Update of the risk assessment of ‘wood flour and fibres, untreated’ (FCM No 96) for use in food contact materials, and criteria for future applications of materials from plant origin as additives for plastic food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) was asked by the European Commission to review whether the authorisation of ‘wood flour and fibres, untreated’ (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004. The additive was included in the list of additives for use in plastic food contact materials (FCM) based on the assumption of its inertness. No toxicological evaluation underlying the inclusion of this entry in the positive list is available. In a literature search, general information on the chemical composition of wood was retrieved showing that wood may contain toxic components and contaminants. The information on migration of substances from wood was found to be limited to its use in the production of wine. Data on migration of substances resulting from the use of wood (flour, fibres) as plastic additive were not available. The Panel therefore concluded that there is insufficient information to support that the current authorisation of ‘wood flour and fibres, untreated’ (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004. As a second step, as requested by the mandate, the Panel set out criteria for future evaluations of wood and similar materials from plant origin as additives for plastic for food contact applications. The Panel noted that due to the chemical differences in composition of plant materials, the safety of migrants from these materials must be evaluated on a case-by-case basis, considering beyond species also origin, processing, treatment for compatibilisation with the host polymer and assessment of the low molecular weight constituents migrating into food. Migration of substances resulting from using wood or other plant materials should be tested comparatively in samples made with and without the additive. Toxicological data should cover the substances detected in this analysis.

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Keywords: wood flour, wood fibres, FCM substance No 96, food contact materials, safety assessment, evaluation criteria

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**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* and the Decision of the Executive Director on Competing Interest Management,** 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.

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* http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
** http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
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1. Introduction

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

Background from the mandate letter

"Untreated wood flour and fibres (FCM No 96) are currently authorised to be used as additives in the manufacture of plastic food contact materials (FCM), and are listed in Annex I of Regulation (EU) No 10/2011 (‘the Regulation’). This is an old authorisation which essentially lacks a detailed description of what constitutes ‘wood’ when wood flour and fibres are used as plastic additives in the context of the Regulation and which flour or fibres of a plant origin are wood, and which materials of a plant origin therefore cannot be regarded as wood. In addition, the meaning of ‘untreated’ in this context is not clear.

The difference between wood and other biological materials recently became relevant in resolving compliance problems in the light of technological developments. Innovative plastic materials now regularly contain substances from different biomass sources, including bamboo. Such materials may be considered as alternatives to traditional plastics, for instance because of environmental policies including the Commissions plastic strategy. One of the problems arising is that these materials may be marketed with a name suggesting that it is not a plastic, but a ‘natural’ or ‘bamboo’ based FCM. Still, such a material could be composed of a polymeric matrix with added wood or plant flour or fibres, which under the definition set out in the Regulation is a plastic.

It is necessary that the Regulation provides an appropriate framework to provide the Competent Authorities of the Member States and industry with a clear framework to determine the compliance of such materials, as these new materials may not be clearly positioned in the context of FCM No 96. Thus, some Member States would interpret FCM 96 as encompassing also many wood-like materials, including bamboo. Business operators may therefore take the same position and would not apply for authorisation of bamboo. Other competent authorities may notice that bamboo is not a wood, and the plastic material would not be compliant as bamboo is not an authorised additive.

In a similar situation, EFSA considered ground sunflower seed hulls (FCM No 1060) not to be covered by the wood (FCM 96) authorisation and evaluated it separately, leading to its own authorisation.

Presently, FCM 96 is authorised because of its inertness. However, some wood species, sources, parts of plants (e.g. leaves, bark) may not be inert or exhibit toxicity, as is for instance apparent from guidance to woodworkers.\(^1\) It is not clear to what extent such different species, sources or parts are covered by FCM 96. Furthermore, the toxicity of this additive may also depend on how it has been treated, processed, and eventually added to plastic.

Consequently, we ask EFSA to evaluate whether the authorisation of FCM 96 based on its inertness is still in accordance with Regulation (EC) No 1935/2004, as provided for in Article 12(3).

It may not be possible to conclude that the authorisation of FCM 96 is still in accordance with the Regulation, for instance because insufficient specific data on the relevant parameters is available.

In that case, EFSA should define to the extent possible, the information that will be necessary, and is not presently set out in its notes of guidance for FCM, to assess the safety and support the use of wood and of similar materials from a plant origin, as plastic additives under Article 9 of Regulation (EC) No 1935/2004. In doing so, EFSA should take account of parameters that EFSA considers relevant such as wood species, sources, plant parts, treatment and processing, and final application in plastic. EFSA should elaborate its views based on a literature search and expert judgement.”

Terms of Reference as provided by the European Commission

"In accordance with Article 12(3) of Regulation (EC) No 1935/2004\(^2\), the European Commission asks EFSA to review whether the authorisation of untreated wood flour and fibres (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004, as provided for in Article 12(3).

The substance is presently authorised based on its inertness as an additive for the manufacture of plastic food contact materials (FCM), and listed in Annex I of Regulation (EU) No 10/2011, with no Specific Migration Limit (SML).

EFSA should evaluate whether the authorisation of FCM 96 based on its inertness is still in accordance with Regulation (EC) No 1935/2004, as provided for in Article 12(3).

It may not be possible to conclude that the authorisation of FCM 96 is still in accordance with the Regulation, for instance because insufficient specific data on the relevant parameters is available.

\(^1\) http://www.hse.gov.uk/pubns/wis30.pdf

\(^2\) OJ L 338, 13.11.2004, p. 4.
In that case, EFSA should define to the extent possible, the information that will be necessary, and is not presently set out in its notes of guidance for FCM, to assess the safety and support the use of wood and the use of similar materials from a plant origin as plastic additives under Article 9 of Regulation (EC) No 1935/2004.

In doing so, EFSA should take account of parameters that EFSA considers relevant such as wood species, sources, plant parts, treatment and processing, final application in plastic, and the final composition of the plastic containing the wood/plants elements. EFSA should elaborate its views based on a literature search and expert judgement.

1.2. Interpretation of the Terms of Reference

The European Commission asked EFSA to evaluate whether the authorisation of FCM No 96 (i.e. ‘wood flour and fibres, untreated’) is still in accordance with Regulation (EC) No 1935/2004. For that purpose, a two-step approach, as outlined in the mandate, was followed.

Additionally the Panel noted that:

- No official interpretation of the terminology ‘untreated’ for the context of the listing of FCM No 96 in Regulation (EU) No 10/2011 is available. For the purpose of this assessment it was therefore considered that whereas the source material (i.e. wood) could indeed be treated (and has to in order to produce flour/fibres), that product, i.e. wood flour and/or fibres, does not undergo any further (chemical, physical, mechanical) treatment.
- The terminology ‘wood’ in the context of this assessment is understood as the hard tissue of trees. Other parts like bark, fruits and leaves of the tree are excluded.
- The assessment of FCM No 96 and the criteria for any future evaluations do not apply to recycled/reused wood and similar materials from plant origin.

2. Data and methodologies

2.1. Data

As no data from a previous evaluation were available, a literature search was deemed necessary in order to possibly retrieve specific data related to the use of wood flour and fibres as additive in plastic FCM. This served as a basis for evaluating whether the authorisation of ‘wood flour and fibres, untreated’ is still in accordance with Regulation (EC) No 1935/2004.

For that reason, literature searches – even though not via a fully systematic approach – were conducted with the aim to retrieve background information on wood/flour/fibres, e.g. chemical composition of wood, and its use in the area of (plastic) FCM more specifically, e.g. migration of substances from wood.

2.2. Methodologies

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.

Literature search

Non-systematic searches were performed by an information specialist in order to identify basic information on the chemical composition of wood or other risk assessments of wood FCM. Different sources of information (i.e. Google, Scifinder-n, and EFSA library electronic holdings) were consulted on 29 March 2019. The first results in each source were browsed by one assessor. 27 publications were identified as relevant and imported into the reference manager software EndNote (Clarivate Analytics).

A targeted literature search was run in Food Science and Technology Abstracts (FSTA) – the Food Science Resource (Web of Science platform) to retrieve information on migration of substances from wood. This source covers pure and applied research in food science, food technology, food-related nutrition, including packaging. 35 publications were retrieved by the search conducted on 4 April 2019 and imported into EndNote.

Additionally, searches were performed by an information specialist in Embase (embase.com) and PubMed (NLM) to retrieve secondary evidence – systematic reviews, guidelines or meta-analysis – on possible occupational diseases caused by wood exposure. Embase and PubMed are the main bibliographic databases covering biomedical literature and were considered as the most relevant
sources for this specific topic. The results retrieved in each database by the searches conducted on 29 March 2019 were imported in EndNote and duplicate references were removed, a final number of 31 results remained.

No restrictions in language or time period were used in the searches in the bibliographic databases. The search strategies as run in the databases and the dates of the search are reported in Appendix A.

All the references that were imported into EndNote as previously described were reviewed by title and abstract by one assessor and shared with the Working Group.

Additional sources of relevant information that the Panel was aware of, but that was not retrieved through the above search, was also considered for this assessment. Those included e.g. reports from public institutes (IARC, 1995; FSA, 2002; AFSSA, 2006).

3. Assessment

3.1. Evaluation of ‘wood flour and fibres, untreated’ for use as additive in plastic FCM

• Background information

The additive ‘wood flour and fibres, untreated’ was included in the list of additives for plastic FCM by Directive 95/3/EC with Ref. No 95920, based on the assumption of its inertness, as outlined in the mandate (see section 1.1). It is now listed under FCM substance No. 96 in Annex I (‘positive list’) of Regulation (EU) No 10/2011. No toxicological evaluation underlying the inclusion of this entry in the positive list is available. It is assumed that wood flour and fibres are used as filler.

Wood itself is listed in Annex I of Regulation (EC) No 1935/2004 as one of the materials which may be covered by specific measures, but no corresponding measure has been adopted.

Wood has a long tradition of use in many food contact applications, e.g. for crates, boxes, pallets, in appliances for food manufacture and processing, skewers and sticks, butcher’s blocks, worktops, boards, and kitchen utensils for all types of foodstuffs. Wooden barrels are used for wines and spirits. However, no toxicological evaluation of wood for these uses is known.

The EFSA ‘Compendium of botanicals reported to contain naturally occuring substances of possible concern for human health when used in food and food supplements’ (EFSA, 2012) lists numerous tree species.

A number of tree species are regarded as ‘poisonous’ or to have ‘poisonous’ parts. In a Project Report (FSA, 2002) on the use of unusual and non-traditional types of wood as FCM, 14 potentially toxic woods are listed (see Appendix A).

The German Official List of Poisonous Plants (German BMUNR, 2000) includes the following tree species:

- yew (Taxus baccata), containing taxines (Frohne and Pfänder, 2004a)
- buckthorn (Frangula alnus), containing anthraquinone derivatives (BfR, 2017)
- golden chain (Laburnum anagyroides), containing cytisine (Frohne and Pfänder, 2004b)
- cherry laurel (Prunus laurocerasus), containing cyanogenic glycosides (BfR, 2017)
- holly (Ilex aquifolium), containing alkaloids and terpenes (BfR, 2017).

It has to be noted that this document does not refer to the use of these species in the context of FCM, but rather to the application of these materials in public areas (e.g. gardens, parks etc.) where especially children could be playing.

So-called wood-plastics-composites (WPC) manufactured from thermoplastics and wood flour/fibres are used in non-food contact applications, e.g. as building materials such as outdoor floors, fences, park benches, window and door frames, for indoor furniture and in the automotive industry. For these applications, wood is used in its natural or recycled form. As softwood, species such as spruce, pine and fir are mentioned; for hardwood, oak or maple are exemplified. The dimensions of individual wood fibers range from 500 to 30,000 μm in length and from 20 to 40 μm in diameter. Due to the characteristics of the wood raw materials, plastic polymers with a melting or processing temperature of less than 200°C are used, as temperatures above 200°C can lead to damage to the components of the wood (lignins, hemicelluloses). Additives, such as coupling agents, UV stabilisers, blowing agents, foaming agents and lubricants, may be used for production of the WPC. In products on the European market, up to 90% wood in WPC may be present (Nova Institut GmbH, 2006).
In the chapter on wood and cork of the Dutch regulation on FCM (NVWA, 2017), the wood species acceptable for use in contact with food are not specified. A positive list for preservatives and pesticides for further processing is provided. Beyond the overall migration limit of 60 mg/kg food or simulant and SMLs related to the further processing, it is stipulated that the migration of fungicides and insecticides (azaconazol, carbendazim, deltamethrin) must not be detectable at a detection limit of 0.05 mg/kg food or simulant.

The French Information Note on wood for food contact (DGCCRF, 2006) provides criteria for wood intended to come into contact with foodstuffs. A list of acceptable wood species is given (originating from 1945), but it is not based on an investigation of potentially toxic compounds. Specifications are added on substances for treatment and contaminants.

According to information from the Chinese National Reference Laboratory for Food Contact Materials about a ‘2nd Draft of a National Standard for Food Contact Materials - Bamboo, Wood and Cork Materials and Articles Intended to Come into Contact with Food’ (IQTC, 2019), there are no restrictions related to wood species that may be used for food contact applications. The specific migration limits concern substances that are used in the further processing of wood. In addition, limits are specified for residues of heavy metals (from soil and pollution; Pb ≤ 5.0 mg/kg, Cd ≤ 0.3 mg/kg, As ≤ 2.0 mg/kg) and of biocides (o-phenylphenol ≤ 4.8 mg/kg, thiabendazole ≤ 3.6 mg/kg, biphenyl ≤ 0.6 mg/kg, imazalil ≤ 0.4 mg/kg).

**Chemical composition of wood**

The chemical composition of wood is complex and varies among species and within given species, depending on age, genetic and geographical factors, as well as growth conditions. Main components are cellulose, lignin and hemicelluloses. For the proportion of these macromolecular substances in European trees the following ranges are indicated (Schmitt et al., 2014):

- Cellulose: 40–44%
- Lignin: softwoods 25–32%, hardwoods 18–25%
- Hemicelluloses: softwoods 25–30%, hardwoods 30–35%

Most European woods contain 1–5% extractives and 0.1–1.0% mineral components. Tropical and subtropical wood types may contain up to 20% extractives and larger quantities of inorganic salts (up to 5% in woods of tropical and subtropical zones). Table 1 gives an overview of the chemical composition of important wood species.

**Table 1:** Chemical comparison of various wood species (% of dry wood weight) (Sjöström, 1993)

| Species         | Common name | Extractives* | Lignin | Cellulose | Glucomannan | Glucoronoxylan | Other polysaccharides |
|-----------------|-------------|--------------|--------|-----------|-------------|----------------|-----------------------|
| **Softwoods**   |             |              |        |           |             |                |                       |
| Abies balsamea  | Balsam fir  | 2.7          | 29.1   | 38.8      | 17.4        | 8.4            | 2.7                   |
| Pseudotsuga menziesii | Douglas fir | 5.3          | 29.3   | 38.8      | 17.5        | 5.4            | 3.4                   |
| Tsuga canadensis | Eastern hemlock | 3.4       | 30.5   | 37.7      | 18.5        | 6.5            | 2.9                   |
| Juniperus communis | Common juniper | 3.2       | 32.1   | 33.0      | 16.4        | 10.7           | 3.2                   |
| Pinus radiata   | Monterey pine | 1.8          | 27.2   | 37.4      | 20.4        | 8.5            | 4.3                   |
| Pinus sylvestris | Scots pine  | 3.5          | 27.7   | 40.0      | 16.0        | 8.9            | 3.6                   |
| Picea abies     | Norway spruce | 1.7          | 27.4   | 41.7      | 16.3        | 8.6            | 3.4                   |
| Picea glauca    | White spruce | 2.1          | 27.5   | 39.5      | 17.2        | 10.4           | 3.0                   |
| Larix sibirica  | Siberian larch | 1.8         | 26.8   | 41.4      | 14.1        | 6.8            | 8.7                   |
For safety evaluation, the composition and content of migratable substances in wood and their transfer into food are of importance, i.e. extractives and mineral components.

Extractives consist of a large number of low molecular weight compounds (Schmitt et al., 2014). As some of them protect the wood against attack from fungi, insects and bacteria, they may have toxic, irritant or sensitising properties. Organic extractives may have aliphatic, alicyclic or aromatic structures and comprise mainly terpenes, fatty acids, resin acids, waxes, alcohols, sterols, stearyl esters, glycerides and phenols (such as tannins, flavonoids, quinones and lignans). Polar substances extracted by hot water are tannins and inorganic salts. Hardwood tends to have a higher percentage of polar extractives than softwood (IARC, 1995).

In a report on the use of wood in contact with wine and other alcoholic beverages, mainly phenolic compounds (lignans, coumarins, multifunctional phenols, quinones and lignans) and to a lesser extent aliphatic compounds (terpenes, lactones, sterols and carotenoids) have been identified by extraction with a 12% alcohol–water solution (AFSSA, 2006).

Table 2 compiles examples of ‘biologically active’ (as stated by IARC) substances occurring in wood as listed by IARC.

**Table 2:** Examples of ‘biologically active’ (as stated by IARC) organic compounds found in wood (IARC, 1995)

| Substance class | Compound          | Wood type       |
|-----------------|------------------|-----------------|
| Terpenes        | α-Pinene         | Softwood        |
|                 | Δ3-Carene        | Softwood        |
|                 | Camphor          | Softwood        |
|                 | Thujone          | Softwood        |
|                 | β-Thujaplicin    | Softwood        |
|                 | Sesquiterpene lactones | Softwood/hardwood |
|                 | Abietic/Neoabietic acid | Softwood/hardwood |
|                 | Saponins         | Hardwood        |

*: Extraction by CH₂Cl₂, followed by C₂H₅OH.
In the Table in the Appendix B, toxins of 14 potentially toxic woods are listed as reported by FSA (2002).

Mineral components are mainly carbonates or glucuronates of calcium (40–70%), potassium (10–30%), magnesium (5–10%), iron (up to 10%) and sodium. Depending on the soil composition, also other metals, such as manganese and aluminium, are present in smaller quantities (Schmitt et al., 2014).

As outlined in the interpretation of the ToR, the Panel considers that, once produced, the flour/fibres are not further treated. However, a possible safety concern may result from cross-contamination and environmental contaminants in wood. The occurrence of, e.g., residues from wood preservation, chlorophenols, polychlorinated dibenzodioxins, polychlorinated dibenzofurans and toxic metals cannot be excluded.

Even though the use of pentachlorophenol (PCP) was already prohibited in most countries, in 2001 PCP and 2,4,6-trichlorophenol were detected in the wood of pallets, containers and crates as well as in cardboard and paper (Diserens, 2001). In containers, PCP was found in the range of 0.05–11 mg/kg and 2,4,6-trichlorophenol in the range of 0.05–31 mg/kg. No more recent data could be retrieved.

AFSSA (2006) listed residues from antifungal treatments of the past or accidental contamination (classes of substances in brackets):

- **Phenols**
  - Coniferyl aldehyde
  - Sinapaldehyde
  - Eugenol
  - 3-(Pentadecyl)catechol
  - 5-(Pentadec-10-enyl)resorcinol

- **Tannins**
  - Catechin derivatives
  - Leucoanthocyanidin derivatives

- **Flavonoids**
  - Kaempferol
  - Quercetin

- **Quinones**
  - 2,5- and 2,6-Dimethoxybenzoquinone
  - 3,4-Dimethoxydalbergione
  - Lapachol
  - Desoxylapachol
  - Juglone
  - Mansonestone A

- **Lignans**
  - Plicatic acid

- **Stilbenes**
  - 2,3’,4’,5’-Tetrahydroxystilbene
  - Chlorophorin
  - Pinosylvin

- **Miscellaneous**
  - Alkaloids (berberin)
  - Furocoumarins (psoralesen)

**Migration of substances from wood**

No information on the migration of wood substances from plastics made with wood flour or fibres could be retrieved from literature, but some data for wood components and pesticides from wood in contact with food. These are related to the use of wood as barrels or chips in wine making and the effect on the sensory properties of wine. The migration of oak wood constituents into 12% alcohol-water solution and Chardonnay wine from oak wood chips and from oak barrels was tested by Moutounet et al. (1989). The chips were screened at 1 and 2 mm and brought into contact with 12% alcohol-water solution and wine for 48 h under agitation and nitrogen atmosphere in a 250 mL flask. The storage in the barrels was at 15°C for 12 months. The results are given in Table 3.
Organoleptic aspects

The Panel noted that, according to what is reported above, the substances detected in wood do also include substances with flavouring properties e.g. coumarins, eugenol, camphor, PCP and chloroanisoles. They may have very low odour and taste thresholds and may therefore affect the sensory properties of the finished plastic and eventually the organoleptic characteristics of the food.

For 2,4,6-trichloroanisole odour thresholds of 3–8 ng/L in water and wine at 20°C have been determined (Cravero et al., 2015). In the WHO Guidelines for Drinking-water Quality odour thresholds for PCP in water of 0.86 mg/L at 30°C and 1.6 mg/L (temperature not specified) and a taste threshold of 0.03 mg/L were reported (WHO, 2003).

Information on occupational diseases related to wood dust

IARC has classified wood dust as carcinogenic to humans (Group 1). Wood dust causes cancer of the nasal cavity and paranasal sinuses and of the nasopharynx in humans exposed by inhalation (IARC, 2012). The mechanism responsible for the carcinogenicity of wood dust is unknown. The most likely mechanism proposed for the carcinogenicity of wood dust is a combination of reduced clearance of particles, leading to mechanical irritation, inflammation and increased cell proliferation (IARC, 2012).

Carcinogenicity of wood dust and all other results of the search on health risks from wood by occupational exposure are related to inhalation or dermal exposure to wood dust and not considered relevant for this opinion with regards to the oral route of exposure from FCM.

Table 3: Amounts of oak wood constituents in 12% alcohol–water solution and in Chardonnay wine (Moutounet et al., 1989)

|                | 12% alcohol–water solution | Chardonnay wine |
|----------------|-----------------------------|-----------------|
|                | Chips 4 g/L | Barrel 12 months | Chips 4 g/L | Barrel 12 months |
| Vanillic acid  | 0.0         | Traces          | 0.0         | n.d.             |
| Syringic acid  | 0.0         | Traces          | 0.0         | n.d.             |
| Vanillin       | 0.04        | 0.3             | n.d.        | 0.2              |
| Syringaldehyde | 0.06        | 0.5             | n.d.        | 0.4              |
| Coniferyl aldehyde | Traces | 0.2             | n.d.        | 0.1              |
| Sinapaldehyde  | Traces      | 0.3             | n.d.        | 0.1*             |
| Lyoniresinol   | 1.2         | 2.6             | 0.7         | 2.8*             |
| Gallic acid    | 7.2         | 5.2             | 5.4         | 7.3              |
| Ellagic acid   | 2.2         | 1.2             | 3.9         | 1.1              |
| Castalagin     | 37.4        | 21.0            | 36.7        | 5.0              |
| Vescalagin     | 66.6        | 25.5            | 65.0        | 0.0              |
| Ellagic tannins index | 58.2 | 27.4          | 55.2        | 7.6              |
| Hydroxymethylfurfural | 0.0 | 1.6           | 0.0         | 1.6              |
| Furfural       | 0.0         | 0.3             | 0.0         | 1.5              |
| Scopoletin     | 9.2         | 14.4            | 9.2         | 30.5             |

n.d.: not determined.
The results are expressed in mg/L with the exception of scopoletin which is in μg/L.
The ellagic tannin index is given in mg/L of ellagic acid.
*: Results estimated by extrapolation on the basis of differences in integration between the wine stored in oak and the control wine.

• Organoleptic aspects

The Panel noted that, according to what is reported above, the substances detected in wood do also include substances with flavouring properties e.g. coumarins, eugenol, camphor, PCP and chloroanisoles. They may have very low odour and taste thresholds and may therefore affect the sensory properties of the finished plastic and eventually the organoleptic characteristics of the food. For 2,4,6-trichloroanisole odour thresholds of 3–8 ng/L in water and wine at 20°C have been determined (Cravero et al., 2015). In the WHO Guidelines for Drinking-water Quality odour thresholds for PCP in water of 0.86 mg/L at 30°C and 1.6 mg/L (temperature not specified) and a taste threshold of 0.03 mg/L were reported (WHO, 2003).

• Information on occupational diseases related to wood dust

IARC has classified wood dust as carcinogenic to humans (Group 1). Wood dust causes cancer of the nasal cavity and paranasal sinuses and of the nasopharynx in humans exposed by inhalation (IARC, 2012). The mechanism responsible for the carcinogenicity of wood dust is unknown. The most likely mechanism proposed for the carcinogenicity of wood dust is a combination of reduced clearance of particles, leading to mechanical irritation, inflammation and increased cell proliferation (IARC, 2012).

Carcinogenicity of wood dust and all other results of the search on health risks from wood by occupational exposure are related to inhalation or dermal exposure to wood dust and not considered relevant for this opinion with regards to the oral route of exposure from FCM.

3.2. Criteria for future evaluations of wood and similar materials from plant origin as additives for plastic for food contact applications

Seeing the variability in composition and the possible presence of toxic substances in some woods, the safety of wood and similar materials from plant origin as additives for plastic FCM should be evaluated as for any other additives following the EFSA Note for Guidance (EFSA, 2008). Specifically, the following aspects should be considered:

- species;
- possible variability related to age, growth conditions and geographical origin;
- treatment during cultivation/storage;
manufacturing from the source material into the additive: physical and mechanical processing, chemicals used in this process; substances used together with the additive to produce the plastic material, e.g. coupling agents; comprehensive analysis of the low molecular weight constituents below 1,000 Da (1,500 Da for poly- and per-fluoro compounds; EFSA, 2016), including contaminants; migration of substances resulting from using the additive, comparing samples made with and without the additive; toxicological data covering the migrating substances detected in this analysis.

4. Conclusions

Wood cannot be considered inert per se owing to the many low molecular weight substances it contains, and when migrating into food, the safety of these constituents must be assessed. Presently available information is insufficient to support that the authorisation of ‘wood flour and fibres, untreated’ (FCM No 96) is in accordance with Regulation (EC) No 1935/2004. Given the chemical differences in composition of wood species, the safety of migrants from these materials must be evaluated on a case-by-case basis, considering beyond species also origin, processing, treatment for compatibilisation with the host polymer and assessment of the low molecular weight constituents migrating into food. This applies to other plant materials as well.

5. Remarks to the European Commission

In case recycled/reused wood and other materials from plant origin should be used as an additive for plastic FCM, further risk assessment considerations are needed. It is noted that when used as fillers in plastics, migration of the additive components may be higher than if the source material (e.g. wood) is used as bulk material, e.g. for crates, due to the larger surface-to-volume ratio.

In particular when the additive is used at high levels, it may influence the migration properties of the host plastic.

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Abbreviations

AFSSA French Food Safety Agency
CEP Panel EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
DGCCRF General Directorate for Competition Policy, Consumer Affairs and Fraud Control
FCM food contact materials
FSA Food Standards Agency
FSTA Food Science and Technology Abstracts
IARC International Agency for Research on Cancer
NVWA Netherlands Food and Consumer Product Safety Authority
PCDD polychlorinated dibenzodioxin
PCDF polychlorinated dibenzofuran
PCP pentachlorophenol
SML specific migration limit
UV ultraviolet
WPC wood-plastic-composites
Appendix A – Search strategies

A.1. Migration of substances from wood

FSTA – Food Science Resource (Web of Science platform)
Date of the search: 4/4/2019

| Set | Query                                                                 | Results |
|-----|----------------------------------------------------------------------|---------|
| #1  | TS=((wood OR woods OR wooden) AND (migra*) AND (packag* OR food* OR wine*))Indexes=FSTA Timespan=All years | 35      |

A.2. Occupational diseases and wood exposure

PubMed (NLM)
Date of the search: 29/3/2019

| Set | Query                                                                 | Results |
|-----|----------------------------------------------------------------------|---------|
| #1  | (Wood[Mesh] OR Wood*[tiab]) AND ("occupational exposure"[tiab] OR occupational disease*[tiab] OR occupational illness*[tiab] OR Air Pollutants, Occupational*[Mesh] OR "Occupational diseases*[Mesh] OR "Occupational exposure*[Mesh]) | 2,038   |
| #2  | (((((Wood[Mesh] OR Wood*[tiab]) AND ("occupational exposure"[tiab] OR occupational disease*[tiab] OR occupational illness*[tiab] OR Air Pollutants, Occupational*[Mesh] OR "Occupational diseases*[Mesh] OR "Occupational exposure*[Mesh]))) AND ("systematic review*[Filter] OR "meta analysis*[Filter] OR "practice guideline*[Filter]) | 24      |

Embase (embase.com)
Date of the search: 29/3/2019

| Set | Query                                                                 | Results |
|-----|----------------------------------------------------------------------|---------|
| #1  | wood:ti,ab OR woods:ti,ab OR wooden:ti,ab OR 'wood'/exp              | 38,722  |
| #2  | 'occupational health'/exp OR ((occupational NEAR/3 (disease OR illness)):ti,ab) OR 'occupational exposure':ti,ab | 241,709  |
| #3  | #1 AND #2                                                           | 1,622   |
| #4  | #1 AND #2 AND ([systematic review]/lim OR [meta analysis]/lim)      | 17      |

Assessment of ‘wood flour and fibres, untreated’ and criteria for applications of plant materials as additives for plastic FCM
# Appendix B – Examples of potentially toxic woods (as reported by FSA, 2002)

| Wood                          | Country of origin            | Toxins                                                                 |
|-------------------------------|------------------------------|------------------------------------------------------------------------|
| White Peroba                  | South America                | Lapachol, β-lapachonone, techoquinone and dexylapachol                |
| Lapacho                       | Central & South America      | Techoquinone and dexylapachol                                          |
| Pau d’arco                    | Central & South America      | Techoquinone and dexylapachol                                          |
| Teheebo                       | Central & South America      | Techoquinone and dexylapachol                                          |
| Ipo roxo                      | Central & South America      | Techoquinone and dexylapachol                                          |
| Cypress family (i.e. cedars, pines and junipers) | North America & Europe | Plicatic acid, abetic (sylvic acid), thymoquinone, tropolones, thujaplicins (i.e. β-thujaplicin (7-hydroxy-4-isopropyltropolone), γ-thujaplicin (5-isopropylpolone) and methyl-7-benzoquinone |
| Prunus spp. (i.e. red cherry, choke cherry, apricot, peach and plum) | North America & Europe | Prunasin, amygdalin, catechin, naingenin and 3-hydroxyaringenin |
| Juglandaceae sp. (i.e. American black walnut, hickory (Pecan) and butternut) | Europe and North America | Juglone (5-hydroxy-1,4 naphthoquinine) 2-methyl-1,4-naphthoquinone, 2,3-dihydro-5-hydroxy-2-methyl-1,4-naphthalenedione (β-hydroplumbagin), 5-hydroxy-2-methyl-1,4-naphthoquinone (plumbagin), 5-hydroxy-3-methyl-1,4-naphthoquinone, 2,3-dimethyl-5-hydroxy-1,4-naphthoquinone, 2,3-dihydro-5-hydroxy-1,4-naphthalenedione (β-hydrojugulone), 1,4-nathoquinone |
| Quercus sp. (i.e. red, white and black oaks) | Europe and North America | Gallotoxins (i.e. gallic acid (2,4,5-trihydroxy benzoic acid), pyrogallol, tannic acid |
| Black locust                  | North America                | Robin, robitin and robinine, phasin                                    |
| Dalbergia spp. (i.e. Kingwood, Sissoo, African blackwood, tulipwoods and rosewoods) Cocobolo | Subtropical regions (Africa, Central and South, America) | 4-Phenylcoumarins (i.e. dalbergin, methyl dalbergin, nordalbergin, isodalbergin, melannein and exostemin), Dalbergiquinols (i.e. latifolin and methoxyobtusasquinol), dalbergiquinones (i.e. dalbergenone, hydroxy-, methoxy- and methoxy-hydroxy substituted dalbergenones), Dalbergichromenes (i.e. dalbergichromene and kumannene), Barzillins (4-phenylcouymarin), methoxydalbergiones (R-4 and S-4), 4-dimethoxydalbergione and 5-4’hydroxy-4-methoxydalbergione |
| Pterocarpus sp. (i.e. red sandalwood) | Central & South America | Pterocarpans (i.e. pterocarpins isomers and maacklain), isoflavones (i.e. prinatin, mundanein, santal, formoneti, methyltectorigenin, 3’-hydroxyformononetin and pseudobaptogenin), deoxybenzoins (i.e. angiolensin) |
| Taxus spp. (i.e. English Yew)  | North America & Europe       | Taxine                                                                 |
| Yellow poplar                 | North America                | Alkaloids (i.e. glaucine, dehydroglaucine, norglaucineliriodenine, α-methylnorliriodenine, nuciferine, normuciferine, N-acetylnorliriodenine, norushinsunsine, asimilobine, and N-acetylasimilobine), sesquiterpenes (i.e. costunolide, tulipolide, epitetulipolide, epitulipolide and γ-liriodenolide) (N.B. these identified as extractive compounds) |