ILSI Europe Report Series

RECYCLING OF PLASTICS FOR FOOD CONTACT USE





GUIDELINES

Prepared under the responsibility of the ILSI Europe Packaging Material Task Force Second printing © 2000 International Life Sciences Institute © 1998 International Life Sciences Institute

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of the copyright holder. The International Life Sciences Institute (ILSI) does not claim copyright on U.S. government information.

Authorization to photocopy items for internal or personal use is granted by ILSI for libraries and other users registered with the Copyright Clearance Center (CCC) Transactional Reporting Services, provided that \$0.50 per page per copy is paid directly to CCC, 222 Rosewood Drive, Danvers, MA 01923. Tel: (+1) 978 750 8400, fax: (+1) 978 750 4744.

ILSI®, "A Global Partnership for a Safer, Healthier World.®", and the ILSI logo image of the microscope over the globe are registered trademarks of the International Life Sciences Institute. The use of trade names and commercial sources in this document is for purposes of identification only, and does not imply endorsement by the International Life Sciences Institute (ILSI). In addition, the views expressed herein are those of the individual authors and/or their organizations, and do not necessarily reflect those of ILSI.

ILSI Press 1126 Sixteenth Street, N.W. Washington, DC 20036-4810 USA Tel: (+1) 202 659 0074 Fax: (+1) 202 659 8654

ILSI Europe Avenue E. Mounier 83, Box 6 B-1200 Brussels Belgium Tel: (+32) 2 771 00 14 Fax: (+32) 2 762 00 44

Printed in Belgium

ISBN 1-57881-035-3

Report on Recycling of Plastics for Food Contact Use

ILSI Europe Packaging Material Task Force, 83 Avenue E. Mounier, B-1200, Belgium



RECYCLING OF PLASTICS FOR FOOD CONTACT USE

GUIDELINES

PREPARED UNDER THE RESPONSIBILITY OF THE ILSI EUROPE PACKAGING MATERIAL TASK FORCE

Recycling of Plastics for Food Contact Use

The guidelines on which this report was based were prepared by the ILSI Europe Packaging Material Task Force, 83 Avenue E. Mounier, B-1200 Brussels, Belgium

CONTENTS

FOREWORD	4
INTRODUCTION	5
SCOPE OF GUIDELINES	5
EFFECT OF MULTIPLE PLASTIC REPROCESSING	6
DIFFERENCES BETWEEN RECYCLING OPERATIONS AND PLASTIC TYPES	7
FEEDSTOCK FOR RECYCLING	8
CHALLENGE TEST FOR ASSESSING THE EFFICIENCY OF CLEANING UP RECYCLED MATERIAL	9
SELECTION OF SURROGATES FOR A CHALLENGE TEST	9
CONCENTRATION OF SURROGATES	11
FREQUENCY OF UNDERTAKING CHALLENGE TESTS	13
MIGRATION TEST CONDITIONS	14
LIMIT FOR MIGRATION TEST USING SURROGATES	15
SUMMARY GUIDELINES FOR RECYCLING	16
GLOSSARY	18
REFERENCES	19
WORKSHOP PARTICIPANTS	20

FOREWORD

s packaging options for the delivery of safe, high-quality food and beverage products continue to grow, the opportunities to re-use materials, especially plastics, are growing as well. For that reason, the safety and quality assurance aspects of recycling technologies will continue to be examined for the major polymer types.

In the examination process, any proper plastics recycling technology for food contact purposes must demonstrate the ability to remove potential chemical contaminants to an acceptable level of safety that addresses public health concerns.

With this in mind, the ILSI Europe Packaging Material Task Force convened a workshop in London (UK) in March 1997 to produce guidelines for the safe recycling of plastics for food contact use. The workshop was followed by meetings and discussions among experts to produce the following guidelines and recommendations.

INTRODUCTION

This document is the result of an ILSI Europe workshop held in London on 24 March 1997. The conclusions of this paper and the workshop itself drew upon the results of an EU-funded project (AIR2-CT93-1014) (1) as well as utilising guidelines developed by the U.S. Food and Drug Administration (FDA) (2) and other organisations (3). This document – the consensus view of the experts present at the ILSI Europe meeting – presents a considered and objective view of the safety issues of recycling, from a purely scientific standpoint. These guidelines should be considered in their entirety, and individual recommendations should not be selectively used, because they are inter-related.

This document is intended to be a resource for administrators considering legislative matters in this field. It will also be of assistance to the food industry and other bodies considering the issue of recycled materials. A glossary of terms is included.

SCOPE OF GUIDELINES

Ithough project AIR2-CT93-1014 was wide-ranging in its scope and considered re-use as well as recycling, this document is restricted to recycling. Furthermore, the document is focused on recycling food grade plastics, i.e., materials already used in contact with or as packaging for foods. Sensory aspects are paramount for many food applications of recycled materials, but these are not considered here, nor are microbiological aspects. The scope of this document is restricted to providing guidelines to ensure the chemical safety of recycled plastics. Implicit in these guidelines is the assumption that recycled materials should be demonstrably equivalent to virgin materials in terms of food safety.

EFFECT OF MULTIPLE PLASTIC REPROCESSING

R ecovered plastics are likely to be blended with virgin material (or material with lower cycle numbers) in various ratios for recycling purposes. The average number of cycles undergone by the material will be a function of both the blend ratio and the number of recycling operations carried out; in practice it can range from one to three cycles (1). Thus, plastics typically are not recycled a large number of times because of the potential for the accumulation of degradation products or changes in physical properties.

For studies undertaken in the EU Agro-Industrial Research Programme (AIR) project for three cycle operations (100% recycled) using polyethylene terephthalate (PET), polystyrene (PS), polyethylene (PE) and polypropylene (PP) materials which had undergone processing, such as washing, melting and re-extrusion etc., no significant effect of these multiple reprocessing operations was found on levels of overall migration, molecular weight distribution of the polymer, monomer migration levels, additive migration levels, the presence of oligomers in the plastics, and the formation and levels of additive degredation products.

Thus, it can be concluded that recycled plastics *per se*, with respect to intrinsic physical properties and their migration behaviour, can be regarded for all practical purposes as equivalent to virgin materials. This conclusion is based on a maximum average number of three cycle operations. Clearly, if in the future new technology enables larger average numbers of cycles to be achieved, these conclusions may need to be re-examined. However, present results indicate that the only significant difference between recycled and virgin materials is the previous use of the material being recycled. Concern then centres on adventitious contaminants that might be introduced that may lead to the contamination of food products.

DIFFERENCES BETWEEN RECYCLING OPERATIONS AND PLASTIC TYPES

t was recognised that existing recycling operations are distinct in terms of the extent of control exerted in the selection of materials, sorting and rejection of unsuitable material, washing operations, deep-cleansing operations (when applied), heating processes, mixing/dilution levels with virgin material, fabrication with or without a functional barrier and ultimate intended food application of the recycled material. Each of these stages in recycling is unique, and each can have an effect on the quality of the finished plastic. Both individually and in combination, these stages significantly influence the overall efficacy of the recycling operation to avoid or remove adventitious contamination. For the future no doubt technical developments and improvements in these processes will continue, which at present cannot be anticipated.

For control purposes recycled materials could be treated identically to virgin materials, with imposition of purity limits on the finished product and, thus, the need imposed on manufacturers to carry out batch testing to ensure compliance. Because any contamination episode is likely to be rare and sporadic, it can be argued that every production batch should be tested. This would be difficult because of the possible unknown nature of adventitious contamination that might be introduced and, thus, the analytical problem of setting up a framework that covers all eventualities. To ensure a sufficient safety margin, the analytical limits would probably need to be set at levels below those that might reasonably be achieved in a routine testing laboratory. This conventional approach of ensuring safety with emphasis on the end product therefore seems to offer less assurance than demonstrating that the process itself has certain protective capabilities.

It can be concluded that it is the recycling process that should be controlled and that the process itself be tested against demanding standards to ensure that it is capable of meeting certain criteria. Because of the individual nature of each recycling process and the interdependencies of each stage, however, it would not be possible to stipulate a single set of operational conditions that should be met for the recycling operation itself. To ensure the safety of recycled materials, each process would have to be considered individually on its merits. Thus, because it is the process itself that should be considered, different recyclers using the same process would not need to be considered as separate cases. Additionally, each type of plastic has unique properties which must be considered in relation to the recycling operations and to the end use. Thus, any assessment must also take into account the process being applied and the nature of the plastics used.

Plastics are known to interact with organic chemicals (i.e., most chemicals) according to their typespecific diffusion and sorption behaviour. This behaviour is a critical parameter that determines the degree of uptake of misuse chemicals and thus the potential risk of food contamination. The diffusivity of plastics generally increases in the sequence:

rigid PVC<polyester<PET<PS<PP/HDPE<LDPE

(polyvinylchloride<polyester<polyethyleneterephthalate<polystyrene<polypropylene/ high-density polyethylene<low density polyethylene).</pre> The sorptive capacity for organic chemicals generally increases in the same way, thus leading to the need to take into account each type of plastic. Low-diffusivity materials, such as rigid PVC or PET, can be treated in a much more general way than polyolefins, although inherent diffusivities and chemical inertness must be taken into account in any testing recommendations. In contrast, for high-diffusivity materials, such as polyolefins, the individual application is a critical consideration that may, for example, require much stricter demonstration of source control.

Recommendation 1: Each and every type of plastic and plastic recycling operation is by its very nature different. Each process must therefore be individually assessed and must demonstrate its effectiveness in meeting the standards set out in these guidelines.

FEEDSTOCK FOR RECYCLING

R ecycling operations are geared to address the question of minimising adventitious contamination of articles returned for recycling. Preliminary sorting may reject unsuitable articles – those that are not food-grade plastics or are identifiably contaminated. The potential impact of substances not detected in these preliminary stages will be further reduced by the effects of dilution. The subsequent clean-up stages undertaken during recycling are aimed at eliminating substances that may contaminate the surface and small, mobile molecules that may penetrate the plastic. In contrast, ingredients of plastics (additives and processing aids) and their degradation products are less likely to be removed by the cleaning process. Thus, if non-food-grade plastics entered the recycling process, the parent polymer could be indistinguishable from food-grade material but there would be a risk (albeit small) of non-approved additives or other ingredients being introduced.

Thus, any recycling operation must demonstrate the capability to select and use only food-grade feedstock. The required minimum efficiency of this sorting operation would have to be decided on a case-by-case basis, which would take into account the likely presence and levels of non-permitted plastics additives in particular plastics. However, even for a polymer such as PET, which does not require the addition of potentially troublesome additives such as stabilisers or plasticisers, it was judged that a minimum effectiveness of 99% should be met.

The situation of recycling through chemical depolymerisation was recognised as being different, and in this case the monomer source would be immaterial and any feedstock would be acceptable. The regulatory situation is clear in that monomers and starting substances derived from chemical depolymerisation would have to comply with EC Directive 90/128/EEC (4).

Recommendation 2: Only food-grade plastics are suitable as feedstock for recycling (with the exception of recycling through chemical depolymerisation). The recycling operation must therefore demonstrate the capability of rejecting non-food-grade plastics. The minimum efficiency of sorting should be decided on a case-by-case basis, although it should be at least 99%.

CHALLENGE TEST FOR ASSESSING THE EFFICIENCY OF CLEANING UP RECYCLED MATERIAL

B ecause there are so many variables that affect the efficiency of the recycling process in removing adventitious contamination, a practical test is the only effective way to assess the complete process. A challenge test must therefore be performed in which a selection of surrogate contaminants are deliberately introduced at the beginning of the process, followed by the various cleaning, heating, and processing stages. The cleaned recycled plastics or the finished material or article manufactured from the recycled material should be tested. A migration test should be carried out according to the intended food contact application under the most severe test conditions appropriate for that application.

Recommendation 3: A challenge test must be performed for the recycling operation where the surrogates are introduced together with uncontaminated feedstock at an appropriate point in the process. End measurements (i.e., migration) for the stipulated surrogates must be undertaken on the recycled plastic prior to manufacture of the finished material or article or on the finished recycled material or article itself.

SELECTION OF SURROGATES FOR A CHALLENGE TEST

The situation to be simulated in a challenge test can be characterized by a consumer who has stored household or garden chemicals in a plastic container which is subsequently returned for recycling. It should be recognised that the range of chemicals available to the consumer is in practice extremely limited, which is especially true for known genotoxic carcinogens. The range of chemicals stipulated for the challenge test can be based on chemicals actually available to the consumer, such as household bleach, engine oil, and garden pesticides. The FDA (2) originally stipulated a test employing chloroform, diazinon, gasoline, lindane, and disodium monomethyl arsenate based on this premise. Although realistic in terms of the actual chemicals available to certain consumers, this test is not the most demanding in terms of the range and aggressiveness of chemical species. The test also may be the source of unnecessary analytical difficulties.

A better approach recognises that the test should cover the full range of chemical/physical properties of potential pollutants such as polarity, volatility and compatibility with the polymer type. Thus, any test should include a range of surrogates which represent the extremes ranging from polar/volatile, polar/non-volatile, non-polar/volatile and non-polar/non-volatile. The test should also include substances which are penetrants for the plastic in question.

The FDA had originally proposed a series of test substances. Through the years industry working in conjunction with the FDA has agreed to the use of additional substances which are representative of the physical/chemical classes of compounds and which would be used as alternative test compounds. To date more than 35 surrogates have been employed in various recycling tests. Some of the typical surrogates now are 1,1,1-trichloroethane as a polar volatile

penetrant; benzophenone as a polar non-volatile; toluene as a non-polar volatile substance; phenyldecane, squalane or eicosane as non-polar non-volatiles; and zinc stearate or copper(2-ethylhexanoate) or monomethylsodium arsenate as organometallic surrogates.

Work in the AIR project has shown consistently, and for a number of different plastics, that lowmolecular-weight aromatics, such as toluene and chlorobenzene, are the most challenging contaminants. The AIR project employed trichloroethane, benzophenone and toluene, which are consistent with the FDA test; chlorobenzene to reinforce the low-molecular-weight aromatics; phenylcyclohexane as a non-polar non-volatile; and (possibly) methyl palmitate or methyl stearate to substitute for the organometallic compound.

Substitution of trichloroethane by acetone or isopropanol is proposed for consideration here because the latter two substances are more polar and hence water soluble., They would, however, require validation of their practicality as surrogates before they could be included in the recommended list. It should also be noted that there is no practical experience in the use of methyl palmitate (or methyl stearate), and this would similarly require practical experience before it could be unequivocally accepted on the list of recommended test substances.

The list of surrogates in Recommendation 4 was justified on the basis of maximising aggressiveness of the test combined with selection of substances to facilitate the adequacy of the analysis. It is recognised, however, that this list cannot forever be definitive and that it may need to be revised in the light of future experience. Additionally, although this list is the preferred one for future EU authorisations, it is also acknowledged that previous work using the former FDA surrogates remains equally valid.

Recommendation 4: The challenge test should be performed using the following substances, which cover a range of chemical types and different behaviours with respect to plastics (as well as simulating the range of chemical types potentially available to consumers):

- trichloroethane: polar, volatile penetrant
- benzophenone: polar, non-volatile penetrant
- toluene and chlorobenzene: non-polar volatile penetrants
- phenylcyclohexane: non-polar, non-volatile penetrant
- methyl palmitate (or methyl stearate): substitute for organometallic compounds

CONCENTRATION OF SURROGATES

The FDA (2) proposes that a cocktail of contaminants should be placed either "undiluted" or "at user strength" concentrations in contact with bottles or flakes of the test material for 2 weeks at 40°C with periodic agitation. After the contaminants are drained, rinsed and dried, the concentration should be determined and the plastic subjected to recycling. If the recycling operation passes this extreme test, there is no problem. If it fails, arguments can be presented why additional factors (such as recycled/virgin blends, source control, restricted uses, functional barrier, actual migration data etc.) would in reality prevent the contamination of foods. This extreme test offers considerable consumer reassurance. If a less severe test is proposed, it must be justified.

Two factors effectively influence the level of surrogates introduced by the challenge test: (i) the concentration of the surrogates used to contaminate the articles and (ii) the number of articles (or weight of the test flakes) to be contaminated (i.e., the amount of contaminated recycled material to be used in the test).

i) *Concentration.* It is proposed that for all of the surrogates, the objective of contaminating the recycled articles should be to simulate worst-case conditions, which in practice would mean a higher concentration than user strength of the contaminants. Examination of typical formulations for domestic products would suggest that "user strength" plus a 10-fold safety factor should be used. This would mean employing the following concentrations for the surrogates in suitable diluents selected carefully with respect to the plastics in question (e.g., propanol or heptane): 1% trichloroethane, 1% benzophenone, 10% toluene, 1% chlorobenzene, 1% phenylcyclohexane, and 1% methyl palmitate (or strearate). These concentrations represent an exaggerated test condition and therefore introduce a safety factor.

The contamination should be performed by filling the stipulated number of containers and exposing them (or exposing the test flakes) for 4 weeks at 35°C or 2 weeks at 40°C, emptying the containers (or decanting the diluent from the flakes), rinsing, drying and then subjecting the material to the recycling operation.

The importance of this test is to establish known concentrations of surrogates in the plastic. Thus, if the concentration of surrogates in the plastics are established after this procedure, future tests may be performed by introducing the appropriate concentration of surrogates directly and using, if appropriate, mixtures of surrogates, provided it is demonstrated that they are absorbed into the plastics and not introduced merely as surface contamination. This can be achieved, for example, by a quick surface rinse using a solvent that does not interact with the polymer.

ii) Number of articles (or weight of the test flakes) to be contaminated. In reality, in the exceptional case where contamination may occur, the number of articles likely to be contaminated will be a small proportion of the total number of articles being recycled. However, as an exaggerated test to introduce a substantial safety factor, it is proposed that 100% of articles should be contaminated with surrogate solutions. This requirement may be relaxed if soundly based information is available on the actual incidence of contamination, but even in these circumstances an additional safety factor of at least 10

should be built into the numbers of articles to be filled with surrogate solutions. If the test is to be carried out on flakes rather than containers, an equivalent weight of flakes would need to be used for the test.

It should be noted that the situation regarding chemical depolymerisation processes is different from the above, and that contamination is normally but not necessarily carried out by spiking the surrogates into the depolymerisation vessel at a level of 1000 mg/kg.

The normal requirement should be for 100% of the test articles to be contaminated with surrogates, although this requirement can be relaxed and a lower level accepted based on sound evidence of actual likely incidence of the contamination in practice.

Recommendation 5: The concentration of surrogates introduced for the challenge test should significantly exaggerate the worst possible contamination that could occur in practice. The surrogates should be used as a mixture (cocktail) above the maximum likely user strength stipulated as follows for filling the articles (or for exposure of the test flakes) for the challenge test: 1% trichloroethane, 1% benzophenone, 10% toluene, 1% chlorobenzene, 1% phenylcyclohexane, and 1% methyl palmitate (or stearate).

FREQUENCY OF UNDERTAKING CHALLENGE TESTS

The workshop participants recognised that it is expensive and timeconsuming to undertake a challenge test and that ideally the test would need to be carried out only once. However, it was also recognised that if any of the several critical inderdependent parameters were changed, the effect could not be judged other than by repeating the challenge test. It would be expected that in tests of a recycling process, the critical parameters would be identified and tolerances stipulated within which changes could be made without affecting the efficiency of contaminant removal. (Any recycling process should operate according to Good Manufacturing Practice [GMP] and be subject to normal regulatory monitoring.) For example, it might be envisaged that the rates of recycled material to virgin material could be varied within agreed ranges without needing to repeat the challenge test. For some critical parameters (e.g., thickness, functional barrier), if it were demonstrated by a validated and recognised model that changes in these parameters could not lead to failure of the test, it would be unnecessary for the test to be repeated.

Otherwise, if changes were sought outside the agreed range of critical parameters, the challenge test would need to be repeated to demonstrate that there had been no loss of protective efficiency.

Recommendation 6: The challenge test must be performed when authorisation of the recycling operation is initially sought. If any changes to the stipulated parameters are proposed, the challenge test should be repeated, focusing as required on those aspects of the test most appropriate for the changes proposed. These critical parameters will be identified at the time of approval of the process and may, for example, include: source control, sorting and rejection regime, washing process, deep cleansing process, heating, mixing/dilution and barriers.

MIGRATION TEST CONDITIONS

fter the challenge test is performed, it is necessary to demonstrate whether the finished material or article meets safety standards for migration into a food product.

It is possible to analyse the concentrations of contaminants in the finished article and then assume 100% migration without the need to perform any further migration testing. It is also possible to undertake a migration test with the actual food intended to be packaged in the recycled article under actual conditions of use. Although this is the more realistic test, it is also the most difficult analytical procedure, and will be time-consuming in the case of food products with a long shelf life.

The recycled material or article can be treated identically to virgin material, and testing can be undertaken following the migration test rules according to EC Directive 82/711/EEC (5) and its amendments. Individual companies might choose to set additional or more severe test conditions.

Recommendation 7: After the challenge test is performed using the surrogates stipulated above at the given concentration, the potential contamination that could arise in the food product from the recycled article must be established by any of the following:

- Determine the concentration of surrogates in the recycled plastic and assume that migration into the food would be 100%.
- Determine the concentration of surrogates in the recycled plastic and use a validated and recognised model to predict expected migration into the food.
- Undertake a migration test with the actual food product under actual conditions of use.
- Undertake a migration test following the migration test rules according to EC Directive 82/711/EEC (5) and its amendments.

LIMIT FOR MIGRATION TEST USING SURROGATES

or any guidelines to be of practical value, the migration limit for the test using surrogates must be set at a sufficiently low level to offer adequate consumer protection (with appropriate safety margins) yet be measurable by today's laboratory instrumentation. Any migration limit must be derived from consideration of a tolerable threshold concentration in the diet. This assessment is ultimately the responsibility of competent bodies expert in toxicology and risk assessment. In preparing these guidelines, the expert group took cognisance of the following facts:

- The range of chemicals generally available to the consumer does not include genotoxic carcinogens, and therefore protection is primarily against toxic compounds, most likely household pesticides.
- If contamination occurs, it will likely be sporadic, so a situation of chronic lifetime exposure is highly unlikely.

An examination of current regulations to control food contaminants shows that for total aflatoxins (of which aflatoxin B1 is a known genotoxic carcinogen), limits generally have been set at between 4 and 10 μ g/kg (6). For pesticides the control limits range from 0.01 to 10 μ g/kg, with most requiring the maximum residue level (MRL) which in crops, food and feedstuffs is 10 μ g/kg (7). For veterinary drug residues the MRLs range from 2 to 1000 μ g/kg (8), with limits in only six cases (mostly for residues in milk) below 10 μ g/kg for the challenge test seems defensible in terms of minimising consumer exposure. This would allow for the fact that potential exposure would be only sporadic at worst and also that the test already includes substantial built-in safety factors of at least 100.

A limit of around 10 μ g/kg for the migration test is also a demanding limit in terms of what is practically achievable in most analytical laboratories. The limit should include any analytical tolerance and would be expected, where chromatographic methods were employed, to represent better than three times the noise level of the procedure.

Recommendation 8: The result of the challenge test conducted with surrogates set out in recommendation 4 above, at concentrations in accordance with recommendation 5 and carried out under test conditions set out in recommendation 7, must demonstrate "no detectable migration" at the limit of detection of the analytical methodology. The limit of detection at which reliable analytical measurement can be made is stipulated to be 10 μ g/kg, including any analytical tolerance.

SUMMARY GUIDELINES FOR RECYCLING

1. Each and every plastics type and recycling operation is by its very nature different. Each process must therefore be individually assessed and must demonstrate its effectiveness in meeting the standards set out in these guidelines.

2. Only food-grade plastics are suitable as feedstock for recycling (with the exception of recycling through chemical depolymerisation). The recycling operation must therefore demonstrate the capability of rejecting non-food-grade plastics. The minimum efficiency of sorting should be decided on a case-by-case basis, although it should be at least 99%.

3. A challenge test must be performed for the recycling operation where the surrogates are introduced together with uncontaminated feedstock at an appropriate point in the process. End measurements (i.e., migration) for the stipulated surrogates must be undertaken on the recycled plastic prior to manufacture of the finished material or article or on the finished recycled material or article itself.

4. The challenge test will be performed using the following substances, which cover a range of chemical types and different behaviours with respect to plastics (as well as simulating the range of chemical types potentially available to consumers):

- trichloroethane: polar, volatile penetrant
- benzophenone: polar, non-volatile penetrant
- · toluene and chlorobenezene: non-polar volatile penetrants
- phenylcyclohexane: non-polar, non-volatile penetrant
- methyl palmitate (or methyl stearate): substitute for organometallic compounds

5. The concentration of surrogates introduced for the challenge test should be such as to significantly exaggerate the worst possible contamination that could occur in practice. The surrogates should be used as a mixture (cocktail) above the maximum likely user strength stipulated as follows for filling the articles for the challenge test (or for exposure to test flakes): 1% trichloroethane, 1% benzophenone, 10% toluene, 1% chlorobenzene, 1% phenylcyclohexane and 1% methyl palmitate (stearate).

The normal requirement should be for 100% of the test articles to be contaminated with surrogates, although this requirement can be relaxed and a lower level accepted based on sound evidence of the actual likely incidence of contamination in practice.

6. The challenge test must be performed when authorisation of the recycling operation is initially sought. If any changes to the stipulated parameters are proposed then the challenge test should be repeated focusing as required on those aspects of the test most appropriate for the changes proposed. These critical parameters will be identified at the time of approval of the process and may for example include: source control, sorting and rejection regime, washing process, deep cleansing process, heating, mixing/dilution and barriers.

7. After the challenge test is performed using the surrogates stipulated above at the concentration given, the potential contamination that could arise in the food product from the recycled article must be established by any of the following:

- Determine the concentration of surrogates in the recycled plastic and assume that migration into the food would be 100%.
- Determine the concentration of surrogates in the recycled plastic and use a validated and recognised model to predict expected migration into the food.
- Undertake a migration test with the actual food product under actual conditions of use.
- Undertake a migration test following the migration test rules according to EC Directive 82/711/EEC (5) and its amendments.

8. The result of the challenge test conducted with surrogates set out in recommendation 4 above, at concentrations in accordance with recommendation 5 and carried out under test conditions set out in recommendation 7, must demonstrate "not detectable migration" at the limit of detection of the analytical methodology. The limit of detection at which reliable analytical measurement can be made is stipulated to be 10 μ g/kg, including any analytical tolerance.

GLOSSARY

Adventitious contaminants Any substance other than the originally intended foodstuff that deliberately or inadvertently comes into contact with the plastic before it is collected for recycling and that therefore may contaminate the plastic.

Challenge test A test of the effectiveness of a recycling process to remove chemical contamination from materials or articles. The test involves introduction of exaggerated levels of a variety of substances representing a wide range of chemical types and physical properties.

Chemical depolymerisation A specific recycling process in which the plastic is converted back to its component monomers/substances for purification before being manufactured as a new plastic.

Cycles The number of times a plastic material passes through the complete operation from an empty article that has contained food, to collection, to washing and so on, to manufacture of a new article.

Feedstock Plastics used as raw materials for recycling.

Food-grade plastics Plastic of a suitable standard for food applications manufactured in compliance with appropriate EU directives (principally 90/128/EEC and amendments).

Functional barrier Any integral layer which under foreseeable conditions of use reduces the migration of components from any layer beyond the barrier to technologically unavoidable and analytically insignificant levels.

Misuse chemicals Chemicals e.g., garden pesticides, fuel, domestic cleaning products available to the consumer which may inappropriately be stored in recyclable plastic bottles.

Model Validated and recognised mathematical model for predicting migration behaviour.

Penetrant Any chemical substance which can interact with a plastic and be absorbed and diffused within the material.

Recycling The process by which collected thermoplastic is melted and reformed into a "new" material or article (also known as mechanical recycling).

Recycling operation The process of collecting, sorting, washing materials through to manufacture of recycled articles.

Re-use The collection of containers that are washed and sterilised before being refilled with the same food product as they were originally used for.

Surrogates A test mixture of a wide range of chemical types representing exaggerated contamination to challenge the safety of recycled materials and articles.

REFERENCES

1. Final report of EU funded AIR project AIR2-CT93-1014 "Program to establish criteria to ensure the quality and safety of recycled and re-used plastics for food packaging". Brussels: Agro-Industrial Research Programme, December 1997*

2. Points to consider for the use of recycled plastics in food packaging: chemistry considerations. Chemistry Review Branch, Office of Pre-market Approval, HFS-247. Washington DC: U.S. Food and Drug Administration, December 1992

3. Guidelines for the safe use of recycled plastics for food packaging applications. Plastics Recycling Task Force. National Food Processors Association. Washington DC: Society of Plastics Industry Inc., March 1995

4. European Commission Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs. *Official Journal of the European Communities*, February 1990

5. European Commission Directive 82/711/EC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with food. *Official Journal of the European Communities*, October 1982

6. World-wide regulations for mycotoxins 1995: Compendium. FAO Food and Nutrition Paper N°64. Rome: Food and Agriculture Organization of the United Nations, 1997

7. Pesticides (maximum residue levels in crops, food and feeding stuffs). Regulations 1994. Statutory Instruments 1994, No. 1985. HMSO, London: 1994

8. Shepherd MJ. Analysis of veterinary drug residues in edible animal products. In Creaser C, Purchase R, eds 'Food contaminants – sources and surveillance'. Cambridge UK: Royal Society of Chemistry, 1991

* Copies of Volume 1 – Overview report (36 pp) available from l.castle@CSL.gov.uk

WORKSHOP PARTICIPANTS

Prof. J. Gilbert (Chair)	Ministry of Agriculture Fisheries & Food	UK
Ir. M. Berci	ILSI Europe	В
Dr. L. Castle	Ministry of Agriculture Fisheries & Food,	
	Food Science Laboratory	UK
Dr. F. Chastellain	Nestlé	CH
Dr. L. Contor	ILSI Europe	В
Ir. N. de Kruijf	TNO Nutrition and Food Research Institute	NL
Dr. P. Dole	National Institute for Agronomical Research	F
Mr. V. Ducasse	Groupe Danone	F
Dr. A. Feigenbaum	National Institute for Agronomical Research	F
Dr. R. Franz	Fraunhofer Institute	D
Mr. M. Holmes	Unilever	NL
Mrs. A. López de Sá	Coca-Cola Greater Europe	Е
Dr. V. Marron	Unilever	NL
Dr. E. Moser	European Manufacturers and Plastic Association	CH
Mr. S. Nichols	Wellman Inc.	USA
Mr. I. Renvoize	European Commission, Directorate-General III	В
Dr. L. Rinzema	Dow Europe	CH
Dr. L. Rossi (observer)	European Commission, Directorate-General III	В
Mr. D. Sgorbani	Unilever	NL

Acknowledgment

We would like to thank the following experts for preparing this report and for their valuable comments and other contributions: Dr. L. Castle (Ministry of Agriculture, Fisheries & Food, U.K.), Ir. N. de Kruijf (TNO Nutrition and Food Research Institute, NL), Dr. R. Franz (Fraunhofer Institute, D), Prof. J. Gilbert (Ministry of Agriculture, Fisheries & Food, U.K.), and Dr. L. Rossi (Observer, European Commission, Directorate-General III, B).

ILSI Europe Report Series

The following titles are available in the series:

Polyethylene Terephthalate (PET) as a packaging material – PET for Food Packaging Applications, 2000 16 pp. ISBN 1-57881-092-2

Salmonella Typhimurium definitive type (DT) 104: a multi-resistant Salmonella, 2000 24 pp. ISBN 1-57881-094-9

Detection Methods for Novel Foods derived from Genetically Modified Organisms, 1999 24 pp. ISBN 1-57881-047-1

Overview of Health Issues Related to Alcohol Consumption, 1999 16 pp. ISBN 1-57887-068-X (Translations available in French, German and Spanish)

Safety Assessment of Viable Genetically Modified Micro-organisms Used in Food, 1999 20 pp. ISBN 1-57881-059-0

Significance of Excursions of Intake above the Acceptable Daily Intake (ADI), 1999 24 pp. ISBN 1-57881-053-1

Validation and Verification of HACCP, 1999 20 pp. ISBN 1-57881-060-4

Addition of Nutrients to Food: Nutritional and Safety Considerations, 1998 24 pp. ISBN 1-57881-036-1

Food Safety Management Tools, 1998 20 pp. ISBN 1-57881-034-5

Recycling of Plastics for Food Contact Use, 1998 20 pp. ISBN 1-57881-035-3

Applicability of the ADI to Infants and Children, 1997 20 pp. ISBN 1-57881-018-3

Antioxidants: Scientific Basis, Regulatory Aspects and Industry Perspectives, 1997 28 pp. ISBN 1-57881-016-7

An Evaluation of the Budget Method for Screening Food Additive Intake, 1997 12 pp. ISBN 1-57881-019-1

Food Consumption and Packaging Usage Factors, 1997 12 pp. ISBN 1-57881-017-5

Food Additive Intake – Scientific Assessment of the Regulatory Requirements in Europe, 1995 13 pp. ISBN 1-57881-032-9

The Safety Assessment of Novel Foods, 1995 16 pp. ISBN 1-57881-033-7

B-Carotene, Vitamin E, Vitamin C and Quercetin in the Prevention of Generative Diseases – The Role of Foods, 1995

Report Series Editor: Kevin Yates



The International Life Sciences Institute (ILSI) is a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, and the environment. By bringing together scientists from academia, government, industry and the public sector, ILSI seeks a balanced approach to solving problems of common concern for the well-being of the general public.

ILSI is affiliated with the World Health Organization as a nongovernmental organisation and has specialized consultative status with the Food and Agricultural Organization of the United Nations.

Headquartered in Washington, D.C. USA, ILSI has branches in Argentina, Australasia, Brazil, Europe, India, Japan, Korea, Mexico, North Africa and Gulf Region, North America, South Africa, South Andean, Southeast Asia, Thailand and a focal point in China.

> ILSI Europe Avenue E. Mounier, 83, Box 6 B-1200 Brussels BELGIUM Telephone: (+32) 2 771 0014 Telefax: (+32) 2 762 0044 E-mail: marc@ilsieurope.be

