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COMMISSION OF THE EUROPEAN COMMUNITIES

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SANCO/2003/2285

EMB/955 REV.3

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Group on Food Contact Materials"**

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DOES NOT NECESSARILY
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COMMISSION SERVICES**

NON PAPER

Draft

COMMISSION DIRECTIVE (EC) No .../..

of [...]

on recycled plastic materials and articles intended to come into contact with foodstuffs

(Version updated to 12. January 2004)

(EN)

(Text with EEA relevance)

Explanatory note

Remark

Phrases in square brackets [] indicate different options or paragraphs, which might not be necessarily included in the Directive.

1. This preliminary draft is an attempt to regulate at Community level the use of recycled materials and articles intended to come into contact with foodstuffs.

It takes into account the comments sent by the representatives of the Member States on the first draft. It is based on the preliminary point of view of a task force composed by experts in this specific field as well as the results of the two research studies subsidised by the European Commission. It does not yet represent the official position of the Commission services and may be subject to relevant changes.

2. The changes compared to EMB955-Rev2 are the following:

- 2.1. **New recitals** have been introduced to explain:

- why in house production scrap and chemical recycling are excluded
- why the authorisation is company specific
- and in case of licensing the conditions necessary to comply with

- 2.2. **New definitions** and changes to definitions for:

- Non food contact plastics
- Recycler
- Processor

- 2.3. **New phrasing of Article 3 (2) and Article 4** to clarify better

(a) the requirements for the recycling process and

(b) what can be regarded as impurities taking into account that the recycled output does not correspond to 2002/72/EC if it contains contamination of previous use or non food contact plastics

- 2.4. **Changes in the authorisation procedure** to better describe the procedure and the responsibilities of EFSA, the national competent authority and authorisation holder – licensee. The changes are described below:

- **Application directly to EFSA**

- Clear time limits for each step in the authorisation procedure and justification for exceeding these limits (according to draft Framework Regulation and Smoke Flavourings proposal)
 - **Authorisation of the recycling process is company specific** to the authorisation holder. The **authorisation holder can license the process** to a licensee. The licensed process needs no new evaluation by EFSA.
 - **The company -after setting up of the recycling process by authorisation holder and/or licensee- shall be audited by an approved auditor, which lies in the responsibility of the authorisation holder/licensee.** The auditor shall write and auditing report which shall be sent to the Member States competent authority. **Member States shall decide, based on the auditing report, if the recycling process in place corresponds to the authorised process.** In case of conformity the Member States shall permit that the recycling output shall be placed on the market and shall inform the other Member States and the Commission hereof. In case of non-conformity the Member States shall forbid the placing on the market of the recycling output and inform the other Member States and the Commission hereof.
 - Member States shall notify to the other Member States and the Commission the list of approved auditors.
 - **Rephrasing of the provisions for modification, suspension and revocation of the authorisation** (in line with Smoke Flavourings proposal). New auditing is only necessary after substantial changes.
 - **Rephrasing of the renewal of authorisation** (in line with Smoke Flavourings proposal). Time period is reduced to 5 years. The authorisation holder needs to supply information gathered by quality assurance system.
- 2.5. **Deletion of the free movement article** because general obligation.
- 2.6. **New phrasing of the traceability article** in accordance with the draft Framework Regulation specifying that the articles should be traced back to the collector of the post use plastics.
- 2.7. **Declaration of compliance and record keeping were amended:**
- to differentiate between the recycler and the processor with different obligations
 - to oblige National competent authorities to make available information on the result of the auditing on request.
- 2.8. **Obligation to public access to non-confidential information** on authorisation as laid down in draft Framework Regulation.
- 2.9. **Obligation to confidentiality and data protection** as laid down in draft Framework Regulation.
- 2.10. **Obligation of inspection and control by Member States** as for other food contact materials.

- 2.11. **Introduction of a transition period of 3 years for processes authorised at national level** for which a valid application has been submitted to EFSA.

NON PAPER

Draft

COMMISSION DIRECTIVE (EC) No .../..

of [...]

on recycled plastic materials and articles intended to come into contact with foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs¹, and in particular Article 3 thereof,

[After consulting the European Food Safety Authority,]

Whereas:

- (1) Commission Directive 2002/72/EC of 15 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs² sets out rules for plastic materials and articles which are intended to come into contact with foodstuffs.
- (2) Post consumer food contact plastics may contain residues from the food they have been in contact with and from misuse. Therefore it is necessary to lay down special requirements to ensure that materials and articles produced from recycled post consumer food contact plastics and intended for food contact respect the requirements of Article 2 of Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs³.
- (3) In house production scrap such as cut-offs generated in the manufacturing process of the virgin food contact articles has not been in contact with food or been contaminated otherwise. It should therefore not fall under the scope of this Directive if it is re-melted on the premises into new products. Production scrap that has been transported off the production site or is printed or otherwise further processed may be contaminated and thus regarded as post consumer food contact plastics and therefore covered by this Directive.

¹ OJ L 40, 11.02.1989, p. 38. Directive as amended by Regulation EC No 1882/2003 of the European Parliament and of the Council (OJ L284, 31.10.2003, p.1).

² OJ L 220, 15.08.2002, p. 18.

³ OJ L 40, 11.02.1989, p. 38. Directive as amended by Regulation EC No 1882/2003 of the European Parliament and of the Council (OJ L284, 31.10.2003, p.1).

- (4) Plastic materials or articles can be recycled by mechanical or chemical recycling. In chemical recycling the polymer is chemically depolymerised to its starting monomers or oligomers. Monomers and oligomers resulting from chemical recycling should not be treated differently from monomers manufactured by chemical synthesis. Therefore, they are covered by Directive 2002/72/EC and they should comply with the specifications and purity criteria established therein.
- (5) Directive 2002/72/EC lays down the list of substances authorised to the exclusion of all others (positive list) to be used in the manufacture of plastic food contact materials or articles. This list should also be respected by the recycled plastic food contact materials and articles and, therefore, only food contact materials and articles should be used as input for the recycling process.
- (6) Post consumer plastics may be contaminated by substances from the previous use or incidental misuse of the plastics. In the mechanical recycling process, in which the post use plastic is ground into small pieces and cleaned, special care has to be taken to remove these contaminations. The recycling process must demonstrate that it can efficiently reduce the contamination to a level that does not pose a risk to human health. The recycled material or article should contain these contaminations only at a level that is comparable to impurities of starting substances and additives in Directive 2002/72/EC. A safety assessment has to verify that the recycling process fulfils these conditions
- (7) Certain types of plastic materials and articles manufactured with recycled plastics may only be suitable for contact with specified types of food under certain conditions. A safety assessment has to identify these materials and articles and appropriate contact conditions.
- (8) Pursuant to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁴, the "European Food Safety Authority" (hereinafter called "the Authority") should be consulted before provisions liable to affect public health are adopted under specific measures.
- (9) Differences between national laws, regulations and administrative provisions concerning the safety assessment and the authorisation of recycling processes, used in the manufacture of materials and articles intended to come into contact with food, may hinder the free movement of these materials and articles, creating conditions of unequal and unfair competition. An authorisation procedure should therefore be established at Community level. In order to ensure harmonised safety assessment of these processes, the Authority should carry out such assessments.
- (10) In order to inform the recycler on the data to be provided for the risk assessment, the Authority is requested to publish a detailed guidance concerning the preparation and the submission of the application.
- (11) The safety assessment of the recycling process should be followed by a risk management decision as to whether this recycling process should be entered on a

⁴ OJ L 31, 1.02.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p.4).

Community list of authorised processes; that decision should be adopted in accordance with the regulatory procedure so as to ensure close cooperation between the Commission and the Member States.

- (12) The recycling process is company specific as regards machinery used, process parameters and others. Therefore, only company specific authorisations should be granted. However the authorisation holder should be allowed to give another company licence to apply the authorised recycling process.
- (13) The recycling process should be accompanied by a quality assurance system that guarantees the reproducible quality of the recycled plastic output.
- (14) Member States should ensure the correct application of the recycling process by companies within their territory. The company that is applying the recycling process should be audited and Member States should only allow the placing on the market of those recycling output from companies which correctly apply the authorised process and have an effective quality assurance system in place. The recycling company should be subject to inspection and control by the Member State.
- (15) The users and the competent authority should be informed on the content of recycled plastics in a plastic material and article. Therefore appropriate labelling should be provided.
- (16) Article 6(5) of Directive 89/109/EEC requires a declaration of compliance for the finished material and article. The processor of a recycled plastic material and articles should declare that he is using only authorised plastic output and that the final products respects provisions of Directive 2002/72/EC. The recycler should provide the processor with the information that the plastic output is produced by an authorised process and specify its field of application. Therefore it is necessary that both the finished recycled plastic materials and articles and the plastic output are accompanied by a declaration of compliance.
- (17) The measures necessary for the implementation of this Regulation and amendments to Annexes I and II should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁵.
- (18) Since recycled materials and articles are already on the market in the Member States, provision should be made to ensure that the transition to a Community authorisation procedure is smooth and does not disturb the existing recycled materials and articles market. Sufficient time should be allowed for the applicant to make available to the Authority the information necessary for the safety assessment of plastic output used in these products. Furthermore, the companies need to be audited. Therefore, a transitional period should be introduced.
- (19) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁵ OJ No L 184, 17. 7. 1999, p. 23

HAS ADOPTED THIS DIRECTIVE:

Article 1
Aim and scope

1. This Directive seeks to ensure the effective functioning of the internal market in relation to the recycled plastic materials and articles intended to come into contact with foods, whilst providing the basis for securing a high level of protection for human health and the interests of consumers.
2. This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC.
3. This Directive shall apply to recycled plastic materials and articles, which in their finished state, are intended to come into contact with food.
4. This Directive does not apply to:
 - (a) recycled plastic materials and articles intended to come into contact with food when they are made with monomers and starting substances derived from chemical depolymerization of plastic materials and articles;
 - (b) recycled plastic materials and articles intended to come into contact with food when they are made from virgin in-house production scrap.

The recycled plastic materials and articles mentioned under (a) and (b) shall comply with the requirements of Directive 2002/72/EC.

Article 2
Definitions

For the purposes of this Directive, the definitions laid down in Regulation (EC) No 178/2002 shall apply, with the exception of the definition of traceability.

The following definitions shall also apply⁶:

1. “Challenge test” means a test of the effectiveness of a recycling process to remove chemical contamination from plastic materials or articles.
2. “Collection” means the logistical process of moving plastic waste from the point at which it arises to a place where it can be sorted for recycling.
3. “Input” means collected and sorted post-use plastic materials and articles.
4. “Non-food contact plastics” means plastics that either does not comply with the compositional provisions of Directive 2002/72/EC or those which have not been used in contact with food although their composition complies with the provisions of Directive 2002/72/EC.

⁶ If this Directive is adopted after the new framework Directive the definitions related to traceability will be deleted from the current text.

5. "Placing on the market" means the holding of recycled plastic materials and articles for the purpose of sale including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves⁷.
6. "Plastic output"⁸ means the plastic material obtained from the recycling process either in form of pellets, flakes or granules, which are suitable to be processed into a recycled plastic material or article.
7. "Processor" means the natural or legal person with responsibility for reclaim before the recycled plastic materials and articles are traded or used for their intended purpose, regardless of whether reclaim is carried out by that person himself or on his behalf by a third party.
8. "Quality Assurance System" means the use of an audited process management system, of the whole recycling process required to ensure that the repeatable characterisation of input plastic material and articles up to plastic output will demonstrate that this plastic output suitable for the defined food contact applications is produced.
9. "Recycled plastic material and article" means the material and article using plastic output, and which in its finished state, is intended to come into contact with foodstuffs.
10. "Recycler" means the natural or legal person with responsibility for reclaim before the plastic output is traded or used for its intended purpose, regardless of whether reclaim is carried out by that person himself or on his behalf by a third party.
11. "Recycling Process" means processing collected and sorted post-use plastic material, in a manner such that the plastic output is suitable to be processed into a recycled plastic material and article.
12. "Sorting" means selective separation of post-use plastic materials and articles.
13. "Traceability" means the ability to trace and follow a recycled material or article through all stages of manufacture, processing and distribution back to the collected post consumer plastic, the starting substance and the additives used.

Article 3

General requirements for placing recycled plastic materials and articles on the market

1. Recycled plastic materials and articles shall only be placed on the market if they comply with the rules of Directive 2002/72/EC while taking account of paragraph 2. Recycled plastic materials and articles shall be manufactured using plastic output obtained from a recycling process, which complies with the requirements of Article 4.

⁷ Definition from Food Law.

⁸ "Plastic recycle" was suggested by as alternative.
Mark Vints: agrees with suggestion

2. Residue substances originating from food use, incidental misuse or incidental presence of non food contact plastics shall be treated as impurities of the recycled materials and articles. They shall only be present in amounts comparable to those of impurities of starting substances and additive and shall comply with the requirements stated in Article 2 of Directive 89/109/EEC.

Article 4
Requirements of recycling process

A recycling process shall comply with the following requirements:

- (a) It shall be authorised according to the procedure of Articles 5 to 8;
- (b) It shall use only input containing plastic materials and articles which have been manufactured in accordance with Directive 2002/72/EC and have only been in contact with food. The sorting efficiency shall be at least 99 %. However, stricter rules may be set for the specific authorised process;
- (c) It shall produce an output that complies with the requirements of Article 2 of Directive 89/109/EEC;
- (d) It shall enable the manufacture of a recycled plastic material and/or article that complies with the requirements of Article 3;
- (e) It shall be accompanied by an appropriate quality assurance system that ensures that the plastic output complies with the requirements set out in the authorisation [(b)-(d)]. The quality assurance system has to meet the requirements laid down in Annex I.

Article 5
Application for authorisation of a recycling process

1. To obtain the authorisation of a recycling process, an application shall be submitted in accordance with the following provisions.
2. The application shall be sent to the European Food Safety Authority (hereinafter referred to as "the Authority")

The Authority shall:

- (a) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
 - (b) inform without delay the Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them on request.
3. The application shall be accompanied by the following
 - the name and address of the applicant;

- a technical dossier containing the information listed in Annex II;
 - a reasoned statement affirming that the recycling process complies with Article 4(b)-(e);
 - a summary of the dossier.
4. The Authority shall publish detailed guidance concerning the preparation and the submission of the application.

Article 6

Opinion of the Authority on a recycling process

1. The Authority shall give an opinion within six months of the receipt of a valid application, as to whether the recycling process complies with the general requirements laid down in Article 4(b)-(e). The Authority may extend the said period. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States.
2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority which in no event shall exceed 12 months. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that this information has been provided. Likewise, this time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.
3. In order to prepare its opinion, the Authority shall
 - (a) verify that the particulars and documents submitted by the applicant are in accordance with Article 5(3) in which case the application shall be regarded as valid;
 - (b) inform the applicant, the Commission and the Member States if an application is not valid;
 - (c) examine if the recycling process complies with the general requirements laid down in Article 4(b)-(e).
4. In the event of an opinion in favour of authorising the evaluated recycling process, the opinion shall include:
 - (a) a short description of the recycling process;
 - (b) where appropriate, any conditions or restrictions on the input
 - (c) where appropriate, any conditions or restrictions on the recycling process
 - (d) where appropriate, any conditions in the field of application of the output.
5. The Authority shall forward its opinion to the Commission, the Member States and the applicant.

6. The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 15.

Article 7
Community Authorisation

1. Within three months of receiving the opinion of the Authority, the Commission shall prepare a draft of a [Directive] measure to be [adopted] taken in respect of the application for inclusion of a recycling process in the list referred to in Article 19, taking into account the requirements of Article 4(b)-(e), Community law and other legitimate factors relevant to the matter under consideration. Where the draft measure is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the reasons for the differences.

The measures referred to in paragraph 1 shall be

- a draft [directive] decision amending the list referred to in Article 17, by including the name and address of the authorisation holder, a short description of the recycling process, and any conditions in the field of application of the output and the date of authorisation or
 - a draft decision, addressed to the applicant, refusing authorisation.
3. The measure referred to in paragraph 1 shall be adopted in accordance with the procedure laid down in Article 20(2). The Commission shall inform the applicant of its adoption without delay.
 4. Without prejudice to Article 8, the authorisation granted in accordance with the procedure laid down in this Directive shall be valid throughout the Community for five years and shall be renewable in accordance with Article 9.

Article 8
Audit

1. After setting up the authorised recycling process and prior to placing the output on the market, the authorisation holder of the recycling process has to have the company audited by an approved auditor. The auditor has to verify that the recycling process corresponds to the authorised process and that an effective quality assurance system according to Annex I is in place. The auditor shall draw up an audit report and send it to the national competent authority.
2. The national competent authority shall decide within 3 months if the quality assurance system ensures the production of an output according to the recycling process authorised. In case of a favourable decision the authorisation holder is authorised to place the output on the market. In case of a non favourable decision the authorisation holder is not authorised to place the output on the market. The national competent authority shall inform the authorisation holder, the Commission, the other Member States and the Authority about its decision.
3. If the authorisation holder is licensing the authorised process to another company, this licensee has to have the company audited by an approved auditor. The auditor

has to verify that the recycling process corresponds to the authorised process and that an effective quality assurance system according to Annex I is in place. The auditor shall draw up an audit report and send it to the national competent authority.

4. The national competent authority shall decide if the quality assurance system ensures the production of an output according to the recycling process authorised. In case of a favourable decision the authorisation holder is authorised to place the output on the market. In case of a non favourable decision the licensee is not authorised to place the output on the market. The national competent authority shall inform the licensee, the authorisation holder, the Commission, the other Member States and the Authority about its decision.
5. The granting of an authorisation shall not diminish the general civil and criminal liability of any business operator in respect to the authorised recycling process, the recycled plastic material and article and the food that is in contact with such material and article.

Article 9

Modification, suspension and revocation of authorisation of a recycling process

1. The authorisation holder may in accordance with the procedure laid down in Article 5, apply for the modification of the existing authorisation.
2. On its own initiative or following a request from the authorisation holder, a Member State or the Commission, the Authority shall deliver an opinion on whether an authorisation is still in accordance with this Directive, following the procedure laid down in Article 6, where applicable.
3. The Commission shall examine the opinion of the Authority without delay and prepare a draft of the decision to be taken.
4. A draft measure modifying an authorisation shall specify any necessary changes in the field of application and, if any, in the restrictions attaching to that authorisation.
5. The final decision measure, i.e. the modification, suspension or revocation of the authorisation, shall be adopted in accordance with the procedure referred to in Article 20(2).
6. The Commission shall without delay inform the authorisation holder of the measure taken.
7. After modification of the quality assurance system the company shall be audited again according to Article 8, if appropriate.

Article 10

Renewal of authorisation of a recycling process

1. Without prejudice to Article 9, authorisations under this Directive shall be renewable for a five-year period, on application to the Commission by the authorisation holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following particulars and documents:
 - (a) a reference to the original authorisation;
 - (b) information gathered in the quality assurance system;
 - (c) any available information concerning the points listed in Annex II, which supplements the information already provided to the Authority in the course of the previous evaluation(s) and updates in the light of the most recent scientific and technical developments;
 - (d) a reasoned statement affirming that the recycling process complies with Article 4(b)-(e).
3. Articles 5 to 8 shall apply mutatis mutandis.
4. Where, for reasons beyond the control of the authorisation holder, no decision is taken on the renewal of an authorisation until one month before its expiry date, the period of authorisation of the recycling process shall automatically be extended by 6 months. The Commission shall inform the authorisation holder and the Member States about the reasons for the delay.

Article 11
Labelling of recycled materials and articles

Recycled plastic materials and articles shall be labelled with the symbol in Annex III, if they contain more than 5 % of the plastic output.

For materials and articles labelled according to the first subparagraph the labelling according Article 6(1)(a) of Directive 89/109/EEC⁹ is not obligatory.

Article 12
Traceability

1. The traceability of the recycled plastic materials and articles shall be established at all stages of manufacture, processing and distribution.
2. Business operators shall have in place systems and procedures to allow the identification of the businesses from which and to which the recycled plastic materials or articles and the substances as well as the output used in their manufacture have been supplied. The recycler shall trace back to the collector of the post use plastics [supplier of the input]. This information shall be made available to the competent authorities on demand.
3. The recycled plastic materials and articles and the plastic output which are placed on the market in the Community shall be adequately labelled or identified to facilitate their traceability through relevant documentation or information.

⁹ If this Directive is adopted after the new Framework Directive this text is replaced by the following " Article 12.1(a) of Regulation xxx/yyyy/EC"

Article 13
Declaration of Compliance and Record Keeping

1. Plastic output and recycled plastic materials and articles shall be accompanied at all marketing stages up to and excluding the retail stage by a written declaration in accordance with Article 6(5) of Directive 89/109/EEC. The declaration has to include the information listed in Annex IV.
2. The recycler must, for a period ending not before the expected shelf life of the product, keep in paper or electronic form at the disposal of the enforcement authority:
 - (a) the application for authorisation including all information as referred to in Annex II;
 - (b) the allowance from the national competent authority to put the plastic output on the market as referred to in Article 6;
 - (c) the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, qualification reports of the personnel concerned, etc.
3. The processor has to keep in paper or electronic form at the disposal of the enforcement authorities appropriate technical documentation able to demonstrate the compliance of the material or article or substances with the provisions of Article 3. This documentation, shall contain the description and the results of the analysis carried out to demonstrate the compliance of the material and article with the restrictions and the specifications set down in Directive 2002/72/EC.
4. The national competent authority must make available to the authorisation holder or licensee, other national competent authorities, the Commission and the Authority, on request, all relevant information concerning the decision following the audit of the company.

Article 14
Public access

1. The application for authorisation and supplementary information from the applicant and opinions from the Authority, excluding confidential information, shall be made accessible to the public.
2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents¹⁰ when handling applications for access to documents held by the Authority.
3. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

¹⁰ OJ No L 145, 31.5.2001, p. 43

Article 15
Confidentiality

1. The applicant may indicate which information submitted under Articles 5 should be treated as confidential because its disclosure may significantly harm his competitive position. Verifiable justification must be given in such cases.
2. Information relating to the following shall not be considered confidential:
 - (a) the name and address of the applicant and the name of the recycling process;
 - (b) information of direct relevance to the assessment of the safety of the recycling process;
 - [(c) the analytical method(s).]
3. The Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.
4. The Authority shall supply the Commission and the Member States with all information in its possession on request.
5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Directive, except for information which must be made public if circumstances so require in order to protect human health.
6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information provided, including research and development information as well as information on which the Commission and the applicant disagree as to its confidentiality.

Article 16
Data protection

The information in the application submitted according to Article 5 may not be used for the benefit of another applicant, unless the other applicant has agreed with the authorisation holder that such information may be used.

Article 17
Inspection and control measures

Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Directive.

Article 18
Approved auditors

1. Member States shall notify to the other Member States and the Commission the list of approved auditors, with full name and address, that are competent and authorised to carry out the audit required by Article 8 of this Directive. Member States shall demonstrate the competence of the above auditors according to Annex V.
2. Where Member State competent authority has grounds for believing that an approved auditor does not possess the competence referred to in paragraph 1, it shall raise the matter in the Committee referred to in Article 20. If the Commission decides that the auditor does not possess the required competence, the name of the approved auditor shall be removed from the list referred to in paragraph 3.
3. The Commission shall publish the list of approved auditors mentioned in paragraph 1, once a year in the *Official Journal of the European Union* to the extent that changes have occurred.

Article 19
Community Register of a recycling process

1. The Commission shall establish and maintain a Community Register of recycling process, referred to in this Directive as "the Register".
2. The Register shall be made available to the public.

Article 20
Implementing powers of the Commission

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, instituted by Article 58(1) of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 21
Implementation, Transitional Measures

1. Member States shall adopt and publish, by [...] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions in such a way as to:

- (a) permit the trade in and use of plastic output and recycled plastic materials and articles intended to come into contact with food and complying with this Directive, from [one year after the date of entry into force];
- (b) prohibit the manufacture and importation into the Community of plastic output and recycled plastic materials and articles intended to come into contact with food and which do not comply with this Directive and for which a valid application is not submitted in accordance with Article 5 and 6(3), from [two years after the date of entry into force].
- (c) prohibit the manufacture and importation into the Community of plastic output and recycled plastic materials and articles intended to come into contact with food and which do not comply with this Directive and which have been authorised in a Member State previous to the entry into force of this Directive and for which a valid application is submitted in accordance with Article 5 and 6(3), from [three years after the date of entry into force].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law, which they adopt in the field covered by this Directive.

Article 22
Entry into force

This Directive shall enter into force on the [...] day following that of its publication in the *Official Journal of the European Communities*.

Done at Brussels, [...]

For the Commission
[...]
Member of the Commission

1 **ANNEX I**

2 **QUALITY ASSURANCE SYSTEM**

3 The technical documentation of the Recycling Process Quality Assurance System must allow
4 an understanding of recycling and must permit uniform interpretation of the quality policy
5 and procedures such as testing methods, recycling programmes, plans, manuals, and records.
6 It must include in particular an adequate description of:

- 7 (a) the characterisation of input,
- 8 (b) the full recycling cycle, including by way of example the operating processes such
9 as: the washing process, the deep cleansing process, the heating process,
- 10 (c) the recyclers quality objectives,
- 11 (d) the organisation of the business and in particular:
- 12 – the organisational structures, the responsibilities of the managerial staff and
13 their organisational authority where recycling is concerned,
- 14 – the methods of monitoring the efficient operation of the quality system and in
15 particular its ability to achieve the desired quality of the recycled materials and
16 articles, including ability to detect recycled materials and articles that fail to
17 conform,
- 18 – the quality manuals for staff and protocols of working, including the standard
19 operating procedures,
- 20 – the inspection and quality assurance techniques and in particular the processes
21 and procedures that will be used to produce the finished recycled materials and
22 articles,
- 23 (e) the analytical protocol, and relevant results, that has been carried out to demonstrate
24 the achievement of the recyclers quality objectives

25

ANNEX II

26

TECHNICAL DOSSIER

27 The technical dossier submitted to the European Food Safety Authority must include:

28 (a) the name and address of the recycler;

29 (b) [a detailed description of] [all relevant information on] the recycling process;

30 (c) a risk analysis of the recycling process including critical points and measures taken
31 to minimising and controlling the risk;

32 (d) all relevant information on the food contact applications covered by the procedure;¹¹

33 (e) the specifications of the plastic output: plastic output intended for the manufacture of
34 plastic materials and articles to be used in a specific food contact application should
35 meet the requirements that are appropriate for this use;

36 (f) protocol and results of the challenge test performed to demonstrate cleaning
37 efficiency.

38

¹¹ Mark Vints: it is very likely that the business operator carrying out the recycling process (indent b) is not the business operator determining the food contact application (indent d)
Annette: They have to talk together and then apply for the possible, safe applications

SYMBOL OF RECYCLED PLASTIC MATERIALS AND ARTICLES



41

ANNEX IV

42

DECLARATION OF COMPLIANCE FOR PLASTIC OUTPUT

43 The written declaration shall contain the following information:

- 44 1. Identity and address of the company which manufactures the plastic output ¹²
- 45 2. Identity of the plastic output and its range of application
- 46 3. Date of the declaration
- 47 4. References to this Directive
- 48 5. The confirmation that the approved Recycling Process Quality Assurance System
49 specified in Annex I is applied
- 50 6. The declaration that the input, the recycling process and the plastic output meet the
51 specifications for which the authorisation has been given.

52

DECLARATION OF COMPLIANCE

53

FOR RECYCLED PLASTIC MATERIALS AND ARTICLES

54 The written declaration shall contain the following information:

- 55 1. Identity and address of the company, which manufactures or imports in the European
56 Union the finished recycled plastic materials and articles
- 57 2. Identity of the finished recycled plastic material and article and its range of
58 application
- 59 3. Date of the declaration
- 60 4. References to national regulations and EU Directives applicable
- 61 5. A declaration that only plastic output from an authorised recycling process according
62 to this Directive has been used
- 63 6. Name and address of the recycler
- 64 7. The written declaration shall contain the following information:
 - 65 (a) the confirmation that finished recycled plastic material or article meets relevant
66 requirements in EU Directives and, in their absence, in national law.
67 References of the EU and national law shall be mentioned,
 - 68 (b) a detailed information testifying the compliance with the relevant restrictions in
69 Directive 2002/72/EC

¹² Also recyclers from outside the EU should have an authorisation

70 (c) when a functional barrier is used in a multilayer plastic material, indication of
71 the date of latest use of the functional barrier as well as the conditions of its use
72 such as temperature of storage and foods in contact with the material

73 The written declaration shall permit an easy identification of the goods for which it is issued.

74

75

Annex V

76

CRITERIA TO BE MET FOR DESIGNATION OF APPROVED AUDITORS

77 1. The auditor must have :

78 (a) sound vocational training covering all the assessment and verification
79 operations for recycling process,

80 (b) satisfactory knowledge of the rules on the inspections which they carry out and
81 the adequate experience of such inspections,

82 (c) the ability required to draw up the certificates, records and reports to
83 demonstrate that the inspections have been carried out.

84 2. The auditor may not be directly involved in the establishment or maintenance of the
85 Recycling Quality Assurance System or the Recycling process nor represent the
86 parties engaged in these activities. This in no way precludes the possibility of
87 exchanges of technical information between the recycler and the auditor.

88 3. The auditor must carry out the assessment and verification operations with the
89 highest degree of professional integrity and the requisite competence in the field of
90 plastic recycling and must be free from all pressures and inducements, particularly
91 financial, which might influence their judgement or the results for the inspections,
92 especially from persons or groups of persons with an interest in the results of the
93 verifications.

94
95 Should the auditor subcontract specific tasks connected with the establishment and
96 verification of the facts, it must first ensure that the subcontractor meets the
97 provisions of the Directive and, in particular, of this Annex. The auditor shall keep at
98 the disposal of the national authorities the relevant documents assessing the
99 subcontractor's qualifications and the work carried out by the subcontractor under
100 this Directive.

101 The auditor must be able to carry out all the tasks assigned to him and for which he
102 has been notified. In particular, he must have the necessary staff and possess the
103 facilities needed to perform properly the technical and administrative tasks entailed
104 in assessment and verification. He must also have access to the equipment necessary
105 for the verifications required.

106 4. The auditor must take out civil liability insurance, unless liability is assumed by the
107 State under domestic legislation.

108 The auditor is bound to observe professional secrecy with regard to all information
109 gained in the course of their duty pursuant to this Directive or any provision of
110 national law putting it into effect.