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Safety assessment of bleached cellulose pulp for use in plastic food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids assessed the safety of the substance bleached cellulose pulp, consisting of cellulose fibres (70–92%) and hemicellulose (8–30%) obtained from pine and spruce wood. The substance is intended to be used [REDACTED] in polyethylene and polypropylene food contact materials. The final articles are intended to be used for all food types and for long-term storage at room temperature, with or without a short time at higher temperature, including hot-fill. Low-density polyethylene samples containing [REDACTED] of the substance were subjected to a broad set of migration tests with food simulants and extraction tests with dichloromethane. The limits of detection ranged from [REDACTED] (when specified). The Panel noted that they do not ensure the detection of genotoxic substances at a concentration leading to a human exposure above the Threshold of Toxicological Concern. Moreover, not all possibly migrating substances were identified or amenable to the analytical methods applied. No toxicological data were provided for the substance itself, as its migration into food is not expected. The safety of the potentially migrating substances of low molecular mass detected was addressed individually and was considered adequate. However, the Panel considered this approach insufficient owing to a substantial fraction of unidentified components. The Panel concluded that the information provided by the applicant does not allow the safety assessment of the substances below 1,000 Da from bleached cellulose pulp from pine and spruce wood used in plastic food contact materials potentially migrating into food. Therefore, the Panel could not conclude on the safety of the use of bleached cellulose pulp from pine and spruce wood as a plastic additive.

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Keywords: bleached cellulose pulp, CAS number 65996-61-4, food contact materials, safety assessment

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Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The following information have been provided under confidentiality and they are deleted awaiting the decision of the Commission: information on the manufacturing process (Section 3.1.1) and on migration of the substance (Section 3.1.3).

Competing interests: R. Franz declared that Fraunhofer institute at which he is employed provides advisory services to private business operators active in the sector on food contact materials. In line with EFSA's Policy on Independence (https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf) and the Decision of the Executive Director on Competing Interest Management (https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf), a waiver was granted to R. Franz regarding his participation to the EFSA's Working Group on Food Contact Materials (FCM WG) in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, the involvement of R. Franz is authorised as member in the FCM WG, allowing him to take part in the discussions and in the drafting phase of the scientific output, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the working group.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

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[†] Deceased.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8, 9 and 10 of Regulation (EC) No 1935/2004¹ of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States' competent authorities which transmit the applications to the European Food Safety Authority (EFSA) for their evaluation.

In this case, EFSA received an application from the Food Standards Agency (United Kingdom), requesting the evaluation of the substance bleached cellulose pulp, with the CAS number 65996-61-4. The dossier was submitted on behalf of Stora Enso.

According to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, EFSA is asked to carry out an assessment of the risks related to the intended use of the substance and to deliver a scientific opinion.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of its application for the authorisation of bleached cellulose pulp to be used in plastic food contact materials.

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 22 October 2018 and 11 September 2019 (see 'Documentation provided to EFSA').

Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity,
- Description of manufacturing process of substance/FCM,
- Physical and chemical properties,
- Intended use,
- Existing authorisation(s),
- Migration of substances,
- Identification, quantification and migration of reaction products and impurities.

Toxicological data

- Toxicological assessment of substances detected in migration tests and of non-intentionally added substances (NIAS).

2.2. Methodologies

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001).

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration and the definition of minimum sets of toxicity data required for safety assessment.

¹ Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently there are three tiers with different thresholds triggering the need for more toxicological information as follows:

- In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
- In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
- In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

Bleached cellulose pulp from softwood (pine and spruce) is a non-defined mixture which is, according to the applicant, intended to be used as an additive [REDACTED] in polyethylene and polypropylene FCM in order to increase their strength and stiffness as well as reduce the production time of the final articles. The weight ratio of spruce to pine woods is variable, depending on the mill that manufactures the product. The substance consists of α -cellulose (70–92%) and hemicellulose (8–30%). The final articles are intended to be used for all food types for long-term storage at room temperature conditions, with or without a short time at higher temperature, including hot-fill.

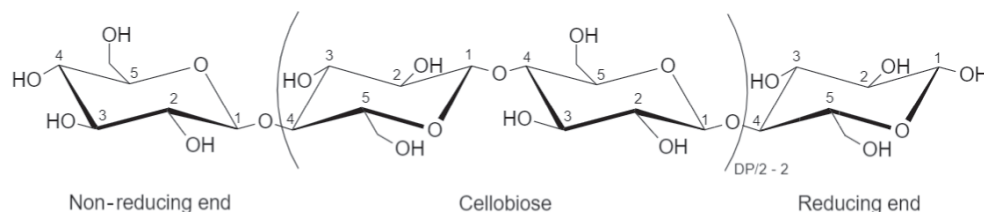
The substance has not been evaluated in the past by the SCF or EFSA. 'Cellulose', FCM Substance No. 553 (CAS 9004-34-6), which is made by further processing of cellulose pulp to reduce the amount of hemicellulose and lignin to virtually zero, is listed in the Regulation on plastic materials and articles intended to come into contact with food (Regulation (EU) No 10/2011) without restrictions. 'Wood flour and fibres, untreated', is currently listed as FCM Substance No. 96 (CAS 65996-61-4) without restrictions. However, a recent EFSA opinion (EFSA CEP Panel, 2019) stated that 'there is insufficient information to support that the current authorisation of 'wood flour and fibres, untreated' is still in accordance with Regulation (EC) No 1935/2004'.

3.1. Non-toxicological data

3.1.1. Identity of the substance²

Chemical structure:

Cellulose



² Technical dossier/ add data Sept 21/Appendix B/Section 1.

The specific migration of substances was determined using low-density polyethylene (LDPE) samples containing [REDACTED] bleached cellulose pulp. The substance was incorporated into the LDPE using [REDACTED] a coupling agent. Migration tests were carried out in 3% acetic acid, 10% ethanol, 95% ethanol and olive oil for 10 days at 60°C, and *iso*-octane for 2 days at 20°C. [REDACTED]

In addition, migration was tested with 95% ethanol for 24 h at 20°C, [REDACTED] The LDPE samples were also extracted with dichloromethane for non-targeted GC analysis. The detection limits (LODs) were estimated to be [REDACTED]

[REDACTED] were identified as possible reaction products based on literature data and their specific migration was found to be [REDACTED]

Regarding the non-targeted GC analysis, [REDACTED] substances were identified to migrate [REDACTED] consisting of [REDACTED]

The overall migration from the same LDPE samples was determined in 3% acetic acid, 10% ethanol, 95% ethanol for 10 days at 60°C and in *iso*-octane for 2 days at 20°C. [REDACTED]

The Panel noted that:

- The data provided are restricted to volatile, semi-volatile and GC-amenable substances. No reliable results from non-targeted LC analysis were provided. However, the results of the overall migration tests indicate [REDACTED] These were not identified and probably not amenable to GC analysis, hence, they were not properly addressed.
- The LODs of the methods ([REDACTED]) were too high to ensure the detection of genotoxic substances at a concentration leading to a human exposure above the Threshold of Toxicological Concern (TTC).

Therefore, extraction and migration tests did not ensure that all migrating substances have been detected and identified.

3.2. Toxicological data⁶

No toxicological data were provided for bleached cellulose pulp. Since the substance is neither expected to migrate into the food nor to be absorbed after ingestion if it were to migrate, no toxicological data on the substance itself were required.

For the safety assessment of the substance, migration and toxicity of reaction/degradation products and impurities were considered. To this end, information on existing evaluations and non-testing methods (QSAR for the identification of genotoxicity alerts and the application of the TTC approach) were applied on a set of substances identified in the screening described in Section 3.1.3. Based on the information available, it was concluded that chemically identified substances are either [REDACTED]

⁶ Technical dossier/add data Sept 21/Appendix B/Section 8.

Therefore, they did not raise safety concerns.

The Panel noted that [REDACTED] compounds were not identified, many substances were present at too low concentrations to be characterised and other substances were not amenable to the analytical methods applied. Therefore, the possible hazard associated with these unidentified or undetected substances was not properly addressed. To this end, the assessment of the fraction of unidentified components – or alternatively of the whole mixture of migrants from the substance – would be necessary, beyond the evaluation of individual components, as indicated in the EFSA recommendations on genotoxicity assessment of complex mixtures (EFSA Scientific Committee, 2019a) and in the Guidance on harmonised methodologies for risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019b).

3.3. Discussion

The Panel considered the data provided insufficient to rule out a safety concern. In particular, the following points were not satisfactorily addressed:

The applicant described many variables in processing wood to cellulose pulp and bleach it, from which it seems evident that the presence of reaction products, extractives and impurities could vary widely. The process is not sufficiently specified to assume that the composition of all bleached cellulose pulp samples will be the same as the ones investigated.

The completeness of the compositional analysis cannot be estimated, because no indication on the total amount of compounds of a molecular mass below 1,000 Da was provided, as requested by the Panel. The [REDACTED] migration into [REDACTED] simulants reported for the LDPE containing the substance compared to LDPE without it indicates [REDACTED] part of which is likely to be of a molecular mass below 1,000 Da. Those identified by the applicant do not fully cover them, as GC analysis is likely to miss many [REDACTED] compounds [REDACTED]

All components below 1,000 Da potentially migrating from the bleached cellulose pulp must be assessed individually or as a mixture according to EFSA Guidance documents (EFSA CEF Panel, 2008; EFSA Scientific Committee, 2019a,b). The Panel noted that the single chemical approach described in Section 3.2 may be inadequate for the evaluation of complex mixtures containing a substantial fraction of unidentified components (EFSA Scientific Committee, 2019a,b).

In consideration of these data gaps, the Panel concluded that the safety of the proposed use of bleached cellulose pulp in plastic FCM was not adequately demonstrated.

4. Conclusions

The Panel concluded that the information provided by the applicant does not allow the safety assessment of substances below 1,000 Da from bleached cellulose pulp from pine and spruce wood used in plastic FCM potentially migrating into food. Consequently, the Panel could not conclude on the safety of use of bleached cellulose pulp from pine and spruce wood in plastic FCM.

The Panel noted that the substance is incorporated into the plastic using a coupling agent, which should be assessed and authorised prior to its use according to the Regulation (EU) No 10/2011.

Documentation provided to EFSA

- 1) Initial dossier on bleached cellulose pulp. June 2018. Submitted on behalf of Stora Enso.
- 2) Additional data. July 2019. Submitted on behalf of Stora Enso.
- 3) Additional data. September 2021. Submitted on behalf of Stora Enso.

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European Commission, 2001. Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorization. Available online: https://ec.europa.eu/food/system/files/2020-12/sci-com_scf_out82_en.pdf

Abbreviations

CAS	Chemical Abstracts Service registry number
CEP Panel	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
FCM	food contact materials
	
LDPE	low-density polyethylene
LOD	limit of detection
NIAS	non-intentionally added substances
	
SCF	Scientific Committee on Food
TTC	Threshold of Toxicological Concern
QSAR	quantitative structure–activity relationship