TECHNICAL REPORT

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Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials

European Food Safety Authority

Abstract

This document provides guidance to applicants submitting applications for authorisation of substances to be used in plastic food contact materials within the scope of Regulation (EC) No 1935/2004 and according to Commission Regulation (EU) No 10/2011, as amended.

This guidance describes the procedures in place in the European Union for handling applications, from submission of an application to the adoption and publication of the EFSA scientific opinion. It provides instructions on how to prepare a dossier for the safety evaluation by EFSA and is supplemented with three appendices downloadable from the EFSA website. The format provided in the appendixes shall be followed by applicants to present data required for the application. The information contained in this guidance is valid for all applications submitted under Articles 9 and 12 of Regulation (EC) No 1935/2004.

The document ultimately presents the different possibilities to interact with EFSA staff and the support initiatives available during the different stages of the application life-cycle.

Key words: Application, submission, food contact materials, plastic, Regulation (EC) No 1935/2004, Commission Regulation (EU) No 10/2011

Requestor: European Food Safety Authority

Question number: EFSA-Q-2016-00687

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Summary

This document provides guidance to applicants submitting applications for the authorisation of substances to be used in plastic materials and articles intended to come into contact with food in the European Union within the scope of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, and according to Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as amended.

This guidance document supersedes Chapter 0 – 'General introduction' and Chapter 1 – 'EFSA Administrative Guidance' of the former 'Guidance document on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA', published by EFSA in 2008, also referred to as 2008 'Note for Guidance for Food Contact Materials'.

The present guidance document consists of three main chapters and three Appendices:

- Chapter 1 provides the Background and Terms of Reference for the publication of this guidance document.
- Chapter 2 describes the procedure, the associated timelines and the documentation to be provided for the evaluation of an application submitted for the authorisation of a substance intended to be used in plastic materials and articles in contact with food (hereinafter referred to as "plastic FCM substances") or for the modification of an existing authorisation of a substance.
- Chapter 3 provides information on the different possibilities to interact with EFSA staff during the life-cycle of the application, from the reception of the application to the adoption and publication of the EFSA Scientific Opinion.
- Appendices from A to C provide the format to be used by applicants when submitting an application for plastic FCM substances. Appendix A shall be used for the submission of the administrative information; Appendix B shall be used by applicants to submit the information to support a request for authorisation of a substance or a request for the modification of an existing authorisation, in accordance with the scientific/technical requirements described in the updated EFSA 'Note for Guidance for Food Contact Materials'; Appendix C requests applicants to clearly indicate the information to be treated as confidential, in accordance with Article 20(1) of Regulation (EC) No 1935/2004.

Like all EFSA guidance documents, this administrative guidance will be updated, if needed, in accordance with relevant changes of the legislation and/or guidance documents.

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1. Introduction

1.1. Background and Terms of Reference as provided by EFSA

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 constitutes the legal basis for the authorisation and use of Food Contact Materials (FCM) in the European Union (EU). It lays down specific measures as regards the presentation of applications and the type of information that should be included in the opinion of the European Food Safety Authority (EFSA). The elements addressing specifically the evaluation of plastic materials and articles intended to come into contact with food are enforced in Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

According to Article 9(2) of Regulation (EC) No 1935/2004, EFSA shall publish detailed guidelines concerning the preparation and the submission of applications for Food Contact Materials. In 2008, EFSA published a first guidance document on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA, also known as 'Note for Guidance for Food Contact Materials'. This 2008 'Note for Guidance for Food Contact Materials' has been revised and updated taking into consideration the latest experience acquired by EFSA in the handling and assessment of applications for Food Contact Materials. This update led to the content of the 2008 'Note for Guidance for Food Contact Materials' being taken over by 3 separate guidance documents:

- The present EFSA 'Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials', which supersedes Chapter 0 – 'General introduction' and Chapter 1 – 'EFSA Administrative Guidance' of the 2008 'Note for Guidance for Food Contact Materials' and provides updated guidelines to applicants to prepare their applications;
- The '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, 2017), containing the scientific requirements to be considered when preparing an application for evaluation by EFSA;
- The 'Technical guidelines for compliance testing of plastic food contact materials in the framework of Regulation (EU) No 10/2011', which will soon be issued by the European Commission Joint Research Centre and published on the European Commission's website. Once published, this guidance will replace the chapter 'Commission Explanatory Guidance on Migration Testing' of the 2008 'Note for Guidance for Food Contact Materials'.

1.2. Interpretation of the Terms of Reference

Since 2013, EFSA has been implementing a project to develop a customer-oriented approach for regulated products[1] aiming at supporting applicants and other stakeholders during the whole life-cycle of the applications for regulated products. In this context, EFSA developed a new 'Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials', in order to replace the administrative information included in the 2008 'Note for Guidance for Food Contact Materials' with updated and detailed information as regards the procedure for submitting an application, the format of the dossier and the handling of the application by EFSA. It aims at improving the understanding of the requirements for applications and the services in place in EFSA during the life-cycle of the applications from submission to adoption and publication of the scientific opinion.

This EFSA Administrative Guidance applies to applications for authorisation of substances 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 and Commission Regulation (EU) No 10/2011. This Guidance is to be

[1] EFSA REPRO Customer oriented approach mandate: http://registerofquestions.efsa.europa.eu/roqFrontend/mandateLoader?mandate=M-2014-0106

read in conjunction with the abovementioned Regulations. In case of discrepancy between the content of this document and a provision of an applicable legal act, the latter prevails.

For the purpose of this guidance, an "applicant" shall mean any legal or natural person (e.g. individuals, food business operators, industry associations, consultancy companies, etc.), no matter whether situated within or outside the EU, which has submitted an application.

EFSA will update this document, if needed, in line with relevant changes of the legislation and/or guidance documents and according to the experience gained in the handling and assessment of applications on plastic FCM substances. Therefore, applicants are advised to always consult the latest published version of this document available on the EFSA website.

2. Guidance

Procedure for handling applications on substances to be used in plastic materials and articles intended to come into contact with food

The various steps and estimated timelines of the procedure for handling applications for authorisation of plastic FCM substances are presented in Figure 1. The workflow starts from the submission of an application to the national Competent Authority of a Member State, followed by its reception and assessment by EFSA, until the adoption of the scientific opinion by the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF).

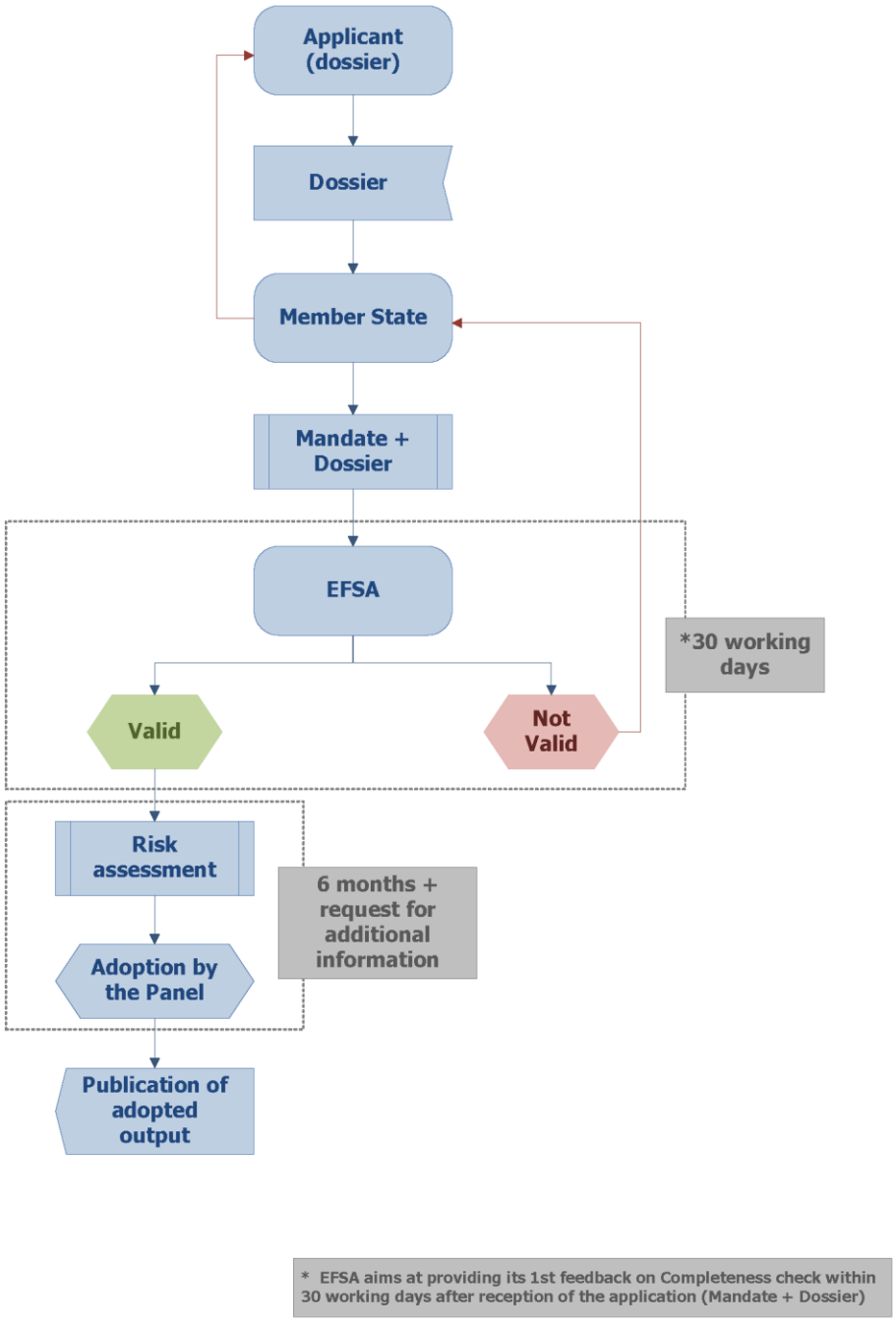

Figure 1 - Applications procedure for Food Contact Materials submitted under Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011

Overview of the main steps related to the preparation of an application for plastic FCM substances

Before preparing an application for the authorisation of a plastic FCM substance, applicants are strongly advised to check the actions listed below concerning the preliminary steps to be considered in order to correctly submit an application.

- ✓ Consult the FCM section on the EC website for information on the regulatory framework and the authorisation process for plastic FCM substances: http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en
- ✓ In case of doubt on the need to submit an application for authorisation, seek confirmation from the European Commission: SANTE-fcm@ec.europa.eu
- ✓ If an application on a plastic FCM substance has to be submitted, consult the FCM section on the EFSA website to access information on the evaluation process: http://www.efsa.europa.eu/en/applications/foodcontactmaterials
- ✓ Consult the EFSA administrative and scientific guidance documents on plastic FCM substances for information on how to prepare an application: http://www.efsa.europa.eu/en/applications/foodcontactmaterials/regulationsandguidance
- ✓ In case of doubt on the requirements described in the EFSA guidance documents, ask clarification to EFSA using the APDESK webform: https://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion
- ✓ Prepare the application
- ✓ Consult the 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products' for an overview of the support initiatives provided by EFSA to applicants: http://www.efsa.europa.eu/en/supporting/pub/1025e

Specific indications on how to prepare and submit the application are provided in the following sections of the guidance (see in particular Sections 2.1-2.2, 2.4).

2.1. Submission of an application for the inclusion of a new substance in the Union list of authorised substances

Any person seeking an authorisation for a plastic FCM substance, according to Article 9 of Regulation (EC) No 1935/2004, shall submit an application to the Competent Authority of a Member State, which will make the application available to EFSA. From reception of an application, EFSA will issue an acknowledgement of receipt letter to the Member State, with the applicant in copy of the correspondence. At that moment, the application is registered in the EFSA Register of Questions[2] and receives a unique identification number (e.g. EFSA-Q-YYYY-XXXX referred to as "EFSA Question number"). The status of the application is regularly updated in the Register of Questions database and can be monitored by the applicant.

Documentation

When submitting an application, the following documents and particulars shall be provided to the corresponding institutions:

1. Member State's Competent Authority[3]
   - **Administrative part**, containing all the administrative information related to the application:
     - Applicant's contact details;
     - Subject of the request.

     The above data should be submitted using the format provided in **Appendix A1**[4] **– Administrative information**.
   - **Technical dossier**, compiled within the legal framework of Regulation (EC) No 1935/2004 and Regulation (EC) No 10/2011. When preparing the technical dossier, applicants should follow the scientific requirements described in the EFSA 'Note for Guidance for Food Contact Materials' and submit the information using the format provided in **Appendix B**[5] **– Technical dossier** as a WORD document. Detailed reports of all studies performed in support of the application, e.g. full documentation of experiments, full description of analytical methods, raw data and bibliographic references should be provided in separate **technical annexes** (one pdf document for each annex is requested).
   - **Justification for confidential information**, according to Article 20(1) of Regulation (EC) No 1935/2004 and consisting in a statement justifying why the confidential information included in the dossier might significantly harm applicant's competitive position. Applicants are strongly recommended to submit the justification using the format provided in **Appendix C – Justification for confidential information**.

   In line with Article 9(1) of the Regulation (EC) No 1935/2004, EFSA will receive the above documentation directly from the Member State. Applicants shall not submit their applications directly to EFSA.

[2] EFSA Register of questions database: http://registerofquestions.efsa.europa.eu/roqFrontend

[3] The complete list of EU national competent Authorities is available at the following link: http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

[4] Appendix A1 supersedes the former Model Letter n°1 of the 2008 'Note for Guidance for Food Contact Materials'.

[5] Appendix B supersedes the former Appendix 6 'Model for a Petitioner Summary Data Sheet (P-SDS)' of the 2008 'Note for Guidance for Food Contact Materials'.

2. European Reference Laboratory (EURL-FCM)

- A physical **sample** of the substance (250 g);
- the **relevant product safety sheet** and **spectroscopic data;**
- the **analytical method(s) including performance parameters** as described in section 5.1.8, 5.3.7, and 6.5 of the EFSA 'Note for Guidance for Food Contact Materials';
- **Appendix A1**, containing the administrative information of the applicant.

The above-listed documents and particulars accompanying the sample shall be supplied in electronic format to the following address:

European Commission
Directorate General Joint Research Centre
Directorate F - Health, Consumers and Reference Materials
Unit Food and Feed Compliance

Food contact materials group
TP 260
Via E. Fermi 2749
I-21027 Ispra (VA)
Italy

The samples provided in the context of submission of applications for the evaluation of substances to be used in Food Contact Materials are collected in the 'Reference collection for monomers and additives' hosted by the EURL-FCM. Further information is available on the EURL-FCM website[6].

[6] European Reference Laboratory for Food Contact Materials
https://ec.europa.eu/jrc/en/eurl/food-contact-materials

2.2. Submission of an application for the modification of the existing authorisation of a substance

In accordance with Article 12 of Regulation (EC) No 1935/2004, the applicant or any business operator using an authorised substance may apply for modification of the existing authorisation[7], by submitting a request to the Competent Authority of a Member State accompanied by the relevant data supporting the request for the changes.

The technical dossier for the modification of an existing authorisation should be a **stand-alone dossier,** prepared following the most up-to-date requirements. Therefore applicants are strongly advised to check the latest version of the current EFSA Administrative guidance and of the EFSA 'Note for Guidance for Food Contact Materials', published on the EFSA website. The technical dossier should contain the complete information. In addition, the new data submitted to support the request for modification should be clearly highlighted in the text.

If the application is submitted by a business operator different from the applicant who submitted the original application, Article 21 of Regulation (EC) No 1935/2004 on sharing of existing data applies. The new applicant should enquire with the Commission and the European professional organisations about an agreement on data sharing with the original applicant. If an agreement is reached, the new applicant should include the written agreement signed by a legal representative of all involved parties in the application for modification of the existing authorisation and submit a technical dossier with the complete information, with the new data clearly highlighted in the dossier. If the original and the new applicant have not agreed on data sharing, the new applicant has to submit a new application according to Article 9 of Regulation (EC) No 1935/2004, including all data (see also point 1.(iv) below).

In any case the applicant should indicate the reason for requesting the modification in the administrative part of the dossier as described hereafter. Background information and detail on the request for modification should be included in the technical dossier.

Documentation

The following documents and particulars shall be provided to the corresponding institutions:

1. Member State's Competent Authority[8]
   - **Administrative part**, containing all the administrative information related to the application:
     - Applicant's contact details;
     - Subject of the request.

     The above data should be submitted using the format provided in **Appendix A2**[9] **– Administrative information**.
   - **Technical dossier**, compiled within the legal framework of Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011. When preparing the technical dossier, applicants should follow the scientific requirements described in EFSA 'Note for Guidance for Food Contact Materials' and submit the information using the format provided in **Appendix B**[10] **– Technical dossier** as a WORD document. Detailed reports of all studies performed in support of the application (i.e. both studies submitted in the context

[7] This is without prejudice to other cases of suspension or revocation of authorisation as also referred to in Article 12 of Regulation (EC) No 1935/2004.

[8] The complete list of EU national competent Authorities is available at the following link: http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

[9] Appendix A2 supersedes the former Model Letter n°2 of the 2008 'Note for Guidance for Food Contact Materials'.

[10] Appendix B supersedes the former Appendix 6 'Model for a Petitioner Summary Data Sheet (P-SDS)' of the 2008 'Note for Guidance for Food Contact Materials'.

of the original application and new studies developed for the request of modification), e.g. full reports of experiments, full description of analytical methods, raw data and bibliographic references should be provided in separate technical annexes (one pdf document for each annex). The new data submitted to support the request for modification should be clearly highlighted in the text.

- **Justification for confidential information**, according to Article 20(1) of Regulation (EC) No 1935/2004 and consisting in a statement justifying why the confidential information included in the dossier might significantly harm applicant's competitive position. **Appendix C – Justification for confidential information**.
- When applicable, a written **agreement on data sharing** signed by a legal representative of all involved parties (see above).

2. European Reference Laboratory (EURL-FCM)

If not provided before:

- A physical **sample** of the substance (250 g);
- the **relevant product safety sheet** and **spectroscopic data**;
- the **analytical method(s) including performance parameters** as described in section 5.1.8, 5.3.7, and 6.5 of the EFSA 'Note for Guidance for Food Contact Materials';
- **Appendix A2**, containing the administrative information of the applicant.

The above-listed documents and particulars accompanying the sample shall be supplied in electronic format to the following address:

European Commission
Directorate General Joint Research Centre
Directorate F - Health, Consumers and Reference Materials
Unit Food and Feed Compliance

Food contact materials group
TP 260
Via E. Fermi 2749
I-21027 Ispra (VA)
Italy

The samples provided in the context of submission of applications for the evaluation of substances to be used in Food Contact Materials are collected in the 'Reference collection for monomers and additives' hosted by the EURL-FCM. Further information is available on the EURL-FCM website[11].

[11] European Reference Laboratory for Food Contact Materials
https://ec.europa.eu/jrc/en/eurl/food-contact-materials

2.3. Submission of new information affecting the safety assessment of an authorised substance

In accordance with Article 11(5) of Regulation (EC) No 1935/2004, the applicant or any business operator using the authorised substance or materials and articles containing the authorised substance shall immediately inform the European Commission of any **new scientific or technical information which might affect the safety assessment of the substance in relation to human health**.

In this case, the provisions of Articles 9 and 12 of Regulation (EC) No 1935/2004 do not apply. Therefore, the new available data which might have an impact on the safety of the substance should be submitted **to the European Commission**, directly or via its relative Member State.

If requested by risk managers, EFSA will then review the assessment of the substance.

2.4. Withdrawal of an application

Should an applicant wish to withdraw its application during the completeness check or risk assessment phase, he should inform in writing the Competent Authority of the Member State to which the application was submitted, notifying also the European Commission and EFSA.

Once the official withdrawal letter from the Competent Authority of the Member State is received by EFSA, it will be made publicly available on the EFSA Register of Questions[12].

[12] EFSA Register of questions database: http://registerofquestions.efsa.europa.eu/roqFrontend

2.5. Preparation of the dossier

2.5.1. Submission format

The above listed documentation should be submitted **electronically** using standard physical mediums (i.e. CD-ROMs, USB keys). It should be accompanied by the original of a signed cover letter listing the annexes of the application.

1 CD ROM shall be provided with the **complete and full information**. This copy shall therefore include:

- Administrative part (Appendix A);
- Technical dossier (Appendix B) with **confidential information highlighted**, in accordance with Article 20(2) of Regulation (EC) No 1935/2004. In case of applications for modification of an existing authorisation, new data shall be clearly highlighted in the text;
- All technical annexes, as separate pdf documents (one pdf document for each annex);
- Justification for confidential information (Appendix C);
- When applicable, the agreement on data sharing (see chapter 2.2).

1 CD ROM **without confidential information** should also be provided. This copy shall therefore ONLY include:

- Administrative part (Appendix A);
- Technical dossier (Appendix B), **without confidential information** or with **confidential information blanked out**;
- Non-confidential technical annexes;
- When applicable and if it is not requested to be considered as confidential, the agreement on data sharing (see chapter 2.2).

2.5.2. Language

In order to facilitate the evaluation of the applications, scientific and technical documentation should be submitted in English. EFSA may ask the applicant to translate the parts of the dossier that would not be submitted in English.

2.5.3. File format, size and name

The Appendix B - Technical dossier shall be submitted to EFSA **in Word format**. The technical annexes included in the technical dossier and all references cited in the technical dossier should be provided preferably as portable document format (PDF). The electronic files should not be password-protected. Each PDF document should be accessible to allow reading, printing, word searching and copying of text from the file using Adobe Acrobat® Standard (version 7.0 or later) software. Text and figures of all parts of the application should be fully legible.

The size of single documents should be limited to 30 MB.

When no standard name is recommended, the file name should be concise and informative of its content and contain no more than 40 characters including spaces.

File and folder names should not include special characters, such as: \ / : * ? \" < > | #.

2.5.4. Standard Units and abbreviations

The International System of Units (SI)[13] must be used. For the naming of chemical compounds, and for chemical quantities, units and symbols, the applicants should follow the International Union of Pure and Applied Chemistry (IUPAC) nomenclature[14].

Explanation for acronyms and abbreviations should be provided in the text when they are used for the first time.

2.5.5. Bibliographical references

The applicant should include in the relevant section of the technical dossier references to all published and unpublished studies. These references should be provided as full text in separate pdf documents and listed under Section 9 of Appendix B - Technical dossier.

EFSA recommends using the following format to cite each published reference within Section 9 of the Appendix B - Technical dossier:

- Authors [add names in the format: Surname followed by Initial(s), Surname followed by Initial(s) and Surname followed by Initial(s)], Year of publication. Title. Periodical Title, Volume(Issue), pp-pp.

See for example:

Alderman G and Stranks MH, 1967. The iodine content of bulk herd milk in summer in relation to estimated dietary iodine intake of cows. Journal of the Science of Food and Agriculture, 18(4), 151–153.

2.6. Completeness check of data for risk assessment and validation of the application

At reception, an application for a plastic FCM substance is given an identification code. This code should be included in all further correspondence with EFSA and the European Commission. After reception, the Applications Desk Unit (APDESK) checks the completeness of the application (Figure 1) and validates it when it fulfils the legal requirements outlined in Regulation (EC) No 1935/2004 and the scientific requirements detailed in the EFSA 'Note for Guidance for Food Contact Materials'. EFSA endeavours to have the first outcome of the completeness check available within 30 working days after the reception date.

The completeness check process might require further exchange of information between the applicant and EFSA. In such case, EFSA informs the applicant, in writing, if certain parts of the application need modification or completion, in order to proceed to validation. After receiving a request for additional information, the applicant should submit the response within 30 days. When this is not possible, the applicant should indicate to EFSA the date by which the response is expected. EFSA will notify the acceptance of the new submission date via e-mail. When responding to EFSA questions, the applicant should submit an updated version of the entire application on 2 CD-ROMs\DVD-ROMs, one with the full information and one containing only the non-confidential version of the application. EFSA advises to accompany the submission of an updated application with a cover letter wherein the applicant precisely describes how each EFSA question was addressed. Missing information should be incorporated in all relevant parts of the application.

[13] http://www.bipm.org/utils/common/pdf/si_brochure_8_en.pdf
[14] http://www.iupac.org/

Should the consolidated version of the dossier include pieces of information that are requested to be considered as confidential, the Appendix C – Justification for confidential information should be updated accordingly.

EFSA endeavours to inform the applicant within 15 working days if the updated application is complete or if further revision is required.

A list of some of the information that will be checked by EFSA to verify whether the application can be considered valid to start the risk assessment is provided below in the form of a self-assessment questionnaire for applicants. The aim of this questionnaire is to guide applicants when preparing an application by listing the main criteria that will be checked by APDESK during the completeness check of the application. Applicants are strongly encouraged to verify that the below listed requirements are fulfilled before submitting their applications.

Scientific information:		
Has the substance to be evaluated and tested been adequately characterised according to the requirements of the EFSA 'Note for Guidance for Food Contact Materials'?	☐ Yes	The EFSA 'Note for Guidance for Food Contact Materials' specifies the information to be provided for the different types of substance i.e. individual substance, defined mixture, non-defined mixture or polymer used as additive. Detailed information on possible impurities, oligomers, breakdown products should be given
Have the conditions of use of the substance been clearly identified and practical examples given?	☐ Yes	The information on the conditions of use of the substance is mandatory for the safety evaluation and should be provided
Are the food simulants selected for the migration tests reflecting the type of food intended to be in contact with the final article?	☐ Yes	Please note that the migration tests should be conducted selecting the appropriate food simulants, in line with the requirements of Regulation EC (No) 10/2011
Is the toxicological data set adequate with respect to the results of the migration tests, i.e. in line with Chapter I of the EFSA 'Note for Guidance for Food Contact Materials'?	☐ Yes	The EFSA 'Note for Guidance for Food Contact Materials' specifies the appropriate set of toxicological studies to be submitted
If one of the above points has not been fully addressed, has a scientifically sound justification been provided to explain the waiving of data?	☐ Yes	Please provide the requested information or a justification for waiving the data

Confidential information:	☐ **Yes**	☐ **No**
If yes, has a verifiable justification been provided?	☐ Yes	Please fill in and submit the Appendix C, in line with the requirements of Regulation (EC) No 1935/2004 (Article 20(1))
If yes, has the confidential information in the application been clearly identified?	☐ Yes	Please clearly mark (e.g. with a different font colour) the confidential information in the confidential version of the application
If yes, has a non-confidential version of the application been provided?	☐ Yes	Please submit a non-confidential version of the application.

2.7. Risk assessment, adoption and publication by EFSA

The CEF Panel is supported by the Working Group (WG) on Food Contact Materials to assess the application submitted to EFSA. Each valid application is tabled for discussion at the meeting of this working group and the outcomes of such discussions are summarised in the WG meeting minutes, published on the EFSA website (see direct link included below in the 'Useful links' section). During this phase, the Food Ingredients and Packaging (FIP) Unit is responsible for the handling of the applications.

According to Article 10(1) of Regulation (EC) No 1935/2004, the timeline to finalise the assessment of an application for Food Contact Materials by EFSA is six months. EFSA may extend this time period by a maximum of a further six months, providing an explanation for the delay to the applicant, the European Commission and the Member States.

During the risk assessment phase by the WG on Food Contact Materials and the CEF Panel, EFSA may request the applicant to submit additional information in line with Article 10(2) of Regulation (EC) 1935/2004. In that case, the limit to deliver an opinion by EFSA shall be extended ("stop-the-clock procedure"). The deadline for providing the additional information is specified in the letter sent by EFSA to the applicant and is in line with the scientific report 'Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products' (EFSA, 2014).

When responding to EFSA questions, the applicant should submit the additional information as one package answering all questions in the form of 1 electronic copy (using a standard physical medium, i.e. CD-ROM, USB key), together with a hard copy of the signed cover letter.

Should the additional information include data that are requested to be considered as confidential, the Appendix C – Justification for confidential information should be updated accordingly.

After its adoption by the CEF Panel at a plenary meeting, the scientific opinion is checked for editorial review and confidentiality following the agreement between the European Commission and the applicant and is published in the EFSA Journal[15].

[15] EFSA Journal: http://www.efsa.europa.eu/en/publications

3. Interaction with EFSA staff during preparation, submission, completeness check, risk assessment and adoption phases

EFSA has implemented several initiatives to support applicants in understanding the evaluation process of applications for regulated products and to engage with them during the life-cycle of applications.

Figure 2 below shows the different services that applicants can take advantage of in the different phases of the life-cycle of the application. The complete list of support initiatives in place and a full description of each service currently implemented can be found in the 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products' (EFSA, 2016).

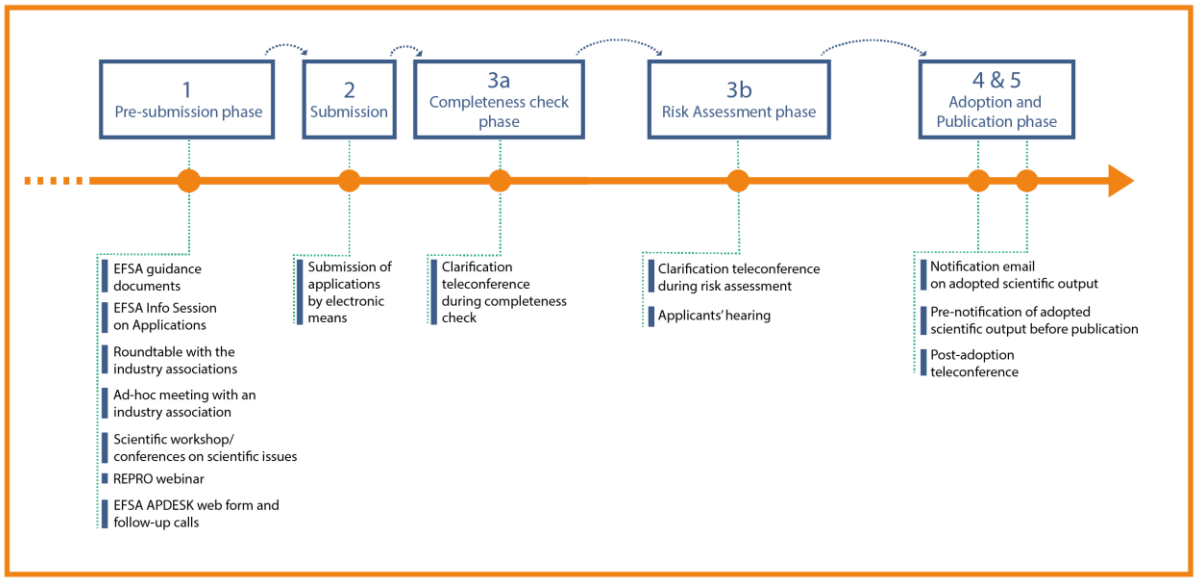

Figure 2 - Overview of EFSA support initiatives available during the life-cycle of an application for a substance to be used in plastic materials and articles intended to come into contact with food

If an applicant is seeking information **during the preparation of an application** for the authorisation of a plastic FCM substance on aspects related to data for risk assessment, EFSA encourages the use of the APDESK web form[16] to submit any queries to EFSA. EFSA endeavours to reply within 15 working days of reception of the query.

If an applicant is seeking information on the **status of an application** already submitted to EFSA, the applicant may check this information in the EFSA Register of questions database[17].

During the completeness check, applicants have the possibility to contact the staff in the APDESK unit. In each correspondence related to an application, the contact details of the EFSA staff following the specific application within the APDESK unit are clearly mentioned to allow direct interaction between EFSA staff and the applicant. Applicants can contact EFSA staff to request further clarifications following a request for missing information letter or to clarify any outstanding issues during the completeness check phase. A telephone conference may be organised to further clarify the outcome of the completeness check.

During the risk assessment phase, applicants have the possibility to contact the staff of the Food Ingredients and Packaging (FIP) Unit. In each correspondence related to an application, the contact details of the EFSA staff within the FIP unit are mentioned. EFSA staff can be contacted to request

[16] EFSA Applications Helpdesk web form: http://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion.htm

[17] EFSA Register of Questions database: http://registerofquestions.efsa.europa.eu/roqFrontend

further clarifications following a stop-the-clock letter. A telephone conference may take place to further clarify the questions of the CEF Panel/WG on Food Contact Materials.

In addition, upon request from EFSA, applicants might be invited to attend a specific agenda item of a working group or Panel meeting - either in person or via teleconference - to answer questions about the submitted data and to clarify any outstanding issues on the application. EFSA will decide if this is necessary after examining the written response from the applicant to the EFSA's initial request for information or in case the experts of the Working group and/or Panel need to clarify any outstanding issues on the application.

Following the publication of an EFSA scientific opinion on a regulated product, applicants have the possibility to request post-adoption teleconference. The EFSA staff may organise the teleconference to explain the scientific rationale of the final opinion from the Panel.

For further details on each service, please consult the EFSA's catalogue of support initiatives on the EFSA website[18].

[18] EFSA's catalogue of support initiatives: http://www.efsa.europa.eu/en/applications/about/services

References

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2017. 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, 41 pp. doi:10.2903/j.efsa.2008.21r

European Food Safety Authority, 2016. EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products. EFSA Supporting Publication 2015; 13(4):EN-1025. 30 pp. doi:10.2903/sp.efsa.2016.EN-1025

European Food Safety Authority, 2014. Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products. EFSA Journal 2014;12(1):3553, 37 pp. doi:10.2903/j.efsa.2014.3553

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

Useful links

- EFSA journal:
  http://www.efsa.europa.eu/en/publications
- Minutes of EFSA Food Contact Materials Working Group and composition of the Working group:
  http://www.efsa.europa.eu/en/food-ingredients-and-packaging/working-groups
- Minutes of EFSA CEF Panel plenary meetings and composition of the CEF Panel:
  http://www.efsa.europa.eu/en/panels/cef
- APDESK section on Food Contact Materials:
  http://www.efsa.europa.eu/en/applications/foodcontactmaterials
- Overview of regulations and guidance documents for Food Contact Materials applications:
  http://www.efsa.europa.eu/en/applications/foodcontactmaterials/regulationsandguidance
- Frequently Asked Questions on Food Contact Materials:
  http://www.efsa.europa.eu/en/applications/foodcontactmaterials/faq
- Food Contact Materials topic:
  http://www.efsa.europa.eu/en/topics/topic/foodcontactmaterials
- European Commission's website on Food Contact Materials:
  https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/index_en.htm
- Applicants can access the status of their application in the EFSA Register of Questions database:
  http://registerofquestions.efsa.europa.eu/roqFrontend

Abbreviations

APDESK	Applications Desk Unit
CD-ROM	Compact Disk - Read Only Memory
CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EURL	European Union Reference Laboratory
FCM	Food Contact Materials
FIP	Food Ingredients and Packaging
IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre
PDF	Portable Document Format
SI	International System of Units
USB	Universal Serial Bus
WG	Working Group

Appendix A1

Administrative data of the applicant submitting an application for authorisation of a substance intended to be use in plastic materials under Regulation (EC) No 1935/2004 and Commission Regulation (EU) No 10/2011

Applicant[19] (Company name):
Telephone:
E-mail:
Address (street, number):
Post code:
City/Town:
Country:
Name of contact person responsible for the application[20]:
Company:
Telephone:
E-mail:
Address (street, number):
Post code:
City/Town:
Country:

This request is for evaluation of a new substance for the inclusion in the Union list established by Commission Regulation (EU) No 10/2011

Name of the substance:
To be used as: ○ Monomer ○ Additive
In case of use as additive, please indicate the technological function:

[19] In case of more than one company submitting an application, their names and addresses should be provided.
[20] To facilitate communication, only one contact person per application should be indicated.

Appendix A2

Administrative data of the applicant submitting an application for modification of authorisation of a substance used in plastic materials under Regulation (EC) No 1935/2004 and Commission Regulation (EU) No 10/2011

Applicant[21] (Company name):
Telephone:
E-mail:
Address (street, number):
Post code:
City/Town:
Country:
Name of contact person responsible for the application[22]:
Company:
Telephone:
E-mail:
Address (street, number):
Post code:
City/Town:
Country:

This request is for modification of authorisation of a substance listed in the Union list established by Commission Regulation (EU) No 10/2011

Name of the substance:
Reason for requesting the modification:

[21] In case of more than one company submitting an application, their names and addresses should be provided.
[22] To facilitate communication, only one contact person per application should be indicated.

Appendix B - Technical dossier

This form shall be used by applicants submitting an application for authorisation of a substance intended to be used in plastic materials and articles in contact with food. It is available to download from Wiley Online Library[23] and shall be returned to EFSA in Word format (see also Sections 2.1-2).

When preparing the technical dossier, applicants should follow the scientific requirements described in the 'Note for Guidance for Food Contact Materials' (EFSA, 2017) and submit the requested information in the appropriate section. Detailed reports of all studies performed in support of the application, e.g. full documentation of experiments, full description of analytical methods, raw data and bibliographic references should be provided as separate technical annexes. One pdf document for each annex is requested.

References to the technical annexes where the complete information is provided should be made in the relevant sections of the technical dossier.

0. SUMMARY OF THE DOSSIER ACCORDING TO ARTICLE 9(1) OF REGULATION (EC) No 1935/2004	**FOR EFSA USE**
Please provide a summary of the technical dossier including information on identity, intended use in the plastic materials, type of contact food, conclusion on migration tests and toxicological studies. In case of a request for modification of the existing authorisation, background information/details on the request for modification should also be provided:	

[23] http://onlinelibrary.wiley.com/wol1/doi/10.2903/sp.efsa.2017.EN-1224/suppinfo

1. IDENTITY OF SUBSTANCE	FOR EFSA USE
1.1 Individual substance: ○ **Yes** ○ **No** 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:	
1.1.2 Synonyms(s):	
1.1.3 Trade name(s):	
1.1.4 CAS N°:	
1.1.5 Molecular and structural formula:	
1.1.6 Molecular weight:	
1.1.7 Spectroscopic data:	
1.1.8 Manufacturing details:	
1.1.9 Purity (%):	
1.1.10 Impurities (%):	
1.1.11 Specifications:	
1.1.12 Other information:	

1.2 Defined mixture: ○ **Yes** ○ **No** 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.	
1.2.1 Chemical name:	
1.2.2 Synonyms(s):	
1.2.3 Trade name(s):	
1.2.4 CAS N°:	
1.2.5 Constituents:	
1.2.6 Proportions in the mixture:	
1.2.7 Molecular and structural formula:	
1.2.8 Molecular weight (M_w) and range:	
1.2.9 Spectroscopic data:	
1.2.10 Manufacturing details:	
1.2.11 Purity (%):	
1.2.12 Impurities (%):	
1.2.13 Specifications:	
1.2.14 Other information:	

1.3 Non-defined mixture: ○ **Yes** ○ **No** Answer 'yes' or 'no'. If 'no' go to 1.4, if "yes" give information requested in 1.3.1 to 1.3.15 as complete as possible.	
1.3.1 Chemical name:	
1.3.2 Synonyms(s):	
1.3.3 Trade name(s):	
1.3.4 CAS N°:	
1.3.5 Starting substances:	
1.3.6 Manufacturing details:	
1.3.7 Substances formed:	
1.3.8 Purification by:	
1.3.9 by-products:	
1.3.10 Molecular and structural formula:	
1.3.11 Molecular weight (M_w) and range:	
1.3.12 Purity (%):	
1.3.13 Impurities (%):	
1.3.14 Spectroscopic data:	
1.3.15 Specifications:	
1.3.16 Other information:	

1.4 Polymer used as additive: ○ **Yes** ○ **No** Answer 'yes' or 'no'. If 'no' go to 2, if "yes" give information requested in 1.4.1 to 1.4.20 as complete as possible.
1.4.1 Chemical name:
1.4.2 Synonyms(s):
1.4.3 Trade name(s):
1.4.4 CAS N°:
1.4.5 Starting substances:
1.4.6 Manufacturing details:
1.4.7 Additives(s):
1.4.8 Structure of polymer:
1.4.9 Weight averaged molecular mass:
1.4.10 Number averaged molecular mass:
1.4.11 Molecular mass range:
1.4.12 Constituents with molecular mass <1000 (%):
1.4.13 Viscosity, if available:
1.4.14 Melt flow index, if available:
1.4.15 Density (g/cm^3):
1.4.16 Spectroscopic data:
1.4.17 Residual monomers (mg/Kg):

1.4.18 Purity (%):	
1.4.19 Impurities (%):	
1.4.20 Specifications:	
1.4.21 Other information:	

2. PHYSICAL AND CHEMICAL PROPERTIES OF SUBSTANCE	FOR EFSA USE
2.1 Physical properties:	
2.1.1 Melting point (°C):	
2.1.2 Boiling point (°C):	
2.1.3 Decomposition temperature (°C):	
2.1.4 Solubility (g/l):	
2.1.5 Octanol/water partition (log Po/w):	
2.1.6 Other information related to lipophilicity:	
2.2 Chemical properties:	
2.2 Chemical properties:	
2.2.1 Nature:	
2.2.2 Reactivity:	
2.2.3 Stability:	
2.2.4 Hydrolysis:	
2.2.5 Intentional decomposition/transformation:	
2.2.6 Unintentional decomposition/ transformation product(s):	
2.2.7 Interaction with food substances:	
2.2.8 Other information:	

3. INTENDED APPLICATION OF SUBSTANCE	FOR EFSA USE
3.1 Food contact material:	
3.2 Technological function:	
3.3 Maximum process temperature (°C):	
3.4 Maximum percentage in formulation:	
3.5 Conditions of contact in practice:	
3.5.1 Contact food:	
3.5.2 Time and temperature:	
3.5.3 Surface to volume ratio:	
3.5.4 Other information:	
3.6 Treatment of food contact material prior to use:	
3.7 Other uses:	
3.8 Other information:	

4. AUTHORISATION OF SUBSTANCE	FOR EFSA USE
4.1 EU countries: ○ Yes ○ No	
4.1.1 In Member States:	
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: ○ Yes ○ No If 'yes' give details and data transmitted:	
4.1.3 Other information:	
4.2 Non-EU countries	
4.2.1 In USA: ○ Yes ○ No If 'yes' give relevant regulation(s) or other and give further details like restrictions and conditions:	
4.2.2 In Japan: ○ Yes ○ No If 'yes' give relevant regulation(s) or other and give further details like restrictions and conditions:	
4.2.3 In other countries: ○ Yes ○ No If 'yes' give relevant regulation(s) or other and give further details like restrictions and conditions:	
4.2.4 Other information:	
4.3 Other information:	

5. DATA ON MIGRATION OF SUBSTANCE	FOR EFSA USE
5.1 Specific migration (SM): ○ Determined ○ Not determined If SM is not determined give reasons:	
5.1.1 Substance:	
5.1.2 Test sample:	
5.1.2.1 Chemical composition:	
5.1.2.2 Physical composition:	
5.1.2.3 Density, melt flow index of polymer:	
5.1.2.4 Dimensions of test sample:	
5.1.2.5 Dimensions of test specimen:	
5.1.3 Treatment of test sample prior to testing:	
5.1.4 Test food(s)/food simulant(s):	
5.1.5 Contact mode:	
5.1.6 Contact time and temperature:	
5.1.7 Surface to volume ratio:	
5.1.8 Analytical method:	
5.1.9 Detection/ determination limit:	
5.1.10 Precision of test method:	
5.1.11 Recovery:	
5.1.12 Other information:	

5.1.13 Results:

5.2 Overall migration (OM):

○ Determined ○ Not determined

5.2.1 Test sample:

5.2.2 Treatment of sample prior to testing:

5.2.3 Food simulant(s):

5.2.4 Contact mode:

5.2.5 Contact time and temperature:

5.2.6 Surface to volume ratio:

5.2.7 Test method:

5.2.8 Other information:

5.2.9 Results:

5.3 Quantification and identification of migrating oligomers and reaction products derived from monomers and starting substances:

○ Determined ○ Not determined

If not determined, please justify:

5.3.1 Test sample:

5.3.1.1 Chemical composition:

5.3.1.2 Physical composition:

5.3.1.3 Density, melt flow index of polymer:

5.3.1.4 Dimensions of test sample:

5.3.1.5 Dimensions of test specimen:	
5.3.2 Treatment of test sample prior to testing:	
5.3.3 Test food(s)/food simulant(s)/extraction solvent(s):	
5.3.4 Contact mode:	
5.3.5 Contact time and temperature:	
5.3.6 Surface to volume ratio in migration tests:	
5.3.7 Analytical method:	
5.3.8 Detection/ determination limit:	
5.3.9 Recovery:	
5.3.10 Other information:	
5.3.11 Results:	

6. DATA ON RESIDUAL CONTENT OF SUBSTANCE IN THE FCM	FOR EFSA USE
6.1 Actual content: ○ Determined ○ Not determined	
6.2 Substance:	
6.3 Test sample:	
6.3.1 Chemical composition:	
6.3.2 Physical composition:	
6.3.3 Density, melt flow index of polymer:	
6.3.4 Dimensions of test sample:	
6.3.5 Dimensions of test specimen:	
6.4 Treatment of sample:	
6.5 Test method:	
6.5.1 Detection/determination limit:	
6.5.2 Precision of test method:	
6.5.3 Recovery:	
6.5.4 Other information:	
6.6 Results:	
6.7 Calculated migration (worst case):	
6.8 Residual content versus specific migration:	

7. MICROBIOLOGICAL PROPERTIES OF SUBSTANCE	FOR EFSA USE
7.1 Is the substance used as an antimicrobial agent? ○ Yes ○ No If 'no' go to 8, if 'yes' go to 7.2	
7.2 What is the intended microbiological function?	
7.2.1 Protection agent during production process or storage of products:	
7.2.2 Means of reducing microbial contamination on the surface of a FCM:	
7.2.2.1 Intended applications of use:	
7.2.2.2 Other information:	
7.3 Spectrum of microbiological activity:	
7.4 Level of activity:	
7.5 Possible consequences of the use of the antimicrobial substance:	
7.6 Efficacy:	
7.7 Efficacy upon repeated use:	
7.8 Demonstration of the lack of antimicrobial activity against microbes in/on the food:	
7.9 Other information:	
7.10 Information on claim or disclaimer in accordance with the requirement of the relevant Regulation:	
7.11 Information on authorisation as biocidal product in the frame of Commission Regulation (EU) No 528/2012:	

8. TOXICOLOGICAL DATA	FOR EFSA USE
8.1 Genotoxicity	
8.1.1 Bacterial reverse mutation assay:	
8.1.2 *In vitro* mammalian cell micronucleus test:	
8.1.3 *In vivo* micronucleus test:	
8.1.4 *In vivo* Comet assay:	
8.1.5 Transgenic rodent gene mutation assay:	
8.1.6 Other information:	
8.2 General toxicity	
8.2.1 Repeated dose 90-day oral toxicity study:	
8.2.2 Combined chronic toxicity/carcinogenicity:	
8.2.3 Reproduction/teratogenicity:	
8.2.4 Other information:	
8.3 Metabolism	
8.3.1 Absorption, distribution, biotransformation and excretion:	
8.3.2 Accumulation in man:	
8.3.3 Other information:	
8.4 Miscellaneous	
8.4.1 Effects on immune system:	
8.4.2 Neurotoxicity:	
8.4.4 Other information:	

9. LIST OF REFERENCES AND TECHNICAL ANNEXES	FOR EFSA USE
Please provide a complete list of the references and technical annexes cited in the technical dossier:	

Appendix C - Justification for confidential information

According to Article 20(1) of Regulation (EC) No 1935/2004, the applicant may indicate which information submitted under Articles 9(1), 10(2) and 12(2) is to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

In filling in this form, applicants are reminded that, in accordance with Article 20(2) of the abovementioned Regulation, information relating to the following shall not be considered confidential:

- the **name and address of the applicant** and the **chemical name of the substance**;
- **information of direct relevance to the assessment of the safety** of the substance;
- the **analytical method** or methods.

Appendix C shall be updated during the life-cycle of the application each time a request for treating a piece of information as confidential is claimed by the applicant (original submission, missing information, additional information).

Information requested to be considered as confidential	Justification
Section x.y (submitted on YYYY/MM/DD)	
Annex X (submitted on YYYY/MM/DD)	
Section x.y.z (submitted on YYYY/MM/DD)	
Annex X (submitted on YYYY/MM/DD)	