GUIDANCE

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NOTE FOR GUIDANCE

FOR THE PREPARATION OF AN APPLICATION FOR THE SAFETY ASSESSMENT OF A SUBSTANCE TO BE USED IN PLASTIC FOOD CONTACT MATERIALS

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Vittorio Silano, Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, Maria Rosaria Milana, André Penninks, Maria de Fátima Tavares Poças, Andrew Smith, Christina Tlustos, Detlef Wölfle, Holger Zorn and Corina-Aurelia Zugravu

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Amendment: The previous version of the document was adopted by the former EFSA AFC Panel (Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food) on 31 July 2008. For transparency reason, it is still accessible, watermarked as 'obsolete', under the 'Supporting information' tab on Wiley Online Library. The current version of the document was endorsed by the EFSA CEF Panel (Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids) on 23 March 2017. The following sections of the document have been updated: (i) Chapters 0, I, II, IV of the version adopted on 31 July 2008 have been removed; (ii) Chapter III of the version adopted on 31 July 2008 have been amended, as detailed in the introduction to the Note for Guidance, i.e. 'Note for the reader'; (iii) Annexes 3, 5 and 6 of Chapter III of the version adopted on 31 July 2008 have been removed.

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NOTE FOR THE READER

List of modifications to the document

In the light of the latest experience gained by EFSA in the context of applications on food contact materials, the present guidance document, related to the preparation of an application for the safety assessment of a substance to be used in plastic materials and articles intended to come into contact with food, falling under the scope of Regulation (EC) No 1935/2004[1] and Commission Regulation (EU) No 10/2011[2], has been revised.

For transparency reason, please note that the previous version of this guidance document is still accessible, watermarked as 'obsolete', under the 'Supporting information' tab on Wiley Online Library.

The following information is updated:

- The former title 'Note for Guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation' has been changed into: 'Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials', to clarify that this document applies specifically to plastic food contact materials.
- Chapter 0 and Chapter I of the previous version of the Note for Guidance, i.e. 'General Introduction' and 'EFSA Administrative Guidance', have been removed and replaced by a separate guidance document, the **'Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials'**.[3]
- Chapter II of the previous version of the Note for Guidance has also been removed from the current version of the document. It consisted of the **'Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation'**,[4] the so-called 'SCF guidelines for Food Contact Materials', issued in 2001 by the Scientific Committee of Food (SCF) of the European Commission's Health & Consumer Protection Directorate-General. It has been removed because it is already publicly available at the European Commission website, where all the original opinions as adopted by the former Scientific Committee on Food can be found.[5] It should be noted that the principles described in the SCF guidelines are still valid and represent the scientific reference for applicants presenting an application for the safety assessment of a substance to be used in food contact materials.
  The only exception to the above assertion is the dataset required to assess the genotoxic potential of a substance. The core set of the three *in vitro* mutagenicity studies, as presented in chapter 8.2 of the 'SCF guidelines for Food Contact Materials' has been superseded and is no longer recommended within the present guidance. The current state of the science on genotoxicity testing is described in the 'EFSA Scientific Committee opinion on genotoxicity testing strategies'[6] issued in 2011 and its recommendations should henceforth be followed by applicants. More specifically, the Scientific Committee recommends the use of the following two *in vitro* tests as the first step in testing:
  - a bacterial reverse mutation assay (OECD TG 471), and
  - an *in vitro* micronucleus test (OECD TG 487).

  This combination of tests fulfils the basic requirements to cover the three genetic endpoints, i.e. gene mutations, structural and numerical chromosomal aberrations, with the minimum

[1] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p. 4–17
[2] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L 12, 15.1.2011, p. 1–89
[3] EFSA (European Food Safety Authority), 2017. Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials. EFSA supporting publication 2017:EN-1224, 41 pp. https://doi.org/10.2903/sp.efsa.2017.EN-1224
[4] https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out82_en.pdf
[5] European Commission's archive of opinions adopted by the former Scientific Committee on Food available at the EC website.
[6] EFSA Scientific Committee; Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379, 69 pp. https://doi.org/10.2903/j.efsa.2011.2379

number of tests: the bacterial reverse mutation assay covers gene mutations and the *in vitro* micronucleus test covers both structural and numerical chromosome aberrations.
The assessment of genotoxicity performed in the past based on the testing strategy as described in the 2001 'SCF guidelines for Food Contact Materials', remains valid and no revaluation is needed in this respect. However, from now on, applicants are recommended to develop new data according to the most up to date requirements on genotoxicity testing, as described in the 2011 'EFSA Scientific Committee opinion on genotoxicity testing strategies' (please refer to section 'Applicability and transitional period' at the end of this document).

- Chapter III of the previous version of the Note for Guidance and has been renamed **'Explanatory Guidance of the SCF Guidelines for Food Contact Materials'**. It contains the scientific requirements to be considered when preparing an application to be submitted for evaluation to EFSA. As explained above, the genotoxicity requirements (i.e. item 8.1) have been revised in line with the recommendations of the 2011 'EFSA Scientific Committee opinion on genotoxicity testing strategies'. To increase transparency, also the toxicological data requirements (i.e. Section 8) have been updated with the general principle reported in the 'SCF Guidelines for Food Contact Materials', stating that the greater the exposure to the substance through migration, the more toxicological information will be needed.
  It should be noted that in January 2016, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), adopted a scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials.[7]
- This opinion was neither intended to be a guidance document nor to replace the 'SCF Guidelines for Food Contact Materials', but to provide the European Commission with a scientific basis for possible future revision of the legislation on food contact materials. Nonetheless, it is a scientific reference that could be considered for the safety evaluation of nanomaterials when used in the manufacture of food contact material and of non-intentionally added substances (NIAS) that may migrate, since the first topic is not covered and the second topic is only partly covered in the 'SCF Guidelines for Food Contact Materials'. In addition, the 2016 EFSA scientific opinion provides references to additional OECD test guidelines, addressing some toxicological endpoints which were not considered in the previous version of the Note for Guidance, i.e. prenatal developmental toxicity, two-generation reproduction toxicity, extended one-generation reproduction toxicity, delayed neurotoxicity of organophosphorus substances, developmental neurotoxicity. To increase awareness, references to these additional OECD test guidelines have been also added in items 8.2.4 'Reproduction/Teratogenicity' and 8.4.2 'Neurotoxicity' of the Explanatory Guidance.
- Chapter IV of the previous version of the Note for Guidance, i.e. 'Commission Explanatory Guidance on Migration Testing', has also been removed from this document, as it is going to be replaced by the 'Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011'[8], which will be soon issued by the European Commission Joint Research Centre (JRC) and published on the European Commission's website.

Besides the above-mentioned revisions, the following updates have also been introduced to this guidance document:

- The introduction to the Explanatory Guidance has been revised.
- All references to old EU Directives have been updated to the legislation currently in force.
- The outdated reference to the 'Commission Explanatory Guidance on Migration Testing' has been replaced throughout the text with a reference to the 'Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011'.
- A reference to the JRC 'Practical guidelines on the application of migration modelling for the estimation of specific migration' has been included in item 5.1 'Specific Migration' of the Explanatory Guidance. This document gives guidance to conservative migration modelling in support of Regulation (EU) No 10/2011.

[7] EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal 2016;14(1):4357, 28 pp. https://doi.org/10.2903/j.efsa.2016.4357

[8] Hoekstra E, Bradley E, Brandsch R, Bustos J, Dainelli D, Faust B, Franz R, Kappenstein O, Rijk R, Schaefer A, Schupp B, Simoneau C, Vints M, 2016. Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011. EUR 28329 EN, https://doi.org/10.2788/54707

- A reference to the JRC 'Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials' has been added in item 5.1.8 'Analytical method' used for specific migration and item 6.5 'Test method' for the determination of the residual content of the substance in the food contact material.
- The list of references reported in section 9 of the Explanatory Guidance has been removed as no longer relevant.
- Annex 3 (Peroxisome proliferation studies) and Annex 5 (Definition of SCF lists) to Chapter III have been removed, as they are no longer relevant to the evaluation of substances for food contact materials.
- Annex 6 to Chapter III (Model for a petitioner summary data sheet (P-SDS)) has been removed, as it is now replaced by the **Appendix B – Technical Dossier** of the 'EFSA Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials'.

Note that minor editorial changes are not specified in the above text.

EXPLANATORY GUIDANCE OF THE 'SCF GUIDELINES FOR FOOD CONTACT MATERIALS'

Introduction

The aim of this Explanatory Guidance is to help applicants in preparing an application for the safety assessment of a substance to be used in plastic food contact materials prior to its authorisation. This guidance amplifies and explains the information requested by the 'SCF guidelines on Food Contact Materials' by giving a more detailed description of the data needed for the safety assessment of the substance.

The below layout explains what information is expected to be contained in the technical dossier. The data requested in the first column should always be provided, either as indicated in the second column or as a statement such as 'yes', 'no', 'not applicable', 'no info', 'not relevant', etc. Justification of any deviation from this Explanatory Guidance must be given in the technical dossier.

All the information should be submitted by using the format of the **Appendix B – Technical Dossier**, included in the 'EFSA Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials' and available for download from the following link: http://onlinelibrary.wiley.com/wol1/doi/10.2903/sp.efsa.2017.EN-1224/abstract

Detailed information of all studies used in support of the application, e.g. full reports of experiments, full description of analytical methods, raw data and bibliographic references should be submitted as technical annexes.

For a complete guidance on the administrative procedure to be followed and the documentation to be provided for the safety assessment of a substance to be used in food contact materials, please refer to the **'EFSA Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials'**.

In addition, note that:

- In accordance with the EU legislation, detailed guidelines on compliance testing have been prepared by the European Commission Joint Research Centre (JRC). These guidelines have not been included in this document, but are described in the JRC 'Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011', which will be soon published on the European Commission's website.
- A reference to the JRC 'Practical guidelines on the application of migration modelling for the estimation of specific migration' has been included in item 5.1 'Specific Migration'. This document provides guidance to conservative migration modelling in support of Regulation (EU) No 10/2011.
- A reference to the JRC 'Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials' has been added in item 5.1.8 'Analytical method' used for specific migration and item 6.5 'Test method' for the determination of the residual content of the substance in the food contact material.
- Section 8, related to the toxicological data requirements, has been updated in line with the general principle described in the 'SCF Guidelines for Food Contact Materials', stating that the greater the exposure to the substance through migration, the more toxicological information will be needed.
- Item 8.1, related to genotoxicity requirements, has been updated in order to reflect the current state of the science on genotoxicity testing as described in the 2011 'EFSA Scientific Committee opinion on genotoxicity testing strategies'.
- References to additional OECD test guidelines have been added in items '8.2.4 Reproduction/ Teratogenicity' and '8.4.2 Neurotoxicity', to address some reproduction toxicity and neurotoxicity endpoints that were not considered in the previous version of the Note for Guidance.

Data requested		Guidance for providing the data requested
1.	**IDENTITY OF SUBSTANCE**	
1.1.	**Individual substance:**	Answer 'yes' or 'no'. If 'no' go to 1.2, if 'yes' give information requested in 1.1.1 to 1.1.11 as complete as possible.
1.1.1.	**Chemical name:**	Give chemical name of substance.
1.1.2.	**Synonym(s):**	Set out synonyms, if any.
1.1.3.	**Trade name(s):**	Set out trade name(s), if any.
1.1.4.	**CAS Nr:**	Set out CAS number, if any.
1.1.5.	**Molecular and structural formula:**	Give molecular and structural formula.
1.1.6.	**Molecular weight:**	Give molecular weight.
1.1.7.	**Spectroscopic data:**	Give spectroscopic data which allow identification of the substance, e.g. FTIR, UV, NMR and/or MS. *Ref:*
1.1.8.	**Manufacturing details:**	Set out production process, including starting substances, production control and reproducibility of the process. If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics. *Ref:*
1.1.9.	**Purity (%):**	Set out percentage purity. Set out how the purity was established. Supporting documentation (e.g. chromatograms) should be provided. The substance will be evaluated for the stated level of purity. *Ref:*
1.1.10.	**Impurities (%):**	Set out: • identity and typical range of percentage of impurities • origin of the impurities (e.g. starting substance, side reaction product, degradation product) • individual impurity levels, • the analytical method(s) to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided. If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities.
1.1.11.	**Specifications:**	Where appropriate, submit a proposal for a specification (e.g. level of purity, nature and percentage of impurities, type of polymer to be used) to be included in Commission Regulation (EU) No 10/2011, as amended. *Ref:*
1.1.12.	**Other information:**	Set out any other information that may be relevant for evaluation. *Ref:*
1.2.	**Defined mixture:**	Answer 'yes' or 'no'. If 'no' go to 1.3, if 'yes' give information requested in 1.2.1 to 1.2.13 as completely as possible.

This section only deals with 'process mixtures', obtained from a reproducible process and where the detailed composition can be easily determined (e.g. mixture of isomers).
'Synthetic mixtures', made up by mixing individual components are not considered here.

1.2.1.	**Chemical name:**	Give chemical name of mixture, if any.
1.2.2.	**Synonym(s):**	Set out synonyms, if any.
1.2.3.	**Trade name(s):**	Set out trade name(s), if any.
1.2.4.	**CAS Nr:**	Set out CAS number (s), if any.
1.2.5.	**Constituents:**	Set out chemical name(s) of constituents of the mixture.
1.2.6.	**Proportions in the mixture:**	Set out proportions of substances in the mixture. *Ref:*
1.2.7.	**Molecular and structural formula:**	Give molecular and structural formula of each component including isomers.
1.2.8.	**Molecular weight (Mw) and range:**	Give molecular weight (weight averaged molecular mass) and molecular weight range. *Ref:*
1.2.9.	**Spectroscopic data:**	Give spectroscopic data which allow identification of the mixture, e.g. FTIR, UV, NMR and/or MS. *Ref:*
1.2.10.	**Manufacturing details:**	Set out production process, including starting substances, production control and reproducibility of the process. If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics. *Ref:*
1.2.11.	**Purity (%):**	Set out percentage purity. Set out in what way the purity was established. Supporting documentation (e.g. chromatograms) should be provided. The substance will be evaluated for the stated level of purity. *Ref:*
1.2.12.	**Impurities (%):**	Set out: • identity and typical range of percentage of impurities, • origin of the impurities (e.g. starting substance, side reaction product, degradation product) • individual impurity levels, • analytical methods to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided. If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities. *Ref:*
1.2.13.	**Specifications:**	Where appropriate, give a proposal for a specification to be included in Commission Regulation (EU) No 10/2011, as amended. *Ref:*

1.2.14.	**Other information:**	Set out any other information that may be relevant for evaluation. *Ref:*
1.3.	**Non-defined mixture:**	Answer 'yes' or 'no'. If 'no' go to 1.4, if 'yes' give information requested in 1.3.1 to 1.3.16 as complete as possible. Non-defined mixtures are mixtures which may vary from batch to batch, but which have a composition within certain specifications. Typical examples of non-defined mixtures are products derived from natural sources. Their composition will depend on the origin of source, climate and treatment. Also, technical processes like ethoxylation, epoxidation or hydrogenation may create a large number of individual components.
1.3.1.	**Chemical name:**	Give description as complete as possible.
1.3.2.	**Synonym(s):**	Set out synonyms, if any.
1.3.3.	**Trade name(s):**	Set out trade name(s), if any.
1.3.4.	**CAS nr:**	Set out CAS number(s), if any.
1.3.5.	**Starting substances:**	Set out substances or raw materials used in manufacturing the mixture.
1.3.6.	**Manufacturing details:**	Set out production process, production control and reproducibility of the process. If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics. *Ref:*
1.3.7.	**Substances formed:**	Set out substances formed during the process. *Ref:*
1.3.8.	**Purification by:**	Set out details of purification of the end product. *Ref:*
1.3.9.	**By-products:**	Give qualitative and quantitative information on by-products, if any. *Ref:*
1.3.10.	**Molecular and structural formula:**	Give molecular and structural formula. For non-defined mixtures, this information may be complicated. In some cases, the information requested could be described as, e.g. 'oil of natural origin' with range of fatty acids and further treatment, if any.
1.3.11.	**Molecular weight (Mw) and range:**	Give Mw (weight averaged molecular mass) and molecular weight range. *Ref:*
1.3.12.	**Purity (%):**	Set out percentage purity. Set out how the purity has been established. Supporting documentation (e.g. chromatograms) should be provided The substance will be evaluated for the stated level of purity. *Ref:*
1.3.13.	**Impurities (%):**	Set out: • identity and typical range of percentage of impurities • origin of the impurities (e.g. starting substance, side reaction product, degradation product)

- individual impurity levels,
- analytical methods to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided.

If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities.

Ref:

1.3.14. Spectroscopic data: Give spectroscopic data which allow identification of the substance, e.g. FTIR, UV, NMR and/or MS.

Ref:

1.3.15. Specifications: Where appropriate, give a proposal for a specification to be included in Commission Regulation (EU) No 10/2011, as amended.

1.3.16. Other information: Set out any other information that may be relevant for evaluation.

Ref:

1.4. Polymer used as additive: Answer 'yes' or 'no'.
If 'no' go to 2, if 'yes' give information requested in 1.4.1 to 1.4.19 as complete as possible.
Polymeric additive means any polymer and/or prepolymer and/or oligomer, which may be added in plastics in order to achieve a technical effect but which cannot be used as such for the manufacture of finished materials and articles. It includes also polymeric substances which may be added to the medium in which polymerisation occurs.

1.4.1. Chemical name: Give chemical name of substance, if any.

1.4.2. Synonyms: Set out synonyms, if any.

1.4.3. Trade name(s): Set out trade name(s), if any.

1.4.4. CAS Nr: Set out CAS number, if any.

1.4.5. Starting substances: Set out monomers and/or other starting substances

1.4.6. Manufacturing details: Set out production process, production control and reproducibility of the process.
If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics.

Ref:

1.4.7. Additive(s): Set out additives used, if any.

1.4.8. Structure of polymer: Give structure of polymer.

1.4.9. Weight averaged molecular mass: Give weight averaged molecular mass.

Ref:

1.4.10. Number averaged molecular mass: Give number averaged molecular mass.

Ref:

1.4.11. Molecular mass range: Give molecular mass range and a distribution curve.
Curve of the distribution of the molecular masses (see figure below). This should be obtained by gel permeation chromatography (GPC) or by another validated method

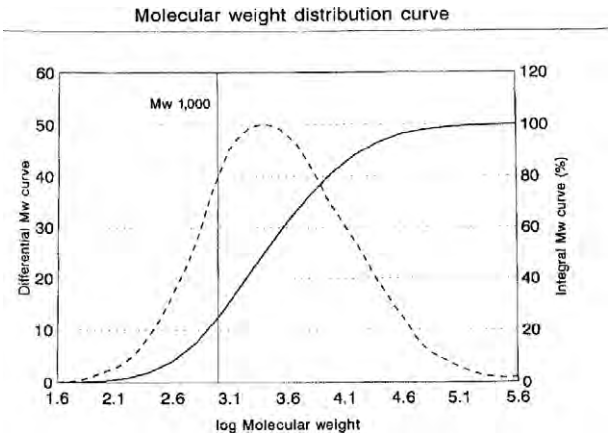
- The GPC calibration supplied should include as standards samples of the same polymer, having their

molecular mass accurately determined by an adequate technique (their molecular mass should lie around 1,000 Da). Determine the weight averaged molecular mass in weight (Mw) and the number averaged molecular mass (Mn).

- If standards of the same polymer are not available, then polystyrene standards should be used. An absolute value of Mw or Mn should then be determined by an adequate technique. The abscissa of the GPC molecular mass distribution curve should then be corrected by the factor:

$$\frac{M_n\ (\text{absolute value})}{M_n\ (\text{GPC value relative to PS})} \text{ or } \frac{M_W\ (\text{absolute value})}{M_W\ (\text{GPC value relative to PS})}$$

On the integrated molecular mass distribution curve (determined according the above mentioned guidelines) determine the point corresponding to abscissa 1,000 Da (true value): this gives the percentage of polymeric additive with molecular mass less than 1,000 Da.



Ref:

1.4.12. Constituents with molecular mass < 1,000 (%): Set out percentage constituents with molecular mass < 1,000 Da. Check this by analysis of the constituents < 1,000 Da by chromatography, e.g. gas chromatography (GC).

1.4.13. Viscosity, if available: Give intrinsic and/or relative viscosity, if any.

Ref:

1.4.14. Melt flow index, if available: Give melt flow index, if any.

Ref:

1.4.15. Density (g/cm^3): Give density, if any.

Ref:

1.4.16. Spectroscopic data: Give spectroscopic data, which allow identification of the subject substance, e.g. FTIR, UV, NMR and/or MS.

Ref:

1.4.17. Residual monomers (mg/kg): Set out monomers as well as individual monomer contents. See also Section 6 (i.e. Data on residual content of substance in the food contact material).

Ref:

1.4.18. Purity (%): Set out percentage purity.
Set out how the purity was established. Supporting documentation (e.g. chromatograms) should be provided.
The substance will be evaluated for the stated level of purity.
Ref:

1.4.19. Impurities (%): Set out:

- identity and typical range of percentage of impurities,
- origin of the impurities (e.g. starting substance, side reaction product, degradation product)
- individual impurity levels,
- describe the analytical methods to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided.

If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities.
Ref:

1.4.20. Specifications: Where appropriate, give a proposal for the specification to be included in Commission Regulation (EU) No 10/2011, as amended.
Ref:

1.4.21. Other information: Set out any other information that may be relevant for evaluation.
Ref:

2. PHYSICAL AND CHEMICAL PROPERTIES OF SUBSTANCE

2.1. Physical properties

2.1.1. Melting point (°C): Give melting point.

2.1.2. Boiling point (°C): Give boiling point.

2.1.3. Decomposition temperature (°C): Give decomposition temperature, if any.
Ref:

2.1.4. Solubility (g/L): Set out solubility in solvents.
If available, solubility in organic solvents should be presented as well as in food simulants.
If in migration tests a fatty food simulant is replaced by a substitute volatile simulant, then solubility both in the oil and in the substitute simulants is required. At least a semi-quantitative estimate of solubility should be presented to make the use of substitute solvents acceptable. The solubility may be given in g/L, or it may be indicated, e.g. miscible, good, moderate, poor or insoluble, etc. The intention here is that comparative information on solubility, which is one of the parameters that may influence migration, is obtained.
Ref:

2.1.5. Octanol/water partition (log $P_{o/w}$): Set out partition coefficient, if available.
Information is obligatory in the following cases:

- Migration is > 0.05 mg/kg of food/food simulant
- Substance is requested to be subject to the Fat (consumption) Reduction Factor (FRF).

If the migration is > 0.05 mg/kg, then information on accumulation in man is requested (see Annex 3). The log $P_{o/w}$ could be a tool to decide for the need of additional data.
Lipophilic substances may be marked as appropriate to apply the FRF. Proper evidence should be provided to demonstrate the lipophilic properties of a substance. A log $P_{o/w}$ value may be one of the three criteria established to classify the substance as lipophilic. The other two are the following:

1) Migration into non-fatty simulants should not exceed 1/10 of the Specific Migration Limit (SML) of the substance or
2) 2 Solubility in the non-fatty simulants should be less than 10% of the SML

Ref:

2.1.6. Other information related to lipophilicity: Give any other relevant information.

Ref:

2.2. Chemical properties

2.2.1. Nature: Answer 'acidic', basic' or 'neutral'.

2.2.2. Reactivity: Give information on reactivity of subject substance.

2.2.3. Stability: Give information on stability of subject substance in the polymer towards light, heat, moisture, air, ionising radiation, oxidative treatment, etc.
Provide a thermogravimetric analysis (for substances other than monomers) of the substance.
For chemicals which are not deemed to react in the polymer, the onset of degradation should in general be 10% above the max. process temperature. If this is not met, an explanation should be given why the substance can be used above or near the decomposition temperature. If any of the other parameters are relevant for authorisation of the substance, then sufficient detailed information shall be provided for a proper evaluation.

Ref:

2.2.4. Hydrolysis: Hydrolysis may simplify the petition if already evaluated chemicals are formed in high yield in body fluid simulants. If relevant, give results of hydrolysis tests carried out according to the guidelines of Annex 1. If hydrolysis tests are carried out, full details shall be provided, including the analytical method.

Ref:

2.2.5. Intentional decomposition/ transformation: Give information on intentional decomposition or transformation of substance, if any, during manufacture of a food contact material or article.
If there might be some concern about decomposition products, migration and/or toxicity data on these products might be requested, and specifications or restrictions may be set.
In this respect, a monomer is considered to be transformed into a polymer additive like scavengers will be transformed and anti-oxidants will be decomposed according to the intention of use. Other substances may be decomposed, e.g. by oxidation or due to high temperature, etc.

Ref:

2.2.6. Unintentional decomposition/ transformation product(s):

Where relevant, set out unintentional decomposition or transformation products

- of the pure substance (see 2.2.3)
- formed in the material during the manufacture of a final article
- formed during various treatments likely to be applied to the finished material or article (e.g. ionising treatments).

Ref:

2.2.7. Interaction with food substances:

Give information on reaction of the substance with food substances, if any.
This item is important for making decisions on the type of restriction to be established (SML, QM or QMA). If migration tests, including recovery tests (see item 5.1.11), have been carried out, reference could be made to item 5.1. In any other situation, stability of the substance in food simulants should be provided, unless a QM or QMA limit is requested by the applicant.

Ref:

2.2.8. Other information:

Set out any other information that may be relevant for evaluation.

Ref:

3. INTENDED APPLICATION OF SUBSTANCE

3.1. Food contact material:

Set out food contact material(s) in which the substance is to be used. Provide specific examples. Information should be provided in what type of polymers the substance is intended to be used, and/or in what type of food contact material, e.g. all kinds of polyolefins, ABS used for manufacture of household machines, only in PET beverage bottles. This information may be important for estimating the real exposure.
Indication of a very restricted or a very broad field of application may influence the final authorisation and the restrictions of the substance.

3.2. Technological function:

Set out the function(s) of the substance in the production process or in the finished product. For example, monomer, co-monomer in the production of polymer X, antioxidant, antistatic agent, preservative, etc. Provide relevant information to demonstrate the functionality of the substance in the final product. If relevant, provide information on the production process.

3.3. Maximum process temperature (°C):

Set out maximum temperature in manufacturing process of polymer as well as final food contact material. (see also 2.2.3).

3.4. Maximum percentage in formulation:

Set out maximum percentage of the substance used in the formulation and/or related to the final food contact material (e.g. a substances added in an aqueous suspension should be related to the dry matter). The maximum percentage to achieve a technological property, as well as the level used in practice should be given, if relevant.
Typically in the case of additives, the maximum percentage will influence the migration of the substance. Materials submitted to migration testing should contain the maximum percentage indicated.

3.5.	**Conditions of contact in practice**	
3.5.1.	**Contact food:**	Set out the foods to be in contact with the finished products. Indicate typical foodstuffs and use for all types of foodstuff. Migration tests should be carried out accordingly.
3.5.2.	**Time and temperature:**	Set out approximate time and temperature of contact in practice as well as restrictions of time and temperature. See Commission Regulation (EU) No 10/2011, as amended for further guidance.
3.5.3.	**Surface to volume ratio:**	Set out the approximate ratio of dm^2 food contact materials to kg food in practice. For materials intended for general application the ratio is conventionally 6 dm^2/kg. For specific applications, the ratio area/food may deviate significantly, e.g. tubing or large tanks, single portion package (see also 3.1). Information requested here should not be confused with the information requested in item 5.
3.5.4.	**Other information:**	Give any other relevant information.
3.6.	**Treatment of food contact material prior to use:**	Give information on treatment of food contact material prior to contact with food, e.g. sterilisation, cleaning with pressurised steam, rinsing, irradiation, e-beam or UV light treatment, etc.
3.7.	**Other uses:**	Set out other uses or intended uses of the substance additional to food contact materials, if any. If the substance is used in other domains than food contact materials, only a fraction of the ADI may be allocated to food contact materials.
3.8.	**Other information:**	Set out any other information that may be relevant for evaluation.
4.	**AUTHORISATION OF SUBSTANCE**	
4.1.	**EU countries**	
4.1.1.	**In Member States:**	Answer 'yes' or 'no'. If 'yes' set out Member State(s), give relevant regulation(s) or other and give further details like restrictions and conditions.
4.1.2.	**Notified as 'new substance' in the context of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures:**	Answer 'yes' or 'no'. If 'yes' give details and data transmitted.
4.1.3.	**Other information:**	Give any other relevant information.
4.2.	**Non-EU countries**	
4.2.1.	**In USA:**	Answer 'yes' or 'no'. If 'yes' give relevant regulation(s) or other and give further details like restrictions and conditions.
4.2.2.	**In Japan:**	Answer 'yes' or 'no'. If 'yes' give relevant regulation(s) or other and give further details like restrictions and conditions.

4.2.3. In other countries: Answer 'yes' or 'no'. If 'yes' set out other countries, give relevant regulation(s) or other and give further details like restrictions and conditions.

4.2.4. Other information: Set out any other information that may be relevant for evaluation.

4.3. Other information: Set out any other information that may be relevant for evaluation, e.g. authorisation on other uses or environmental regulations.

5. DATA ON MIGRATION OF SUBSTANCE

If food simulants are used, the provisions concerning the specific and overall migration set out in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as amended, should be followed. Further guidance can be also found in the 'Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011', which will be soon issued by the European Commission Joint Research Centre (JRC) and published on the European Commission's website.

5.1. Specific migration (SM): Answer 'SM determined' or 'SM not determined'. If SM is not determined, give reasons. In general, the determination of the specific migration will be requested to estimate the worst case migration. Based on the level of migration, the number of toxicity tests can be established. However, there are a number of exceptions where the determination of specific migration can be replaced by the determination of the content of the substance followed by worst case calculation. If it is impossible to measure specific migration because of the properties of the substance, e.g. polymeric additives, the overall migration can be used to demonstrate worst case migration of the substance. All experiments required in specific migration testing should be performed in triplicate
If migration modelling is applied, useful guidance can be found in the JRC Technical Report 'Practical guidelines on the application of migration modelling for the estimation of specific migration'.[9]

Ref:

5.1.1. Substance: Set out substance(s) determined.
Information on migration of decomposition products (e.g. antioxidant) and/or impurities – if any – may be required as well.

Ref:

5.1.2. Test sample: The test sample should always represent the worst-case situation. This means the highest concentration of additive or co-monomer should be present. Also, the thickness of the test sample should represent the worst case situation. If the test sample is intended to represent a range of materials of different brands or grades, it should be assured that the material selected represents the worst-case situation in the migration testing. If the substance is used in different kinds of polymers, in principle each type of polymer should be tested. However, if it is properly argued, only migration tests with the polymer representing worst case can be acceptable.

Ref:

[9] Hoekstra EJ, Brandsch R, Dequatre C, Mercea P, Milana MR, Störmer A, Trier X, Vitrac A. Schäfer O and Simoneau C, Practical guidelines on the application of migration modelling for the estimation of specific migration; EUR 27529 EN, https://doi.org/10.2788/04517

5.1.2.1. Chemical composition: Set out the chemical composition of the test sample. Information should be provided particularly on the initial concentration of the substance, but also on the total composition of the test specimen, as this may influence the final migration of the substance.

5.1.2.2. Physical composition: Set out the physical composition of test sample, such as homogeneous material or multilayer material. In case of a multilayer material, it should be indicated in which layer the substance is present. If this is not the direct food contact side, also information on the top layers is needed.

5.1.2.3. Density, melt flow index of polymer: Set out density and melt flow index (if relevant) of the polymer containing the substance. This information is required for mathematical modelling. In multilayer constructions, also the density of the barrier layers shall be given.

5.1.2.4. Dimensions of test sample: Set out dimensions of test sample.
Test sample is the sample manufactured for the purpose of the migration study. Provide information on shape, e.g. bottle, film, sheet, etc., and the thickness of the test sample. For laminates, the total thickness and the thickness of each relevant layer should be indicated. For articles with inhomogeneous thickness, the thickness at various places should be given. The dimensions of an article should be set out (height, length, width and/or diameter).

5.1.2.5. Dimensions of test specimen: Describe briefly the part or section of the test sample from which the test specimen was taken particularly in case of inhomogeneous materials (e.g. bottle).
Set out spatial dimensions of test specimen (length, height, width, diameter).
Calculate the total area of the test specimen. In case of two-sided contact (see 5.1.5), also calculate the total area of both sides. If the test specimen does not come into contact completely with the simulant (with use of one side migration cells), then calculate the actual contact area.

5.1.3. Treatment of test sample prior to testing: Set out to what treatment the food contact material was subjected prior to testing, e.g. cleaning, washing, etc. The treatment should be representative of the use in practice.

5.1.4. Test food(s)/food simulant(s): Set out foodstuff(s) or food simulant(s) used in migration testing. Commission Regulation (EU) No 10/2011, as amended, should be followed for the selection of the food simulant. Especially when olive oil is replaced by substitute food simulants, this document should be studied carefully. The JRC 'Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011' should be also taken into account. Data on solubility as requested in item 2.1.4 shall also be provided in those cases. Replacement of olive oil by substitute simulants is only acceptable in cases of technical problems. Therefore, the necessity of the use of substitute simulants should be clarified, preferably supported by analytical data. Olive oil should not be replaced for convenience only. Arguments will be considered for validity. Poor analytical chemistry or lack of facilities may not appear acceptable arguments for replacement of olive oil by substitute simulants.

In the special case of migration of metal ions where ion exchange is the driving force, migration experiments should also be performed in the following simulants: 40 mM sodium acetate buffer at pH 5 and 50 mM sodium phosphate buffer at pH 7.

5.1.5. Contact mode: Set out whether the sample was tested on one or on two sides and in which way contact with the simulants was achieved, e.g. cell, pouch, total immersion, etc. If tested on two sides, set out whether one or both sides of the test specimen are used in the calculation of the contact area.

5.1.6. Contact time and temperature: Set out the duration of the test and test temperature. Time temperature combinations should be determined in accordance with Annex V to Regulation (EU) No 10/2011.
In case of short contact times ($\leq$ 2 h) at high temperature ($\geq$ 100°C), describe the temperature profile over the test period.

5.1.7. Surface to volume ratio: Set out dm^2 test sample per kg food or L simulant. Give the actual contact area and the volume of simulant. Calculate from these data the actual surface to volume ratio applied in the migration test. Conventionally the ratio is 6 dm^2/kg simulant. For analytical reasons, it may be necessary to deviate from that ratio, which in principle is acceptable. However, it should be considered whether using a different ratio of area to volume could influence the migration due to saturation of the simulant.

5.1.8. Analytical method: Set out the principle of the analytical method used, and submit a copy in standard format.
Useful guidance can be found in the JRC 'Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials'[10] and in the JRC 'Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011'.
The technical dossier should contain, e.g. actual data concerning the preparation of calibration solutions, typical chromatograms, calibration curves, correlation coefficients and all other relevant data needed for a proper evaluation of the method and the migration data provided. The method may be used by enforcement laboratories and should, therefore, use generally available equipment. Use of very sophisticated methods should be justified.
Please note that Article 20 (2)(c) of Regulation (EC) No 1935/2004 applies, i.e. information relating to the analytical methods shall not be considered confidential.

Ref:

5.1.9. Detection/ determination limit: Give the detection and/or determination limit of the method, and set out the way the detection limit was established. Detection limits are particularly important when migration is not detectable or near the detection limit. Where relevant,

[10] Bratinova S, Raffael B, Simoneau C, (2009) Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials. 1st edition 2009. Publication Office of the European Union, Luxembourg, JRC Scientific and Technical Report, EUR 24105 EN.

visual information such as typical chromatograms, calibration curve and blank values should be provided.

Ref:

5.1.10. Precision of test method: Give the repeatability (r) of the method at the migration level. For example, repeatability of the method can be obtained from the standard deviation of triplicate migration experiments or from recovery experiments.

Ref:

5.1.11. Recovery: Set out the percentage of substance recovery as determined in recovery experiments under time-temperature conditions of the migration tests. To obtain data on the suitability of the analytical method as well as the stability of the substance in the food simulants, recovery experiments (triplicate) shall be performed with the food simulants used spiked with the substance at a level of interest (e.g. 50 μg/kg) or at the actual level of the migration values. The spiked food simulants shall be kept under the same conditions of time and temperature, in the same or equivalent containers as used in the migration experiments. Provide all actual data to allow proper evaluation of the results, such as the method of standard addition (solvent used, volume added), amount of substance added to a known volume of simulant (x μg/y mL), storage condition, etc.
If low recovery values are obtained, reasons for this should be explained.
Results of the recovery test may influence the type of restriction to be established.

Ref:

5.1.12. Other information: Set out any other information that may be relevant for evaluation.

Ref:

5.1.13. Results: Give all individual migration data obtained, blank and recovery data inclusive. Preferably, the data should be presented in a table, which should contain sufficient details to follow the way the final results are obtained, e.g.:

- test conditions of time and temperature
- simulant
- contact area
- volume of food simulant used in the test
- actual concentration of the substance in the simulant as obtained from the migration experiment
- migration in the food simulant expressed in mg/dm^2
- migration in the food simulant using the conventional factor of 6 dm^2/kg or any other relevant ratio
- amount of substance added in the recovery tests.

Ref:

5.2. Overall migration (OM): Answer 'determined', 'not determined'.
In general, the determination of the OM is not required for petitioning of an additive or a monomer. The overall migration may be used as a replacement for specific migration in those cases where the specific migration is impossible to measure because of the properties of the substance, e.g. polymeric additives. The overall migration may be used to demonstrate worst case migration of the substance.