

As at: 16<sup>th</sup> December 2019

## RULES OF PROCEDURE

# Rules of procedure of the German Environment Agency for the management of the positive list of starting substances for organic materials in contact with drinking water

English translation, only the German document version is legally binding

## General

The German Environment Agency (UBA) has published the evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL)<sup>1</sup>, various guidelines and the silicone transition recommendation for the hygienic assessment of different organic materials in contact with drinking water. The requirements of the evaluation criteria, including the positive lists contained therein, are binding from 21 March 2021. The evaluation criteria contain the positive lists for plastics, coatings and lubricants in the polymer-specific section. The elastomer guideline<sup>2</sup> and the silicone transition regulation<sup>3</sup> list the accepted substances for the production of the various types of materials in question (elastomers, silicones).

Inclusion of substances in the positive lists presupposes either submission of an application to UBA (case A) or assessment by the competent authority of another Member State of the EU according to the specifications of the 4MS Initiative<sup>4</sup> and the forwarding of this assessment to UBA by the responsible unit in other Member State (case B).

In both cases, UBA takes the decision on the inclusion of a substance in a positive list of evaluation criteria.

<sup>1</sup> <https://www.umweltbundesamt.de/en/document/evaluation-criteria-document-for-plastics-other>

<sup>2</sup> <https://www.umweltbundesamt.de/en/document/guideline-for-hygienic-assessment-of-elastomers-in>

<sup>3</sup> <https://www.umweltbundesamt.de/en/document/transitional-recommendation-for-preliminary>

<sup>4</sup> <https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative>

German Environment Agency  
Section II 3.4  
Heinrich-Heine-Str. 12  
08645 Bad Elster  
Germany

[www.umweltbundesamt.de](http://www.umweltbundesamt.de)

The assessment relates to the type of material for which the substance may be included in a positive list and the restrictions to be applied.

## **Case A: Submission of an application to the German Environment Agency for assessment**

### **A 1 Application**

For the inclusion of a substance in a positive list for organic materials, an application must be submitted to

German Environment Agency  
Section II 3.4  
Distribution of Drinking Water  
Heinrich-Heine-Straße 12  
D-08645 Bad Elster  
Germany

Applications may be submitted by the manufacturer of the substance, those companies that want to use the substance for the production of organic materials in contact with drinking water or that manufacture products from such materials, and federations and associations of industrial companies.

The complete application dossier must be available for the UBA by 1st September or 1st April of the year in question so that they may be discussed by the appropriate committees. Confidential data contained in the application must be marked as such and the reasons for their confidentiality must be stated.

The application dossier must include:

- A completed application form for the inclusion of a starting substance in a positive list of the evaluation criteria for organic materials in accordance with section 17 TrinkwV (**Annex 1 to the Rules of Procedure**),
- A version of the completed supplementary application form corresponding to the application type (I, II or III) (see A.1.1), including all annexes, in hard copy form, and an electronic version, for example, on a CD/USB stick in a searchable format as a Word or PDF document (**Annex 2, 3 or 4 to the Rules of Procedure**),
- Safety data sheet for the requested starting material,
- A version of the completed supplementary application form (see A1.1), including all annexes, without the confidential data, in hard copy and electronic format, for example, on a CD/USB stick in a searchable format as a Word or PDF document. In the event of a positive assessment of the application, the non-confidential application documents will be forwarded along with the opinion of UBA to the competent authorities of the other Member States (see A 2.4). In the event of requests under the Environmental Information or Freedom of Information Acts, the data will be forwarded in this form.
- For forwarding to the Federal Institute for Risk Assessment (BfR):

- Completed application form for inclusion of a starting material present in a positive list of the evaluation criteria for organic materials according to § 17 of the Drinking Water Ordinance (TrinkwV) (**Annex 1 of the Rules of Procedure**),
- A version of the completed supplementary application form, including all annexes, in hard copy and electronic format, for example, on a CD/USB stick in a searchable format as a Word or PDF document (**Annex 2 of the Rules of Procedure**),
- Safety data sheet for the requested starting material

## **A 2 Application for the inclusion of a new substance**

There are three different types of application for the inclusion of a substance in a positive list of starting substances, which differ in respect of the availability of toxicological studies or assessment:

- I      There is no assessment of the substance by any authority or international organisation publicly available.
- II     EFSA/SCF<sup>5</sup> assesses the substance for the manufacture of plastics intended to come into contact with food.
- III    There is a publicly accessible assessment of the substance by another authority or international organisation e.g. WHO, ECHA, EFSA.

### **I Application for the inclusion of a not fully evaluated substance**

With its application documents the applicant must submit information concerning the nature and amount of the passage of substances relevant to the application (the substance to which the application refers including its impurities and any resulting reaction and degradation products) from the organic material into drinking water under the least favourable envisaged conditions of use and submit the required toxicological studies.

The supplementary application form (**Annex 2 to the Rules of Procedure**) contains the following chapters which are based on the EFSA questionnaire:

1. Identification of the substance,
2. Physical and chemical properties of the substance,
3. Intended use of the substance,
4. Authorisation of the substance in other countries,
5. Data on the migration of the substance (including impurities and resulting degradation and reaction products),
6. Data on the residual content of the substance (including impurities and resulting degradation and reaction products) in the material which comes into contact with drinking water,
7. Microbial properties of the substance (if relevant) and
8. Toxicological studies<sup>6</sup>.

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<sup>5</sup> European Food Safety Authority/ Scientific committee on food

<sup>6</sup> The requirements on the scope of the toxicological data to be provided vary according to the level of migration of the substance to which the application refers according to DIN EN 12873-1/2 and the specifications in the evaluation criteria. For concentrations of up to 2.5 µg/l in the migration tests it must be demonstrated that the

The documents/test reports required for the evaluation must be included as original studies as annexes to the completed application form.

Moreover, a safety data sheet for the substance to which the application refers must be enclosed with the application documents.

## **II Application for the inclusion of a substance which has already been assessed by EFSA**

For the inclusion of a substance which has already been assessed by EFSA/SCF and is listed in the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, a simplified substance application is sufficient.

The pre-condition for a simplified application is that the technological function and the reaction and degradation products and their migration potential correspond to those of the existing assessment. If this is not the case, a full application must be submitted pursuant to I or III. Based on the restrictions which EFSA has set for a substance, a restriction specific to drinking water is derived, assuming a daily in-take of two litres of drinking water, a body weight of 60 kilograms and a contribution of exposure via drinking water of 10 percent of total exposure. (4MS Common Approach).

This results in the determination of the migration limit for materials in contact with drinking water according to 1 kg /20 l\* SML.

For substances with QMA limits that are stable and identifiable in the test water, a migration limit is derived (assuming 1 kg of food is packed in a cube with a surface area of 6 dm<sup>2</sup> and the factor of 1 kg /20 l).

The supplementary application form (Annex 3 to the Rules of Procedure) contains the following chapters which are based on the EFSA questionnaire:

1. Identification of the substance,
2. Physical and chemical properties of the substance,
3. Intended use of the substance and
4. Authorisation of the substance in other countries

The following documents are additionally to be included with the application:

- A safety data sheet for the substance to which the application refers,
- Published scientific opinion on the assessment of this substance by EFSA/SCF,
- Declaration of conformity of the function of the substance with that listed in the EFSA/SCF evaluation.

## **III Application for the inclusion of a substance which has already been assessed by other authorities/international organisations**

For the inclusion of a substance which has already been toxicologically assessed by other authorities or international organisation, an abridged application (excluding toxicological studies) is sufficient.

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substance is not mutagenic (OECD mutagenicity tests Nos. 471 and 487). For the concentration range from 2.5 µg/l to 250 µg/l, a 90-day oral feeding study (OECD No. 408) and bioaccumulation data are additionally required. If the level of migration exceeds 250 µg/l, the full toxicological data set, as described in “Note for Guidance”, is required. In addition, all available toxicological data are to be presented.

An abridged substance application presupposes that the toxicological data of the existing assessment cover exposure through migration (see I). If this is not the case, further toxicological studies must be presented and thereby a full application submitted pursuant to I.

The supplementary application form (Annex 4 to the Rules of Procedure) contains the following chapters which are based on the EFSA questionnaire:

1. Identification of the substance,
2. Physical and chemical properties of the substance,
3. Intended use of the substance,
4. Authorisation of the substance in other countries,
5. Data on the migration of the substance (including contamination and resulting degradation and reaction products),
6. Data on the residual content of the substance (including contamination and resulting degradation and reaction products) in the material which comes into contact with drinking water and
7. Microbial properties of the substance (if relevant).

The following documents are additionally to be included with the application:

- A safety data sheet for the substance to which the application refers,
- Published toxicological assessment of the authority/international organisation.

## **A 3 Application processing**

### **A.3.1 Review of the documentation for completeness**

UBA will review the documents for completeness within three months of receipt of the application. Should the documents be incomplete, the applicant will be informed and asked to submit the missing documents.

### **A.3.2 Assessment procedure for the inclusion of substances in a positive list**

The criteria for the inclusion of starting substances for organic materials in a positive list are defined in the evaluation criteria. The assessment of the substances follows the procedure applied by the EFSA to evaluate starting substances used in the manufacture of food contact materials.

This approach for the inclusion of substances in a positive list was adopted from the document entitled “4MS Common Approach: Positive Lists for Organic Materials” agreed between Germany, France, the Netherlands and the United Kingdom.

### **A.3.3 Involvement of professional bodies**

UBA assesses a substance not previously assessed (I) with the support of the Federal Institute for Risk Assessment (BfR). The BfR gives its opinion on the application. By submitting the application, the applicant gives permission that the application dossier is made available to the BfR. The BfR is obligated to treat the documents as confidential.

Substances evaluated according to II and III are assessed by UBA only. However, UBA can involve BfR.

### **A.3.4 Decision-making process for inclusion**

Not later than three months after the BfR has given its opinion (I) or, in the case of applications according to II and III, three months after receipt of the application, UBA draws up an assessment and notifies the applicant of it in writing.

In the event of a positive assessment, UBA will forward its opinion along with the non-confidential application documents to the authorities of the other EU Member States cooperating within the framework of the 4MS Initiative. By submitting the application, the applicant gives permission that the non-confidential application documents may be forwarded to the competent offices of the other Member States. The other Member States have six months to raise objections. UBA decides on the inclusion and updates the corresponding positive list.

At the same time as the opinion is sent, the applicant is notified of the provisional decision for the potential inclusion of the substance in the relevant positive list pending approval by the other Member States.

## **A 4 Fees**

The German Drinking Water Fee Ordinance (Trinkwasser-Gebührenverordnung, TrinkwGebV) came into force on 17 December 2013. Since that date the German Environment Agency levies fees for services individually attributable according to the German Drinking Water Ordinance (TrinkwV).

According to the Annex to § 1 of the German Drinking Water Fee Ordinance (TrinkwGebV), the inclusion of starting substances or raw and other materials in a positive list is a chargeable event pursuant to § 17(3)(2)(2) or (3) of the German Drinking Water Ordinance (TrinkwV) on application pursuant to § 17(4)(2). Applications that lead to the inclusion of the substance or material in one of the positive lists are therefore chargeable. The binding evaluation criteria for plastics and other organic materials in contact with drinking water together with the positive lists of starting substances was published on 21 March 2019. These will gradually replace the previous guidelines and recommendations for materials in contact with drinking water. All applications received after the publication of the evaluation criteria will be chargeable. All applications submitted before the publication of the evaluation criteria will likewise be chargeable if they lead to the inclusion of the substance in the positive list.

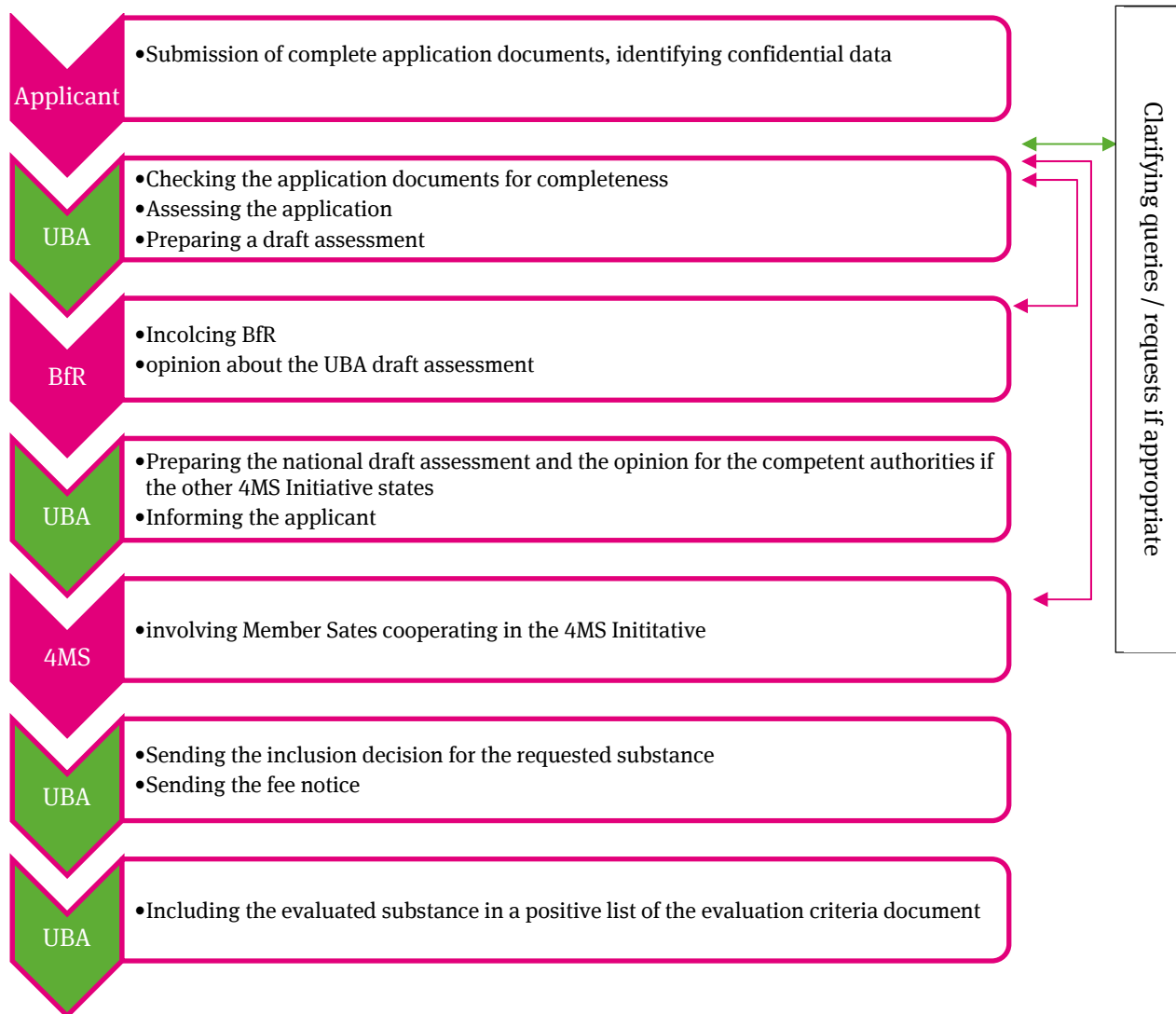
## **Case B: Assessment of a substance by another EU Member State**

If a competent authority of another Member State of the EU has carried out an assessment of a substance in accordance with the specifications of the 4MS Initiative for the evaluation of starting substances for organic materials in drinking water and said competent body forwards its judgement to UBA, UBA will decide on the inclusion of the substance in the positive list. In this case, too, it can seek the professional opinion of the BfR.

If UBA does not agree with an evaluation carried out by a competent authority of another EU Member, it will inform said competent authority thereof.

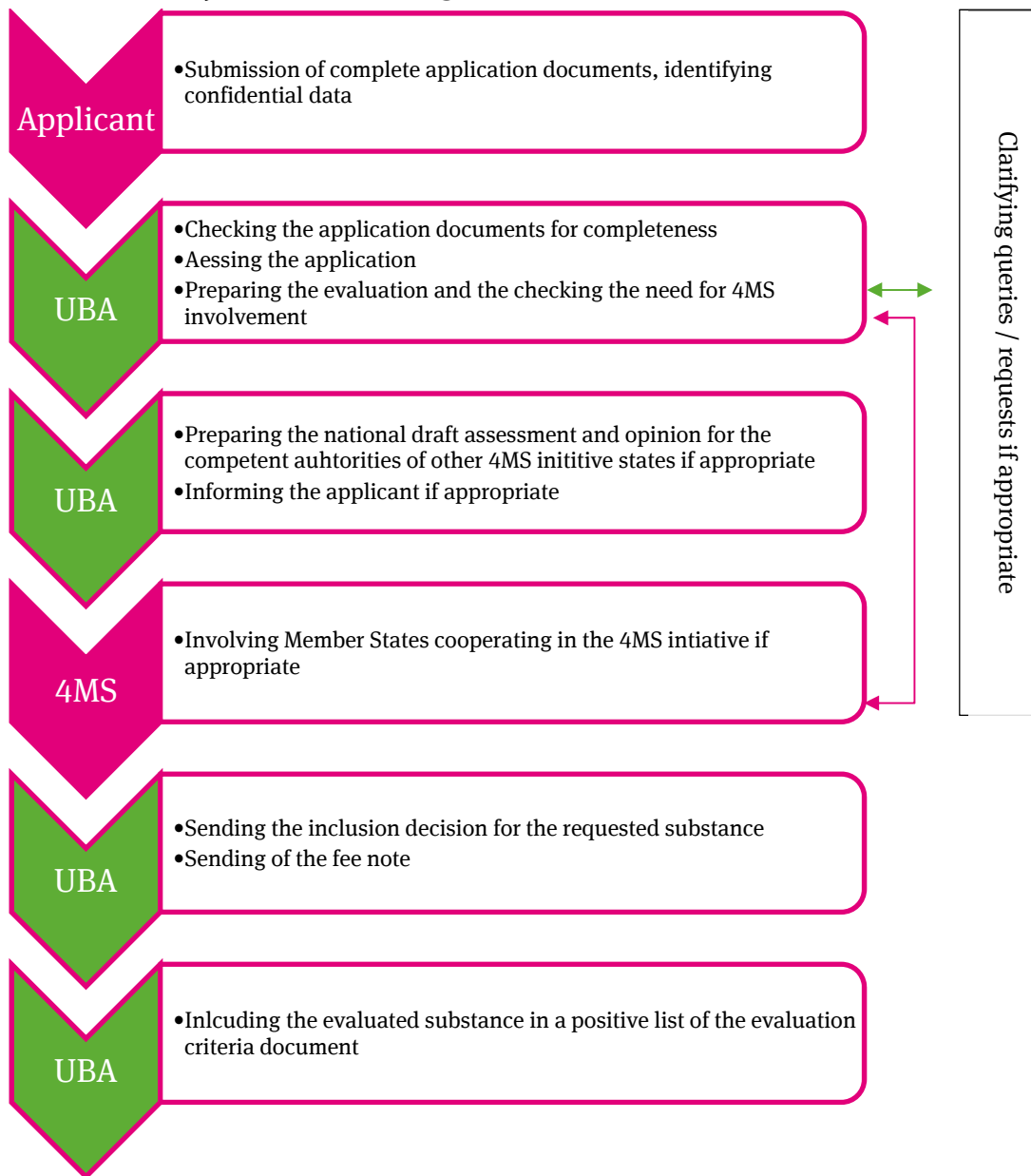
# Addendum 1: Scheme for the application procedure – Case A procedure

## I Application for inclusion of a substance not fully evaluated



**II Application to include a substance already evaluated by EFSA**

**III Application to include a substance already evaluated by another authority/international organisation**





## Addendum 2: Assessment of a substance by another EU Member State

