European Committee for Food Contact Materials and Articles (Partial Agreement) (CD-P-MCA)

# Technical guide on documentation supporting compliance and safety of food contact materials and articles, 1st edition

Draft for the public consultation of stakeholders

**CONSULTATION PERIOD**

**19 March – 30 April 2024**

Feedback and comments further to the proposed texts are welcome for the duration of the consultation.

**HOW TO PARTICIPATE**

1. Download the **Excel submission form here** and save a local copy.
2. Fill in contact details, as needed.
3. Select section range/line numbers from the drop-down list, as needed; type or paste comments and suggested texts. Complete one row per comment or suggestion.
4. Save the completed Excel file.
5. Send as attachment by e-mail to: fcm.consultation@edqm.eu.
6. Deadline for comments by e-mail: 30 April 2024.

*Please note: comments submitted in any other format will not be treated.*

EDQM will not publish all comments received but reserves the right to publish or otherwise make public the conclusions of this consultation. Name and affiliation details submitted may be disclosed to mandated reviewers. Submissions without name or other details will be treated anonymously. Personal data will be stored for 2 years by the EDQM for the purpose of comment assessment and follow-up.

**CONSULTATION ASSESSMENT**

The EDQM Secretariat shall support the CD-P-MCA in the review of consultation feedback and recommendations of due follow-up, with a view to the release of the technical guide.

**OUTCOME**

For further information, subscribe to the EDQM newsletter or follow the work programme of the CD-P-MCA.

# Technical guide on documentation supporting compliance and safety of food contact materials and articles

## 1. Introduction

There is usually a chain of manufacturers contributing to a final food contact material (FCM). Compliance work will generally involve the following steps:

(i) receipt of starting materials (substances, materials, or articles) with a declaration of compliance (DoC) containing information to be considered,

(ii) processing of these starting materials, which usually involves compliance work, and

(iii) compiling information for compliance work yet to be undertaken in subsequent manufacturing steps.

This Technical Guide supports business operators in demonstrating compliance of products with the applicable requirements. It provides a checklist [*editable file to follow on publication*] of the potentially relevant steps and details that should be considered. This checklist helps the business operator to provide the evidence and rationale that supports compliance for each of these check points and to issue a DoC.

The DoC provides information that enables subsequent business operators along the supply chain to carry out any additional compliance work necessary to deliver safe and compliant food contact materials and articles.

**Supporting documentation is for in-house use only** (see Figure 1).

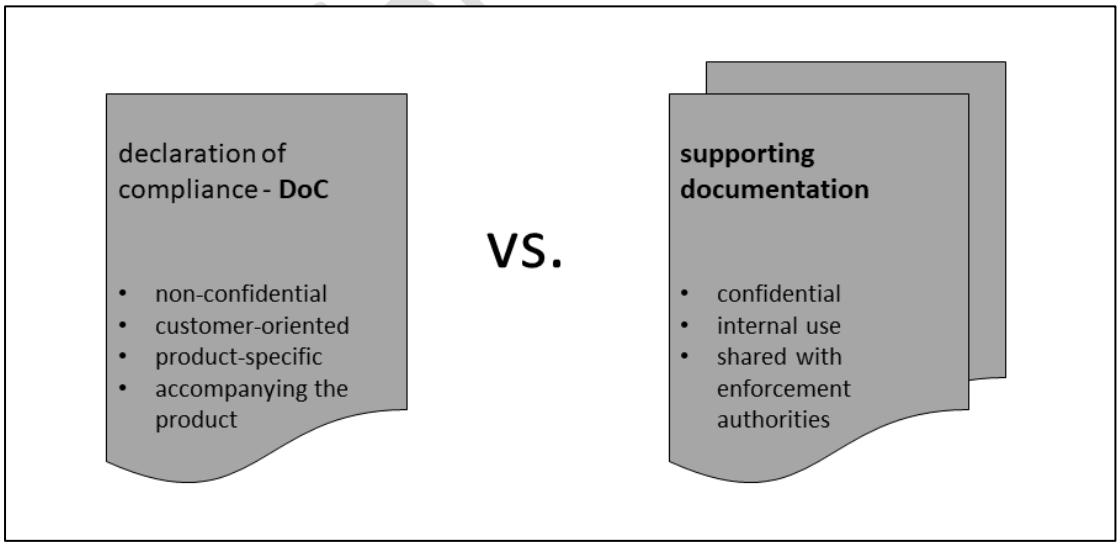


Figure 1 - Comparison between DoC and supporting documentation

Compliance work is iterative and a shared responsibility among all the contributors to a final FCM. Its success relies on completing the compliance work at the earliest stage, not only because it is challenging for several businesses to replicate the same work, but also because

a producer has the best understanding of their product. Business operators producing intermediate products should also contribute to the compliance work.

It is important that information flow between suppliers and customers is ensured in both directions of the supply chain to enable appropriate compliance work.

The business operator declares compliance of the product within the range of the specifications/restrictions provided in the DoC, considering those already declared by the upstream suppliers in their DoC. Compliance work that has been identified but is yet to be undertaken in subsequent manufacturing steps must also be indicated in the DoC. This means that for each step in the process, it should be decided which aspects of the compliance work are required and what information subsequent operators in the manufacturing chain will need, to complete their own compliance work. The business operator at the end of the manufacturing chain should be able to declare compliance of the final product(s), based on the compliance work and the information exchanged within the supply chain, with relevant specifications/restrictions. The compliance of the final article remains a shared responsibility of all actors involved in the manufacturing chain.

# 2. Scope and definitions

## 2.1. Scope

This Technical Guide applies to FCMs and articles under the scope of Resolution CM/Res(2020)9, hereinafter called "the Resolution". It supplements the Resolution by elaborating on the required content of the compliance and safety documentation (Guiding Principles, Section 8.1).

Section 8.1 of the Guiding Principles requires in-house documentation to demonstrate that FCMs and articles, as well as products intended for their manufacture, comply with the requirements in the Resolution, the relevant material-specific Technical Guides, European or national legislation, and official recommendations. This documentation is confidential but is to be made available in an accessible format and language to the competent authorities upon request, without undue delay.

Section 8.2 of the Guiding Principles requires that manufacturers of FCMs and articles, including intermediate products, under the scope of the Resolution derive a DoC from the supporting documentation. The DoC must provide all relevant information needed to enable the compliance work yet to be undertaken in subsequent manufacturing steps to be identified.

## 2.2. Definitions

**Business Operator**: natural or legal persons responsible for ensuring that the requirements of the Resolution, the relevant material-specific Technical Guides, European or national legislation or official recommendations are met within the business under their control.

**Checklist**: compilation of critical points for the compliance work with room for presenting the relevant data and reasoning, possibly summarising the accompanying documents, to ensure complete and coherent compliance work.

**Compliance work**: generation of data and rationale to demonstrate compliance of the FCMs and articles with the specifications/restrictions/legislation.

**Dual-use substances:** substances migrating from FCMs that are also subject to a restriction in food, such as food additives, according to Regulation (EC) No 1333/2008 and flavourings, according to Regulation (EC) No 1334/2008, and their implementing measures.

**Intermediate product:** any product which is not a basic chemical and not yet a finished FCM or article.

**Not officially evaluated substances:** substances for which risk assessment has not been carried out according to the principles stated under section 4 of the Resolution by a competent authority of a Council of Europe member state or a relevant European authority.

**Set-off:** transfer of substances from one side of a material or article to another through direct contact between these different sides caused by the stacking or reeling of the materials. Set-off may be visible or invisible.

**Supporting documentation:** collection of pertinent information required to support the compliance declared in the DoC. This may include technical information, declarations from suppliers, test reports etc. The aim of the supporting documents is to demonstrate that the compliance work was conducted on a sound basis.

# 3. Checklist for the supporting documentation

The checklist is available as an editable electronic file here [*made available on publication – see Annex 1*].

The content of the supporting documentation depends on the position of the business operator within the chain of manufacturers as well as on the type and application of the FCM. Therefore, not all points of the following list apply equally or at all.

1. Identity of the business operator responsible for the product.

2. Product or family of products covered by the supporting documentation:

    a. Identification/trade name, including part number(s);

    b. general description of the product(s);

    c. justification for the compliance work.

3. Intended use(s) of the product(s) to be covered by the DoC, as requested by customers or the intended market; restrictions of use covered by the compliance work:

    a. for intermediate products:

i. intended range of applications for FCMs;

ii. conditions of use of the product at subsequent manufacturing.

b. for final FCMs:

i. storage, such as stacking/reeling (risk of set-off), and treatments before food contact, such as decontamination by disinfection, heating or irradiation;

ii. type(s) of food that may be safely brought into contact with the FCM;

iii. FCM intended for single or repeated contact/use;

iv. maximum duration and temperature during food processing; maximum duration and temperature for storage in contact with the food;

v. contact surface area per amount of food for which compliance needs to be shown;

vi. use in contact with foods consumed by infants and young children, as defined in Article 2(2)(a) and Article 2(2)(b) of Regulation (EU) No 609/2013.

4. Starting materials – (including any non-listed, not specifically regulated substances, such as production aids, catalyst preparations and solvents:

a. chemical name or description; Chemical Abstracts Service (CAS) number; internationally recognised chemical identifier; trade name(s) used by the supplier(s); information on the source of biological materials, if applicable;

b. name(s) and address(es) of supplier(s), per chemical;

c. information included in the technical documentation provided by the supplier(s):

i. specifications - including purity, impurities and reaction products, stability, maximum use level, conditions and restrictions for use;

ii. reaction products to be expected;

iii. information for compliance work yet to be undertaken in subsequent manufacturing steps.

**The information may be tabulated as shown in Table 1.**

## Table 1. Substances used per supplier, impurities and reaction products thereof as well as information for compliance work yet to be undertaken in subsequent manufacturing steps

| Chemical name | CAS number | Trade name | Supplier | Impurities/reaction products | Maximum use level | Instructions and restrictions | Information for subsequent compliance work |
|---|---|---|---|---|---|---|---|

**Note:** all substances used, as well as reaction products and impurities, along with compliance work yet to be undertaken in subsequent manufacturing steps are also to be listed in Table 2 by substance name, type (e.g., monomer, additive, production aid) and CAS number: officially evaluated substances in Table 2a, not officially evaluated substances used, reaction products and impurities in Table 2b.

5. Manufacturing process(es) and reaction conditions used:

a. manufacturing formulae, including amounts of components used;

b. reaction conditions and cleaning procedure;

c. known and/or predicted side-reactions and by-products with the estimated/measured concentrations. If there are wide tolerances in the production system, e.g., in terms of temperature, the worst-case scenario should be taken into account;

d. specifications of the product, e.g., regarding impurities.

6. Potentially migrating reaction products and impurities as identified by chemical analysis, in addition to the substances mentioned in points 4 and 5:

a. analysis in solvent extracts or food simulants

b. short description of the applied analytical method(s), further described in detail in an annex, if referring to an in-house method, a method from the literature or a method adapted from the literature;

c. detection limits, ranges of substances assessed by the method(s), e.g., in terms of polarity, volatility range or molecular mass, detectability, uncertainty;

d. summarised validation data for the method(s);

**Note:** the substances should be added to Table 2 (mainly under “Not officially evaluated substances”) with information about the type, e.g., component, reaction product or impurity.

7. In case of possible set-off during storage of the product on reels or in stacks or gas phase transfer:

a. specifications/restrictions on storage and use that avoid set-off of potential concern, if any;

b. if set-off or gas phase transfer of potential concern cannot be ruled out by specification of storage conditions, add substances potentially transferred to the food contact surface to Table 2b, with a corresponding remark under type.

8. Reactions potentially occurring in the product at later stages of the manufacturing chain or during the use of the FCM, that could generate substances requiring compliance work, such as during processing with heat, reactions with substances introduced later, heating or treatment for decontamination (e.g., irradiation or chemical decontamination) or during use (e.g., owing to exposure to air or light):

a. if substances are covered by the compliance work performed at this stage: list reaction/degradation products to be expected under the intended conditions of use (specification) in Table 2b with a remark under type such as “potentially formed at later stage”.

b. if the related compliance work is yet to be undertaken in subsequent manufacturing steps, list the substances that may react, or from which reaction products may be formed and inform your customer.

## Table 2. Substances potentially migrating into food and their evaluation

### 2a. Officially evaluated substances for FCMs

| Substance name | CAS number | Type (monomer, additive, etc.) | Evaluation body | Restriction (e.g., SML and/or conditions of use) | Maximum expected migration | Other sources for the substance[1] | Information for subsequent compliance work |
|---|---|---|---|---|---|---|---|

### 2b. Not officially evaluated substances for FCMs

| Substance name | CAS number | Type (components, reaction products, impurities, etc.) | Maximum expected migration | Reference for safety assessment | Maximum safe migration | Other sources for the substance[2] | Information for subsequent compliance work |
|---|---|---|---|---|---|---|---|

9. Substances officially evaluated (according to the definition in the Guiding Principles) for use in FCMs

a. who (authority, agency, institution) evaluated the use of the substance? and/or where is the substance officially listed?

b. specific migration limits (SML), restrictions in use, maximum use levels.

**Fill in Table 2.**

10. Maximum migration (mg/kg or mg/dm$^2$) to be expected

**Note:** source of the migration or extraction data, such as experimental measurement in foods or simulants, assumption of complete transfer to food or estimation by modelling.

a. for experimental determination, a summarised description of the analytical methods applied, and validation, with reference to a full description in an annex or reference to a method from the literature;

b. for calculated migration, the assumptions used and outline of calculations;

c. for modelling: software and parameters used.

**Maximum expected migration to be provided in Table 2; further information in an annex.**

11. Toxicological assessment of substances not officially evaluated for FCM applications. Data may come from:

[1] *Other sources for the substance* may refer to food, food contaminants, other FCM...
[2] same comment

a. official evaluation for other uses (such as food additives or flavourings) or documented in the context of another evaluated substance (e.g., assessed in a EFSA opinion as a reaction product or impurity);

b. scientific literature;

c. experimental tests on genotoxicity, e.g., according to Organisation for Economic Co-operation and Development (OECD) test guidelines;

d. experimental tests on general toxicity, e.g., according to OECD test guidelines;

e. non-experimental assessment of impurities, reaction products and by- products (not acceptable for intentionally added substances): threshold of toxicological concern (TTC), read-across or Quantitative Structure-Activity Relationship (QSAR). Provide justifications.

**Data for Table 2: reference to the safety evaluation with details provided in an annex and conclusions on the maximum safe migration (such as from a non-observed-adverse-effect level (NOAEL), an EFSA tier or a TTC value).**

12. For each substance in Table 2, check whether one of the following could be applicable:

a. is it subject to a restriction in food, such as for use as a food additive or flavouring (dual-use substance)?

**If yes, provide information about the type, restrictions, and maximum concentrations in food in Table 2,** with more detailed information in an annex.

b. could it migrate from a part of the finished article that is added at a later manufacturing stage, such as another article (e.g., closure of a tray), a layer of a multilayer film, or printing, possibly adding up to a migration exceeding a restriction?

**If yes, each supplier must communicate substances with restrictions and dual-use additives for their component(s)** so that the manufacturer of the final product can complete the compliance work.

13. If the compliance work is to be completed further downstream, for each substance in Table 2 it should be decided what information is needed for this work.

a. what compliance work is yet to be undertaken in subsequent manufacturing steps? (e.g., determination of migration, safety evaluation);

**Note:** A justification as to why this is necessary or the reasons why this has not yet been done would be useful, such as determination as to the type of food to be in contact has yet to be made.

b. Data and/or other information needed for compliance work yet to be undertaken in subsequent manufacturing steps or otherwise useful for the customers.

**Transfer this information to the DoC, with a short indication in Table 2 and further instructions, if possible, in a separate text.**

Is the substance list complete?

If not, what specific analytical work is still needed?

**Further aspects to be taken into consideration:**

14. Is the product classified as a nanomaterial or does it contain components to be classified as nanomaterials (Commission Recommendation 2022/C 229/01)? If yes:

    a. characteristics according to EFSA nano guidance (Table 1).

15. Is a functional barrier relevant for migration into food?

    a. characterisation of (the nature) of the barrier, description of the location in the FCM or article and information about the other layers;

    b. criterion applied for the definition of barrier effectiveness;

    c. methodology and results demonstrating barrier effectiveness;

    d. duration of sufficient effectiveness under the intended conditions of use.

16. Changes in the organoleptic characteristics of the food: data on sensory tests.

17. Other provisions in the relevant EU or national legislation, official recommendations or set out in the Technical Guides, such as on overall migration. Provide a list.

18. GMP requirements: critical control points related to the product that is the subject of this documentation and how they are addressed by the quality assurance system in place, including specifications/restrictions on storage, as found in the Technical Data Sheet (TDS) of a substance. Provide a list.

**Note:** In this context, the requirements of Art. 17 of Regulation (EC) No 1935/2004 concerning traceability are important.

# 4. Data requirements for risk assessment of migrants

The safety of substances or components that are not listed as evaluated in the Technical Guides or legislation/official recommendations, reaction products (including oligomers and degradation products) and impurities must be evaluated “in accordance with internationally recognised scientific principles on risk assessment, and with, where appropriate, EFSA guidance” (Resolution CM/Res(2020)9, Guiding Principles, Section 4).

# 5. Authority access to compliance and safety documentation

For the control of compliance of an FCM to be effective, authorities may be required to review the documentation from all business operators that contributed to its manufacture. If authorities only want to check the compliance of one specific aspect, such as the migration of a given substance, they need to trace back to the supporting documentation of the business operator that completed the particular compliance work. This could be the operator who introduced the substance, or the first along the supply chain that performed the specific compliance work, as recorded by the DoC.

Control authorities act nationally or regionally on products on the market. When the compliance of a product depends on the work of suppliers located outside the geographical area for which they are competent, supporting documentation must still be made available. The local business operator is therefore responsible for providing sufficient access to the relevant documents when required. If there are confidentiality issues, this operator should agree with the supplier(s) on how the required information will be provided to the authorities. If a business operator subcontracts compliance work to a third party (e.g., laboratory or law firm), the responsibility remains with the business operator to provide the relevant documents from third parties, on demand.

Supporting documentation should be submitted without undue delay (Guiding Principles, Section 8.1).

# 6. References

The following official publications further elaborate on supporting documentation for FCMs:

- Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain [available from: https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/brochures_en].
- German ALS: Gute Herstellungspraxis (GMP) und Konformitätserklärung für Lebensmittelbedarfsgegenstände: Interpretation der amtlichen Überwachung (2009/52) [available from: http://bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/ALS_ALTS/ALS_Stellungnahmen_93_Sitzung_2009.pdf?__blob=publicationFile].
- Istituto Superiore di Sanità: CAST Project. Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food [available from: https://www.iss.it/documents/20126/45616/11_37_web.pdf/dfaa215a-c020-14d2-5956-f3cbba5a7f66?t=1581095200630].
- Istituto Superiore di Sanità: CAST Project. Guidelines on the Supporting Documentation to the Declaration of Compliance to the legislation on food contact materials and articles. ISTISAN 18/24 [available in Italian from: https://www.iss.it/documents/20126/45616/18_24_web.pdf/03932d51-b003-65f1-3972-748c28b0581e?t=1581099419247].
- Nordic Council of Ministers: Nordic checklist food contact materials. Declaration of compliance and supporting documentation [available from: http://norden.diva-portal.org/smash/get/diva2:858441/FULLTEXT01.pdf].

The following documents by EFSA are pertinent guides on risk assessment for FCMs:

- 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 Journal 2008;6(7):21r [available from: https://www.efsa.europa.eu/de/efsajournal/pub/rn-21].

- 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 [available from: https://www.efsa.europa.eu/de/efsajournal/pub/4357].

- Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment. EFSA Journal 2019;17(6):5708 [available from: https://www.efsa.europa.eu/en/efsajournal/pub/5708].

# 7. Annex 1 Checklist for supporting documentation

*[file to be made available on publication]*

*Please complete the below in-house form to the best of your knowledge for **each product or family of products** covered by the supporting documentation. Insert additional documentation and separate files where needed, naming each file clearly incl. product name or description.*

| **1. Identity of business operator responsible for the product** | |
|---|---|
| **Company Name** | |
| **Address** | |
| **Country** | |
| **Contact Person** | *(Name and email address)* |

| **2. Product (or family of products) covered by the supporting documentation** | |
|---|---|
| **a. Identification/trade name(s)** | *including part number(s) of kitchenware, appliances, etc.* |
| **b. General product description** | *such as the type of material and design and the principal intended use(s): for example, teats for baby bottles made of rubber or silicone, or stoppers for wine or juice bottles made of cork.* |
| **c. Justification for any omission of the compliance work** | *if the compliance work was performed for one of several similar products, a justification describing the similarity is needed for a read-across of the compliance work. In case of uncertainty, the worst-case scenario should be considered.* |

| **3. Intended use**<br>*Intended use(s) of the product(s) to be covered by the ATD/DoC, as requested by customers or the intended market; restrictions of use covered by the compliance work.* | |
|---|---|
| **a. FOR INTERMEDIATE PRODUCTS** | |
| **i. Intended range of applications for FCMs** | *e.g., ink only to be used in the presence of a barrier layer or a gasket only to be used in contact with aqueous foods* |
| **ii. Conditions of use** | *conditions of use of the product at subsequent manufacturing stages, such as maximum temperatures or conditions for curing* |
| **b. FOR FINAL FCMs** | |

| | | |
|---|---|---|
| **i. Storage conditions** | *such as stacking/reeling (risk of set-off), and treatments before food contact, such as decontamination by disinfection, heating or irradiation* | |
| **ii. Type(s) of food** | *type(s) of food that may be safely brought into contact with the FCM* | |
| **iii. FCM intent of use** *(select)* | Single use ☐ | Repeated contact use ☐ |
| **iv. Maximum duration and temperature during food processing** | *(if applicable)* | |
| **Maximum duration and temperature for storage in contact with food** | *(if applicable)* | |
| **v. Contact surface area per amount of food for which compliance needs to be shown** | | |
| **vi. Use in contact with foods consumed by infants and young children** | Select: YES ☐ or NO ☐ | |

| **4. Starting materials used at the manufacturing stage covered by this documentation**<br>***(including any non-listed, not specifically regulated substances, such as production aids, catalyst preparations and solvents)*** | |
|---|---|
| **a. - Chemical name or description**<br>**- CAS number** | |
| **- Trade name(s) used by the supplier(s)** | |
| **b. Name(s) and address(es) of supplier(s)** *(per chemical)* | **insert new rows as needed* |
| **c. Information included in the technical documentation provided by the supplier(s)**<br>*e.g., the ATD/DoC(s), as applicable* | |
| **i. Specifications** | *including purity, impurities and by-products, stability, maximum use level, conditions, and restrictions for use* |
| **ii. Reaction products to be expected** | |
| **iii. Information for compliance work yet to be undertaken in subsequent manufacturing steps** | |
| **The information may be tabulated as shown in Table 1.** | |

**TABLE 1. Substances used – per supplier above, impurities and reaction products thereof, as well as other information from supplier; information for compliance work yet to be undertaken in subsequent manufacturing steps**

| Chemical name | CAS number | Trade name | Supplier | Impurities/reaction products | Maximum use level | Instructions and restrictions | Information for subsequent compliance work |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**insert new rows as needed*

**Note:** all substances used, as well as reaction products and impurities, along with compliance work yet to be undertaken in subsequent manufacturing steps are **also to be listed in Table 2** by substance name, type (e.g. monomer, additive, production aid) and CAS number: evaluated substances in section 2a, not officially evaluated substances used, reaction products and impurities in section 2b.

| **5. Manufacturing process(es) and reaction conditions used** | |
|---|---|
| **a. Manufacturing formulae** | *including amounts of components used* |
| *1.* | |
| *2.* | |
| **b. Reaction conditions and cleaning procedure** | |
| **c. Known and/or predicted side-reactions and by-products** | *known and/or predicted side-reactions and by-products with the estimated/measured concentrations. If there are wide tolerances in the production system, e.g., in terms of temperature, the worst-case scenario should be considered.* |
| **d. Specifications of the product** | *e.g., regarding impurities* |

| **6. Potentially migrating reaction products and impurities as identified by chemical analysis in addition to the substances mentioned in 4 and 5** | |
|---|---|
| **a. Analysis in solvent extracts or food simulants** | Select: Solvent extracts ☐ or food simulants ☐ |
| **b. Short description of the applied analytical method(s)** | *Further described in detail in an annex, if referring to an in-house method, a method from the literature or a method adapted from the literature* |
| **c. Detection limits, ranges of substances assessed by the method(s)** | *for example, in terms of polarity, volatility range or molecular mass, detectability, uncertainty* |
| **d. Summarised validation data for the method(s)** | |
| **The substances should be added to Table 2 (mainly under "Not officially evaluated substances") with information about the type, e.g., reaction product or impurity.** | |

| **7. In case of possible set-off during storage of the product on reels or in stacks or gas phase transfer** | |
|---|---|
| **a. Specifications/restrictions on storage and use that avoid set-off of potential concern, if any** | |

| | |
|---|---|
| **b. If set-off or gas phase transfer cannot be ruled out, indicate it here and list potentially transferred substances in Table 2b.** | *Add substances to Table 2b with a corresponding remark under "Type".* |

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## 8. Reactions potentially occurring in the product at later stages of the manufacturing chain or during the use of the FCM, that could generate substances requiring compliance work

*such as during processing with heat, reactions with substances introduced later, heating or treatment for decontamination (e.g. irradiation or chemical decontamination) or during use (e.g. owing to exposure to air or light).*

| | |
|---|---|
| **a. If substances are covered by the compliance work performed at this stage** | *List reaction/degradation products to be expected under the intended conditions of use (specification) in **Table 2b** with a remark under "Type", such as "potentially formed at later stage".* |
| **b. If the related compliance work is yet to be undertaken in subsequent manufacturing steps** | *List the substances that may react or from which reaction products may be formed* |

324 **TABLE 2. Substances potentially migrating into food and their evaluation** [possibly referring to
325 annexes]

326 **2a. Officially evaluated substances for FCMs**

| Substance name | CAS number | Type (monomer, additive, etc.) | Evaluating body | Restriction (e.g., SML and/or conditions of use) | Maximum expected migration | Other sources for the substance[3] | Information for subsequent compliance work |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

327 **2b. Not officially evaluated substances**

| Substance name | CAS number | Type (components, reaction products, impurities, etc.) | Maximum expected migration | Reference for safety assessment | Maximum safe migration | Other sources for the substance[4] | Information for subsequent compliance work |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

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## 9. Substances officially evaluated (according to the definition in the Guiding Principles) for use in FCMs

| | |
|---|---|
| **a. Who (authority, agency, institution) evaluated the use of the substance?**<br>and/or<br>**Where is the substance officially listed?** | |
| **b. Restrictions** | *such as specific migration limits (SML), restrictions in use, maximum use levels* |

[3] *Other sources for the substance* may refer to food, food contaminants, other FCM, etc.
[4] Same comment

**Fill in Table 2a.**

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| **10. Maximum migration to be expected** | |
|---|---|
| **Source of the migration or extraction data** | *such as experimental measurement in foods or simulants, assumption of complete transfer to food or estimation by modelling* |
| **a. For experimental determination:** | *summarised description of the analytical methods applied and validation with reference to a full description in an annex or reference to a method from the literature* |
| **b. For calculated migration:** | *assumptions used and outline of calculations* |
| **c. For modelling:** | *software and parameters used* |
| **Do values refer to real applications, simulation of real conditions or calculations for a standard assumption, e.g., 6 $dm^2$/kg food?** | |
| **Maximum expected migration to be provided in Table 2a; further information in an annex.** | |

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| **11. Toxicological assessment of substances not officially evaluated for FCM applications**<br>*Data may come from:* | |
|---|---|
| **a. Official evaluation for other uses** | *(such as food additive or flavouring) or documented in the context of another evaluated substance (e.g. assessed in an EFSA opinion as a reaction product or impurity)* |
| **b. Scientific literature** | |
| **c. Experimental tests on genotoxicity** | *e.g., according to OECD test guidelines* |
| **d. Experimental tests on general toxicity** | *e.g., according to OECD test guidelines* |
| **e. Non-experimental assessment of impurities, reaction products and by-products (not acceptable for intentionally added substances)** | *threshold of toxicological concern (TTC), read across or QSAR. Provide justifications* |
| **Data for Table 2b: reference to the safety evaluation with details provided in an annex and conclusions on the maximum safe migration (such as from a NOAEL, an EFSA tier or a TTC value).** | |

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| **12. For each substance in Table 2a, check whether one of the following could be applicable:** |
|---|
| **Is it subject to a restriction in food, such as for use as a food additive or flavouring (dual-use substance)?**<br>**Select: YES ☐ or NO ☐**<br><br>**If yes, provide information about the type, restrictions, and maximum concentrations in food in Table 2a,** possibly with more detailed information in an annex. |

**Could it migrate from a part of the finished article that is added at a later manufacturing stage, such as another article (e.g., closure of a tray), a layer of a multilayer film, or printing, possibly adding up to a migration exceeding a restriction?**

**Select:** **YES ☐ or NO ☐**

**If yes, each supplier must communicate substances with restrictions and dual-use additives for their component(s)** so that the manufacturer of the final product can complete the compliance work.

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## 13. If compliance work is to be completed further downstream

*For each substance in Table 2, it should be decided whether the compliance work can be completed or what information is needed for compliance work yet to be undertaken in subsequent manufacturing steps.*

| | |
|---|---|
| **a. What compliance work is yet to be undertaken in subsequent manufacturing steps?** | |
| **b. Data and/or other information needed for compliance work yet to be undertaken in subsequent manufacturing steps or otherwise useful for the customers** | |

**Transfer this information to the ATD/DoC with a short indication in Table 2 and possible further instructions in a separate text.**

**Is the substance list complete?**

**Select:** **YES ☐ or NO ☐**

**If not, what specific analytical work is still needed?**

333 **Further aspects to be taken into consideration:**

## 14. Is the product classified as a nanomaterial or does it contain components to be classified as nanomaterials?

**Select:** **YES ☐ or NO ☐**

**If yes:**

| | |
|---|---|
| **Characteristics according to EFSA nano guidance** | |

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## 15. Is a functional barrier relevant for migration into food?

**Select:** **YES ☐ or NO ☐**

**If yes:**

| | |
|---|---|
| **a. characterisation of (the nature) of the barrier, description of the location in the FCM or article and information about the other layers** | |
| **b. criterion applied for the definition of barrier effectiveness** | |

| | |
|---|---|
| **c. methodology and results demonstrating barrier effectiveness** | |
| **d. duration of sufficient effectiveness under the intended conditions of use** | |

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| **16. Changes in the organoleptic characteristics of the food** | |
|---|---|
| **Data on sensory tests** | |

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| **17. Other provisions in the relevant EU or national legislation, official recommendations or set out in the Technical Guides, such as on overall migration** | |
|---|---|
| **List** | |

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| **18. GMP requirements**<br>*Critical control points related to the product that is the subject of this documentation and how they are addressed by the quality assurance system in place, including specifications/restrictions on storage as found in the Technical Data Sheet (TDS) of a substance. In this context, the requirements of Art. 17 of Regulation (EC) No 1935/2004 concerning traceability are important.* | |
|---|---|
| **List** | |

# 8. Annex 2 Example of a DoC