material which had been chemically reprocessed by depolymerisation into monomers or oligomers from which after purification a new polymer has been regenerated.

Class 4 corresponds to US FDA's Category "Chemical Reprocessing: Tertiary Recycling".

From given reasons, class 1 and class 4 feedstock materials can be considered to be safe and in compliance with the legal requirements and are not anymore dealt with in the further discussion.

Secondary recycling of class 2 and class 3 materials is economically and from a mass fraction standpoint of highest interest and challenge with regard to consumer safety considerations. It must be noted that "eligible" feedstock PET material must be of "food grade" quality. Furthermore, it should also be noted that it has been verified by industry that PET produced for both food and non-food (e.g. personal hygiene products and household cleansers) containers is compliant with EU Directive 2002/72/EEC as well as 21 CFR 177.1630 and 21 CFR 177.1315 [9, 18, 19].

For further discussion an additional differentiation concerning recycling process technologies is necessary.

3.1. Conventional reprocessing or recycling

Class 2 and 3 PCR PET collections are mechanically recycled by operations which aim to reclaim the food grade PET at an appropriate purity. These processes include technological steps like sorting, grinding, washing and surface drying of the recollected PCR PET articles. In most cases, the output material are PCR PET flakes. An additional extrusion step can also be included for production of PCR PET pellets. The products from conventional recycling are predominantly used for fibres but are of increasing relevance as a feedstream material into super-clean technologies.

3.2. Super-clean recycling technologies

In general, super-clean processes which are feedstreamed by conventional PET recycling products apply further deep cleansing steps based on high temperatures and vacuum stripping. In many cases a solid state post-condensation phase is included to repair broken polymer chains and install the necessary intrinsic viscosity for further processability of the product which can be used for food packaging articles with direct contact. Another option of a super-clean mechanism involves chemical depolymerisation of the PET surface layer followed by usual mechanical cleaning parameters and thus forms a hybrid chemo-mechanical process.

Finally, it should be noted that also other physico-chemical principles may also be applicable to regenerate a purified plastic. For instance, polymer separation and purification by selective or fractionating dissolution and reprecipitation is an option which is under development and may be suitable to produce PET for direct food packaging [20].

4. Historical perspectives and global status of PCR PET in food applications

4.1. The United States

Historically the United States industry initiated talks with the US Food and Drug Administration (US FDA) concerning the use of post-consumer plastics in food applications in the late 80s. These discussions were held due to the fact that no formal regulations existed in the US Code of Federal Regulations that allowed for the use of recycled plastics in food contact applications. However, the US FDA had indicated that they did have concerns about such use and that resulted in a desire to come to an agreement with industry as to how to mutually deal with this situation. Industry and US FDA jointly came up with an approach that consisted of challenging the PET or the plastic with a surrogate cocktail and then processing the material to establish the capabilities of the process to remove contaminates below a certain established threshold level. The US FDA issued the first no objection letter to the use of a chemical PET recycling process (methanolysis) to Hoechst Celanese for food contact applications in January of 1991. The US FDA issued their formal guidelines "Points to Consider for the use of Recycled Plastics in Food Packaging: Chemistry Considerations" in May of 1992 [21]. Since that time, they have reviewed and issued "no objection" letters for some 47 processes involving PET. The US FDA is currently revising their guidelines to more accurately reflect this current state of knowledge with regards to use of post-consumer PET in food contact applications. The major highlights in the new proposed guidelines [18] are as follows:

- Lowering from 1 pbb to 0.5 pbb the dietary concentration that would correspond to negligible risk for contaminant migrating from recycle plastic.
- Increasing the number of examples of surrogate contaminants that are suitable for use in evaluating the recycling process.
- Eliminating the need to include a heavy metal contaminant in the surrogate testing of recycling processes for PET.
- Addressing secondary recycling of plastics for cases in which containers from non-food contact applications (those that originally contain for example house cleaners, soaps, shampoos or motor oil) will be included in the post consumer feedstock.
- Eliminating all data requirements for tertiary recycling polyethylene terephalate (PET) and polyethylene naphthalate (PEN).
- Maintaining 0.05 as the consumption factor (CF) for recycled PET for food contact use (in opposite to virgin PET where CF was updated to 0.16).

4.2. Europe

Industry has pressed for the issuance of an EU Directive on recycling since the early 90s. To-date no such Directive exist. This has necessitated interested members of industry to seek approval from the individual member states of the European Union or European country governments. The United Kingdom was the first country in Europe to issue a letter of no objection for the use of post-

consumer recycle PET for process via depolymerisation for direct food contact use in 1992. Since that time both multilayer and monolayer (direct contact/super-clean processes) have been given clearance via letters of no objection or approval by a number of the European countries. Multilayer has received clearances for use in Austria, Belgium, Finland, France, Norway, Sweden and the United Kingdom. The monolayer direct contact approach has received clearance for use in Austria, Belgium, France, Germany, The Netherlands, Norway, Sweden and Switzerland. The heterogeneity in Europe is most clearly indicated by the fact that in some countries such as Italy or Spain plastics recycling into direct food packaging application is currently still prohibited.

The continuing need for guidance in assessing the use of PET recycling technologies in food contact applications resulted in a workshop being sponsored under the auspices of the International Life Science Institute (ILSI) Europe Packaging Material Task Force. The workshop participants consisted of representatives from many of the major European Regulatory/Independent Industrial Research Laboratories, representatives from major industry companies and representatives from the European Commission, Directorate – General III. Two years of diligent work resulted in the issuance of guidelines for recycling of plastics for food contact use in May 1998 [22]. These guidelines contain eight key recommendations. And for all practical purposes parallel the US FDA guidelines with the exception of the bases of the end point. US FDA guidelines base their end point on the concept of the Threshold of Regulation whereas the ILSI guidelines focus on an end point of demonstrating no detectable migration at the limit of detection of analytical methodology. It should be noted, however, the final end point in both instances i.e. the Threshold of Regulation and the non-detectable migration limit are in fact the same value for PET recycling (10 ppb or $\mu g\ kg^{-1}$).

In 2000, the German BfR (the former BgVV) has issued a statement to ensure the safe mechanical recycling of plastics made from polyethylene terephthalate (PET) for the manufacture of articles for direct food contact. This statement which has been adopted under BfR recommendation XVII for PET [17] introduces additionally two interesting novelties: (i) the concept of analytical quality assurance connected with the requirement that PCR PET products must not be disadvantageously distinguishable from virgin material and (ii) the 10 ppb migration limit for surrogates as a technical cleaning efficiency criterion for evaluation of the super-clean process capability and not understood as a toxicology based end parameter.

5. Technological principles and strategies to ensure high PCR PET quality

5.1. Recollection systems

In the European member states different recollecting systems for post-consumer PET bottles have been or are currently established. Each of these recollecting systems has special properties and impacts on the quality of the recollected post-consumer PET bottles. However, principally, there are only two major systems: deposit systems and curbside collections. In deposit systems the customer brings the post-consumer PET bottles back to the store in connection with redemption of the deposit. These systems are established e.g. in Germany or Scandinavian countries. From a contamination point of view these systems are advantageous because the post-consumer PET is normally not cross-contaminated by other materials or fillings during the recollection. On the other hand, recollected deposit bottles are usually 100 % bottles from the food packaging area. The second recollection system uses curbside collections where the post-consumer PET bottles are collected as PET only fractions or together with other packaging materials e.g. green dot systems. In these systems normally a separation of food packaging materials from PET used as non-food packaging materials is hardly or not possible. Therefore the fractions have a certain amount of post-consumer PET bottles which originate from non-food packaging applications.

As a result of the Europe wide screening of post-consumer PET flakes from different recollection systems the differences between the recollection systems in view of migrateable substances are very small [12]. Therefore, in principle, all of the above-mentioned recollecting systems are suitable for recycling. However, it should be noted that source control is one important step in order to assure the quality of PCR PET for direct food contact applications.

5.2. Conventional recycling processes

Conventional recycling procedures comprise as principal process steps either grinding of post-consumer PET containers followed by flake washing or whole bottle wash followed by grinding and subsequent flake washing. Both technologies are followed by dewatering and surface drying of the produced PET flakes. For further extrusion into new pellets pervasive drying of the flakes is necessary. The PET flakes output material of conventional recycling processes are customary used for fibres, non-food packaging or for the core layer of multi-layer applications. Another option is to feedstream conventionally recycled PET flakes into super-clean recycling processes as described below (Chapter 5.3). Conventional recycling processes have important functions for the safe PET recycling. During washing and grinding the post-consumer material is homogenized and dirt, labels, glue, residual foodstuffs etc. as well as foreign polymers (e.g. closures, barrier materials like polyamide) are to be eliminated. The output material of conventional recycling processes should therefore be a nearly 100 % PET fraction without surface contamination and a residual water content of <0.7 %. The purification and conditioning steps like washing and drying to achieve these parameters do have the positive side-effect that contaminants are already very efficiently reduced under the applied conditions.

The particular conditions applicable and the technical minimum requirements to fulfil these specifications depend on the input materials and will be optimised by a recycler.

5.3. "Super-clean" processes

Super-clean recycling processes normally use the output materials of conventional recycling processes as input material and apply further deep-cleansing steps in order to remove post-consumer substances. In most instances, these processes uses special washing processes, high temperature, vacuum, surface treatment, melting, melt filtration and melt degassing steps to remove post-consumer contaminants. The product of super-clean processes may be used for packaging applications in direct contact to the foodstuff provided they meet the appropriate regulatory guidelines or legal requirements. If so, these products do not contain measurable migrants other than those in virgin food grade PET.

6. Cleaning efficiency testing of reprocessing technologies

The use of PCR PET in food contact applications must assure for the safety of the material. The concern is that the consumer may have used the bottle/container for mixing or storing some adventitious substances prior to disposal thus generating an unwanted migration potential in the PET material. Therefore it is necessary to ensure that any recycling process has the ability to render these materials safe for the food contact application.

The first approach to manage these potential problems was addressed by the US FDA guidelines of 1992 [21]. At this time the relative incidence of the contamination rate in the PCR PET feedstreams was not known and consequently FDA took the position that one must contaminate 100 % of the feedstock for testing. The test that was recommended is called a "challenge test" which is used to establish the efficacy of the recycling technology and the involved cleaning steps. In this challenge test, organic chemicals with varying chemical and physical properties are introduced into the PET material which is then carried through the complete washing and recycling process to be assessed. The organic substances serve as model contaminants or so-called surrogates. It is important that the contamination must be carried out such that considerable amounts of chemicals can diffuse into the plastic material. The initial concentrations of the surrogate contaminants must be sufficiently high enough to establish a worst-case scenario for the recycling system to be assessed or, if necessary, the modular cleaning step which is to be checked. Concerning the question, however, what exactly must be understood by these worst-case challenge test conditions, there was an enormous increase of research data in the past decade and particularly in the last three years through the FAIR-CT98-4318 project as well as other relevant studies [7, 8, 9, 10, 11, 12, 14].

For PET, US FDA originally [21] recommended a set of five surrogate categories where each set stands for a different chemical polarity and volatility and where the individual surrogates should represent certain "common" materials which are accessible to the consumer and therefore potential candidates for misuse or abuse of plastic containers. One of the five categories should represent heavy metals but was deleted again for PET challenge testing because, based on new scientific data, it is not considered to constitute a regulatory issue [18]. The applicable initial concentrations of these surrogates are defined by the test protocol through the recommended concentrations of surrogates in the contamination cocktails and the time and temperature conditions (14 d at 40 °C) recommended for the soaking procedure. Undoubtedly, this approach represents more than a worst-case scenario, since it simulates the scenario that all PET food container material entering the recycling stream is contaminated practically at maximum possible levels. For inclusion of non-food containers (of initially food grade PET quality) into the feedstream, FDA has specified the minimum concentrations of surrogates to be used on the basis of sorption equivalents achievable after a one year storage at around room temperature. Depending on the chemical structure of the surrogate the required initial target concentrations range from 49 ppm (benzophenone) to 1100 ppm (trichloroanisole) with two exceptions (chloroform and diethyl ketone) set at 4860 ppm each.

In Europe, the experts from the above-mentioned ILSI workshop came to the conclusion that for ensuring a sufficient safety margin a factor of 10 should be applied to both factors influencing the level of surrogates introduced by the challenge test. These factors are: (i) the concentration of surrogates used to contaminate the articles and (ii) the number of articles or weight of flakes to be contaminated (i.e. the amount of contaminated recycled material to be used in the test). With respect to each factor, the guide sticks on the one hand to the FDA guidelines recommending the same surrogate concentrations and 100 % contamination but offers, on the other hand, also relaxed requirements based on sound evidence of actual likely incidence of the contamination in practice [22]. At this time, however, typical contamination levels were not known and consequently the final factor which is the product from both contributions (i) and (ii) remained undefined. This fact was indeed one of the driving forces to initiate the EU project [14] in which exactly this open question was resolved.

The German position as laid down by BfR recommendation XVII [17] recommends as a sufficient initial challenge test concentrations a range from 500 ppm to 1000 ppm per surrogate contaminant for checking the entire process. This document states also that 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 recycled material and the surrogates containing model article. In addition it says that the specified concentration range includes a safety factor of 100 to 1000 in relation to the real maximum occurring initial feedstream concentrations of foreign substances which are untypical for PET in recycled PET and which do not come from the previously filled foodstuff.

As an assessment criterion for the sufficient cleaning efficiency of the recycling process all of the above mentioned documents have in common that the final measurable migration of the spiked surrogates from a model food contact article into a food simulant must not exceed of 10 ppb (µg kg^{-1}).

6.1. Selection and application of surrogates for input from food packaging applications as feedstock

As mentioned above, surrogates should represent commonly accessible chemicals and include representative and relevant chemical structures. In addition, they must be chemically stable during the challenge test steps and should be comfortably analytically quantifiable. From these considerations, and in accordance with FDA recommendations, a set of surrogates (Table 1) has been selected as a result from extensive experimental and analytical experience from the EU project FAIR-CT-98-4318 [14] and from numerous challenge tests.

Table 1: List of chemicals to be used as surrogates in a challenge test

Surrogate	Formula (MW in g mol^{-1})	Functional group	Properties
Toluene	C_7H_8 (92.1)	aromatic hydrocarbon	volatile, non-polar, liquid
Chlorobenzene	C_6H_5Cl (112.6)	halogenated aromatic hydrocarbon	volatile, medium-polar, liquid, aggressive to PET
Phenyl cyclohexane	$C_{12}H_{16}$ (160.3)	aromatic hydrocarbon	non-volatile, non-polar, liquid
Benzophenone	$C_{13}H_{10}O$ (182.2)	aromatic ketone	non-volatile, polar, solid
Methyl stearate	$C_{19}H_{38}O_2$ (298.5)	aliphatic ester	non-volatile, polar, solid

The selected surrogates cover not only a wide spectrum of volatility and polarity properties but also the full range of migration-relevant molecular weights. Due to its inherent low diffusivity PET allows under normal food packaging filling and storage conditions relevant migration of its constituents up to a molecular weight of around 350 g mol^{-1}. Substances with higher molecular weights do not play a role anymore in migration and are nearly immobilised in the polymer matrix, if present. This is illustrated by Figure 1 which models the migration after 10 d at 40 °C from PET in dependency of the molecular weight of a migrant and its residual content $C_{P,0}$ (migration model applied as described in [23]). According to this figure and assuming a $C_{P,0}$ = 10 ppm for any PET constituent, toluene (MW = 92) as a surrogate would give a migration value of approx. 7 ppb whereas methyl stearate (MW = 298) migrates at approx. 2.4 ppb only. Or when defining the maximum initial concentration (MIC in ppm) of a surrogate in PET which corresponds to a migration value of 0.01 ppm (10 ppb) in food simulant then the following ratios of MIC values can be derived for contact conditions 10 d at 40 °C (see Table 2). It should be noted that two MIC columns have been generated each with a different A_P value where the A_P = 1 values are overconservative and too exaggerating (compare discussion under 7.1).

Table 2: Surrogate dependent MIC values (in ppm) corresponding to a migration value of 10 ppb

Surrogate (MW)	MIC for A_P= -1 (in ppm)	MIC for A_P= 1 (in ppm)
Toluene (92)	12	4.5
Chlorobenzene (113)	14	5.3
Phenyl cyclohexane (160)	20	7.5
Benzophenone (182)	23	8.6
Methyl stearate (298)	46	16.9
fictive substance (400)	76	28.0
fictive substance (500)	119	43.6
fictive substance (750)	327	115

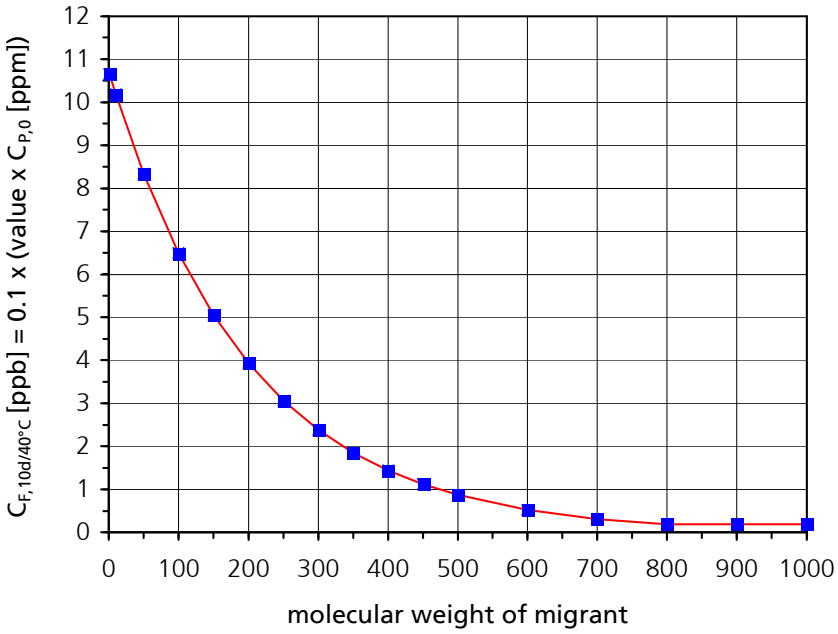


Figure 1: Molecular weight dependent relationship between residual content $C_{P,0}$ of a substance in PET and its migration (after 10 d at 40 °C) into a food simulant or food with high solubility for the substance (Piringer Model with A_P = -1). For a substance with MW = 200 for instance: a $C_{P,0}$ of 10 ppm corresponds to a migration of 4 ppb.

Application of the surrogates may occur by soaking PET bottles or flakes with each individual surrogate dissolved at the specified concentration in an appropriate solvent for 14 d at 40 °C as recommended by US FDA [18] or using mixtures. This procedure, however, was found to be time consuming and excessive chemical waste producing. Therefore another soaking procedure was

developed [7, 11] working with a mixture of the surrogates at higher temperature (50 °C) and shorter time (7 d). This procedure which is much more convenient with respect to the handling steps was found to be equivalent to the "classical" FDA soaking procedure. Furthermore, it avoids production of excessive chemical waste due to quantitative absorption of the surrogates.

Following this new quantitative absorption procedure the surrogates are applied to PET flakes such that after the absorption phase the contaminated PET flake batch should contain approximately 500 ppm to 350 ppm of the above listed surrogates where the more volatile surrogates such as toluene should approach the 500 ppm level and the most non-volatile compound (methyl stearate) may be present rather at the lower 350 ppm level. The so-contaminated PET flake batch is introduced directly into the super-clean process which is to be assessed. Therefore, taking cleaning efficiencies of conventional recycling technologies of 20 % to 80 % (achieved by washing and flash-drying) and finally 89 % to 99 % (achieved by pervasive drying for extrusion) into account [24, 25], this recommended concentration range of 500 to 350 ppm contains a large safety margin because it translates to much higher concentrations (at 80 % wash efficiency: 2500 ppm to 1750 ppm) in comparison to the classical FDA approach where the soaked PET flakes undergo at first a conventional washing and drying process before being further deep-cleansed by a super-clean process.

When comparing the above recommended surrogate concentration ranges with the EU project findings from conventionally recycled PET flakes then the following safety factors (washing and drying effects are already excluded) can be discussed. It should be noted that these safety factors do not include the effect of the super-clean process which reduces the contamination concentrations to non-detectable levels [12].

With respect to PET unspecific compounds which, however, are food constituents from the first use, and more specifically for limonene:

- Maximum level found : 20 ppm, i.e. safety factor range from 18 to 25.
- 98 percentile level found: 10 ppm, i.e. safety factor range from 35 to 50.
- Average concentration found: 2.9 ppm, i.e. safety factor range from 120 to 170.

With respect to PET unspecific compounds such as phthalates, adipates, erucamide etc. which had a technological function (for instance softener or lubricant) as an additives in the first application and were introduced as external contaminants from residues of other polymer types, affixed labels, closures and others. Observed concentrations ranged around the detections limits of approximately 0.05 to 0.2 ppm with a maximum value of 0.5 ppm found in one case for dioctyl adipate. Taking the highest, singular observation of 0.5 ppm then safety factors range from 700 to 1000.

With respect to misuse chemicals, the PET recycling feedstream contains 1.4 to 2.7 ppm. Using 3 ppm as an upper limit value the safety factors range from 120 to 170.

In conclusion, science and practice have demonstrated that both the US FDA soaking procedure (14 d at 40 °C) and the above mentioned alternative elevated temperature contact approach (7 d at 50 °C) are suitable to evaluate decontamination technologies with respect to their potential of producing regulatorily acceptable food grade recycled PET qualities. The preferred

procedure may be selected case by case according to the particular requirements of the technological process and the end user (customer).

6.2. Selection and application of surrogates for input from non-food packaging applications as feedstock

It was the major intention of the EU project [12] to investigate into the average contamination levels from food containers. However, due to inclusion of the numerous samples with unknown origin and from curbside collections e.g. green dot systems, considerable information about possible contamination levels when including also non-food containers was collected and it was found that the contamination patterns after the conventional recycling steps did not differ significantly from food containers. This finding can also be rationalised by the inherent PET properties more specifically the low diffusivity and by the above discussed washing and drying cleaning efficiency of conventional reprocessing.

Besides the project related information, other information from published literature [9, 10] allow the conclusion of possible inclusion of non-food containers into the PET recycling feedstream as well as the fact that several FDA approvals have been received for the recycling non-food containers into food contact applications [26]. These FDA decisions were based on demonstrating that there was no difference in the end product PCR PET when processed from 100 % beverage bottles or 100 % non-food containers and on additional data generated internally by FDA [10, 18]. In addition, the fact that also non-food containers are produced from food grade PET [19], was an additional factor in the FDA's decision. In accordance with FDA's recommendation [18] it is recommended to include into the set of surrogates as another non-food container application typical contaminant methyl salicylate ($C_8H_8O_3$, MW = 152) such that a contamination level of at least 200 ppm is achieved after the absorption phase in the contaminated PET flake batch.

6.3. Practical instructions for challenge tests

Typically a super-clean recycling process consists essentially of three steps: (i) washing of the incoming PET flakes obtained from grinding of used soft drink bottles followed by drying, (ii) remelting of the washed and surface-dried PET flakes for extrusion to form new PET pellets and (iii) additional deep-cleansing steps using high temperatures as high as conditions used in solid stating and a high vacuum e.g. solid-phase condensation.

Since challenging real manufacturing facilities can be very complicated or impossible, down-scaling of the process to pilot plant dimensions but keeping process parameters as close as possible to the industrial scale is possible or even recommendable. One realistic option to challenge test on the industrial scale is to contaminate a coloured batch of PET flakes and carry them either through the whole process or process steps, depending on the technology applied. The coloured material may be separated and analysed separately.

The cleansing efficiency of a washing and drying steps (i) is well known (see discussion above) [24, 25], surrogate contaminated PET flakes can be directly (without washing or rinsing) introduced into step (ii), the remelting/extrusion process. Even when the flakes are not homogeneously contaminated after the

contact with the surrogates such a procedure leads automatically to a homogeneous distribution of the surrogates in the extruded pellets. Alternatively to the classical soaking procedure using the single surrogates in appropriate solutions and applying standard contact conditions according to FDA guidelines [18], the preparation of contaminated PET flakes can be achieved much simpler and faster by the following procedure.

For instance: The cocktail of surrogates (for instance 100 g per surrogate) are given into and mixed with 5 kg of virgin PET flakes. This master-batch is mixed with another portion of 50 kg of virgin PET material and then stored in a closed steel container for 7 d at 50 °C to 60 °C. This procedure allows to achieve sufficient sorption of the chemical compounds into the PET material due to the relatively high temperature and because of the aggressive character of the volatile surrogates under these conditions. The concentration levels obtained in this way are determined analytically as described below to give the "initial concentrations" for the challenge test.

When challenging a process for the first time it was found very useful to contaminate at three different concentration levels of the surrogates in the PET flakes in order to check the purification efficiency over a wider concentration range. This allows an extrapolation of the results to higher or lower initial concentration levels not actually measured in the challenge test and may give additional useful information. A fully detailed technical description can be found in the published literature [7, 11].

After introduction of the contaminated PET flakes into the process facilities the purification progress of the technology should be monitored by taking PET samples at any sampling possibility during the process until generation of the final product which in most cases are pellets and depending on the technology may also be flakes. The drawn PET samples are analysed for the surrogates by validated methods, for example by headspace sampling or solvent extraction procedures in combination with GC/FID or GC/MS techniques. Appropriate analytical methods can be found in the literature [7, 11]. It must be noted that performing laboratories should have an accreditation for these methods.

7. Evaluation of (potential) surrogate migration

The recycling process to be assessed by the challenge test must be able to remove the recycling-related substances so efficiently that the finished product (recycled PET pellets) meets food legal requirements. To guarantee this, the PET product from the challenge test or a model food contact article produced from the challenge test product, respectively, shall be evaluated or tested with regard to its migration potential.

Any procedure for control of migration from food packages must be linked either directly or indirectly to the measurement or evaluation of the actual or possible concentration of an undesired compound in food(simulants). In principle, this can be achieved by two sequential steps [27]: (i) indirect migration assessment by compositional analysis of the package material and either assumption of total mass transfer or migration modelling and (ii) migration assessment by analysis of mass transfer from the package material either by direct migration measurement or semi-directly by alternative migration tests.

For each approach taken, a conclusion must be drawable as to whether migration from a (hypothetical) model food contact article will exceed 10 ppb or not. The 10 ppb level understood as migration related concentration in the appropriate food simulant will be the assessment criterion regardless whether it is understood as a toxicological parameter (as for instance by FDA including CF) or as a purely technical cleaning efficiency criterion (as for instance by German BfR). In this context, it must be noted that food contact articles made from the same recycled PET raw material may vary in migration rates due to the final morphology of the article. For instance, an amorphous PET sheet will have higher diffusivity than more crystalline PET bottles.

7.1. Evaluation of migration by calculations

It is logical and consistent with FDA recommendations to first check residual surrogate concentrations in the PET raw material from which new food contact articles may be produced. Instead of verification of the assessment criterion by migration testing this requirement can be checked via determination of residual surrogate content in the recycling product (recycled PET pellets or bottles and other articles) or in the surrogate article, in connection with a scientifically recognised method for migration estimation.

If the concentrations of the surrogates in the output material (e.g. pellets) are such that under the assumption of 100 % migration of the whole surrogate amount will not lead to concentrations above 10 ppb in the foodstuff, no migration testing is necessary. The foodstuff/PET relation and the amount of recyclates in the bottle wall (e.g. 25 % recycled material and 75 % virgin PET or other ratios) can and should be taken into account. This is virtual justifiable because exactly PET food contact articles such as bottles and sheets do under no practical circumstances completely release their migrants into food(simulants). In opposite, due to the already mentioned low diffusivity, only a marginal fraction of a migrant will be transferred. Table 2 and Figure 1 demonstrate impressively how small these migrant structure dependent fractions are.

If it is found from the 100 % mass transfer approach that potential migration would exceed the 10 ppb criterion then mathematical models can be applied for further evaluations. A generally recognised migration model based on diffusion coefficient estimation or organic chemical substances in polymers [28] has been recently finished within the European project SMT-CT98-7513 "Evaluation of Migration Models in Support of Directive 90/128/EEC" [29]. For migration estimation of surrogates from PET, however, this migration model turns out to be overconservative [measured surrogate migration data from 7, 8, 11 in comparison to calculated ones, 18]. According to [29] the efficient PET diffusivity at 40 °C is described by a value $A_P = 1$ whereas the more realistic diffusion behaviour is described by $A_P = -1$. This value is still overestimative and was therefore used for Figure 1 and included also in Table 2. This table can serve as an indication whether residual contents of surrogates will lead to migration exceeding the 10 ppb criterion. It is recommended to allow for a sufficient safety margin to ensure fulfilling the 10 ppb requirement. Therefore the values found in the $A_P = 1$ column can be considered as the MIC limits below which migration tests are totally superfluous. With increasing values above the $A_P = 1$ MIC limits migration testing is more and more recommended and even necessary when the $A_P = -1$ MIC limits are approached.

7.2. Manufacture of model food contact articles

To enable migration testing as the most direct evaluation step a model food contact article shall be manufactured from the particular challenge test product. The model article should be manufactured as close as possible to the real industry scale conditions. However, technical difficulties may occur due to relatively high contamination levels and also mechanical adverse effects or optical impairments may be observed on the final model articles from the same reasons. Nevertheless, these articles can be used for migration testing since they rather generate a worse case concerning the out diffusion of surrogates. Similar, when different types and geometries of food contact articles are foreseen, it is recommended to manufacture that type which is expected to have the highest diffusion rate. For instance, amorphous sheets do have higher diffusion rates compared to bottles.

7.3. Migration testing

Migration testing is generally recommended but, as discussed above (Chapter 7.1), not always necessary. In any case where the challenge test product fails the above-mentioned criteria or in cases of doubt migration testing is obligatory and need to be carried out according to provisions of EU Directives 97/48/EC and 85/572/EEC as well as eventual amendments. The conditions of foreseeable use of the PCR PET containing article do influence the extent of possible migration into food. The migration rate determining parameters are contact time and temperature as well as the nature of the real filled product respectively the corresponding test conditions according to EU Directive 97/48/EC and EU Directive 85/572/EEC. With regard to the conditions of use it also has to be considered whether the recycled PET is in direct contact to 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.

The assessment criterion to decide whether the challenge test has passed the crucial requirement of efficient removal of potential contaminants is defined by a maximum migration rate leading to a concentration of 10 ppb (µg l^{-1}) in the food simulant. It must be noted that initial surrogate concentrations introduced by a challenge test into a super-clean process range several orders of magnitude higher compared to what can be found in reality. Therefore, reduction of these initially high concentrations to such low levels in the challenge test product or in the model food contact article which correspond with or lead to migration values smaller than or equal to 10 ppb demonstrates the deep-cleansing efficiency of the technology and is not connected to any consumer exposure considerations.

8. Quality assurance

As with any other industrial production of food packaging materials also production of PCR PET for food contact application needs a quality assurance system. Essentially this system needs to address the following issues:

- Frequency of carrying out the challenge test on a given technology
- Analytical monitoring of the feedstream and/or product
- Sensory testing of the product or final articles.

Besides these issues the traceability from the food contact article to its raw material is of increasing importance. This is by its nature a more complicated point to consider compared to virgin materials. However, when considering that super-clean processes that are approved to fulfil the food legal requirements, do produce a PET quality which cannot be disadvantageously distinguished from virgin food grade PET then it is logical that the traceability chain does not need to go further back than to the production facility of the PCR PET. In other words, this production technology appears to be equivalent to the chemical polymerisation of virgin PET where the traceability chain for virgin PET ends up.

8.1. Frequency of the challenge test

A given super-clean recycling technology needs at least to be systematically checked and evaluated once by a challenge test. When the applied process parameters are kept constant or are not disadvantageously changed, the same cleaning efficiency can be assumed for other equipment 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 been compromised. Depending on the particular situation, this can also be achieved via a modular test of the respective process steps and by means of a reduced-scale test. If necessary, the test should be repeated. A process description with the parameters installed for the challenge test should be made and accessible as a reference for any modifications.

8.2. Analytical monitoring

Suitable analytical monitoring programmes are recommended to ensure continued product quality as once demonstrated by the challenge test. Useful and in practice feasible approaches have been developed and published in the literature. Possible methods and techniques include sniffing devices for returned used bottles as well as instrumental analysis techniques such as headspace or thermodesorption gas chromatography coupled to FID or MS detectors [7-11, 30, 31]. Other suitable methods may also be established. These analytical methods can be comfortably implemented into the production process for checking either the input quality to allow early sorting out of any inconvenient post-consumer qualities from conventional recycling as well as for super-clean product control.

With respect to necessary evaluation of large amounts of raw data, a methodology based on principal component analysis (PCA) has turned out to be very useful since it allows quick online and automated quality controls [12].

8.3. Sensory testing

To comply with the general requirements of Article 2 of the Framework EU Directive 89/109/EC sufficient sensory inertness of the PCR PET product of food contact articles needs to be assured. Therefore appropriate sensory testing of food contact articles made from super-clean products is recommended. As worse case test conditions for this purpose storage of the article in direct contact with water for 10 days at 40 °C have been generally accepted. However, depending on the particular application modified tests may be more suitable.

9. Acknowledgements

This work was largely funded by the European Union under contract FAIR-CT98-4318 ("Recyclability of PET, paper&board and plastics covered by a functional barrier for food packaging"). The findings and the conclusions in this paper are the responsibility of the authors alone and they should not be taken to represent the opinion of the European Commission.

The authors gratefully appreciate pleasant cooperation with all of the project partners involved in section I (PET) of the project. These partners are:

- Dr. Laurence Castle and Mr. Mark Philo, DEFRA Central Science Laboratory, York, United Kingdom
- Mr. Juha Lahti and Dr. Jari Vartiainen, VTT Biotechnology and Food Research, Espoo, Finland
- Dr. Catherine Simoneau and Dr. Barbara Raffael, Joint Research Centre for the European Commission, Institute for Health and Consumer Protection, Ispra, Italy
- Prof. Christina Nerin, University of Zaragoza, Dept. Quimica Analitica, Centro Politécnico Superior, Zaragoza, Spain
- Prof. Panagiotis Demertzis, University of Ioannina, Department of Chemistry, Laboratory of Food Chemistry, Ioannina, Greece
- Mr. Rüdiger Fredl, Dr. Thomas Natter and Mr. Matthias Prebentow, OHL Apparatebau & Verfahrenstechnik GmbH, Limburg/Lahn, Germany
- Mr. Caspar van den Dungen, ITW Poly Recycling GmbH, Weinfelden, Switzerland
- Mr. Fritz Kehlert, Texplast GmbH, Wolfen, Germany
- Mr. Juan Carlos Ruiz, Envases de Plastico, Espila, Spain
- Mr. Osmo Bolander, WM Ympäristöpalvelut Oy, Jyväskyla, Finland

Moreover, the authors thank also Mr. Timothy Begley from the US FDA in Washington for experimental contributions and helpful discussions.

Finally, fruitful cooperation with the Commission project officers from DG Research, Dr. Alkmini Katsada and D r. Xabier Goenaga is greatly appreciated.

10. References

[1] EEC, 1994, Council Directive 94/62/EEC on Packaging and Packaging Waste, *Official Journal of European Communities*, **1994**, *L365*, 10-23.

[2] Begley, T. H., Hollifield, H. C., Recycled polymers for food packaging: migration considerations, *Food Technology*, **1993**, *47(11)*, 109-112.

[3] Bayer, F. L., Myers, D. V., Gage, M. J., Consideration of poly(ethylene terephthalate) recycling for food use, 208th American Chemical Society National Meeting, Washington DC, August 25, **1994**, 152-160.

[4] Begley, T. H., Hollifield, H. C., Food packaging made from recycled polymers: Functional barrier considerations, in: Plastic, Rubber and Paper Recycling: A pragmatic approach. C.P. Rader, S.D. Baldwin, D.D. Cornell, G.D. Sadler and R.E. Stockel (eds.), ACS Symposium Series 609, American Chemical Society: Washington DC, **1995**, 445-457.

[5] Sadler, G. D., Recycled PET for food contact: current status of research required for regulatory review, Proc. Society of Plastic Engineering Regional Technical Conference, Schaumburg, IL, USA, November **1995**, 181-191.

[6] Franz, R., Huber, M., Piringer, O. G., Damant, A. P., Jickells, S. M., Castle, L., Study of functional barrier properties of multilayer recycled poly(ethylene terephthalate) bottles for soft drinks, *Journal of Agricultural and Food Chemistry*, **1996**, *44*, 892-897.

[7] Franz, R., Huber, M., Welle, F., Recycling of post-consumer poly(ethylene terephthalate) for direct food contact application - a feasibility study using a simplified challenge test, *Deutsche Lebensmittel-Rundschau*, **1998**, *94(9)*, 303-308.

[8] Franz, R., Welle, F., Post-consumer poly(ethylene terephthalate) for direct food contact applications - final proof of food law compliance, *Deutsche Lebensmittel-Rundschau*, **1999**, *95(10)*, 424-427.

[9] Bayer, F. L., Polyethylene terephthalate (PET) recycling for food contact applications: Testing, safety and technologies -A global perspective, *Food Additives and Contaminants*, **2002**, *19*, Supplement, 111-134.

[10] Begley, T. H., McNeal, T. P., Biles, J. E., Paquette, K. E., Evaluating the potential for recycling all PET bottles into new food packaging, *Food Additives and Contaminants*, **2002**, *19*, Supplement, 135-143.

[11] Franz, R., Welle, F., Post-consumer poly(ethylene terephthalate) for direct food contact application - challenge-test of an inline recycling process, *Food Additives and Contaminants*, **2002**, *19(5)*, 502-511.

[12] Franz, R., Mauer, A., Welle, F., European survey on post-consumer poly(ethylene terephthalate) materials to determine contamination levels and maximum consumer exposure from food packages made from recycled PET, *Food Additives and Contaminants*, **2003**, submitted for publication.

[13] Fritsch, C., Welle, F., Polyethylene terephthalate for packaging, *Plast Europe*, **2002**, *92(10)*, 40-41.

[14] Franz, R., Programme on the recyclability of food packaging materials with respect to food safety considerations - polyethylene terephthalate (PET), paper & board and plastics covered by functional barriers, *Food Additives and Contaminants*, **2002**, *19*, Supplement, 93-110.

[15] WHO Food Additives Series 40: Safety evaluation of certain food additives and contaminants, prepared by the 49th Meeting of JECFA, Annex 5: I.C. Munro and R. Kroes: Application of a threshold of toxicological concern in the safety evaluation of certain flavouring substances, WHO, Geneva **1998**, 499-532.

[16] WHO Technical Reports Series 884: Evaluation of certain food additives and contaminants, prepared as 49th Report of JECFA, WHO, Geneva **1999**, 3-6.

[17] Use of mechanical recycled plastic made from polyethylene terephthalate (PET) for the manufacture of articles coming in contact with food, Bundesinstitut für Risikobewertung (BfR), Berlin, October **2000**. Internet: http://www.bgvv.de. Also implemented into BfR Recommendation XVII.

[18] Guidance for industry: Points to consider for the use of recycled plastics in food packaging: Chemistry considerations – Version 2.0, as of August 15, **2002**; US Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), 5100 Paint Branch Parkway, College Park, Washington DC, MD 20740-3835.

[19] Phoenix Technologies, L.P. June 18,**1998**, "RPET Source Control Submission Data", US FDA Submission CTS# 51519.

[20] Michaeli, W., Bittner, M., Sorting by Chemical Dissolution in: Recycling and Recovery of Plastics, Brandrup, Bittner, Michaeli, Menges (eds.) Carl Hanser Verlag, Munich, Vienna, New York, **1996**.

[21] Points to consider for the use of recycled plastics in food packaging: Chemistry considerations, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFF-410), May **1992**, 200 C Street SW, Washington, DC 20204.

[22] Recycling of plastics for food contact use, guidelines prepared under the responsibility of the International Life Sciences Institute (ILSI) European Packaging Material Task Force, 83 Avenue E. Mounier, B-1200 Brussel, Belgium, May **1998**.

[23] Baner., A., Brandsch, J., Franz, R., Piringer, O., The application of a predictive migration model for evaluating the compliance of plastic materials with European Food Regulations, *Food Additives and Contaminants*, **1996**, *13(5)*, 587-601.

[24] Komolprasert, V., Lawson, A., Effects of aqueous-based washing on removal of hydrocarbons from recycled polyethylene terephthalate (PETE), Congress Proceedings ANTEC'94, San Francisco, May 1-5, **1994**, 2906-2909.

[25] Komolprasert, V., Lawson, A., Residual contaminants in recycled polyethylene terephthalate – effects of washing and drying, 208th American Chemical Society National Meeting. Washington DC, August 25, **1994**, 435-444.

[26] Recycled Plastics in Food Packaging, US Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Premarket Approval, internet: URL: http://vm.cfsan.fda.gov/~dms/opa-recy.html.

[27] Franz, R., Migration of plastic constituents in: Piringer, O.-G. and Baner, A. L. (editors): Plastic packaging materials for food - barrier function, mass transport, quality assurance and legislation, Wiley-VCH, Weinheim, **2000**, Chapter 10, 287–357.

[28] Piringer O.-G., Baner A. L., Plastic packaging materials for food - barrier function, mass transport, quality assurance and legislation, Wiley-VCH, Weinheim, **2000**.

[29] Piringer, O., Hinrichs, K., Evaluation of migration models, Final Report of the EU-project contract SMT-CT98-7513, Brussels **2001**.

[30] Franz, R., Welle, F., Analytisches Screening und Bewertung von marktüblichen "post-consumer" PET-Recyclaten für die erneute Anwendung in Lebensmittelverpackungen (Analytical screening and assessment of commercial available post-consumer PET recyclates for the re-use in food packaging), *Deutsche Lebensmittel-Rundschau*, 1999, *95(3)*, 94-100.

[31] US Patents 5,569,606 (1996), 5,688,693 (1997), 5,733,783 (1998).

European Commission

EUR 21155 — Programme on the Recyclability of Food Packaging Materials with Respect to Food Safety Considerations - Polyethylene Terephthalate (PET), Paper & Board and Plastics Covered by Functional Barriers (PET Recyclability)

Luxembourg: Office for Official Publications of the European Communities

2004 — VIII, 26 pp. — 21.0 x 29.7 cm

ISBN 92-894-6776-2

KI-57-03-071-EN-C

The development of modern recycling processes allows cleansing and reconditioning of used beverage bottles (Post-Consumer Recycled-Polyethylene Terephthalate: PCR-PET) to be reused as packaging material in direct contact with foodstuffs. This publication gives practical guidelines and reliable criteria for the safe recycling of PCR PET using modern "super clean" technologies and harmonised test protocols so that recycled PET can be reused for food packaging applications meeting food safety and consumer health protection demands. It also summarises the state of the art in PCR PET reprocessing for food packaging from a historical, legal and food safety point of view with short notices on technological aspects. This publication is a partial outcome of project FAIR-CT98-4318 carried out with the financial support of the European Commission, DG-RTD, E.2-Food Quality.

Publications Office
Publications.eu.int

ISBN 92-894-6776-2