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SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the processes ‘Biffa Polymers’ and ‘CLRrHDPE’ used to recycle high-density polyethylene bottles for use as food contact material[1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety assessment of the recycling processes ‘CLRrHDPE’ and ‘Biffa Polymers’. These processes are used to recycle post-consumer high-density polyethylene (HDPE) bottles which have been in contact with food, mainly milk, to produce recycled HDPE pellets. Post-consumer HDPE bottles are collected in the United Kingdom and processed by conventional recycling including manual sorting into washed and dried HDPE flakes containing no more than 1 % HDPE from non-food consumer applications. The washed and dried HDPE flakes are heated in two successive continuous reactors under vacuum before being extruded under vacuum into pellets. Recycled pellets are blended with virgin HDPE to produce bottles (both processes) and with virgin polypropylene to produce trays (Biffa Polymers). Bottles are intended for storage of milk and fruit juices. Trays are intended for storage of animal products and raw fruits, vegetables and mushrooms. Having examined the challenge tests provided, the Panel noted the limited decontamination efficiency under the conditions of testing and concluded that the processes do not satisfy criteria set for HDPE. Uncertainties and consequent conservatism of the selected criteria could allow the conclusion that a process is safe when these criteria are met but not when they are not met. Therefore, the CEF Panel considered that, for the manufacture of recycled bottles for milks and fruit juices and trays for animal products, additional data should be provided before it can conclude on the safety assessment. For the manufacture of recycled trays intended for contact with whole fruits and vegetables including mushrooms, at room temperature or below, the CEF Panel concluded that recycled HDPE obtained from the process Biffa Polymers is not considered of safety concern under the restriction given in the opinion.

KEY WORDS

food contact materials, plastic, high-density polyethylene (HDPE), recycling process, EREMA Advanced technology, safety assessment, criteria

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[2] Panel members: Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Wim Mennes, Maria Rosaria Milana, André Penninks, Vittorio Silano, Andrew Smith, Maria de Fátima Tavares Poças, Christina Tlustos, Fidel Toldrá, Detlef Wölfle and Holger Zorn. Correspondence: fip@efsa.europa.eu

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SUMMARY

According to Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials intended to come into contact with foods and amending Regulation (EC) No 2023/2006, EFSA is requested to evaluate processes for recycling plastic waste. In this context, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) evaluated the processes ‘CLRrHDPE’ and ‘Biffa Polymers’.

The Food Standards Agency, United Kingdom (UK), requested the evaluation of the two recycling processes, ‘Biffa Polymers’ and ‘CLRrHDPE’, submitted by Biffa Polymers Limited and Closed Loop Recycling Limited, respectively. These applications have been allocated European Commission (EC) register numbers RECYC023 and RECYC063, respectively. The processes are used to recycle high-density polyethylene (HDPE) bottles which have been used in contact with food, mainly milk, and collected in the UK through post-consumer collection systems to produce recycled HDPE pellets. Recycled HDPE pellets are blended up to 50 % with virgin HDPE to produce new single-use bottles (both processes) and up to 30 % with virgin polypropylene to produce single-use trays (Biffa Polymers only). The bottles are intended to be used for storage of milk and fruit juices at chill temperature or below (both processes). The trays are intended to be used for animal products, fruits and vegetables including mushrooms.

The processes comprise four steps. Applicants purchase pre-sorted, post-consumer HDPE bottles that are further sorted at the recycler site by conventional recycling, including manual sorting, to produce washed and dried HDPE flakes that contain no more than 1 % HDPE from non-food consumer applications (step 1). The washed and dried HDPE flakes are treated in a first reactor under vacuum (step 2), then in a second reactor under vacuum (step 3) before being extruded under vacuum into pellets (step 4).

The CEF Panel pointed out that it should be remembered that, according to Regulation (EU) 282/2008, applicants must ensure that the input HDPE bottles have been manufactured in accordance with Community legislation on plastic food contact materials and articles.

The CEF Panel considered that all the recycled articles, including trays for whole fruits and vegetables, made with post-consumer HDPE bottles collected from an open-loop process should be evaluated following the same approach. The recycling processes should demonstrate, by means of a challenge test or other appropriate scientific evidence, their ability to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health.

Based on data provided by the applicants and those available in the literature, the criteria for the safety evaluation of recycled HDPE, following the same principle as for recycled polyethylene terephthalate (PET), could be set for Biffa Polymers and CLRrHDPE used to recycle post-consumer HDPE bottles collected in the UK. The CEF Panel is aware of the conservatism of the criteria in order to address uncertainties derived from a lack of sufficient scientific data.

Having examined the challenge tests provided, the Panel noted the limited decontamination efficiency under the conditions of testing and considered that the processes do not satisfy criteria set for HDPE. However, the CEF Panel emphasised that the uncertainties arising from the lack of sufficient scientific knowledge and the consequent conservatism of the selected criteria could allow the conclusion that a process is safe when criteria are met but do not allow a conclusion to be reached on the safety of the processes when the criteria are not met. In such cases, additional data are needed for this.

Consequently, for the manufacture of recycled bottles for milks and fruit juices and trays for animal products, the CEF Panel concluded that additional data should be provided before a conclusion on the safety assessment can be made. The CEF Panel recommended that efforts should be directed towards chemical analysis of the feedstock (to inform this assessment) rather than on analysis of the recycled plastic. For instance, the monitoring of post-consumer HDPE bottles before recycling, especially

misused milk bottles, could provide useful data on the nature/identity of the chemicals involved, to help refine the contamination scenario and possibly the set of surrogates used for the challenge test. This analysis should cover potential polar and non-polar contaminants with molecular weights up to 1 000 Da using an analytical method of adequate performances at low detection limits. The CEF Panel also considered that additional study of the determination of diffusion coefficients in HDPE at chill temperatures could be carried out to refine the migration model used for this evaluation.

For the manufacture of recycled trays intended for transport, storage and display of whole fruits and vegetables including mushrooms at room temperature or below, the CEF Panel concluded that recycled HDPE obtained via the process Biffa Polymers is not considered of safety concern when:

- post-consumer HDPE bottles are collected in the UK;
- the sorting process results in at least 99 % of HDPE bottles having been previously used in food applications;
- the process is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process; and
- it is used at levels up to 30 % to manufacture trays for transport, storage and display of whole fruits and vegetables, including mushrooms, at room temperature or below.

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1. Introduction

1.1. Background and Terms of Reference as provided by the legislation

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorized, EFSA opinion on its safety is required. This procedure has been established in Article 5 of the Regulation No (EC) 282/2008[4] of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of the Regulation (EU) No 1935/2004[5] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure the industry submits applications to the Member States competent Authorities which transmit the applications to the EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the EFSA guidelines on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food (EFSA, 2008).

In this case, EFSA received, from the Food Standards Agency, United Kingdom, two applications for evaluation of the recycling processes ‘Biffa Polymers’ and ‘CLRrHDPE’. These applications have been allocated the European Commission register number RECYC023 and RECYC063, respectively.

EFSA is required by Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods to carry out risk assessments on the risk originating from the migration of substances from recycled food contact plastic materials and articles into food and to deliver a scientific opinion on the recycling processes examined.

According to Article 4 of Regulation No (EC) 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling processes ‘Biffa Polymers’ and ‘CLRrHDPE’ are able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health.

2. Assessment

2.1. Introduction

The European Food Safety Authority was asked by the UK Food Standards Agency to evaluate the safety of the processes CLRrHDPE (EU register number RECYC063) and Biffa Polymers (EU register number RECYC023). The requests were registered in the EFSA’s register of questions under the numbers EFSA-Q-2010-00020 and EFSA-Q-2009-00961, respectively. The dossiers were submitted by Closed Loop Recycling Limited and Biffa Polymers Limited, respectively.

The dossiers submitted for evaluation followed the EFSA Guidelines for the submission of an application for safety evaluation by EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation (EFSA, 2008).

[4] Regulation No (EC) 282/2008 of the Commission of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.03.2008, p. 9–18.

[5] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

2.2. General information

According to the applicants, the recycling processes CLRrHDPE and Biffa Polymers are used to recycle high-density polyethylene (HDPE) bottles which have been used in contact with food, mainly milk, to produce recycled HDPE pellets using the EREMA Advanced technology (with or without stripping). Recycled HDPE pellets are blended up to 50 % with virgin HDPE pellets to produce new single-use bottles (for both applicants) and up to 30 % with virgin polypropylene pellets to produce single-use trays (Biffa Polymers only). The bottles are intended to be used for storage of milk and fruit juices at chill temperature or below (both applicants). The trays are intended to be used for animal products, fruits and vegetables including mushrooms.

2.3. Description of the process

2.3.1. General description

The recycling processes Biffa Polymers and CLRrHDPE produce recycled HDPE pellets from pre-sorted HDPE bottles coming from post-consumer collection systems. The recycling processes are composed of four steps:

- In step 1, pre-sorted post-consumer HDPE bottles are processed by conventional recycling. This includes further sorting by hand, automatic sorting, grinding, washing and drying steps to produce hot caustic-washed and dried flakes (CLRrHDPE) or detergent-washed and dried flakes (Biffa Polymers).

- In step 2, the flakes are treated in a continuous reactor at high temperature and vacuum (and stripping with steam for Biffa Polymers).

- In step 3, the flakes are treated in a second continuous reactor at high temperature and under vacuum (and stripping with gas for Biffa Polymers).

- In step 4, the material is extruded under vacuum and pellets are produced.

According to both applicants, recycled HDPE pellets, the final product of the processes, are checked against technical requirements on melt flow index density, flexural modulus, tensile strength (yield)/break, pellet size, particulate filtration, foreign contamination, colour and organoleptic properties.

The operating conditions of the two processes have been provided to EFSA.

<u>Intended uses of the recycled pellets</u>

The use of the recycled pellets depends on the applicant. Recycled HDPE pellets from CLRrHDPE are intended to be used blended up to 50 % with virgin HDPE to manufacture bottles intended to be in contact with, for example, pasteurised (fresh or flavoured) milk and pasteurised fruit juices for 12 to 15 days at a temperature below 5 °C.

Recycled HDPE pellets from Biffa Polymers are intended to be used blended:

- up to 50 % with virgin HDPE to manufacture bottles intended to be in contact with milk or chilled fruit juice-based drinks (filled, typically, at 4 °C) for up to 30 days in the case of filtered milk and for up to 15 days in the case of for other milks and fruit juices; and
- up to 30 % with virgin polypropylene resin to manufacture trays intended to be in contact with uncooked protein/animal products (chicken, beef, fish, etc.), cooked and chilled proteins, breaded or not, with or without sauces, for 10 to 12 days at chill temperature, and for raw fruits, vegetables and mushrooms for up to 30 days at room temperature. Trays made of this recycled HDPE are not intended to be used in microwaves or conventional ovens.

2.3.2. Characterisation of the input

2.3.2.1. Input of the recycling process Biffa Polymers

According to the applicant, Biffa Polymers Limited, the input material of the recycling process consists of detergent-washed and dried flakes obtained from post-consumer, mostly pigment-free (‘natural’), milk HDPE bottles[6] from the post-consumer waste stream (household dry mixed recyclables[7] or mixed plastics collection scheme). Typical milk bottles are shown in Figure 1 to illustrate the specific shape that makes sorting easier.

Figure 1: Examples of natural and white milk bottles as provided by Biffa Polymers Limited

Biffa Polymers Limited purchases bales of pre-sorted HDPE bottles from audited and approved suppliers against specifications that include the type of bottles (natural HDPE milk bottles) and the appearance (clean, free from dirt/rust). In 2008, the applicant analysed the purchased bales from five different suppliers. The analysed bales consisted predominantly of natural HDPE food bottles (an average of 81 %) along with coloured and white HDPE food bottles (an average of 4.3 %) and other materials (such as natural, coloured and white non-food HDPE, other polymers (e.g. polyethylene terephthalate (PET), polyvinyl chloride (PVC), polypropylene (PP)), non-melting materials). Non-food HDPE bottles (natural, coloured and white) represented, on average, 12 % of the total volume. Natural non-food HDPE bottles (an average of 6.8 %) were identified as packaging for direct and indirect body contact (shampoo, creams, lotions, washing liquids, fabric softeners) and for other uses or chemical use (household cleaning products, screenwash, medical). From the analysis of non-food use bottles, the applicant noted that natural or white bottles are not used to contain oil or pesticides.

The purchased bales of pre-sorted HDPE bottles are further sorted at the recycler site during conventional recycling[8], which includes manual sorting. Manual sorting aims to remove, primarily, natural and white non-food use HDPE and PP bottles, such as those used for detergent, household cleaning products and liquid soap. Natural and white non-food use bottles are given priority in this sorting step because there is no other stage to differentiate and remove non-food-use HDPE bottles from food-use natural HDPE bottles, and even then only partial removal of non-food-use white HDPE bottles is possible. Manual sorting also sorts other possible residual coloured HDPE bottles, cans and tramp materials. Coloured HDPE bottles (food or non-food) are further removed through automatic sorting steps. After manual sorting, the input is controlled every hour according to a defined quality procedure and should consist of at least 99 % HDPE bottles previously used in food applications (mostly milk and juice natural HDPE bottles). According to the applicant, at the end of conventional recycling (input of step 2), based on specifications of virgin-grade HDPE publicly available and considering that the composition of all ‘regular’-grade HDPE manufactured in Europe (for both food

6 Natural HDPE bottles might have been used also for fresh fruit juice which, in the UK, is packaged in bottles of identical design and made with the same HDPE as milk bottles.

7 Dry mixed recyclables are card, paper, cans and plastics.

8 Conventional recycling commonly includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

and non-food use) is declared to be compliant with Regulation (EU) No 10/2011, 99.9 % of flakes are expected to be HDPE manufactured according to food contact-grade specifications.

Technical data for the washed and dried flakes, such as information on bulk density, particle size, melting point, PVC, PET, metals and polyamide, have been provided for Biffa Polymers in Appendix A.

2.3.2.2. Input of the recycling process CLRrHDPE

According to the applicant, Closed Loop Recycling Limited, the input material of the CLRrHDPE recycling process consists of hot caustic-washed and dried flakes obtained from post-consumer, mostly pigment-free (‘natural’), HDPE bottles from mixed post-consumer plastic bottle waste (selective or non-selective kerbside or bring scheme collection). Mixed plastic bottle waste comprises plastic bottles with other rigid plastic packaging (all plastics) or without (bottles only) and with multiple recyclable materials (non-selective) or without (selective).

Closed Loop Recycling Limited purchases pre-sorted bottle bales from audited or self-assessed suppliers against specifications. The bales must consist of at least 38 % natural HDPE milk bottles, 38 % clear and light-blue PET bottles and 24 % other bottles (such as natural non-milk and pigmented HDPE bottles, clear and pigmented PET bottles or any PP used for food and non-food contact). In 2009, the applicant analysed a typical purchased bale. Apart from the 50.4 % clear and light-blue PET, the bale consisted predominantly of natural HDPE food bottles (40.1 % of the total) along with natural HDPE non-food bottles (1.5 % of the total) and coloured HDPE bottles (4.4 % of the total) as well as other bottles (3.6 % of the total).

The purchased bales of pre-sorted HDPE bottles are further sorted at the recycler site during conventional recycling, which includes manual sorting. For the same reasons as explained in section 3.2.1 for Biffa Polymers, manual sorting aims to remove natural and white non-food-use HDPE bottles, such as detergent bottles. It also contributes to sort other residual non-food and coloured HDPE bottles. Automatic sorting is also used in step 1 to sort the material by plastic type and colour. After manual sorting, the input is controlled and should comprise at least 99 % HDPE bottles previously used in food applications (predominantly for milk, but also for fruit juices). It can include both natural HDPE milk and fruit juices bottles (the majority) and residual white HDPE milk bottles. Samples are taken regularly to ensure that this standard is maintained. The remaining 1 % is predominantly natural HDPE non-food bottles (such as for detergents and other household cleaning products) and a small proportion of coloured HDPE bottles that have been in contact with either food (e.g. fruit juices) or non-food (e.g. detergents). According to the applicant, based on specifications of virgin-grade HDPE publicly available and considering that the composition of all ‘regular’-grade HDPE manufactured in Europe (both food and non-food use) is declared to be compliant with the Regulation (EU) No 10/2011, the remaining fraction is expected to be compliant with Regulation (EU) No 10/2011.

Technical data for the washed and dried flakes, such as information on bulk density, PET and metals, have been provided for CLRrHDPE in Appendix A.

2.3.2.3. Considerations for the presence of HDPE bottles from non-food contact applications

According to Regulation (EC) No 282/2008, as a regulatory prerequisite, the plastic input for recycling must originate from plastic materials and articles that have been manufactured in accordance with Community legislation on plastic food contact materials and articles (i.e. to avoid the use of non-authorised substances). To ensure that non-food-use HDPE bottles available from the UK domestic market are largely, if not completely, compliant with Regulation (EU) No 10/2011, the two applicants jointly contacted, in 2014, the main European producers of UK HDPE bottles and other articles. At the date of the submission of the additional data requested by EFSA on this aspect, 8 of the 10 identified producers provided information on the grade of the resin used to manufacture HDPE articles. It was found that one producer was manufacturing only HDPE trays (which are not used as input for manufacturing recycled HDPE) whereas all of the other seven producers manufacturing bottles and/or caps and/or other articles used food contact-grade resins.

2.4. EREMA Advanced technology with and without stripping

2.4.1. Description of the main steps

To decontaminate post-consumer HDPE, the recycling processes Biffa Polymers and CLRrHDPE use the EREMA Advanced technology with and without stripping, respectively. The main steps of the technology are described below and the general scheme is reported in Figure 2. In step 1, post-consumer HDPE bottles that, according to the applicants, have been sorted such that at least 99 % were previously used in food applications are granulated and processed into hot caustic-washed (CLRrHDPE) or detergent-washed (Biffa Polymers) and dried flakes.

Decontamination in a first continuous reactor KT (step 2): The flakes are introduced into a continuous reactor with a bottom-mounted rotating mixing device in which high temperature, vacuum and water (steam) stripping (for Biffa Polymers only) are applied for a predefined residence time. The stripping through injection of water aims to facilitate the removal of contaminants from the surface of flakes. The residence time is controlled by throughput.

Decontamination in a second continuous reactor R (step 3): The flakes from the previous reactor are fed into a second continuous reactor and processed under higher temperature, vacuum and stripping using air injection (for Biffa Polymers only) for a predefined residence time. These process conditions favour the transfer of possible contaminants out of the polymer and reactor. The residence time is controlled by throughput.

Extrusion (step 4): The flakes continuously arriving from the previous reactor (step 3) are melted in the extruder under high temperature and dual vacuum in the middle of the extruder screw to produce recycled HDPE pellets. Residual solid particles (paper, aluminium, etc.) are filtered out of the extruded plastic before the final pellets are produced.

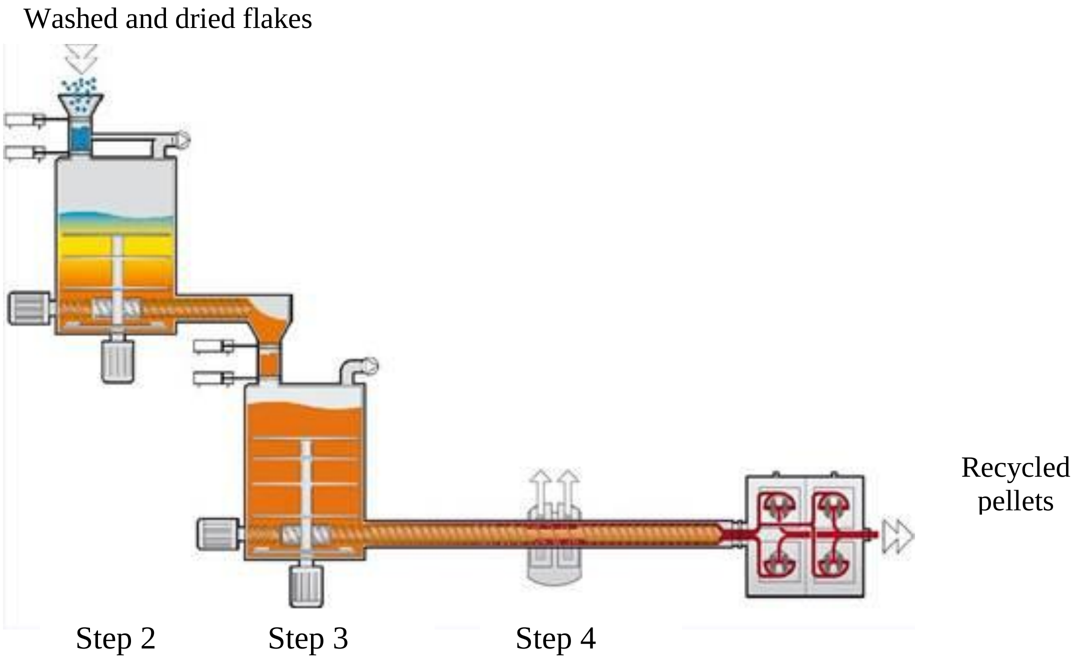

Figure 2: General scheme of the EREMA Advanced technology

Both processes run in continuous mode and are operated under defined operating parameters of water (steam) and air injection (Biffa Polymers only), temperature, pressure and residence time (Biffa Polymers and CLRrHDPE).

2.4.2. Decontamination efficiency of the processes

To demonstrate the decontamination efficiency of the processes Biffa Polymers and CLRrHDPE, the results of challenge tests on the EREMA Advanced technology were submitted to EFSA. Both companies, Biffa Polymers Limited and Closed Loop Recycling Limited, submitted several challenge tests, most of which were used to set up the one submitted to support their application. Only the challenge test from which the decontamination efficiency of each process could be calculated based on the total amounts of surrogates added and leaving the processes is reported below.

2.4.2.1. Decontamination efficiency determined for the recycling process Biffa Polymers

HDPE flakes were contaminated with selected chemicals, chloroform, toluene, chlorobenzene, butyl salicylate, benzophenone, phenylcyclohexane and methyl palmitate, used as surrogate contaminants. The surrogates are of different molecular weights and polarities to cover possible chemical classes of contaminants of concern.

For the preparation of the contaminated HDPE flakes, approximately 50 kg of post-consumer washed and sorted HDPE flakes was mixed with a solution of heptane containing the surrogates to prepare a masterbatch. The masterbatch was stored under daily agitation for seven days at 50 °C. The contaminated flakes were rinsed with water. The concentration of surrogates in the contaminated flakes was determined before and after rinsing.

The three steps of the EREMA Advanced technology with stripping in the two reactors, first reactor KT (step 2) and second reactor R (step 3), and the extruder (step 4) were challenged in a full-scale industrial process. The contaminated flakes were added to the first reactor KT (step 2) operating with real post-consumer washed and sorted HDPE flakes under stable conditions. The recycled pellets (after extrusion step 4) were regularly sampled, starting before the introduction of contaminated flakes, and analysed for their residual concentration of the applied surrogates. Because some of the surrogates (e.g. toluene, chlorobenzene) can also be found in the non-surrogate contaminated flakes (the real post-consumer washed and sorted HDPE flakes), the average concentration of potential residual surrogates in the recycled HDPE pellets before and at the introduction of contaminated flakes in KT (step 2) was measured. This is referred to as ‘background level’ by the applicant.

The most volatile surrogates (chloroform, toluene and chlorobenzene) were analysed by headspace–gas chromatography–flame ionisation detector (HS–GC–FID) and the less volatile surrogates (butyl salicylate, benzophenone phenylcyclohexane and methyl palmitate) by xylene extraction–GC–FID. Information on residual concentrations of chloroform in recycled pellets (after extrusion step 4) was not reported whereas concentrations of toluene and chlorobenzene in recycled pellets were reported to be within background level range.

The decontamination efficiency was calculated based on the total amount of surrogates introduced in the first reactor KT (step 2) and leaving extrusion (step 4). The total amount of surrogates leaving extrusion was calculated using an integrative method and then subtracting the background levels. When the concentration of surrogates was within background level range (for toluene and chlorobenzene), the concentration of the background level was considered for the calculation of the decontamination efficiency. The results are summarised in Table 1.

Table 1: Decontamination efficiency of the two consecutive reactors (steps 2 and 3) and extrusion (step 4) of the recycling process Biffa Polymers

Surrogates	Total mass of surrogates introduced in the first reactor (step 2) (grams of surrogate)	Total mass of surrogates in the pellets after extrusion (step 4) (grams of surrogate)	Decontamination efficiency (%)
Toluene	23.2	< 0.009	> 99.96
Chlorobenzene	35.4	< 0.004	> 99.99
Butyl salicylate	36.7	20.08	45.28
Benzophenone	36.1	11.22	68.95
Phenylcyclohexane	34.1	9.78	71.34
Methyl palmitate	39.3	26.68	32.23

As shown above, the decontamination efficiency of the most volatile surrogates (i.e. toluene and chloroform) is more than 99.9 %. For the less volatile surrogates, the decontamination efficiency ranged from 32.2 % for methyl palmitate to 71.3 % for phenylcyclohexane. The Panel considered the decontamination efficiency calculated for butyl salicylate (45.3 %) to be an over-estimate as some recycled pellets were still contaminated in the last sample.

2.4.2.2. Decontamination efficiency determined for the recycling process CLRrHDPE

Washed HDPE flakes were contaminated with selected chemicals, toluene, chlorobenzene, phenylcyclohexane, benzophenone and methyl stearate, used as surrogate contaminants. The surrogates are of different molecular weights and polarities to cover possible chemical classes of contaminants of concern.

For the preparation of the contaminated HDPE flakes, approximately 55 kg of post-consumer washed HDPE flakes was mixed with a solution containing the surrogates. The mixture was stored in an airtight, sealed container for 10 days at 40–45 °C. The contaminated flakes were hot caustic-washed in a small-scale washing process. The concentration of surrogates in the contaminated flakes was determined before and after washing. After washing, no residual concentration of toluene and chlorobenzene was detected; hence the decontamination efficiency of the EREMA Advanced technology for these two surrogates could not be calculated.

The three steps of the EREMA Advanced technology, first reactor KT (step 2), second reactor R with stripping (using water injection) (step 3) and the extruder (step 4), were challenged in a full-scale industrial process. A total of 25 kg of washed contaminated flakes was added to the first reactor KT (step 2) operating with real post-consumer washed and sorted HDPE flakes. The recycled pellets (after extrusion step 4) were regularly sampled starting from the introduction of contaminated flakes and analysed for their residual concentration of the applied surrogates. Because some of the surrogates (i.e. benzophenone, methyl stearate) can also be found in the non-surrogate contaminated flakes (real post-consumer washed and sorted HDPE flakes), the concentration of potential residual surrogates in the recycled HDPE pellets at the introduction of contaminated flakes in KT (step 2) was measured. This is referred to as ‘background level’ by the applicant.

Surrogates phenylcyclohexane, benzophenone and methyl stearate were analysed by GC–mass spectrometry (MS) after dichloromethane extraction.

The decontamination efficiency was calculated based on the total amount of surrogates introduced in the first reactor KT (step 2) and leaving the extruder (step 4). The total amount of surrogates leaving the extruder was calculated using an integrative method and then subtracting the background levels. The results are summarised in Table 2.

Table 2: Decontamination efficiency of the two consecutive reactors (steps 2 and 3) and extrusion (step 4) of the recycling process CLRrHDPE

Surrogates	Total mass of surrogates introduced in first reactor (step 2) (grams of surrogate)	Total mass of surrogates in the pellets after extruder (step 4) (grams of surrogate)	Decontamination efficiency (%)
Phenylcyclohexane	8.5	3	64.7
Benzophenone	9.8	7.4	24.5
Methyl stearate	24.2	24.7	0

As shown in Table 2, the decontamination efficiency is 64.7 % for phenylcyclohexane and 24.5 % for benzophenone.

In the case of methyl stearate, the calculated mass of surrogate leaving the extruder could be slightly lower depending on the value of the background level considered. Consequently, the decontamination efficiency could be higher. Nevertheless, the Panel considered that, overall, the results show that the decontamination efficiency of methyl stearate is very low, if any, and the possible difference is likely not to impact on the safety evaluation.

The CEF Panel took note that in the challenge test, unlike the commercial process, stripping using water injection was carried out in the second reactor R. This could challenge the representativeness of the challenge test. Nevertheless, based on similar results of another provided challenge test performed without stripping (and also without rinsing/washing of contaminated flakes) and the limited decontamination efficiency of the technology under the operated conditions, the use of such stripping has not changed significantly the decontamination efficiency.

2.5. Discussion

2.5.1. Description

Considering the high temperatures (230 °C) used in the extrusion of the flakes, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

The two processes, Biffa Polymers and CLRrHDPE, are well described. Data presented by the applicants allow identification of the technology used for recycling, the inputs to the process, its output and the intended uses of the final articles. Post-consumer HDPE bottles are made into recycled pellets which, blended up to 50 % with virgin HDPE, are used to manufacture recycled bottles (both applicants) and, blended up to 30 % with virgin polypropylene, are used to manufacture recycled trays (Biffa Polymers). The two processes are entirely managed under the quality assurance system to ensure the quality of the final product.

The input materials are produced from HDPE bottles previously used mostly for milk and possibly fruit juices and are collected from mixed post-consumer plastic bottle waste (CLRrHDPE) and from the post-consumer waste stream (Biffa Polymers). Those materials are pre-sorted by audited and approved suppliers against pre-established specifications and further sorted at the recycling site by conventional recycling (step 1), including manual and automatic sorting, and then used to produce washed and dried HDPE flakes. According to the applicants, the production of washed and dried flakes through conventional recycling is under control, and the sorting steps of the processes ensure that the fraction of HDPE food bottles after manual sorting, and thus the input of step 2 (first reactor), is more than 99 %. According to the applicants, considering that the composition of all ‘regular’-grade HDPE manufactured in Europe (both food and non-food use) is declared to be compliant with Regulation (EU) No 10/2011, 99.9 % of washed and dried flakes is HDPE manufactured in accordance with food contact-grade specifications. As this was confirmed by the main European producers of UK HDPE bottles and other articles, the CEF Panel concurs that the remaining 1 % is likely to be food contact-grade material and recommended that applicants ensure that HDPE bottles used as input have been manufactured in accordance with Community legislation on plastic food contact materials and articles. Technical data, including information on bulk density, PET, metals, are provided for washed and dried flakes.

The Panel noted that hand sorting during the conventional recycling step (step 1), after which the percentage of HDPE bottles previously used in food applications (mostly milk and juice natural HDPE bottles) is at least 99 %, is critical and should be controlled. Controlled sorting steps could also help to remove from the waste stream bottles that may have been contaminated as a result of misuse by consumers. However, the benefit of such a procedure cannot be quantified using the data available.

Washed and dried flakes are then submitted to the EREMA Advanced technology to recycle flakes into decontaminated pellets. The EREMA Advanced technology comprises the following steps, with (Biffa Polymers) or without stripping (CLRrHDPE): heating in first reactor KT (step 2), heating in second reactor R (step 3) and then extrusion (step 4). The applicants supplied EFSA with the following operating parameters: water injection (Biffa Polymers only), temperature, residence time and pressure for step 2; air injection (Biffa Polymers only), temperature, residence time and pressure for step 3; and temperature, residence time and pressure for step 4 have been provided to EFSA.

The CEF Panel took note of the statement from the applicants that no re-additivation is used to recycle the post-consumer washed and dried flakes into recycled pellets.

Recycled pellets are intended to be used (i) mixed up to 50 % with virgin HDPE to manufacture bottles that, at temperatures below 5 °C, will come into contact with filtered milk for up to 30 days and with other milks and fruit juice for up to 15 days (Biffa Polymers and CLRrHDPE) and (ii) mixed up to 30 % with virgin polypropylene to manufacture trays for contact with animal products (chicken, beef, fish, etc.) for 10 to 12 days at chill temperature and with whole fruits and vegetables for up to 30 days at room temperature (Biffa Polymers only).

The CEF Panel considered that all the recycled articles, including trays for whole fruits and vegetables, made with post-consumer HDPE bottles collected from an open-loop process should be evaluated following the same approach. According to Regulation (EC) No 282/2008, it should be demonstrated, by means of a challenge test or other appropriate scientific evidence, that these recycling processes have the ability to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The criteria for the safety evaluation of recycled HDPE are discussed and laid out in the next section.

2.5.2. Criteria for safety evaluation of a mechanical recycling process to produce recycled HDPE

2.5.2.1. Overview of the criteria for safety evaluation of a mechanical recycling process to produce recycled PET and applicability to HDPE

In 2011, EFSA published an opinion on the safety evaluation of a mechanical recycling process to produce recycled PET (EFSA CEF Panel, 2011). The principle presented in this opinion is applicable to any plastic. However, some of the criteria used in the evaluation procedure are specific to PET and, therefore, cannot be applied to HDPE.

According to the evaluation principles for PET (EFSA CEF Panel, 2011), a mechanical recycling process is not of safety concern if the residual concentrations of potential unknown contaminants in pellets (C_{res}) are not higher than a modelled concentration of PET (C_{mod}).

C*mod* is calculated from a migration criterion using generally recognised conservative migration modelling (EC, 2010; Piringer and Hinrichs, 2001) under defined conditions of uses. The migration criterion should not give rise to a dietary exposure exceeding 0.0025 µg/kg body weight (bw)/day,[9] the exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity below which the risk to human health would be negligible (EFSA CEF Panel, 2011; EFSA Scientific Committee, 2012). The migration criterion is derived by applying a defined exposure scenario to the exposure threshold. The exposure threshold and exposure scenarios used to determine the migration criterion are independent of the recycled polymer and therefore they are also applicable to HDPE. Hence, taking into account the intended uses of milk and milk products, the toddlers' exposure scenario considering a consumption of 90 g/kg bw/day is deemed appropriate and gives a migration criterion of 0.028 µg/kg food. In contrast, the modelling migration used to calculate the corresponding concentration C*mod* is polymer specific. Therefore, C*mod* values calculated for PET cannot be used to estimate migration from HDPE and new C*mod* values specific to HDPE need to be calculated, which should also take into account different conditions of use of the articles containing the recycled HDPE.

C*res* for PET is calculated by applying the decontamination efficiencies obtained for each surrogate contaminant from the challenge test to the reference contamination level of 3 mg/kg PET. This reference contamination is specific to PET, as explained in the EFSA PET criteria (EFSA CEF Panel, 2011). Therefore, a reference contamination of post-consumer HDPE articles needs to be set.

In addition, if the principle of the challenge test also applied to HDPE, further considerations on the molecular weight and polarities of the surrogates to be used need to be addressed.

The CEF Panel has therefore considered the data provided by the applicants and those available in the literature on the three aspects specific to HDPE: the reference contamination of post-consumer HDPE articles, the modelling to estimate migration from HDPE to foodstuffs and the surrogates to be used in the challenge test.

2.5.2.2. Criteria specific to the safety evaluation of recycled HDPE

<u>(i) The reference contamination of conventionally recycled post-consumer HDPE bottles</u>

The establishment of the reference contamination level for an unknown contaminant potentially present in the input of a PET recycling process is based on experimental data of an EU survey, the FAIR-CT98-4318 project (Franz et al., 2004a, b). In this survey, performed in the framework of a European project, thousands of collected PET bottles were examined. Post-use residual substances were identified and quantified, and the level (severity) and the frequency of misused bottles were determined. For polyolefins, the CEF Panel considered a survey based on the same approach as the FAIR project with the exception that it was carried out in the UK only (Welle, 2005). In this survey, about 600 conventionally recycled flake samples from HDPE bottles collected and sorted in the UK were screened for post-consumer contaminants. As for PET, each sample consisted of about 40–50 flakes considered to come from individual bottles, allowing analysis of about 24 000–30 000 bottles. It was found out that predominant contaminants were unsaturated oligomers (also found in virgin HDPE pellet samples). The concentrations of both decene and dodecene were around 20 mg/kg (similar in virgin samples). The flavour compound limonene, the degradation product of antioxidant additives di-tert-butylphenol and small amounts of saturated oligomers were found at higher concentrations in the post-consumer samples than in the virgin HDPE. One sample was found to contain an unknown

[9] To cover the endpoint of cancer, a human exposure threshold value of 1.5 µg/person/day was derived by the US Food and Drug Administration (FDA) (Rulis, 1986, 1989, 1992) to be applied to substances for which there is no structural alert for genotoxicity/carcinogenicity. The threshold value was derived by mathematical modelling of risks from animal bioassay data on over 500 known carcinogens, based on their carcinogenic potency. Assuming that only 10 % of untested chemicals were carcinogenic, at this exposure level, 96 % of the chemicals would pose a lifetime risk of cancer of less than 1 in 1 million (Munro, 1990; Barlow et al., 2001). In 1995, the FDA incorporated this threshold value in its TOR policy for substances present in food contact materials (FDA, 1995). Kroes et al. (2004) refined the threshold for the endpoint of cancer by deriving a value of 0.15 µg/person/day for substances for which there is a structural alert for genotoxicity.

substance at around 130 mg/kg in the recycled plastic and another one at 40 mg/kg which could be caused by the presence of a non-milk HDPE bottle or by misuse.

Following the same approach used for the evaluation of recycled PET, the CEF Panel considered that the highest potentially misuse contamination level in washed and dried HDPE flakes was 6 500 mg/kg HDPE (based on a concentration of 130 mg/kg measured for 50 flakes) and that 2 out of every 24 000 bottles were contaminated with misuse contaminants (0.008 %), giving a reference contamination level of 0.5 mg/kg HDPE.

Therefore, for the evaluation of these two recycling processes, of which the input is collected in UK, the CEF Panel proposed to use a reference contamination level of 0.5 mg/kg HDPE. This reference contamination does not apply to the evaluation of recycling process operating in the rest of Europe and more data should be provided for setting of a European reference contamination for HDPE as for PET.

The Panel noted that the monitoring of post-consumer HDPE bottles before recycling, especially misused milk bottles, could provide useful data on the nature/identity of the chemicals involved, to help refine the contamination scenario.

(ii) The modelling to calculate migration from HDPE to foodstuffs

Migration modelling from polyolefins, including HDPE, is available (Piringer and Hinrichs, 2001) and recognised by the European legislation (EC, 2010). Conservative migration modelling based on the Piringer approach was initially developed for polyolefins (i.e. PP, HDPE and low-density polyethylene (LDPE)) and was based on real migration measurements of known additives at temperatures typically above 40 °C (Piringer and Baner, 2000; Begley et al., 2005). The model was refined many times to get parameters that closely match the real migration. Today, most of the modelled/measured migration ratio values range between 2 and 5 (Piringer and Hinrichs, 2001) for the usual migration conditions, i.e. between 40 and 70 °C. Owing to a lack of data at lower temperatures, the model does not sufficiently cover chilled conditions (5 °C) as requested by the applicants. Nevertheless, the diffusion coefficient could be estimated at this lower temperature using the Arrhenius relationship, an extrapolation that is subject to uncertainty. To ensure conservative estimation, C_{mod} was calculated considering the lowest ratio modelled/measured migration of 2 (instead of, for example, 5) to estimate the highest acceptable migration of a contaminant.

The CEF Panel therefore considered that C*mod* values for the surrogates used in the challenge test can be calculated using available migration modelling (EC, 2010) and applying a conservative factor of 2. The parameters of the model used to calculate C*mod* can be found in Appendix C.

The CEF Panel also considered that, even though the applied parameters are conservative, additional study on the determination of diffusion coefficients in HDPE at chilled temperatures could be carried out to reduce the uncertainties and to refine the model.

(iii) The surrogates to be used in the challenge test

The surrogates used in challenge tests to determine the decontamination efficiency of PET recycling processes are substances with different molecular weights and polarities representative of possible chemical classes of contaminants of concern that were demonstrated to be suitable to monitor the behaviour of PET during recycling (Pennarun et al., 2005; FDA, 2006).

Unlike PET, HDPE is non-polar and its diffusivity is several orders of magnitude higher than that of PET. This means that non-polar contaminants, in particular, have the potential to be sorbed in post-consumer HDPE, and those with higher molecular weights might migrate into food if the recycled input material is not sufficiently decontaminated. Hence, on the one hand, non-polar substances with high molecular weight are more difficult to remove during the decontamination but, on the other hand, they are also expected to migrate into food less than substances with a lower molecular weight. The balance between these two factors has not been studied sufficiently for the recycling of polyolefins.

However, relatively little is known about whether or not non-polar contaminants with high molecular weight are actually present in post-consumer HDPE bottles.

More scientific knowledge on this specific issue should be acquired, and the CEF Panel recommends that additional data on the contamination of post-consumer HDPE bottles (identity of contaminants) used as feedstock are provided. For instance, monitoring of post-consumer HDPE bottles before recycling, with a special emphasis on misused milk bottles, should cover potential polar and non-polar contaminants with high molecular weights (up to 1 000 Da) using an analytical method of adequate performance at low detection limits. This would provide better coverage of the possible contaminants adsorbed in HDPE that is to be recycled.

Nevertheless, taking into account that the surrogates used in the challenge tests represent chemical classes of contaminants with a range of polarity, molecular weight and volatility that can migrate from HDPE, useful information can be derived about the decontamination efficiency of the processes. The CEF Panel considered that, pending the submission of the required additional information, the surrogate contaminants used for the provided challenge tests should be used to calculate a decontamination efficiency profile.

2.5.2.3. Application of criteria for safety evaluation of a mechanical recycling process to produce recycled HDPE

Whilst acknowledging that a number of uncertainties derive from a lack of exhaustive scientific data, the CEF Panel used the data available to set and apply criteria for the safety evaluation of two mechanical recycling processes to produce recycled HDPE following the principle presented in the EFSA opinion on the safety evaluation of a mechanical recycling process to produce recycled PET (EFSA CEF Panel, 2011).

Considering the dietary exposure threshold of 0.0025 μg/kg bw/day, below which the risk to human health would be negligible, and 90 g food/kg bw/day as the 95th consumption by toddlers of all beverages, including bottled water and milk and excluding tap water (toddlers scenario, EFSA CEF Panel, 2011), the corresponding migration is calculated to be 0.028 μg/kg food.

Applying migration modelling and using the conservative factor of 2 (instead of 5), the migration criterion for food satisfying the above criterion for toddlers is calculated to be 0.06 μg/kg food (= 0.028 × 2 = 0.056) in food or food simulant. It should be stressed that the figure of 0.06 μg/kg food is used for calculations only, and does not represent an accepted level of migration. Therefore, 0.06 μg/kg food is used to determine C*mod* for surrogate contaminants. The results of these calculations are shown in Appendix C and Tables 2–4.

The calculated modelled concentration in HDPE (C*mod*) is then compared with the residual concentration of each contaminant in recycled HDPE (C*res*) (see sections 2.5.4.4 and 2.5.2.5) in accordance with the evaluation procedure described in the scientific opinion on 'the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011) and adapted to HDPE (Appendix B).

C*res* is obtained by applying the decontamination efficiency percentage to the reference contamination level of 0.5 mg/kg HDPE taking into account the mixing of recycled pellets with virgin material.

To measure the decontamination efficiency of the processes, each applicant submitted a challenge test on steps 2, 3 and 4 (first rector KT, second reactor R and extruder) conducted in a full-scale industrial process (in continuous mode).

All steps were operated under parameters of residence time, pressure, temperature and water/air stripping (stripping in the commercial process only for Biffa Polymers) at least as severe as those of the corresponding industrial process, with the exception of water injection in the second reactor R of the process CLRrHDPE. Indeed, for CLRrHDPE the challenge test was carried out with stripping using water injection in the second reactor R whereas in the commercial process stripping is not applied. This could, in theory, challenge the representativeness of this challenge test. Nevertheless, based on similar results obtained in another challenge test submitted without stripping and the limited decontamination efficiency of the technology under the operated conditions, it is observed that the use of such stripping has not significantly changed the decontamination efficiency of the process; hence, it does not significantly impact the safety evaluation. Therefore, the Panel used the indicative decontamination efficiencies from the provided challenge test for the safety evaluation.

The two processes were challenged using both contaminated and non-contaminated flakes; nevertheless, decontamination was calculated using an integrative method based on the total amount of surrogates introduced in the first reactor KT (step 2) and leaving extrusion (step 4). Therefore, cross-contamination was not an issue in these tests.

The Panel considered that steps 2, 3 and 4 are all critical for the decontamination efficiency of both processes. Consequently, the temperature, the pressure, the residence time and the air/water stripping (stripping for Biffa Polymers only) should be controlled to guarantee the performance of the decontamination.

The Panel highlighted that, for future work, the contamination procedure used in the challenge test, in which the surrogate contaminants are carried deep into the polymer matrix by a swelling solvent that interacts strongly with HDPE, might not be representative of possible contamination episodes caused by consumer misuse of such HDPE milk bottles. Hence, the decontamination efficiency might be over- or under-estimated compared with the real situation. In addition, the challenge test was carried out with real post-consumer flakes that lead to problem of detection owing to background contamination. Using virgin flakes could prevent this situation.

2.5.2.4. Biffa Polymers

The decontamination efficiencies, at each of the three steps in the technology, of each of the surrogate contaminants, obtained from the challenge test, and ranging from 32.2 % to more than 99.9 %, were used to calculate the residual concentrations of potential unknown contaminants in pellets (C*res*) in accordance with the evaluation procedure described in Appendix B. By applying the decontamination efficiency percentage to the reference contamination level of 0.5 mg/kg HDPE and using a dilution factor of 2 (final article made of 50 % post-consumer HDPE mixed with 50 % virgin materials) or 3.3 (final article made of 30 % post-consumer HDPE mixed with 70 % virgin materials), the C*res* for the different surrogates is obtained (Tables 3 and 4).

Table 3: Decontamination efficiency from the challenge test, residual concentration of surrogate contaminants in recycled HDPE (C*res*) <u>calculated for 50 % addition to virgin material</u> and calculated concentration of surrogate contaminants in HDPE (C*mod*) corresponding to a modelled migration of 0.06 µg/kg food after <u>30 days at 5 °C</u>

Surrogates	**Decontamination efficiency (%)**	**C*res* (mg/kg HDPE)**	**C*mod* (mg/kg HDPE)**
Toluene	> 99.9	0.0001	0.004
Chlorobenzene	> 99.9	0.0001	0.0045
Phenyl cyclohexane	71.34	0.0717	0.006
Benzophenone	68.95	0.0776	0.0068
Butyl salicylate	45.28	0.1368	0.0074
Methyl palmitate	32.23	0.1694	0.0115

Table 4: Decontamination efficiency from the challenge test, residual concentration of surrogate contaminants in recycled HDPE (C*res*) calculated for 30 % addition to virgin material and calculated concentration of surrogate contaminants in HDPE (C*mod*) corresponding to a modelled migration of 0.06 µg/kg food after 15 days at 5 °C

Surrogates	Decontamination efficiency (%)	C*res* (mg/kg HDPE)	C*mod* (mg/kg HDPE)
Toluene	> 99.9	< 0.0001	0.005
Chlorobenzene	> 99.9	< 0.0001	0.006
Phenyl cyclohexane	71.34	0.043	0.008
Benzophenone	68.95	0.047	0.010
Butyl salicylate	45.28	0.082	0.011
Methyl palmitate	32.23	0.102	0.017

The residual concentrations of the most volatile surrogates in HDPE after decontamination (C*res*) are lower than the corresponding modelled concentrations in HDPE (C*mod*), whereas the residual concentration of all the less volatile surrogates in the HDPE after decontamination are higher than the corresponding modelled concentrations in HDPE (C*mod*). Therefore, the Panel considered that data provided do not allow to demonstrate that the recycling process under evaluation is effective at ensuring that the level of migration of the unknown less volatile contaminants from the recycled HDPE into food is below the modelled migration of 0.06 µg/kg food when the recycled HDPE is mixed up to 50 % with virgin HDPE for manufacturing bottles and when mixed up to 30 % with virgin PP for manufacturing trays.

2.5.2.5. CLRrHDPE

The decontamination efficiencies, at each of the three steps in the technology process, of each surrogate contaminant, obtained from the challenge test and ranging from 24.5 % to 64.7 %, were used to calculate the residual concentrations of potential unknown contaminants in pellets (C*res*) in accordance with the evaluation procedure described in Appendix B. By applying the decontamination efficiency percentage to the reference contamination level of 0.5 mg/kg HDPE and a dilution factor of 2 (final article made of 50 % post-consumer HDPE mixed with 50 % virgin materials), the C*res* for the different surrogates is obtained (Table 5).

Table 5: Decontamination efficiency from the challenge test, residual concentration of surrogate contaminants in recycled HDPE (Cres) calculated for 50 % addition to virgin HDPE and calculated concentration of surrogate contaminants in HDPE (Cmod) corresponding to a modelled migration of 0.06 µg/kg food after 15 days at 5 °C

Surrogates	Decontamination efficiency (%)	C*res* (mg/kg HDPE)	C*mod* (mg/kg HDPE)
Phenylcyclohexane	64.7	0.162	0.008
Benzophenone	24.5	0.061	0.010
Methyl stearate	0	0.250	0.019

The residual concentrations of phenylcyclohexane, benzophenone and methyl stearate in the HDPE after decontamination are higher than the corresponding modelled concentrations in HDPE (C*mod*). Therefore, the Panel considered that the data provided do not allow to demonstrate that the recycling process under evaluation is effective at ensuring that the level of migration of unknown contaminants from the recycled HDPE into food is below the modelled migration of 0.06 µg/kg food when the recycled HDPE is mixed up to 50 % with virgin HDPE for manufacturing bottles.

2.5.2.6. Further considerations on trays for contact with whole fruits and vegetables including mushrooms

The Panel considered the level of decontamination of the EREMA Advanced technology used by Biffa Polymers for the most and the less volatile surrogates associated with the maximum use of the recycled HDPE pellets blended up to 30 % with virgin material to manufacture trays. The most volatile contaminants, which have a higher potential for migration, are expected to be efficiently removed by the process, as demonstrated by the challenge test, whereas the less volatile surrogates are less efficiently removed.

The Panel also considered the intended uses for transport, storage and display of whole fruits and vegetables including mushrooms at room temperature or below, under which conditions migration is expected to be unlikely, if any (solid–solid contact and small surface of contact). In fact, Regulation EU No 10/2011 does not foresee use of the migration test for compliance of plastic packaging for such food types.

The Panel concluded that the exposure of consumers to contaminants resulting from the recycling of misused post-consumer HDPE bottles that are subsequently used to manufacture trays intended to be in contact with only whole fruits and vegetables is probably extremely low and not of safety concern provided that the recycled materials are produced under the operating conditions of the Biffa recycling process, and the maximum level of 30 % recycled pellets blended with virgin material is respected. Such uses are for transport, storage and display of whole fruits and vegetables including mushrooms at room temperature or below.

3. Conclusions

The Panel considered that the processes are well characterised and the main steps used to recycle the HDPE flakes into decontaminated HDPE pellets are identified. The recycling processes CLRrHDPE and Biffa Polymers are intended to recycle HDPE post-consumer bottles, which are sorted to reach at least 99 % HDPE bottles previously used in food applications (mostly milk), to produce recycled HDPE pellets. The CEF Panel took note of the consultation of the main European producers of UK HDPE bottles and other articles. The consultation supports the claim that UK domestic non-food use bottles are largely, if not completely, manufactured in accordance with Community legislation on plastic food contact materials and articles. Nevertheless, the CEF Panel points out that it should be remembered that, according to Regulation (EU) 282/2008, applicants should ensure that HDPE bottles used as input have been manufactured in accordance with Community legislation on plastic food contact materials and articles.

Having examined the challenge tests provided, the Panel noted the limited decontamination efficiency under the conditions of testing and considered that the processes do not satisfy criteria set for HDPE following the same principle as for recycled PET (EFSA CEF Panel, 2011). On the other hand, the CEF Panel emphasised that the uncertainties arising from the lack of sufficient scientific knowledge and the consequent conservatism of the selected criteria could allow the conclusion that a process is safe when criteria are met but do not allow a conclusion to be reached on the safety of the processes when the criteria are not met. In such cases, additional data are needed.

Therefore, to reach a conclusion on the safety assessment of the processes for the recycling of post-consumer HDPE bottles into pellets to manufacture <u>bottles for milks and fruit juices and trays for animal products</u>, additional data should be provided to reduce the uncertainties, especially on the misuse contamination scenario, the migration model and on the surrogates and the method of contamination used for challenging the decontamination efficiency.

The contamination scenario used here is a periodic misuse contamination level in washed and dried HDPE flakes of 6 500 mg/kg HDPE occurring at a frequency of 2 out of 24 000 bottles and always with a genotoxic substance. It is not clear if this is representative of the feedstock, especially after the extensive sorting steps conducted by both applicants. Furthermore, the contamination procedure used in the challenge test, in which the surrogate contaminants are carried deep into the polymer matrix by a swelling solvent that interacts strongly with HDPE, might not be representative of possible contamination episodes caused by consumer misuse of such HDPE milk bottles. The possible presence of non-polar contaminants with high molecular weight in post-consumer HDPE bottles is not addressed. The diffusion coefficients were extrapolated from room temperature to chill temperatures, also with some uncertainties. Finally, carrying out the challenge test using virgin flakes instead of post-consumer flakes could prevent the problem of detection due to background contamination.

Consequently, the CEF Panel concluded that additional data should be provided on the determination of diffusion coefficients in HDPE at chilled temperatures to refine the migration model used for this evaluation and on the contamination of post-consumer HDPE bottles used as input. The Panel recommended that efforts be directed towards chemical analysis of the feedstock (to inform this assessment) rather than on analysis of the recycled plastic, because any potential contaminant of individual feedstock bottles will first be partly eliminated by the clean-up procedures and will then be highly diluted (by the overwhelming mass of the non-contaminated bottle) to a concentration that is below the detection level of the analytical method used but at which the detection limit is insufficient to ensure the safety of the output (i.e. the concentration value C*mod*). For instance, the monitoring of post-consumer HDPE bottles before recycling, especially misused milk bottles, could provide useful data on the nature/identity of the chemicals involved, to help refine the contamination scenario and possibly the set of surrogates used for the challenge test. This analysis should cover potential polar and non-polar contaminants with molecular weights up to 1 000 Da using an analytical method of adequate performances at low detection limits. This would better address the coverage of the possible contaminants adsorbed in the HDPE to be recycled.

The CEF Panel had further considerations on the use of the recycled pellets to manufacture recycled <u>trays intended to be in contact with whole fruits and vegetables including mushrooms</u> (requested only by Biffa Polymers Limited). Even though the scenario is associated with uncertainties, the Panel considered the specific use of the recycled trays for transport, storage and display of whole fruits and vegetables including mushrooms at room temperature or below, and concluded that recycled HDPE obtained from the process Biffa Polymers is not of safety concern when:

1. post-consumer HDPE bottles are collected in the UK;

2. the sorting process results in at least 99 % HDPE bottles having been previously used in food applications;

3. the process is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process; and

4. it is used at levels up to 30 % to manufacture trays for transport, storage and display of whole fruits and vegetables including mushrooms at room temperature or below.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier CLRrHDPE. End December 2019. Additional data and clarifications: 12 November 2010, 22 May 2014, 9 June 2014, 4 July 2014, 15 July 2014, 24 October 2014, 28 November 2014, 1 and 3 December 2014. Submitted by Close Loop Recycling Limited.

2. Dossier Biffa Polymers (formerly Greenstar WES). 1 December 2009. Submitted by Greenstar WES. Additional data and clarifications: 10 June 2014, 16 June 2014, 24 October 2014, 12 November 2014, 28 November, 1 and 3 December 2014. Submitted by Biffa Polymers Limited.

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APPENDICES

Appendix A. Technical data for the washed flakes as provided by the applicants

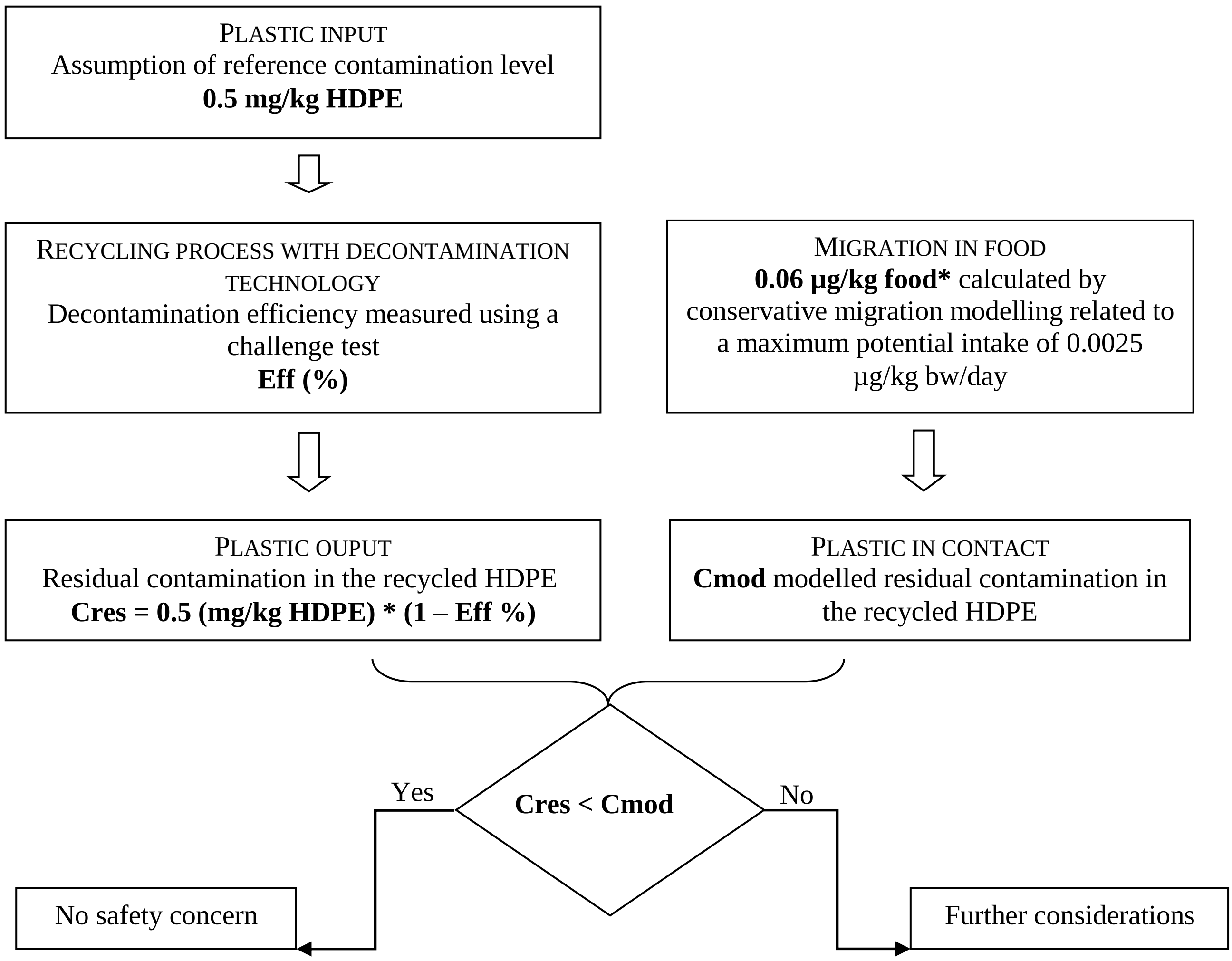
Technical data for the conventionally recycled flakes as provided for CLRrHDPE

Parameters	Value	Unit
Material source	Milk bottles	–
Colour of material source	Natural and white	–
Flake colour		
Natural HDPE flakes	≥ 70	%
White HDPE flakes	≤ 13	%
Foreign materials		
Pigmented HDPE (cap) flakes	≤ 2.5	%
Flakes with glue residue and label adhesion	≤ 6	%
Loose labels	< 1	%
Polystyrene	< 0.2	%
Other	< 0.5	%

Technical data for the washed and dried flakes as provided for Biffa Polymers

Parameters	Value	Unit
Humidity	< 0.1	%
Bulk density	0.20–0.25	g/cm^3
Coloured and white flakes	< 2	%
Particle size	8–12	mm
Melting point	> 130	°C
Density	0.950–0.964	g/cm^3
PVC/PET	0	%
Metals	< 50	mg/kg
Polyamide	0	%

Appendix B. Relationship between the key parameters for the evaluation scheme



*Default scenario (toddlers) for milk HDPE bottles applied for Biffa Polymers and CLRrHDPE processes.

Appendix C. Modelling parameters

Modelling parameters used to calculate concentration in HDPE (C*mod*) corresponding to migration of 0.06 µg/kg food (toddlers scenario)

For 30 and 15 days at 5 °C.

Good solubility of the migrant in food simulant is assumed, ($K_{p,F} = 1$).

A food contact material or article made entirely with 100 % recycled HDPE.

A surface area to volume ratio of 6 dm^2 HDPE to 1 kg food/drink.

A material thickness of 300 µm and a density of 0.95 g/cm^3 are assumed.

For the calculation of the diffusion coefficient in HDPE, a modelling parameter $A_p' = 14.5$ is used and $\tau = 1577$ (EC, 2010).

C*mod* for the most common surrogate contaminants corresponding to a migration level of 0.06 µg/kg food (toddlers scenario) and calculated by diffusion modelling (EC, 2010) using the above parameters

Surrogate	MW (Da)	C*mod* (mg/kg HDPE) 30 days at 5 °C	C*mod* (mg/kg HDPE) 15 days at 5 °C
Toluene	92	0.004	0.005
Chlorobenzene	113	0.0045	0.006
Phenylcyclohexane	160	0.006	0.008
Benzophenone	182	0.0068	0.010
Butyl salicylate	194	0.0074	0.011
Methyl palmitate	270	0.0115	0.017
Methyl stearate	299	0.0135	0.019

MW, molecular weight.
This table is for the toddler scenario (EFSA CEF Panel, 2011). C*mod* corresponding to other scenarios can be calculated by using the above parameters.
Other figures could be considered if appropriate scientific argumentations, when necessary supported by experimental data, is provided to EFSA.

ABBREVIATIONS

bw	body weight
CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
EC	European Commission
EU	European Union
EFSA	European Food Safety Authority
FID	flame ionisation detector
GC	gas chromatography
HDPE	high-density polyethylene
HS	headspace
LDPE	low-density polyethylene
MS	mass spectrometry
PET	poly(ethylene terephthalate)
PP	polypropylene
PVC	poly(vinyl chloride)
UK	United Kingdom
US FDA	United States Food and Drug Administration