# Checklist for supporting documentation

*Please complete the form below to the best of your knowledge and as applicable for* ***each product or family of products*** *covered by the supporting documentation. Save the completed form for in-house purposes and add additional documentation and files separately as needed, naming each file clearly (include the product name or description).*

|  |
| --- |
| Identity of business operator responsible for the product |
| **Company name** | Click or tap here to enter text. |
| **Address** | Click or tap here to enter text. |
| **Country** | Click or tap here to enter text. |
| **Contact person**  | *Name and email address*Click or tap here to enter text. |

|  |
| --- |
| Product (or family of products) covered by the supporting documentation |
| 1. **Identification/trade name(s)**
 | *Including part number(s) of kitchenware, appliances, etc.*Click or tap here to enter text. |
| 1. **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*Click or tap here to enter text. |
| 1. **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*Click or tap here to enter text. |

|  |
| --- |
| Intended use*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** |
| 1. **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*Click or tap here to enter text. |
| 1. **Conditions of use**
 | *Conditions of use of the product during subsequent manufacturing steps, such as maximum temperatures or conditions for curing*Click or tap here to enter text. |
| **b. FOR FINAL FCMs** |
| 1. **Storage conditions**
 | *Such as stacking/reeling (risk of set-off), and treatments before food contact, such as decontamination by disinfection, heating or irradiation*Click or tap here to enter text. |
| 1. **Type(s) of food**
 | *Type(s) of food that may be brought safely into contact with the FCM*Click or tap here to enter text. |
| 1. **Intended use of FCM** *(select)*
 | Choose an item. |
| 1. **Maximum duration and temperature *during food processing***
 | *(if applicable)*Click or tap here to enter text. |
| **Maximum duration and temperature for storage *in contact with food*** | *(if applicable)*Click or tap here to enter text. |
| 1. **Contact surface area per amount of food for which compliance needs to be shown**
 | Click or tap here to enter text. |
| 1. **Use in contact with foods intended for infants and young children** *(select)*
 | Choose an item. |

|  |
| --- |
| Starting materials used during the manufacturing step covered by this documentation***(including any non-listed, not specifically regulated substances, such as processing aids, catalyst preparations and solvents)*** |
| 1. **Trade name(s) used by the supplier(s)**

**Name(s) and address(es) of supplier(s)** | Click or tap here to enter text. |
| Click or tap here to enter text. |
| 1. **Chemical name or description**

**Chemical Abstracts Service (CAS) Numbers and/or internationally recognised chemical identifier****Information on the source of natural materials**  | Click or tap here to enter text. |
| *(if applicable)*Click or tap here to enter text. |
| *(if applicable)*Click or tap here to enter text. |
| **c. Information included in the technical documentation provided by the supplier(s)***e.g. the DoC(s), as applicable* |
| 1. **Specifications**
 | *including purity, impurities and by-products, stability, maximum use level, conditions and restrictions for use*Click or tap here to enter text. |
| 1. **Reaction products to be expected**
 | Click or tap here to enter text. |
| 1. **Information on potentially migrating substances**
 | Click or tap here to enter text. |
| 1. **Information for compliance work yet to be undertaken in subsequent manufacturing steps**
 | Click or tap here to enter text. |
| **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 |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

*(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, processing aid) and CAS number: officially evaluated substances in Table 2a, not officially evaluated substances used, reaction products and impurities in Table 2b.

|  |
| --- |
| Manufacturing process(es) and reaction conditions used |
| 1. **Manufacturing formulae**
 | *including amounts of components used*Click or tap here to enter text. |
| 1. **Reaction conditions and**

**cleaning procedure** | Click or tap here to enter text. |
| 1. **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.*Click or tap here to enter text. |
| 1. **Specifications of the product**
 | *e.g. regarding impurities*Click or tap here to enter text. |

|  |
| --- |
| Potentially migrating reaction products and impurities as identified by chemical analysis in addition to the substances mentioned in 4 and 5 |
| 1. **Short description of the analytical method(s) applied including information on used solvents or food simulants**
 | *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*Click or tap here to enter text. |
| 1. **Detection limits, arrays of substances assessed by the method(s)**
 | *for example, in terms of polarity, volatility or molecular mass, detectability, uncertainty*Click or tap here to enter text. |
| 1. **Summarised validation data for the method(s)**
 | Click or tap here to enter text. |
| **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.** |

|  |
| --- |
| In case of possible set-off during storage of the product on reels or in stacks or gas phase transfer |
| 1. **Specifications/restrictions on storage and use that avoid set-offs of potential concern, if any**
 | Click or tap here to enter text. |
| 1. **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”*Click or tap here to enter text. |

|  |
| --- |
| Reactions potentially occurring in the product during later steps in 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, during decontamination by heating, irradiation or disinfection or during use (e.g. owing to exposure to air or light).* |
| 1. **If substances are covered by the compliance work performed during this step**
 | *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 during a later step”*Click or tap here to enter text. |
| 1. **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*Click or tap here to enter text. |

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

**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[[1]](#footnote-1) | Information for subsequent compliance work |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

*(insert new rows as needed)*

**2b. Not officially evaluated substances**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Substance name | CAS number | Type (components,reactionproducts,impurities, etc.) | Maximum expected migration | Referencefor safetyassessment | Maximum safe migration | Other sources for the substance[[2]](#footnote-2) | Information for subsequent compliance work |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

*(insert new rows as needed)*

|  |
| --- |
| Substances officially evaluated (according to the definition in the Guiding principles) for use in FCMs |
| 1. **Evaluation body of the substance (authority, agency, institution)**

and/or**Where is the substance officially listed?** | Click or tap here to enter text.Click or tap here to enter text. |
| 1. **Restrictions**
 | *such as specific migration limits (SML), restrictions for use, maximum use levels*Click or tap here to enter text. |
| **Fill in Table 2a.** |

|  |
| --- |
|  Maximum expected migration |
| **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*Click or tap here to enter text. |
| 1. **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*Click or tap here to enter text. |
| 1. **For calculated migration:**
 | *assumptions used and outline of calculations*Click or tap here to enter text. |
| 1. **For modelling:**
 | *software and parameters used*Click or tap here to enter text. |
| **Maximum expected migration to be provided in Table 2a; further information in an annex.** |

|  |
| --- |
| Toxicological assessment of substances not officially evaluated for FCM applications*Data may come from:* |
| 1. **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).* *Include a reference to the evaluation and explain why the evaluation is applicable to the use of substance in FCM*Click or tap here to enter text. |
| 1. **Scientific literature**
 | Click or tap here to enter text. |
| 1. **Genotoxicity testing**
 | *e.g. according to OECD test guidelines*Click or tap here to enter text. |
| 1. **General toxicity testing**
 | *e.g. according to OECD test guidelines*Click or tap here to enter text. |
| 1. **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*Click or tap here to enter text. |
| **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).** |

|  |
| --- |
| For substances in Table 2a, check whether one of the following applies: |
| 1. **Is it subject to a restriction in food, such as for use as a food additive or flavouring (dual-use substance)?**

**Select:** Choose an item.***If yes*, provide information about the type, restrictions and maximum concentrations in food in Table 2a,** possibly with more detailed information in an annex.  |
| 1. **Could it migrate from a part of the finished article that is added during a later manufacturing step, 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:** Choose an item.***If yes,* each supplier must communicate substances with restrictions/dual-use substances for their component(s)** so that the manufacturer of the final product can complete the compliance work. |

|  |
| --- |
| Information for subsequent compliance work*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.* |
| 1. **What compliance work is yet to be undertaken in subsequent manufacturing steps?**

Click or tap here to enter text. |
| 1. **Data and/or other information needed for compliance work yet to be undertaken in subsequent manufacturing steps or otherwise useful for the customers.**

Click or tap here to enter text. |
| **Transfer this information to the DoC with a short indication in Table 2 and possible further instructions in a separate text.** |
| **Is the substance list complete?****Select:** Choose an item.***If not,* what specific analytical work is still needed?**Click or tap here to enter text. |

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

|  |
| --- |
| Is the product classified as a nanomaterial or does it contain components to be classified as nanomaterials? **Select:** Choose an item.***If yes:*** |
| **Characteristics according to** [**EFSA nano guidance**](https://www.efsa.europa.eu/en/efsajournal/pub/6768)  | Click or tap here to enter text. |

|  |
| --- |
| Use of a functional barrier**Select:** Choose an item. **If yes:** |
| 1. **characterisation of (the nature) of the barrier, description of the location in the FCM or article and information about the other layers**
 | Click or tap here to enter text. |
| 1. **criterion applied for the definition of barrier effectiveness**
 | Click or tap here to enter text. |
| 1. **methodology and results demonstrating barrier effectiveness**
 | Click or tap here to enter text. |
| 1. **duration of sufficient effectiveness under the intended conditions of use**
 | Click or tap here to enter text. |

|  |
| --- |
| Changes in the organoleptic characteristics of the food |
| **Data on sensory tests** | Click or tap here to enter text. |

|  |
| --- |
| Other provisions in the relevant EU or national legislation or official recommendations or set out in the technical guides, such as on overall migration |
| **List** | Click or tap here to enter text. |

|  |
| --- |
| 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. In this context, the requirements of Art. 17 of Regulation (EC) No 1935/2004 concerning traceability are important.* |
| **List** | Click or tap here to enter text. |

# THIS SECTION FOR ADDITIONAL INFORMATION

(or supply separate files as needed)

1. *Other sources for the substance* may refer to food, food contaminants, other FCM, etc. [↑](#footnote-ref-1)
2. Same comment [↑](#footnote-ref-2)