
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	<p>Chapter 3.1.2 Existing authorisations:</p> <p>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...</p> <p>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</p>
2) Administrative part	<p>Chapter 2) Administrative part:</p> <p>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.</p> <p>This addition is needed in order to avoid possible confusions between business operators in charge of application.</p>
3) Technical Dossier	<p>Lines 296-300</p> <p>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? Lines 237-249</p>
3) Technical Dossier	<p>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?</p>
3) Technical Dossier	<p>Chapter 3.2.2: Characterisation of the input</p> <p>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.</p> <p>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.</p>
REFERENCES	<p>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:</p> <p>¿ 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</p> <p>¿ 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</p> <p>¿ 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</p> <p>¿ 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</p> <p>¿ R. Franz, F. Welle Post-Consumer Poly(ethylene terephthalate) for Direct Food Contact Application -</p>

CHAPTER_TEXT	COMMENT_TEXT
	<p>Final Proof of Food Law Compliance, Deutsche Lebensmittel-Rundschau, 1999, 95(10), 424-427 ħ 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 ħ F. Blanchard, A. Christel, G. Gorski, F. Welle Drinks from the Detergent Bottle Plast Europe, 2003, 93(9), 42-45 ħ 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 ħ 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.</p>
3) Technical Dossier	<p>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.</p> <p>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.</p> <p>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.</p>
3) Technical Dossier	<p>3.2.6 Compliance with the relevant provisions on food contact materials and articles (lines 296-300) l 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.</p>
3) Technical Dossier	<p>3.2.5 Intended application in contact with food (lines 289-294) l 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.</p>
3) Technical Dossier	<p>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</p>

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 recycle 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	<p>Reference to Section 3.2.2 Line 246/247 "with particular emphasis on the aspects of traceability"</p> <p>To what extent is traceability of the input material required.</p> <p>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?</p>
3) Technical Dossier	<p>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.</p> <p>– 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.</p>
3) Technical Dossier	<p>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?</p>
3) Technical Dossier	<p>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. I.e 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?</p>
INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR THE AUTHORISATION OF A RECYCLING PROCESS	<p>Reference to lines 163 – 165 Will EFSA supply standard format/forms for submissions?</p>
SUBMISSION OF AN APPLICATION	<p>Reference to line 140 – all available relevant data How do we know what data is relevant without EFSA guidance?</p>

CHAPTER_TEXT	COMMENT_TEXT
INTRODUCTION	<p>Reference to lines 63- 75 How will EFSA respond to an application from a machine manufacturer?</p> <p>It is inevitable that a machine manufacturer will need/want to demonstrate compliance with the regulation on recycled plastic materials.</p> <ul style="list-style-type: none"> - 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? <p>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].</p> <p>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.</p> <ul style="list-style-type: none"> - 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	<p>No Reference line number</p> <p>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.</p> <p>In short is the same measuring device used everywhere, and how can this be ensured?</p>
GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD	<p>Reference to line 119 "the QAS evaluation and audit will be performed by Member States"</p> <p>QAS will be performed by the member states, by whom?</p> <p>It is not clear to what extent this audit can go.</p> <p>In case of process duplication:</p> <ul style="list-style-type: none"> - 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	<p>General comment:</p> <p>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.</p> <p>Line 176: Administrative part</p> <p>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.</p>

CHAPTER_TEXT	COMMENT_TEXT
	<p>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?</p>
REFERENCES	<p>I think it would be important to take into account the following references:</p> <ul style="list-style-type: none"> - "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 Seminario Internacional Reciclagem de PET pós-consumo para contato com alimentos". Campinas, Sao Paulo, Brazil, 17-18 September 2003.
QUALITY ASSURANCE SYSTEM (QAS)	<p>331. (on Quality assurance system). Following Franz, Bayer and Welle (2004), I think that the quality assurance must take into account three aspects:</p> <ol style="list-style-type: none"> 1. Frequency of the challenge test (covered by "Re-evaluation of a process")(313-318) 2. Analytical monitoring 3. Sensory testing <p>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.</p>
3) Technical Dossier	<p>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 grammatically, or if it is the right subtitle to place it.</p>

CHAPTER_TEXT	COMMENT_TEXT
	<p>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.)"..</p> <p>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)).</p>
<p>GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD</p>	<p>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 Decision 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.</p>
<p>INTRODUCTION</p>	<p>69. MERCOSUR Resolution 30/07 takes into account that the provider of decontaminated PET can sell the product either to a manufacturer of trilayer or 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.</p>
<p>INTRODUCTION</p>	<p>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.</p> <p>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?</p>

CHAPTER_TEXT	COMMENT_TEXT
<p>GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF RECYCLED PLASTICS INTENDED TO BE USED FOR MANUFACTURE OF MATERIALS AND ARTICLES IN CONTACT WITH FOOD</p>	<p>lines 85 ff:</p> <p>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.</p> <p>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.</p>
<p>REFERENCES</p>	<p>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.</p>