European Food Safety Authority

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Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on

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

Question number EFSA-Q-2004-168

Adopted on 21/05/2008

AFTER PUBLIC CONSULTATION
AND DISCUSSION IN PANEL 21 MAY 2008

INTRODUCTION

According to the Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods (European Commission, 2008), hereafter referred to as "the Regulation", recycled plastics used to manufacture materials and articles intended for food contact shall be obtained only from processes authorised by the Commission following a safety assessment performed by the European Food Safety Authority (EFSA). The Regulation also states that the recycling process shall be managed by a quality assurance system (QAS) that has to meet the requirements laid down in the Annex of Regulation (EC) No 2023/2006 (European Commission, 2006).

The purpose of these guidelines is to give guidance to applicants wishing to obtain authorization for production processes of recycled plastics according to the "Regulation". It gives guidance on the administrative and technical data required and on the format of applications for the evaluation by the EFSA.

These guidelines apply to processes using mechanical recycling, whereby the collected plastics are ground into small pieces and decontaminated before being processed to new food contact materials. Chemical recycling processes, whereby the plastic is completely depolymerised into monomers and starting substances which are then reused in a polymerisation reaction are not in the scope of the Regulation and are not covered by these guidelines. Processes where the mechanical recycling is the main part of the whole process are in the scope of these guidelines provided that the plastic is not subsequently depolymerised.
In addition, these guidelines do not apply to the following materials which are not in the scope of the Regulation:

(i) recycled plastics used behind a plastic functional barrier, as specified in Directive 2002/72/EC[1], (European Commission, 2002)

(ii) offcuts and scraps from the production of plastic food contact materials that have not yet been in contact with food and which are recycled within the manufacturing site or at another site where an audited quality assurance system is in place, that meets the requirements laid down in the Annex of Regulation (EC) No 2023/2006 (European Commission, 2006).

[1] According to the Commission Directive 2002/72/EC (European Commission, 2002), a plastic functional barrier means a barrier, consisting of one or more layers of plastic which ensures that the finished materials or articles are compliant with Regulation (EC) No 1935/2004, Art. 3 (European Commission, 2004), i.e. they do not transfer their constituents to food in amounts which could endanger human health or bring about unacceptable changes in the composition of the food or of its organoleptic properties.

GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD

The risks associated to the use of recycled plastic materials and articles in contact with foods come from the possible migration of chemicals such as:

- **Contaminants of the input**
    - **contaminants which may be introduced in the input stream by materials which are not suitable for food contact applications.** According to the Regulation, the plastic input shall originate from plastic materials manufactured in accordance with Community legislation on plastic food contact materials and articles. However if the sorting system is not completely efficient, the input stream may contain plastics manufactured from substances which have not been authorised for food contact applications (AFSSA 2007),
    - **incidental contaminants from previous uses including possible misuse.** Plastic containers designed for food may be misused by consumers who could use them to store chemicals which may be toxic and which may be present in the input (Begley *et al.*, 2002; FDA, 2002; FDA, 2006; Franz *et al.*, 2004a; Komolprasert and Lawson, 1994; Welle, 2005).
- **Chemicals used in the recycling process**, e.g. detergents, which may not be completely eliminated from the recycled plastic (AFSSA, 2007, Begley *et al.*, 2002, Welle, 2005).
- **Degradation products of the polymer or of plastic additives**. During the various steps of the recycling process, e.g. high temperature treatments, the polymeric chain may break down to smaller molecules and the additives may react and be converted into new compounds (Vilaplana *et al.*, 2007).

Chemicals are of concern if they are present in the recycled plastic and if they migrate into the food in amounts which could endanger human health (AFFSA, 2007; FDA, 2007, Pennarun *et al.*, 2005). The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are all crucial points for the risk assessment. Taking into account all potential sources of contamination of the input, it has to be demonstrated that the process is able to reduce it to levels not posing a risk to human health for the intended use of the final product (Franz *et al.*, 2004a; Komolprasert and Lawson, 1994; AFSSA, 2007; Coulier *et al.*, 2007; FDA, 2006).

The dossier submitted by the applicant shall include all the relevant information enabling the EFSA to perform a safety assessment. The EFSA will, where appropriate, issue opinions, recommendations, specifications or restrictions on the input, on the recycling process or on the use of the recycled plastic.

According to the Regulation, the QAS evaluation and audit will be performed by Member States and not by the EFSA. However, these guidelines do include a requirement for the QAS documentation to be provided when the applicant considers it relevant for the safety assessment.

It should be noted that these guidelines do not cover environmental aspects such as persistence in the environment, ecological impact of food contact materials constituents and their fate after the food contact material has been submitted to waste disposal treatment.

SUBMISSION OF AN APPLICATION

Applicants should note that competent authorities in Member States will get full access to any dossier submitted to the EFSA (Art. 9 of the Regulation (EC) No1935/2004) (European Commission, 2004). It should also be noted that there will be public access to applications except for the parts which are clearly marked as confidential. Information of direct relevance to the safety evaluation cannot be confidential. Only information which might significantly harm the competitive position of the applicant can be treated as confidential. In such a case verifiable justification must be provided (Art. 19 and 20 of Regulation (EC) No 1935/2004**)** (European Commission, 2004)**.**

Applications shall be submitted in accordance with Article 5 of the "Regulation". The applicant shall provide all available data relevant for the evaluation by the EFSA. For the purposes of the current guidelines, the definitions laid down in the "Regulation" shall apply.

The applicant should submit a dossier with the full information, both on paper and in electronic format on standard physical media (CD-ROM). It has to be declared by letter that the electronic and the paper versions are identical.

In addition to the complete version with the full information, applicants are requested to provide a second version of the CD- ROM without the confidential information. This version will be made available to anyone who might submit a request to the EFSA, according to Regulation (EC) No 1935/2004, Art. 19 (European Commission, 2004).

Any specific literature reference (such as scientific papers) mentioned and used to support the petition must be supplied in the dossier as full length paper. When reference is made to a book or to extensive publications, only the relevant parts need be supplied.

Applicants may deviate from the guidelines, provided valid and documented scientific reasons are given in the dossier. In all cases the EFSA may request additional data.

INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR THE AUTHORISATION OF A RECYCLING PROCESS

The dossier shall be composed of three sections: the summary document, the administrative part and the technical dossier. To allow a complete safety assessment, information is required in all the sections 1 to 3.

1) Summary document

The summary document shall summarise the information provided in the technical dossier and the safety evaluation of the process, including possible recommendations on restrictions of use and special applications. The summary document should follow the same order as described for the technical dossier. This document shall be a stand alone document.
If a reference is made to other documents, a summary of the relevant information in these documents shall also be given.

Applicants should also present their own conclusions, drawing attention to any unusual features in the data presented and their own evaluation of the process, including possible restrictions of use on special applications.

2) Administrative part

The data supplied shall identify the legal entities and the business involved, as well as the person in charge of the application.[2]

1) Name of the applicant (company, organisation, etc), address and other means of communication, e.g. telephone, telefax, e-mail.
2) Name of the business operator intended to be the authorisation holder (if different from above), address and other means of communication, e.g. telephone, telefax, e-mail.
3) Name of the person responsible for the application, address and other means of communication, e.g. telephone, telefax, e-mail.
4) Date of submission of the application.
5) Table of contents of the application.

[2] For conditions of authorisation of a recycling process, interested parties should refer to article 4 of Regulation (EC) No 282/2008 (European Commission, 2008) and to DG SANCO http://ec.europa.eu/dgs/health_consumer/index_en.htm

3) Technical Dossier

3. 1 General information

3.1.1 General description

This information is destined to be published in the Register of authorised recycling processes by the Commission services.
The subject of the application should be described clearly, with a description of the type of plastic and, in general terms, of the main key steps of the process, especially those contributing to removal of potential contaminants. Information on the intended use of the recycled plastic such as percentage in the final article, single-use or repeated-use applications, food types and contact conditions should also be provided. This part should not contain any data which cannot be disclosed to the public**.**

3.1.2 Existing authorisations

Any information concerning existing legislation and/or authorisations in EU Member States and other countries should be included.
It should be indicated whether the process has been already authorised as such (the same process, for the same plant), for the same company (e.g. on another plant) or a similar process (e.g. a process having similar characteristics and key steps). If available, the internet address for the authorisation should be supplied; a copy of an authorisation letter can be annexed. Any other useful and relevant information on the existing authorisations should be supplied.

In this section the applicant should provide information on the status of the recycling process, that is, if the process is already running or if it is going to be set up.

3. 2 Specific information

3. 2. 1 Recycling process

In this section, the recycling process, that is the process to obtain the recycled plastic, starting from the input, should be described in detail.
A flow chart diagram showing the relevant key steps in the process should be included, accompanied by a short written description (1-2 pages) of the reported process steps.
Then, a more detailed description of all the relevant steps of the process, starting from the input and ending with the recycled plastic, or articles made of it, should be given. In accordance with the flow chart, the objective of each step should be indicated: e.g. input control, sorting, cleaning, drying, grinding or flake production, distribution, recollection.
The applicant should identify and describe the steps within the process that are applied to reduce the level of any contaminant possibly present in the input. In addition the issue of the chemicals used in the cleaning steps and of the possible degradation products of the polymer or of plastics additives should be addressed.
This section should be detailed enough to allow the EFSA to evaluate any possible risks to human health.

The applicant should highlight the parameters that are relevant to characterise the process and the relevant steps (e.g. temperatures, pressures, times, operative details, special devices).
The applicant should demonstrate that the critical parameters related to the safety assessment are well controlled.

3. 2. 2 Characterisation of the input

In this section the applicant should demonstrate how it is ensured that the input does not contain chemicals which could survive the recycling process and migrate into food from the final food contact materials and articles in amounts which would be of concern for public health.
The applicant should describe the specifications for the input with regard to possible contaminants and the plan for evaluation and qualification of the suppliers based on their ability to meet specific requirements. Relevant information on the origin of the input should be provided (e.g. kerbside collection, deposit system, bins, bells, closed loop circuit etc.) with particular emphasis on the aspects of traceability and on the actions to prevent entry into the input stream of materials and articles not suitable for food contact applications.
Identify the steps that are critical for the safety assessment.

3.2.3 Determination of the decontamination efficiency of the recycling process

Chemical contaminants of concern are those which are not eliminated during the process, e.g. by washing or evaporation and which may migrate into food at levels which may be of concern for human health. This is related to the physical and chemical properties of the contaminants, mainly their polarity and their molecular weight. These two parameters influence the affinity to the polymer, to the washing media and to the food, the migration rate and the volatility.

To demonstrate the decontamination efficiency of the recycling process, specially designed tests are performed, called challenge tests in which sets of surrogate contaminants are used. These surrogates are substances with different molecular weight and polarity representative of all possible contaminants of concern (FDA, 1992; Pennarun *et al.*, 2005). The yield of decontamination (reduction of each surrogate level) of a recycling process should be determined by means of plastics spiked with surrogates, then submitted to all the steps of the recycling process. In these challenge tests, the surrogates shall be used at concentrations in the plastic allowing their easy analytical detection at the relevant stages of the process. Spike levels may be several orders of magnitude higher than realistic concentrations of contaminants. Sets of surrogates have been proposed in the literature, depending on the polymer and on its intended uses (Begley *et al.*, 2002; FDA, 1992; FDA, 2006; Pennarun *et al.* 2005; Franz *et al.*, 2004a; Vilaplana *et al.*, 2007).

All relevant experimental data shall be provided. The procedure and the results of challenge test(s) to determine the yield of decontamination after the relevant steps of the process should be described in detail. Experimental or theoretical considerations on the possible migration into the foods destined to come into contact should be laid out with clarity. Relevant scientific evidence supported by adequate documentation and / or scientific literature should be provided.

In many cases, the use of some machinery may have a strong impact on the yield of decontamination. Therefore it is acceptable that the challenge test is done by the producer of such a machinery.

3. 2. 4 Characterisation of the recycled plastic

In this section, the applicant should provide relevant data showing that the recycled plastic produced (e. g. flakes, resins, materials etc.) is suitable for the manufacture of food contact materials and articles.
The applicant should identify the parameters that are important in characterising the recycled plastic and report their specifications (e.g. melt flow index, glass transition temperatures). If several grades of recycled plastics are characterised, the intended use of each grade should be indicated as it is described in the section 3.2.5.

3. 2. 5 Intended application in contact with food

Detailed information on the type(s) of food intended to come in contact, along with the duration and temperature of the contact, the surface of plastic/volume of food ratio, single-use or repeated-use applications shall be provided to enable an evaluation of the possible migration (AFSSA, 2007; FDA, 2006; Franz *et al.*, 2004b; Welle, 2005).

3. 2. 6 Compliance with the relevant provisions on food contact materials and articles

Any evidence to demonstrate that recycled plastic and/or the final materials and articles produced from it meet the requirements of the relevant provisions on food contact materials and articles should be provided.

3. 2. 7 Process analysis and evaluation

Applicants shall perform their own risk analysis and give their own conclusions taking into account all the data above (AFSSA, 2007).

A justified identification of the critical steps should be provided. An analysis of the possible consequences of an incidental failure of compliance of some critical parameters with pre-established values, e.g. sorting efficiency, temperature range during washing or decontamination should be provided.

RE-EVALUATION OF A PROCESS

Authorisation holders should note that any significant modification to the process could lead to a request for a re-evaluation of the process by the EFSA. Depending on the importance of the changes, the request for re-evaluation can range from a simple notification by letter to a complete dossier. A complete dossier shall be submitted when the parameter(s) modified is (are) critical for the safety assessment.

QUALITY ASSURANCE SYSTEM (QAS)

Where appropriate, information on those parts of the Quality Assurance System (QAS) that are relevant for the safety assessment shall be submitted together with the technical dossier.
The provided information should highlight only the key points of the QAS that ensure the recycled plastic meets pre-established criteria fundamental for compliance of the final material and articles with the relevant provisions on food contact materials.
Certification of the QAS conformity to a relevant norm (e.g. ISO 9000) is not required by the Community provisions. However, when the QAS conformity to any relevant norm has been certified, the certification documents could be enclosed with the petition.

REFERENCES

Note: The references cited below are those used by the EFSA to draft the guidelines. The reference section is not aimed to be an exhaustive bibliography.

AFSSA, Agence Française de Sécurité Sanitaire des Aliments, 2007: Opinion of the French Food Safety Agency on the assessment of health risks associated with the use of materials made from recycled poly(ethylene terephthalate) intended for or placed in contact with foodstuffs and drinking water; http://www.afssa.fr/Ftp/Afssa/38790-40715.pdf

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

Coulier L., Orbons H.G.M., Rijk R., 2007: Analytical protocol to study the food safety of (multiple-)recycled, **high-density polyethylene** (HDPE) and polypropylene (PP) crates: Influence of recycling on the migration and formation of degradation products, Polymer Degradation and Stability, **92**, 2016-2025

European Commission, 2002: Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs; OJ L 220 15.8.2002

European Commission, 2004: 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

European Commission, 2006: Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food; OJ L 384 29.12.2006

European Commission, 2007: Document [SANCO 3447/2007] [Draft} Commission Regulation (EC) No [XXX/2008]on recycled plastic materials and articles intended to come into contact with foods and amending Commission Regulation (EC) No 2023/2006

European Commission, 2008: COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006

FDA, Food and Drug Administration, 1992: Points to consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations, December 1992, http://www.cfsan.fda.gov/~dms/opa-cg3b.html

FDA, Food and Drug Administration, 2006: Use of Recycled Plastics in Food Packaging: Chemistry Considerations, Division of Food Contact Notifications HFS-275, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740 http://www.cfsan.fda.gov/guidance.html

Franz R., Bayer F. and Welle F., 2004a: Guidance and Criteria for Safe Recycling of Post Consumer Polyethylene Terephthalate into New Food Packaging Applications. Report EUR 21155 - Luxembourg: Office for Official Publications of the European Communities ISBN 92-894-6776-2 (the report will be available on the Ispra JRC web site and the link will then be added)

Franz R., Mauer A. and Welle F., 2004b: European Survey on Post-Consumer Poly(ethylene terephthalate) Materials to Determine Contamination Levels and Maximum Consumer Exposure from Food Packages Made from Recycled PET. Food Additives and Contaminants 21, 265 – 286

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

Pennarun P.Y., Saillard P., Feigenbaum A., Dole P., 2005: Experimental Direct Evaluation of Functional Barriers in **PET Recycled** Bottles: Comparison of Migration Behaviour of Mono- and Multilayers, Packaging Technology and Science; **18**: 107–123

Vilaplana F., Ribes-Greus A., Karlsson S., 2007: Analytical strategies for the quality assessment of recycled high-impact **polystyrene**: A combination of thermal analysis, vibrational spectroscopy, and chromatography, Analytica Chimica Acta **604**, 18-28

Welle F., 2005: Post-consumer contamination in **high-density polyethylene** (HDPE) milk bottles and the design of a bottle-to-bottle recycling process, Food Additives and Contaminants; **22**: 999–1011

ANSWERS TO COMMENTS ON RECYCLING PLASTICS GUIDELINES RECEIVED FOLLOWING PUBLIC CONSULTATION

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SUBMITTED COMMENTS IN ANNEX

Following public consultation on the draft EFSA guidelines on evaluation of recycling processes for plastics (from 9th January to 6th March 2008), EFSA received 48 questions and comments from 11 persons or organisations from 7 countries. These submitted comments have been compiled in annex.
This document sets out answers to these questions.
The line numbers cited in this document refer to the version of the guidelines which was submitted for public consultation.

1 Scope of EFSA's guidelines: mechanical – chemical recycling versus hybrid processes

→COMMENT- QUESTION
It is proposed to write in line 63 "using mechanical or mechanical-chemical recycling (hybrid processes)" to take into account hybrid processes (question 36). It should be emphasised that there is a wide range of recycling possibilities and decontamination technologies, ranging from 100% mechanical recycling to 100 % chemical depolymerisation, with intermediate "hybrid processes". For instance hybrid technologies use fresh monomers (in the case of PET) to increase the polymeric chain length of collected plastics.

BACKGROUND – EXPLANATION
Recycling processes which do not fall under the guidelines are those which are excluded from the scope of the regulation (article 1, paragraph 2 of Regulation (EC) No 282/2008): (a) chemical recycling processes, (b) materials made from production offcuts, and (c) materials with a functional barrier.
Hybrid processes cited in question (36) are covered by the regulation and are in the scope of these guidelines, provided they do not result in breakdown to monomers and starting substances that are re-used in polymerisation.

CURRENT VERSION
These guidelines apply to processes using mechanical recycling, whereby the collected plastics are ground into small pieces and decontaminated before being processed to new food contact materials. Chemical recycling processes, whereby the plastic is completely depolymerised into monomers, are not in the scope of the "Regulation" and are not covered by these guidelines.

PROPOSED AMENDMENT
To clarify this point, the proposal is to add one sentence line 63 of the guidelines. The whole paragraph would read as follows:
These guidelines apply to processes using mechanical recycling, whereby the collected plastics are ground into small pieces and decontaminated before being processed to new food contact materials. Chemical recycling processes, whereby the plastic is completely depolymerised into monomers and starting substances which are then reused in a polymerisation reaction are not in the scope of the Regulation and are not covered by these guidelines. Processes where the mechanical recycling is the main part of the whole process are in the scope of these guidelines, provided that the plastic is not subsequently depolymerised.

2 Who is the applicant? who is authorisation holder?

EFSA has received questions on who should apply, who is the authorisation holder (questions 1, 2, 7, 9, 22, 24, 27, 30 and 31). Has it to be an operator running the whole process, from the input to the final recycled product? Can it be a machinery producer? Is it necessary to mention in an application all companies working under license?

→COMMENT- QUESTION

Can a machinery producer be applicant or authorisation holder (questions 7, 22 and 27)?

BACKGROUND

From the point of view of risk assessment, an application must cover the whole process: the input characterisation, the sorting and cleaning efficiency of the process and the quality and the intended use of the recycled plastic.

The Regulation (EC) No 282/2008, article 4, specifies that in order for a recycling process to be authorised, the quality of plastic input as well as that of the recycled plastic "must be **characterised** and **controlled**". Therefore a machinery producer can only be an applicant if he can characterise **and** control all the aspects: input characterisation, sorting and cleaning efficiency and quality of the recycled plastic.

PROPOSED CLARIFICATION IN THE GUIDELINES

The definition of applicants and authorisation holders is given by the risk manager. According to article 4 of Regulation (EC) No 282/2008, an applicant should characterise and control all the aspects from the input characterisation, including the sorting and cleaning efficiency of the process and to final recycled plastic.

In the course of this public consultation, the EFSA has received comments from DG SANCO, indicating that "control" means to be able to make prescriptions and/or recommendations to customers of machinery producers.

This will not lead to a modification of the guidelines, except a footnote inviting interested parties to refer to the Regulation and to DG SANCO.

→ QUESTIONS ON LINKS WITH OPERATORS UNDER LICENCE

These questions refer to section 3.1.2 of guidelines: Existing authorisations:

"It should be indicated whether the process **or the same process under licence** has been already authorized as such and if the process is **already running or running under licence** or if it is going to be set up."

BACKGROUND

For the purpose of risk assessment, it is only important for the EFSA to know whether the process under examination is identical to one already evaluated.

CURRENT VERSION OF THE EFSA GUIDELINES (§ 3.1 .2)

Line 207 of the version submitted to public consultation:

It should be indicated whether the process has been already authorised as such (the same process, for the same plant), for the same company (e.g. on another plant) or a similar process (e.g. a process having similar characteristics and key steps). If available, the internet address for the authorisation should be supplied; a copy of an authorisation letter can be

annexed. Any other useful and relevant information on the existing authorisations should be supplied.

BACKGROUND & ANSWER
For the purpose of risk assessment, the EFSA guidelines already require details on authorisation, independently of the fact that a process may be running under licence. If the application and the opinion of EFSA mentioned all other operators working with the same process under licence, this may facilitate the control operations by Member States. However (a) this is out of the scope of the risk assessment, and (b) the EFSA cannot keep updated a list of operators under licence.

PROPOSED MODIFICATION
Given clear statements in Regulation (EC) No 282/2008 on operators under licence, no modification is proposed.

GENERAL COMMENT
The questions discussed in this section on machinery producers and on the possibility to run a challenge test on a pilot plant correspond to the need that, before setting up a plant, a business operator wishes to ascertain that he will be in a position to produce recycled materials suitable for contact with food. To take the related comments and concerns into account, an amendment is proposed in the section "challenge test" below.

3 Characterisation of the input (section 3.2.2)

This part of the technical dossier raised many comments and questions.

➔ **COMMENT-QUESTION**
EFSA was asked to add examples of collection systems "bins and bells" to paragraph 3.2.2 (questions 5 and 17).

ANSWER
It is clear that the list of sorting systems is not aimed to be exhaustive and consists only of examples. However EFSA could add two more examples of collection system to the guidelines, "bins, bells", as follows:

CURRENT VERSION
Relevant information on the origin of the input should be provided (e.g. kerbside collection, deposit system, closed loop circuit etc.)...

PROPOSED AMENDMENT (line 246)
Relevant information on the origin of the input should be provided (e.g. kerbside collection, deposit system, bins, bells, closed loop circuit, etc.)

➔ **QUESTIONS** were raised about the control of the quality of the input and EFSA was asked to give precise guidance

- about the traceability of the collected waste plastics in the input, which may be constituted of waste from many diverse collection sources (e.g. municipalities...) (questions 11, 21)
- about means to achieve a suitable control of the input (questions 10, 21 and 33)

- about a detailed procedure for control of a single batch (questions 11, 13). Question 13 is also related to traceability of the input.

BACKGROUND & ANSWER

It is not possible to give such detailed guidance, which is outside of the scope of the guidelines. Traceability as such is neither part of the guidelines nor of the evaluation. What is important for the applicant is to demonstrate that the input is characterised and that these input characteristics can be realistically achieved. If the input characteristics in the plant that is applying the process are not met, the recycler should be in a position to identify the source and to remedy the situation. This is more an issue of the quality assurance and control system than part of the safety evaluation.

For example, the quality of the input could be demonstrated by supplying the following documents in the technical dossier:

- specifications to the suppliers, with tolerable range
- results from statistical controls demonstrating that the specifications are met
- demonstration that a bad batch can be traced.

PROPOSED AMENDMENT

None.

➔ QUESTION:

A European Printing Inks Manufacturer Association raised the issue of collected packaging materials initially intended for food contact but containing constituents not listed in Directive 2002/72/EC (question 37). This situation may arise from parts of the materials which are not specifically regulated like printing inks or adhesives. The proposal was that unless the recycling process guarantees complete removal of printing ink constituents, printed plastic packaging should not be accepted in the input stream.

ANSWER

EFSA considered that these considerations should not lead to a modification of the guidelines. The risk of the possible presence of contaminants in the input stream has to be considered as part of the risk assessment, taking into account the process decontamination capacity. If the applicant cannot ascertain that contaminants of concern are removed during the process, specifications to exclude or restrict their presence in the input stream should be put in place.

PROPOSED MODIFICATION

None

➔ COMMENT - PROPOSAL

It has been proposed to modify line 109 of the guidelines (question 16) and to replace "**if there is any contamination of the input**" by "**in order to take into account all potential sources of contamination of the input**"

CURRENT VERSION

If there is any contamination of the input, it has to be demonstrated that the process is able to reduce it to levels not posing a risk to human health for the intended use of the final product

PROPOSED MODIFICATION

The proposal is to accept the suggestion, line 109. The text would thus become:

Taking into account all potential sources of contamination of the input, it has to be demonstrated that the process is able to reduce it to levels not posing a risk to human health for the intended use of the final product.

4 Challenge test

Questions were raised about the challenge test and its procedure.

→ QUESTION ABOUT THE PROCEDURE OF THE CHALLENGE TEST

There was a question about the need to use a swelling solvent to incorporate the surrogates (question 20).

BACKGROUND

Use of a swelling solvent allows flakes to be penetrated in the mass, which is a worst case, but sometimes possible situation. If a process is capable of decontaminating a worst case material, this is a strong point. Several references are given in the guidelines, without imposing a specific procedure.

PROPOSED MODIFICATION:

None

→ QUESTION ON A POSSIBLE CORRELATION BETWEEN THE RESIDUAL CONTENT IN A CHALLENGE TEST WITH A POSSIBLE THRESHOLD OF CONCERN (QUESTION 33).

There is a proposal to add to line 277:

"Evaluate the decontamination efficiency comparing the challenge tests results with the values considered as sanitary safe and established by the sanitary authorities" (surrogate migration limit 10 ppb (EU); threshold of regulation (TOR) (0.5 ppb (dietary basis)) and derived parameters (surrogate content in flake or pellet (220 ppb for PET) or surrogate migration limit (10 ppb) (FDA-USA)).

BACKGROUND & ANSWER

In challenge tests, the concentration of surrogates is usually unrealistically high in order to ensure that the process can decontaminate the recycled plastic even under conditions that are unlikely to occur in practice under normal operation of the process. Large concentrations of surrogates in challenge tests should facilitate the determination of decontamination yields and, if relevant, of migration. There is no intention that the challenge test should mimic realistic contamination levels.

Although this is mentioned in several publications in the reference list, there is no intended correlation between a residual concentration in the material and an acceptable concentration in the recycled plastic or in food following migration.

PROPOSED MODIFICATION
None

➔ QUESTIONS ON THE POSSIBLE INVOLVEMENT OF MACHINERY PRODUCERS AND THE POSSIBILITY TO RUN CHALLENGE TESTS ON PILOT PLANTS (see section 2 of the current document)
The questions on machinery producers and on running the challenge test on a pilot plant (chapter 2 of the current document, questions 20, 22 –related to authorisation holders) are addressed here.

BACKGROUND
These questions address the need of a business operator to be able to assess, before a plant is built, whether he will be in the position to produce recycled materials suitable for contact with food. In practice, the use of some machinery may have a strong impact on the recycling process and on the decontamination of collected plastics. A challenge test characterising the decontamination efficiency of machinery may then be an important part of the technical dossier. Since such a test would refer to this specific machinery, it may not be necessary to repeat this test if the process is carried out under exactly the same operating conditions.

PROPOSED AMENDMENT
To take these concerns into account, an amendment is proposed in the section "challenge test" at the end of section 3.2.3, line 278:
In many cases, the use of some machinery may have a strong impact on the yield of decontamination. Therefore it is acceptable that the challenge test is done by the producer of such machinery.

5 Characterisation of the recycled plastic

➔ QUESTION – COMMENT
One comment indicated that according to the guidelines, the characterisation and the definition of potential applications should be for each batch (question 10), which would be a burden for industry.

BACKGROUND & ANSWER
Whether or not dealing with recycled plastics, a business operator is responsible to ensure that the materials he produces are suitable for contact with food. For that purpose he should use adequate control methods. The operator should also ensure that differences in analytical data of different batches are within the specifications set for the materials.

PROPOSED MODIFICATION
None

➔ QUESTION – COMMENT
EFSA was asked to make clear that real-life conditions must be taken into account (question 3): "Should it not be made clear that the evidence provided should take into account the real-life conditions which apply, or could well apply, in the recycling loop?"

ANSWER

This was considered irrelevant, as the specifications are for actual plastic produced, which clearly takes into account real-life conditions.

PROPOSED MODIFICATION
None

6 Responsibility for the recycled plastics

→ QUESTION
Questions were raised on the relative responsibilities of the recycler and of the final packer (question 8).

ANSWER
This question is beyond EFSA's scope but is clearly defined by the Regulation.

PROPOSED MODIFICATION
None

→ QUESTION
A question dealt with the diffusion of information on possible restrictions of use (questions 19).
"It is surely better to use the trade route to ensure the recycled plastic is fit for purpose rather than to try to fit trade around an authorisation"

ANSWER
This question deals with the Regulation more than with evaluation.
Following the evaluation of a recycling process, EFSA will indicate for which types of food the recycled plastic is suitable. If the Commission follows EFSA's evaluation, this will be specified in the authorization. Each successive operator should then provide to his customers a declaration of compliance for the type and amount of information under his responsibility, according to Article 9 of Directive 2002/72/EC and the Annex of Regulation (EC) No 282/2008. This information will contain the conclusions of the evaluation.
Any analytical controls to verify that the recycled plastics comply with the authorisation are under the responsibility of the operators. They are in the scope of the audits which will be carried out by Member States.

PROPOSED MODIFICATION
None

7 References

→ QUESTION
EFSA was asked to include more references from the scientific literature as well as information about a resolution of Mercosur (Mercosur/GMC/Res N° 30/07) published shortly after the public consultation (questions 6, 31, 32-36, 38).

ANSWER

The references cited in the version for public consultation are those used by EFSA to draft the guidelines. The reference section is not aimed to be an exhaustive bibliography.

PROPOSED AMENDMENT:

To clarify the scope and the use of the references, it is proposed to add the following paragraph:

The references cited are those used by the EFSA to draft the guidelines. The reference section is not aimed to be an exhaustive bibliography.

Annex:
Submitted comments from public consultation

CHAPTER_TEXT	COMMENT_TEXT
3) Technical Dossier	Chapter 3.1.2 Existing authorisations: Line 207, an addition to the sentence: It should be indicated whether the process or the same process under licence has been already authorised as such… Line 214, an addition to the sentence: …. if the process is already running or running under licence or if it is going to be set up
2) Administrative part	Chapter 2) Administrative part: Addition of a new point 3) Names of the other business operator(s) using the same recycling process under licence if already running and included in the application. This addition is needed in order to avoid possible confusions between business operators in charge of application.
3) Technical Dossier	Lines 296-300 Should it not be made clear that the evidence provided should take into account the real-life conditions which apply, or could well apply, in the recycling loop?
3) Technical Dossier	Lines 237-249 Should it not be made clear that the required demonstration and description should be in the context of the real-life conditions which apply, or could well apply, in the recycling loop?
3) Technical Dossier	Chapter 3.2.2: Characterisation of the input Under the application of the principles mentioned in chapter 3.2.2 (Characterisation of the input) other systems of collection can be mentioned, e.g. kerbside multi-material, mono and multi-material bins or bells. Under this point of view is important to guarantee an adequate control of the contamination along the whole chain "collection/sorting/recycling", despite the specificity of the collection system apply for the input.
REFERENCES	332 - 385 As the harmonisation of the EU regulation should be based upon a fundament of a lot of publications we like to add the following publications to the list. These recognized and accepted data by authorities and industry is necessary to feed the dossiers: ¿ F. Welle Investigation into the decontamination efficiency of a new post-consumer poly(ethylene terephthalate) recycling concept Food Additives and Contaminants, 2008, 25(1), 123-131 ¿ F. Welle, R. Franz Recycled Plastics and Chemical Migration into Food in "Chemical migration and food contact materials", K. A. Barnes, C. R. Sinclair, D. H. Watson (Editors), ISBN 1-84569-029-X, Chapter 9, Woodhead Publishing Cambridge, 2006, 205-227 ¿ R. Franz, F. Welle Recycling Packaging Materials in "Novel Food Packaging Techniques", R. Ahvenainen (Editor), ISBN 1 85573 675 6, Chapter 23, Woodhead Publishing Cambridge, 2003, 497-518 ¿ R. Franz, F. Welle Recycled Poly(ethylene terephthalate) for Direct Food Contact Application - Challenge-Test of an Inline Recycling Process Food Additives and Contaminants, 2002, 19(5), 502-511 ¿ R. Franz, F. Welle Post-Consumer Poly(ethylene terephthalate) for Direct Food Contact Application -

CHAPTER_TEXT	COMMENT_TEXT
	Final Proof of Food Law Compliance, Deutsche Lebensmittel-Rundschau, 1999, 95(10), 424-427 ¿ R. Franz, M. Huber, F. Welle Recycling of Post-Consumer Poly(ethylene terephthalate) for Direct Food Contact Application - a Feasibility Study Using a Simplified Challenge Test, Deutsche Lebensmittel-Rundschau, 1998, 94(9), 303-308 ¿ F. Blanchard, A. Christel, G. Gorski, F. Welle Drinks from the Detergent Bottle Plast Europe, 2003, 93(9), 42-45 ¿ Use of mechanical recycled plastic made from polyethylene terephthalate (PET) for the manufacture of articles coming in contact with food, Bundesinstitut für Risikobewertung BfR, Berlin, 2000 ¿ Use of mechanically recycled plastic made from polyethylene terephthalate (PET) for the manufacture of articles coming into contact with food, publication of BgVV (BfR) Germany.
3) Technical Dossier	l 296-301 : The safeguarding of the quality of the food articles is mainly determined by the decontamination. Today decontamination can take place on different locations. Integrations of food approved processes are not limited to the traditional chain-players but have advanced into direct production of articles. Even combinations in the production of virgin PET and recycled material are able to make direct food grade articles. Important capacities have been installed over the last years. Much data is available and those final decontamination processes have proved to operate safely under the supervision of different Member States authorisations. The suppliers of the recycled material have also been integrated in the development of the successful technical adaptation to the converting process for a final decontamination at the converter. Therefore, an authorisation procedure for recycled material which is limited to only the location of the recycler does not cover the current established market situation. The authorization should also consider this second decontamination existing in some market situations. In order to deal with this situation, the manufacturer of converting machinery that performs the final decontamination at the converters level should be able to file a petition to EFSA for his process, the recycler, having only to refer to this approved process in its conditions of use. No converter using the converting machinery should file a petition. The lines 296-301 would allow this. It should be made more clear this possibility is open in the EFSA guideline. E.g. by inserting a section “who should apply”. More information and charts are available; please specify an email address to send them.
3) Technical Dossier	3.2.6 Compliance with the relevant provisions on food contact materials and articles (lines 296-300) I recon that the provision of the information mentioned here is not the responsibility of the recycler or the producer of articles to come in contact with food, but of the packer and filler based on a declaration of compliance from the previous links in the product chain. If so it should be stated.
3) Technical Dossier	3.2.5 Intended application in contact with food (lines 289-294) I recon that the provision of the information mentioned here is not the responsibility of the recycler or the producer of articles to come in contact with food, but of the packer and filler based on a declaration of compliance from the previous links in the product chain. If so it should be stated.
3) Technical Dossier	3.2.4 Characterisation of the recycled plastic (lines 279-287) The demand of relevant data showing that the recycled plastic produced is suitable for food contact should literally be batch specific. Such a demand would kill all small and medium size recyclers. A more detailed description of the procedure (especially number or frequency of analyses) is necessary in the guidelines

CHAPTER_TEXT	COMMENT_TEXT
3) Technical Dossier	3.2.2 Characterisation of the input (lines 237-249) In many cases the recycler receives the plastic input from many different collection sources (ex. sorted house holding waste from different municipalities). Although all material might be food contact materials sorted out according to the specific polymer there could be differences in the content of additives, dual-use substances etc. And the recyclate would not be totally identical from batch to batch. Traceability would not be possible and the plastic input would change from batch to batch. How should the recycler demonstrate the quality of the input material? Analyses of the single batch would be prohibitive for the business. A more detailed description of the procedure is necessary in the guidelines
QUALITY ASSURANCE SYSTEM (QAS)	322-326 The challenge test protocol, as well as the standard operating procedures for all analytical monitoring methods to be employed once the process is established, will be relevant for the safety assessment.
3) Technical Dossier	231, 232: This may be an appropriate place to reiterate that safety is paramount by stating that preparatory work should ensure all potential hazards – chemical, biological or physical – are highlighted and appraised. Similar words might be helpful in the General Principles section.
3) Technical Dossier	239-242 The guidance could usefully point to an acceptable standard of practice. For example, should every input batch be tested, in order to facilitate the detection of highly hazardous contaminants before they are diluted by processing? (This strategy would also allow the operator to avoid wider contamination events that could lead to more costly risk management measures.) Should processes deliver a certain dilution in order to minimise the acute effects of possible toxic spikes? Powerful generic techniques are now available for the extraction, screening and identification of unknown contaminants; the methods usually combine chromatography and advanced mass spectrometry. In addition, the applicant's own appraisal of hazards may need to inform recommendations on an agreed schedule of analytical tests for specific substances of concern.
3) Technical Dossier	256 As well as polarity and molecular mass, there is a possibility that more specific properties will lead to the retention of some contaminants by the post-consumer matrix material. The retained contaminants may chance to be highly hazardous, and could be released under the different conditions of subsequent end use. Applicants may be best placed to consider this possibility, which might for example be more of an issue if there were regular features inherent in the molecular structure of the input material that could act as binding sites.
3) Technical Dossier	261-262 It is doubtful whether any set of surrogate compounds could be 'representative of all possible contaminants', but this is certainly the key criterion for challenge testing. Perhaps it is more realistic to ask for a brief appraisal of the chemical scope and limitations of the challenge test.
3) Technical Dossier	284 New hazards will come into play after the recycling process, including potential contamination with chemicals used in the washing steps, and formation of degradation products by the polymer and additives. At this stage it may again be helpful to point applicants toward the adoption of both substance-specific and generic analytical monitoring procedures.
3) Technical Dossier	307-310 Regular analytical monitoring is the obvious safety net.
2) Administrative part	180, 181, 184, 185 Will the distinction between 'Name of the applicant' and 'Name of the person responsible for the application' be clear, e.g. if reference is made to the Regulation?
SUBMISSION OF AN APPLICATION	152-154 This paragraph could perhaps be clarified by defining the requirement a little more. Maybe the full length paper is only needed when it describes aspects of the recycling

CHAPTER_TEXT	COMMENT_TEXT
	process, or key technical supporting operations such as analytical monitoring, challenge testing or closed-loop supply chain technology.
GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD	82-103 Should there be a bullet point for adventitious environmental contamination, e.g. from contact with non-dedicated areas during transportation or storage? 109 'If there is any contamination of the input …' Although this sentence is based on supporting references, would it be more fully in accordance with the objectives of framework legislation to say 'Taking account of all potential sources of contamination of the input …'?
3) Technical Dossier	chapter 3.2.2. Under the application of the principles mentioned in chapter 3.2.2. (Characterization of the input) other systems of collection can be mentioned, e.g. kerbside multi-material, mono and multi-material bins or bells. Under this point of view is important to guarantee an adequate control of the contaminations along the whole chain "collection/sorting/recycling", despite the specificity of the collection system apply for the input.
REFERENCES	See line 275- 277, the applicant is required to provide copies of literature references in the Dossier. Surely EFSA must publish on a Recycle section of its website the literature references listed in this guideline and make them available for use by applicants.
3) Technical Dossier	Reference to Section 3.2.4 Line 284 – 287 Characterisation of the recycled plastic. From a commercial point of view a recycler has to trade his product and the recycled plastic must meet his customer's specifications. General characterisation of recycled plastic could be extremely difficult and is unnecessary for the purposes of authorisation. It is surely better to use the trade route to ensure the recycled plastic is fit for purpose rather than to try to fit trade around an authorisation ie "does the tail wag the dog ? "
3) Technical Dossier	Reference to Section 3.2.3 Line 259/260 " demonstrate the decontamination efficiency . . challenge tests . . are performed" It is not clear at what capacity level a recycling process has to demonstrate its decontamination efficiency. - Can a challenge test be performed on pilot plant scale or is it compulsory to perform the challenge test on a commercial recycling plant? - If the second applies, what is the cut-off? - How are half commercial demonstration plants viewed?
3) Technical Dossier	Reference to Section 3.2.3 Line 259/260 " demonstrate the decontamination efficiency . . challenge tests . . are performed" IGuidance is given toward the selection and concentration of the surrogate contaminants by reference. However, it is not clear if this also includes how homogeneously these contaminants have to be diffused into the input material. Specifically: is a swelling agent required or will challenge tests only relying on surface contamination be accepted?

CHAPTER_TEXT	COMMENT_TEXT
3) Technical Dossier	Reference to Section 3.2.2 Line 246/247 "with particular emphasis on the aspects of traceability" To what extent is traceability of the input material required. Is it sufficient to know the general type of articles (material class) and the area and method of their collection or is there a requirement to trace information about each individual collected article with respect to its material composition, former use etc.? If the second applies: - What tolerances of un-traceable articles apply? - How can the industry evaluate to what extent un-traceable articles are acceptable in a given material stream?
3) Technical Dossier	How can a converter demonstrate compliance of input material? If a converter owns machinery specifically designed to upgrade material (usually PET) to food contact quality. How do they get the input stream authorised, by source, by country when it is currently impossible to have this data supplied as described in the guidelines. – will EFSA supply an authorisation for “input” materials to be supplied forward to Converting companies for use in machinery specifically designed to upgrade materials. If this can happen then the converter can refer to EFSA authorised “input” in an application for an Evaluation of their process by EFSA.
3) Technical Dossier	Reference to Section 3.2.2. lines 237-249 Characterisation of the input All requests are written as "should" which makes them totally unclear. What is compulsory, what is optional?
3) Technical Dossier	Reference to Section 3.1.1 lines 198 - 201 Unless an Authorisation is given for a very narrow specific use, how can a seller supply to a buyer and specify what the buyer can do with his product? It is true that a seller can suggest but cannot compel. - A polymer manufacturer generally does not sell for a specific use but rather for generic uses. Ie food contact, non food contact, - With reference to 2002/72/EC, should not the final manufacturer of the article satisfy himself that materials used in the construction of his article comply with all relevant regulations?
INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR THE AUTHORISATION OF A RECYCLING PROCESS	Reference to lines 163 – 165 Will EFSA supply standard format/forms for submissions?
SUBMISSION OF AN APPLICATION	Reference to line 140 – all available relevant data How do we know what data is relevant without EFSA guidance?

CHAPTER_TEXT	COMMENT_TEXT
INTRODUCTION	Reference to lines 63- 75 How will EFSA respond to an application from a machine manufacturer? It is inevitable that a machine manufacturer will need/want to demonstrate compliance with the regulation on recycled plastic materials. - Can they obtain a single authorisation for use of their equipment? - Or does the customer (recycler) of the equipment manufacturer need to demonstrate whole process compliance which includes the machine? Although the guidelines apply to processes [line 63] they also require an applicant to describe the specifications for the input material [line 243] and give information about traceability [line 247]. A machine manufacturer could file an application for a defined material with a defined process but only under the assumption that the traceability aspect of the input material will be fulfilled by a potential user. - Is this acceptable to EFSA? - Assuming it will accept the application for evaluation and the machine fulfils the requirements, what type of approval will EFSA give? (temporary/conditional upon demonstration of traceability or a full approval of the technical dossier?)
INTRODUCTION	No Reference line number Is authorisation in any country valid for all of Europe? If yes, how can it be ensured that the authorisation procedure and the subsequent auditing is done in the same manner? Will this be according to a standard Europe wide checklist which will ensure a uniform approach? This would ensure that a company's location "interpretation of authorisation" and "auditing" by a national body ensures equal treatment in each country. In short is the same measuring device used everywhere, and how can this be ensured?
GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD	Reference to line 119 "the QAS evaluation and audit will be performed by Member States" QAS will be performed by the member states, by whom? It is not clear to what extent this audit can go. In case of process duplication: - Will an auditing authority check the design and process parameters to be in line with an existing EFSA approved process, or can the auditing authority request additional challenge tests to check compliance? - If the second applies, can the auditing authority request a specific (different from earlier approval) challenge test?
2) Administrative part	General comment: We welcome the Guidance and the opportunity to comment on the text. We see the Guidance as a living document that will need to be changed from time to time to reflect the experience gained from making submissions and to take into account technological progress. Line 176: Administrative part We would like clarification on whether there is any restriction on who can make the application (recycler, converter, importer, bottler?) and whether the authorisation given is for a particular process or given to the business ("authorisation holder") making the application for a particular process.

CHAPTER_TEXT	COMMENT_TEXT
	If the authorisation is for a particular process, would it be possible for businesses other than the authorisation holder to use the same process without making another application?
REFERENCES	I think it would be important to take into account the following references: -"Guidance and criteria for safe recycling of post consumer polyethylene terephthalate (PET) into new food packaging applications". Roland Franz, Forrest Bayer and Frank Welle. EU-Project FAIR-CT98-4318 ¨Reciclability¨. European Commission, Brussels, 2004. -"The threshold of regulation and its application to indirect food additive contaminants in recycled plastics". Forrest L. Bayer. Food Additives and Contaminants, 1997, vol. 14, No. 6-7, 661-670. - "PET recycling for food-contact applications: testing, safety and technologies: a global perspective". Forrest L. Bayer. Food Additives and Contaminants, 2002, vol. 19, Supplem., 111-134. - Resolución GMC 30/07 MERCOSUR. "Reglamento Técnico MERCOSUR sobre envases de polietilentereftalato (PET) reciclado postconsumo grado alimentario (PET-PCR grado alimentario) para contacto con alimentos. December 2007. (www.mercosur.org.uy; www.puntofocal.gov.ar) - "Recycled materials and safety considerations for direct food contact - FDA view". Paul M. Kuznesof (Office of Food Additive Safety; Center for Food Safety and Applied Nutrition (CFSAN-FDA-USA)). In: "Memorias del Seminário Internacional Reciclagem de PET pós-consumo para contato com alimentos". Campinas, Sao Paulo, Brazil, 17-18 September 2003.
QUALITY ASSURANCE SYSTEM (QAS)	331. (on Quality assurance system). Following Franz, Bayer and Welle (2004), I think that the quality assurance must take into account three aspects: 1. Frequency of the challenge test (covered by "Re-evaluation of a process")(313-318) 2. Analytical monitoring 3. Sensory testing Resolution MERCOSUR 30/07 states the need of (translation from Spanish): "Analytical monitoring: programs of analytical monitoring that ensure the continuity of the food grade PCR-PET quality with time". "Sensory analysis: to ensure that food grade PCR-PET does not alter the sensorial characteristics of food, sensorial analysis shall be performed, with the adequate frequency, on the packages (produced with PCR-PET)according to ISO 13302 ´Sensory analysis - Methods for assessing modifications to the flavour of foodstuffs due to packaging´ or equivalents." Ref.: "Guidance and criteria for safe recycling of post consumer polyethylene terephthalate (PET) into new food packaging applications". Roland Franz, Forrest Bayer and Frank Welle. EU-Project FAIR-CT98-4318 ¨Reciclability¨. European Commission, Brussels, 2004.
3) Technical Dossier	239-242 (on the characterisation of the input). I think that actually this paragraph should apply to the characterisation of the product, through the concept of the decontamination efficiency concept, and not to the input. The concept of validation of the technology through the challenge test with surrogates, has arisen to avoid making assertions or essays referred to each particular contaminant (which can be millions) present in the input. I understand the goal of the paragraph, but it´s difficult to understand it gramatically, or if it is the right subtittle to place it.

CHAPTER_TEXT	COMMENT_TEXT
	264. (on the determination of the decontamination efficiency of the recycling process): In line 264 it would be important to state ..."by means of plastics spiked with surrogates under standardized conditions (time, temperature, concentration, ecc.)".. 277. After describing the validation of the decontamination efficiency process, I think that it should be added, the final step: "Evaluate the decontamination efficiency comparing the challenge tests results with the values considered as sanitary safe and established by the sanitary authorities" (surrogate migration limit 10 ppb (EU); threshold of regulation (TOR) (0.5 ppb (dietary basis)) and derived parameters (surrogate content in flake or pellet (220 ppb for PET) or surrogate migration limit (10 ppb) (FDA-USA)).
GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD	85. Contaminants in the input: in PC-PET feedstream contaminants can be also residues of the original foodstuff or product (non-food product, like cosmetics, mouthwash, cleaners). Resolution MERCOSUR 30/07 allows the use as feedstream of PET packages of food and non-food products, providing that the PET used is food grade. Nevertheless, in Argentina each technology is going to be evaluated if it has a no-objection letter from FDA-USA or a Decission on its use from the EU or EU Member States. There in those documents, it is stated or will be stated the kind of packages that the technology has been found able to process, by the respective sanitary authorities.
INTRODUCTION	69. MERCOSUR Resolution 30/07 takes into account that the provider of decontaminated PET can sell the product either to a manufacturer of trilayer of monolayer parisons, for the production of trilayer or monolayer bottles. If the material complies with the requisites (more strict) in the case of the monolayer article, there is no problem to use the material in the intermediate layer of the trilayer bottle, which also has the functional barrier.
INTRODUCTION	63. There are decontamination technologies for certain condensation plastics as PET, which work through a chemical attack on the flake surface followed by mechanical cleaning (hybrid processes, e.g. URRC, USA). There is a wide range of recycling possibilities from: 100% mechanical (e.g. Buhler, Switzerland); hybrid processes; polymerisation reactors by trans-sterification, than can work with fresh monomers (ethyleneglycol and terephthalic acid and post-consumer PET (PC-PET))and some possible contaminants can remain in the mixture in the reactor; and 100 % chemical depolymerisation. If in line 63 you write "using mechanical or mechanical-chemical recycling (hybrid processes)" you take into account the three first possibilities (of high interest for PET recycling). In the Southern Common Market (MERCOSUR) a Resolution (30/07) has been sanctioned last December 2007 (I can send a copy by mail), that takes into account also the chemical recycling. In our countries it was politically and technically necessary to cover all the possibilites mentioned above. Because in theory no contaminants remain in 100% chemical recycling, in practice is that the case? What happens if a mixture of 70% fresh monomers and 30% PC-PET (with possible contaminants) is treated in a trans-sterification reactor?

CHAPTER_TEXT	COMMENT_TEXT
GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD	lines 85 ff: The paragraph on contaminants which may be introduced in the input stream by materials which are not suitable for food contact application states that any materials which are components of recycled plastic for food contact use would need to be set out in the Plastics directive 2002/72/EC and its amendments. Since many ink raw materials are not listed in the above Directive, and unless there is evidence of an established recycling process that guarantees the complete removal of printing ink constituents from the recyclate, it is recommended that printed plastic packaging is not reused in the manufacture of recycled film for primary food packaging.
REFERENCES	Line 337: I believe the AFSSA document in question is at http://www.afssa.fr/Documents/MCDA-Ra-PET.pdf and not at the URL you provide.

CHECK LIST

For applications for plastics recycling processes evaluations
Changes to the previous version are marked in turquoise

SUBMISSION OF THE APPLICATION		
1	Letter addressed to a competent Member State Authority.	Requesting the evaluation of the process by EFSA (Art. 5 of Regulation 1935/2004).
2	Hard copy of the dossier	The hard copy will include all the technical information provided as well as the summary document. Any confidential information must be adequately marked.
3	CD-ROM With the complete information	All the information in hard copy should be on CD, too. The CD ROM should contain two files or sets of files. One should be protected from modification for example as a locked Acrobat or Word document(s). The second should be identical to the first except that it should not be protected, so that all the information can be copied, summarised and/or annotated as necessary, to facilitate the evaluation process. Appropriate labels should be attached on the CD jewel case, including the following information: Name of the recycling process, REF No (when it is known), company, date of submission and CD-ROM number (if more than one per dossier, e.g. disk # of #). Each CD-ROM should contain a file with the names of the files in the disk and their contents.
4	CD-ROM With only the non-confidential information	Only the information which is not considered as confidential by the petitioner should be on this CD-ROM. This information will be readily available to anyone who might so request, according to Regulation (EC) No. 1935/2004, art. 19
5	Additional copies	The applicant should keep additional paper and electronic copies readily available in case the EFSA requires them.
CONTENTS OF THE DOSSIER **(**for more details on this topic petitioners are invited to consult the EFSA guidelines available on-line at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178717811412.htm)		
1	Cover letter addressed to EFSA	Requesting the evaluation of the process and containing all the administrative information as detailed in the guidelines under the section “Administrative part”.
2	Table of contents	A table which will give the contents of the dossiers including Annexes, e.g. Annex 1, Flow chart of the process.
3	Summary document	A stand alone document summarising the information provided in the technical dossier and the safety evaluation of the process, including conclusions, possible recommendations on restrictions of use and special applications.
4	General description	This information is destined to be published in the Register of recycling processes managed by the Commission services and it cannot contain any confidential information.

5	Existing authorisations	Any information concerning existing legislation and/or authorisations in EU Member States and other countries. The status of the recycling process, that is, if the process is already running or if it is going to be set up.
6	Recycling process description	Detailed description of the process starting from the input. A flow chart diagram and description of all steps. The operating parameters must all also be highlighted. Demonstration that the critical parameters are controlled must be provided. (for more details see Section 3.2.1 of the guidelines)
7	Characterisation of the input	Description of the specifications for the input with regard to possible contaminants and the plan for evaluation and qualification of the suppliers based on their ability to meet specific requirements
8	Decontamination efficiency	All relevant experimental data shall be provided. The procedure and the results of challenge test(s) to determine the yield of decontamination after the relevant steps of the process should be described in detail. Experimental or theoretical considerations on the possible migration into the foods destined to come into contact should be laid out with clarity. Relevant scientific evidence supported by adequate documentation and / or scientific literature should be provided.
9	Characterisation of the recycled plastic	Identification of the parameters that are important in characterising the recycled plastic and their specifications (e.g. melt flow index, glass transition temperatures).
10	Intended use	Detailed information on the type(s) of food and conditions of contact to enable an evaluation of the possible migration
11	Compliance with the relevant provisions	Evidence that the final product meets the requirements of the relevant legislative provisions.
12	Process analysis and evaluation	A self evaluation of the process must be provided.
13	Quality assurance system	Where appropriate, information on those parts of the Quality Assurance System (QAS) that are relevant for the safety assessment shall be submitted.