Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the risks associated with the use of medium-density fibreboard (MDF) as food contact material for fresh or refrigerated fruits and vegetables that are not peeled or cut

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Abstract

Regulation (EC) No. 1935/2004 establishes the legal bases with regard to materials and articles intended to come into contact with food. This regulation provides for the adoption of specific measures or regulations for 17 groups of materials. Nevertheless, as of now, only plastics, regenerated cellulose, active and intelligent materials and ceramics are specifically subject to regulation.

Medium-density fibreboard (MDF) is a material that consists of wood, adhesive and water, for which there are no specific rules. Therefore, the Scientific Committee has been tasked with assessing a methodological proposal for verifying that MDF boards comply with article 3 of Regulation (EC) No. 1935/2004.

This article establishes that the materials and articles shall be manufactured in compliance with

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good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: a) endanger human health; b) bring about an unacceptable change in the composition of the food; or c) bring about a deterioration in the organoleptic characteristics thereof.

In the view of the Scientific Committee, the proposed analytical strategy that consists of identifying the possible compounds that may migrate into foods and conducting specific tests, is correct and constitutes a good starting point for assessing compliance with the requirements established in article 3 of Regulation (EC) No. 1935/2004 for MDF boards as single-use packaging for fresh or refrigerated fruits and vegetables that are not peeled or cut.

Additionally, it makes a series of recommendations with regard to the woods and adhesives used, and the strategy for selecting the substances detected in the stage of raw material screening for monitoring their migration into foods.

The Scientific Committee recommends drawing up a sector-based Guide that outlines a detailed Protocol to be followed in order to demonstrate that these requirements are fulfilled in the process of manufacturing food contact articles from MDF boards, including the considerations made by the Committee.

In any case, the use of MDF boards as a food contact material must be limited to a single use, without being re-used for the same purpose by both industries and consumers.

Key words

MDF, migration, fruits, vegetables, materials, food contact.

Suggested citation

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1. Introduction

Medium-density fibreboard (MDF) is a material that consists of wood, adhesive and water.
As indicated by the applicant, the use of MDF boards for the packaging of whole fruits and fresh vegetables has increased considerably and according to industry figures, wood and boards account for 15 to 20 % of the packaging used for these products.

Regulation (EC) No. 1935/2004 of the European Parliament and of the Council establishes the legal bases with regard to materials and articles intended to come into contact with food (EU, 2004). This regulation provides for the adoption of specific measures or regulations for 17 classified groups of materials. Nevertheless, up to now or until now only plastics (including recycled plastics), regenerated cellulose, active and intelligent materials, and ceramics are specifically subject to regulation.

In the absence of specific regulations for wood in general and especially for MDF material, a consortium formed by the leading Spanish manufacturers of packaging made with this material, in coordination with the National Association of Board Manufacturers (ANFTA), have proposed a methodology to assess the suitability of MDF boards as a food contact material.

In this regard, the ANFTA has requested the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) to assess the appropriateness of the proposed methodology to verify that MDF boards comply with Article 3 of Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

2. Legislation

2.1 European Union legislation and other reference documents

There is a legislative framework in the European Union that covers all materials and articles intended to come into contact with food; 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 (EU, 2004). This regulation establishes the general safety requirements to ensure that the substances released by the materials into foods do not pose a risk to consumer health or an alteration of the food. Likewise, its objective is also to ensure free trade between the Member States of the European Union.

Especially with regard to consumer health protection, Article 3 of Regulation (EC) No. 1935/2004 establishes that materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with Good Manufacturing Practices so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

a) endanger human health, or

b) bring about an unacceptable change in the composition of the food, or

c) bring about a deterioration in the organoleptic characteristics thereof.

This legislative framework also includes the adoption of specific measures to regulate the groups of materials and articles listed in Annex I of Regulation (EC) No. 1935/2004, and where appropriate, of combinations of these materials and recycled materials (EU, 2004). These specific measures may include lists of authorised substances, restrictions on substances, migration limits, testing conditions, specifications for traceability, additional labelling considerations, etc. Concretely, these specific harmonised measures enable both operators and official control bodies to fulfil the provisions of Regulation (EC) No. 1935/2004. Nevertheless, until now, specific regulations have only been published for 4 of the 17 groups listed in the Regulation, which include active and intelligent materials, ceramics, plastics (including recycled materials) and regenerated cellulose. Therefore, for groups of wood and adhesives, the components of the material which is the focus of this report, there is no specific community regulation, rather the national legislation of each Member State of the European Union is applied, which in the case of Spain, refers to adhesives, in Royal Decree 847/2011 (BOE, 2011).

In addition to the aforementioned Regulation on materials and articles intended to enter into contact with foods, there is another EU provision whose scope includes all groups of materials intended to enter into contact with foods, in all stages of manufacturing, processing and distribution, with the exception of the production of raw materials or starting materials; Regulation (EC) No. 2023/2006 of the Commission, of 22 December 2006, on good manufacturing practices of materials and articles intended to enter into contact with foods (EU, 2006). Within the scope of this Regulation, the food business operators involved are required to establish, implement and adhere to quality assurance systems. It also establishes indications related to the application of printing inks to the non-food contact side of an article or object. The ultimate objective of this Regulation is compliance with Article 3 of Regulation (EC) No. 1935/2004 (EU, 2004). In this regard, some industrial associations or industry sectors have developed their own directives on Good Manufacturing Practices for specific materials. Good Manufacturing Practices are a tool aimed at enhancing self-assessment and responsibility of the manufacturers, processors and distributors of food contact materials. Thus, the Spanish Federation of Wood Packaging and its Components has developed a Guide for Good Manufacturing and Hygiene Practices (FEDEMCO, 2010).

2.2 National legislation

Royal Decree 847/2011 of 17 June which establishes the positive list of permitted substances for the manufacture of polymeric materials intended to enter into contact with foods, mentions different polymeric materials including adhesives, establishing a list of monomers and starting substances for manufacturing, as well as the migration limits and conditions regarding the identity and purity of the colouring materials (BOE, 2011). With regard to migration test conditions, it is line with the provisions of Regulation (EU) No. 10/2011 (EU, 2011). Apart from the substances listed in Royal Decree 847/2011, the use of substances listed in Annex I of Regulation (EU) No. 10/2011 is permitted with the stipulated restrictions, as well as substances authorised in other Member States of the European Union, with restrictions and limits similar to those present in the Member States and for the same goals.

With regard to wood intended to enter into contact with food, there is no specific national legislation. The only applicable regulation, since it involves food containers, is Royal Decree 888/1988, of 29 July, which approves the general regulations for containers that hold fresh, perishable food products that are not packaged or wrapped (BOE, 1988). Article 5 of this Royal Decree states that containers made of wood, cardboard and expanded polystyrene, as well as containers that cannot be cleaned and sanitised after use, cannot be reused for food storage purposes.

2.3 Other reference documents

In the case of wood intended to enter into contact with food, which is the principal component of MDF boards, there is currently no specific European regulation or national legislation, as mentioned before. In these cases, the legislation or recommendations of other EU Member States may be followed, when present, based on the principle of mutual recognition in the EU single market (EU, 1999).

It is worth highlighting the report published by the Joint Research Centre (JRC) of the European Commission on food contact materials that are not harmonised in the European Union, which conducts a national and sector-based review of food contact materials for which there is no specific EU regulation (JRC, 2016). With regard to wood, there are few countries with pertinent legislation or recommendations; some of them are France, the Netherlands and Croatia. Annex 15 of the JRC report includes references to the documents of these countries, as well as descriptions of some of the measures included. These measures may include lists of authorised substances with migration limits as in the case of Dutch legislation (Netherlands, 2014), prohibited substances, mainly those used to treat wood (antifungals, biocides), or lists of authorised wood species. In the case of France, the use of certain woods has been authorised since 1945 (France, 1945), and its regulation is supplemented by Sheet No. 2012-93 of the *Direction Générale de la Consommation, de la Concurrence et de la Répression des Fraudes* (DGCCRF, 2012), which lists certain requirements for their use such as the wood must not have been subjected to chemical treatment, restrictions on the use of biocides, restrictions on unwanted substances, organoleptic criteria, etc. It includes a list of authorised woods, mentioning the possibility of using other woods provided they comply with Article 3 of Regulation (EC) No. 1935/2004.

Other European reference documents that may be considered, without the status of law, are the Resolutions of the Council of Europe. Thus, there is a Resolution for cork intended to enter into contact with foods (COE, 2004), which includes a positive list of assessed substances and testing conditions, although no specific Resolution has been published for wood.

In the United States, Chapter 4 of the Food Code of the FDA (Food and Drug Administration) on Equipment, Utensils and Linens mentions certain restrictions on the use of wood (FDA, 2017).

3. Medium-density fibreboard

MDF boards are a processed material manufactured by means of hot pressing, consisted of lignocellulosic fibres bonded together with water and an adhesive.

In accordance with the information provided by the applicant, one of the advantages of MDF boards is their full use of the wood, compared to other uses that only employ 50 % of the tree. It is also a uniform material and easy to rework, not prone to splintering and provides greater surface quality.

Tree trunks without bark are converted into chips and subsequently sifted and washed with water. Next, the chips are softened with steam as previous step to convert them into fibres by mechanical defibration.

The wood fibres are mixed with the adhesive and dried with hot air until they reach the desired level of humidity. Next, they are pressed at a temperature of more than 100 ºC, to convert the glue into a polymer, releasing water and the free formaldehyde that may have remained in the adhesive. Finally, the boards are cut into manageable sizes.

As informed, the final composition of the product at the time of manufacture process is wood (84-88 %), and amino-resin as adhesive (6-7 %) and water (5-10 %).

The thickness of MDF boards ranges between 2 and 7 mm, and their density is around 850 kg/m^3 although the faces of the board have a density of 1000 kg/m^3. The boards used to manufacture food packaging have a thickness of ≤3 mm.

Environmental humidity affects the moisture content, dimensions and the resistance of MDF boards. Thus, at a relative humidity of 90 %, the MDF material can hold 13-17 % of water. However, water immersion renders it unusable.

Manufacturing the final package intended for food use involves cutting the boards into the required sizes and assembling them. The sizes of the most common formats for fresh or refrigerated fruits and vegetables range between 150 x 100 mm and 600 x 400 mm, and their holding capacity is between 1 and 20 kg. The interior of the package which is intended to enter into contact with foods, is not subjected to sanding or varnishing.

However, the submitted documents make no mention of the use of printing inks on the boards.

The applicant states that the manufacturers of these types of packages follow the Guide for Good Manufacturing and Hygiene Practices of the Spanish Federation of Wood Packaging and its Components (FEDEMCO, 2010) in their facilities. With regard to formaldehyde emissions, the quality of boards is E1 according to the standards UNE-EN-ISO 12460-5:2016 (ISO, 2016) and ISO 12460-2:2018 (ISO, 2018), and UNE UNE-EN ISO 12460-3:2021 (ISO, 2021).

3.1 Intended use

The applicant states that the intended use of the material is the single-use packaging of fresh or refrigerated fruits or vegetables that have not been peeled or cut.

3.2 Raw materials

3.2.1 Wood

In addition to wood from logging, MDF boards may also be manufactured using wooden off-cuts and other by-products of untreated wood from the manufacturing of plywood, or sawmill residue, but not with recycled wood or reused MDF boards.

It also states that the wood of the boards intended for food use that are the subject of this application are from sustainable sources and coniferous and non-coniferous species are used. The most frequently-used coniferous species is *Pinus pinaster* but *Pinus radiata, Pinus sylvestris* and *Pinus nigra* are also used. Some manufacturers use a certain percentage (≤10 %) of non-coniferous wood, the most common ones being *Eucalyptus globulus and Populus alba*.

3.2.2 Adhesive

The adhesive is an amino-resin obtained by a condensation polymerisation of formaldehyde, urea, and in some cases, a small percentage of melamine. The exact composition depends on the manufacturer, although a table with three typical compositions is provided (Table 1).

Table 1. Typical compositions of adhesives used in MDF boards

Compound	kg/ton adhesive			% of adhesive		
	A	B	C	A	B	C
Formaldehyde	260	250	230	26	25	23
Urea	530	510	510	53	51	51
Melamine	0	30	50	0	3	5
Water	210	210	210	21	21	21

This adhesive permits the agglomeration of fibres and makes the MDF material moisture-resistant. As informed, the composition of the adhesive used to manufacture boards for packages ensures that the contribution of formaldehyde to the finished product does not make it unfit for food use.

3.2.3 Water

Water is not added. The water that is present comes from the wood and the adhesive. In the process of hot pressing, a part of the water evaporates until it reaches the level established in the specifications.

3.3 Specifications

The applicant has set the following specifications for MDF boards intended to enter into contact with foods, without sanding and with a thickness of ≤3.0 mm (Table 2).

Table 2. Specifications of MDF boards for food use

Parameter	Test	Value	Units
Dimensional tolerance			
Thickness	UNE-EN 324-1:1994 (UNE,1994a)	±0.2[a, b]	mm
Length and breadth	UNE-EN 324-1:1994 (UNE,1994a)	±2.0[a, b]	mm/m
Squaring	UNE-EN 324-2:1994 (UNE, 1994b)	±2.0[a, b]	mm/m
Straightness of edge	UNE-EN 324-2:1994 (UNE, 1994b)	±1.5[a, b]	mm/m

Table 2. Specifications of MDF boards for food use

Parameter	Test	Value	Units
Dimensional stability			
Length and breadth	UNE-EN 318:2002 (UNE, 2002)	0.4[a, b]	%
Thickness	(UNE-EN 318:2002 (UNE, 2002)	10[a, b]	%
Humidity	ISO (2018). Standard ISO 12460-2:2018 (UNE, 1994c)	5 a 10[a, b]	%
Mechanical properties			
Average Density	UNE-EN 323:1994 (UNE, 1994d)	870 ± 30[a, b]	kg/m^3
Expanded thickness, 24 hours in water	UNE-EN 317:1994 (UNE,1994e)	<45[a, b]	%
Resistance to traction	UNE-EN 319:1994 (UNE,1994f)	>0,90[a, b]	N/mm^2
Bending resistance	UNE-EN 310:1994 (UNE, 1994g)	>23[a, b]	N/mm^2
Formaldehyde			
Class	-	E1	-
Content	UNE-EN ISO 12460-5:2016 (UNE, 2016)	<8[a, b]	mg/100 g dry board
Emission	ISO 12460-2:2018. (ISO,2018) UNE-EN ISO 12460-3:2021 (UNE, 2021)	<0.124[a, b] de >2 a < 3.5[a, b]	mg/m^3 air mg/h.m^2 board
Food safety			
Specific migration Formal-dehyde	Internal procedure No. 7	<15[c]	mg/kg simulant or food
Mineral oils MOAHs	(BMEL, 2020)	<0,5[d]	mg/kg food
		Mineral oils MOAHs	mg/kg simulant
Melamine	Internal procedure No. 1	<2.5[c]	mg/kg simulant or food
Bisphenol A	Internal procedure No. 2	<0.05[c]	
Primary aromatic amines	Internal procedure No. 4	<0.01[c]	
Pentachlorophenol	Internal procedure No. 3	<0.15[e]	mg/kg material

Table 2. Specifications of MDF boards for food use

Parameter	Test	Value	Units
Al	Internal procedure No. 5	<1.0[c]	mg/kg simulant or food
Ba		<1.0[c]	
Co		<0.05[c]	
Cu		<5.0[c]	
Fe		<48[c]	
Li		<0.6[c]	
Mn		<0.6[c]	
Zn		<5.0[c]	
As		<0.02[f]	
Pb		<0.01[f]	
Cd		<0.005[f]	
Hg		<0.003[f]	
Ni		<0.02[c]	
V		<0.010[f]	
Cr		<0.25[f]	
Organoleptic impact on strawberries	UNE ISO 13302:2008 (UNE, 2008)	No impact	-

In relation to food safety specifications, the applicant provides the internal test procedures applied as well as the following references to the values displayed in the previous Table:

a) (UNE, 2004).
b) (UNE, 2010).
c) (UE, 2011).
d) (BMEL, 2020).
e) (Council of Europe, 2002).
f) (Council of Europe, 2013).

4. Methodology used to verify compliance of MDF boards with the requirements of Article 3 of Regulation (EC) No. 1935/2004

This methodology was developed in different stages. Section 4.1 describes a preliminary screening that helped to select the substances to be analysed. Section 4.2 presents the strategy to be followed based on the assessment of the content of the selected substances in the material from Section 4.1 and decision-making on whether to conduct migration tests or not. Sections 4.3 and 4.4 describe the tests conducted on substance content in the material and specific migration, respectively.

4.1 Screening of potentially migrant compounds

4.1.1 Methodology

Firstly, potential volatile migrant substances were screened by means of gas chromatography-mass spectrometry, after sample concentration by a purge-and-trap system, applied to raw material samples (wood and aminoplast adhesive) as well as intermediate products (wood fibre and glued fibre) and to two samples of MDF boards, one made of a mix of coniferous and non-coniferous wood (%) (A) and the second one solely of coniferous wood (B).

For the screening of semi-volatile substances, the same samples were subjected to a process of extraction with solvents (acetonitrile) and analysed by gas chromatography-mass spectrometry without prior concentration.

The identification of the compounds was based on the search and comparison of the spectra obtained from commercial mass spectral libraries (NIST/EPA/NIH and FFNSC). Only those with a good correlation (match factor between unknown spectra and that from the spectral library) higher than 800 were considered.

The screening methods used were validated in terms of specificity and sensitiveness against reference substances with known concentrations (2-propanol and hexanal in the case of volatile compounds and Di-n-Butyl Phthalate-d4 for semi-volatile compounds).

4.1.2 Results

By means of these two experimental processes 52 potentially migrant compounds, 37 volatile compounds, and 15 semi-volatile compounds were detected and identified. Of the 52 substances, 47 were present in the MDF board and 5 in the raw materials. Of the 47 compounds present in the MDF board, 38 were found in the two board types and 9 in only one board type (4 only in type A, non-coniferous boards, and 5 only in type B; coniferous boards) (Tables 3 and 4).

The detection of compounds in the MDF boards that were not detected in the raw materials suggests that they may have been formed during the manufacturing process.

Table 3. Volatile compounds detected by means of gas chromatography-mass spectrometry after sample concentration by the purge-and-trap system (grey denotes their presence, and the letter the presence in the specific board type, not in both (A and B))

CAS Number	Compound	Analytical technique	Detected in:			
			MDF		Raw material	Intermediate product
			A	B		
119-99-7	2,3-Dihydrofuran	P&T GC-MS				
75-07-0	Acetaldehyde	P&TC G-MS				
67-56-1	Methanol	P&TC G-MS				
64-17-5	Ethanol	P&TC G-MS				
67-64-1	Acetone	P&TC G-MS			B	
67-63-0	Isopropanol	P&TC G-MS				B
109-87-5	Dimethoxymethane	P&TC G-MS				
75-05-8	Acetonitrile	P&TC G-MS				
110-62-3	Pentanal	P&TC G-MS			B	B
108-03-2	1-Nitropropane	P&TC G-MS			B	
108-88-3	Toluene	P&TC G-MS				
66-25-1	Hexanal	P&TC G-MS				
98-01-1	Furfural	P&TC G-MS				
7446-09-05	Sulphur dioxide	P&TC G-MS				
80-56-8	α-Pinene	P&TC G-MS				
79-92-5	Camphene	P&TC G-MS				
127-91-3	β-Pinene	P&TC G-MS				
3777-69-3	2-Pentylfuran	P&TC G-MS				B
71451-00-8	Urea-15N	P&TC G-MS				
100-52-7	Benzaldehyde	P&TC G-MS			A	A
124-13-0	Octanal	P&TC G-MS				
586-62-9	α-Terpinolene	P&TC G-MS				
8013-00-1	Terpinene	P&TC G-MS				
124-19-6	Nonanal	P&TC G-MS				B
119613-19-3	1,4-Dimethoxy-2,3-butanediol	P&TC G-MS				
1632-73-1	D-fenchyl alcohol	P&TC G-MS				
562-74-3	Terpineol	P&TC G-MS				B
464-45-9	L-Borneol	P&TC G-MS				B
507-70-0	DL-Borneol	P&TC G-MS				
470-08-6	β-fenchyl alcohol	P&TC G-MS				

Table 3. Volatile compounds detected by means of gas chromatography-mass spectrometry after sample concentration by the purge-and-trap system (grey denotes their presence, and the letter the presence in the specific board type, not in both (A and B))

CAS Number	Compound	Analytical technique	Detected in:			
			MDF		Raw material	Intermediate product
			A	B		
98-55-5	α-Terpineol	P&TC G-MS				
475-20-7	Longifolene	P&TC G-MS				
87-44-5	Caryophyllene	P&TC G-MS			B	
6753-98-6	Humulene	P&TC G-MS				
30021-74-0	γ-Muurolene	P&TC G-MS				
10208-80-7	α-Muurolene	P&TC G-MS				
483-76-1	δ-Cadinene	P&TC G-MS				

Table 4. Semi-volatile compounds detected by gas chromatography-mass spectrometry (Grey denotes presence)

Number CAS No.	Compound	Analytical technique	Detected in:			
			MDF		Raw material	Intermediate product
			A	B		
625-74-1	2-methyl-1-nitropropane	GC-MS				
75-98-9	2,2-Dimethylpropanoic acid	GC-MS				
108-88-3	Toluene	GC-MS				
57-13-6	Urea	GC-MS				
1003-29-8	Pyrrole-2-carboxaldehyde	GC-MS				
66988-08-7	2,6,10,14-Tetramethyl-1-hexadecanol	GC-MS				
10544-96-4	6-Methyloctadecane	GC-MS				
2316-85-0	4-Cyclohexylbutan-2-one	GC-MS				
6895-56-3	Bergamotene	GC-MS				
2027-47-6	9-Octadecenoic acid	GC-MS				
593-45-3	Octadecane	GC-MS				
5333-42-6	2-Octyl-1-dodecanol	GC-MS				
629-62-9	Pentadecane	GC-MS				
1185-02-0	3,4-Dimethyl-3,4-hexanediol	GC-MS				
55282-12-7	3-Ethyl-5-(2-ethylbutyl) octadecane	GC-MS				

4.1.3 Assessment and selection of analytes

The compounds to be assessed were selected according to their potential risk to consumer health and changes to the organoleptic properties of the packaged product.

With regard to the potential risk to consumer health, formaldehyde, bisphenol A, melamine, primary aromatic amines, metals and mineral oil aromatic hydrocarbons (MOAH) were selected, obtaining the results listed in Table 5.

With regard to possible changes to the organoleptic properties of the packaged product, the selection criterion was the odour detection threshold of the detected compounds.

Thus, of the 52 compounds detected in MDF boards, 7 compounds that had a higher chromatographic signal (4 aldehydes and 3 terpenes) were selected. Their odour detection threshold was shown to be low (high odour level with little quantity) in several databases (Van Gemert, 2011) (Leffingwell, 2021) and thus an assessment of their organoleptic impact was made.

Wood is especially authorised as a food contact material in France (DGCCRF, 2012) and the tree species used to manufacture MDF are adjusted to the species authorised there. The screening also did not detect any of the 7 biocides mentioned in the Annex to the French document (DGCCRF, 2012) or any potentially toxic substances linked to the 14 species of wood listed in Appendix B of the Scientific Opinion of the EFSA on untreated sawdust and wood fibres intended for use in food contact materials, and criteria for future applications of plant-based materials as additives to plastic food contact materials (EFSA, 2019).

With regard to the composition of the adhesive, it is in line with the provisions of Royal Decree 847/2011 on polymeric materials, especially the stipulations of Article 4, Section b (BOE, 2011).

4.2 Analytical strategy proposed to verify compliance with Article 3 of Regulation (EC) No. 1935/2004

The applicant has proposed an analytical strategy for decision-making in relation to tests that must be performed on the material to ensure compliance with migration limits. The proposal is presented as a flowchart (Figure 1).

The first stage consists of determining the content of the analytes selected in the MDF material. Once the content is known, the maximum possible migration is estimated, assuming that the substance present migrates completely and only on the side that is in contact with the food. To do so, the conventional ratio of 6 dm^2 of contact surface per kg of food is applied, in order to determine the level of migration by mathematical calculations. If this estimated value does not exceed the applicable specific migration limit, then experimental migration testing is not required; however, if it exceeds the limit, then we proceed to the stage of migration testing in simulant E in order to ascertain the migration value through testing, which is compared with the migration limit, after applying a reduction factor of 1/10 (factor applicable to fresh or refrigerated, fruit and vegetables that have not been peeled or cut in accordance with Regulation (EU) 2016/1416 (EU, 2016)).

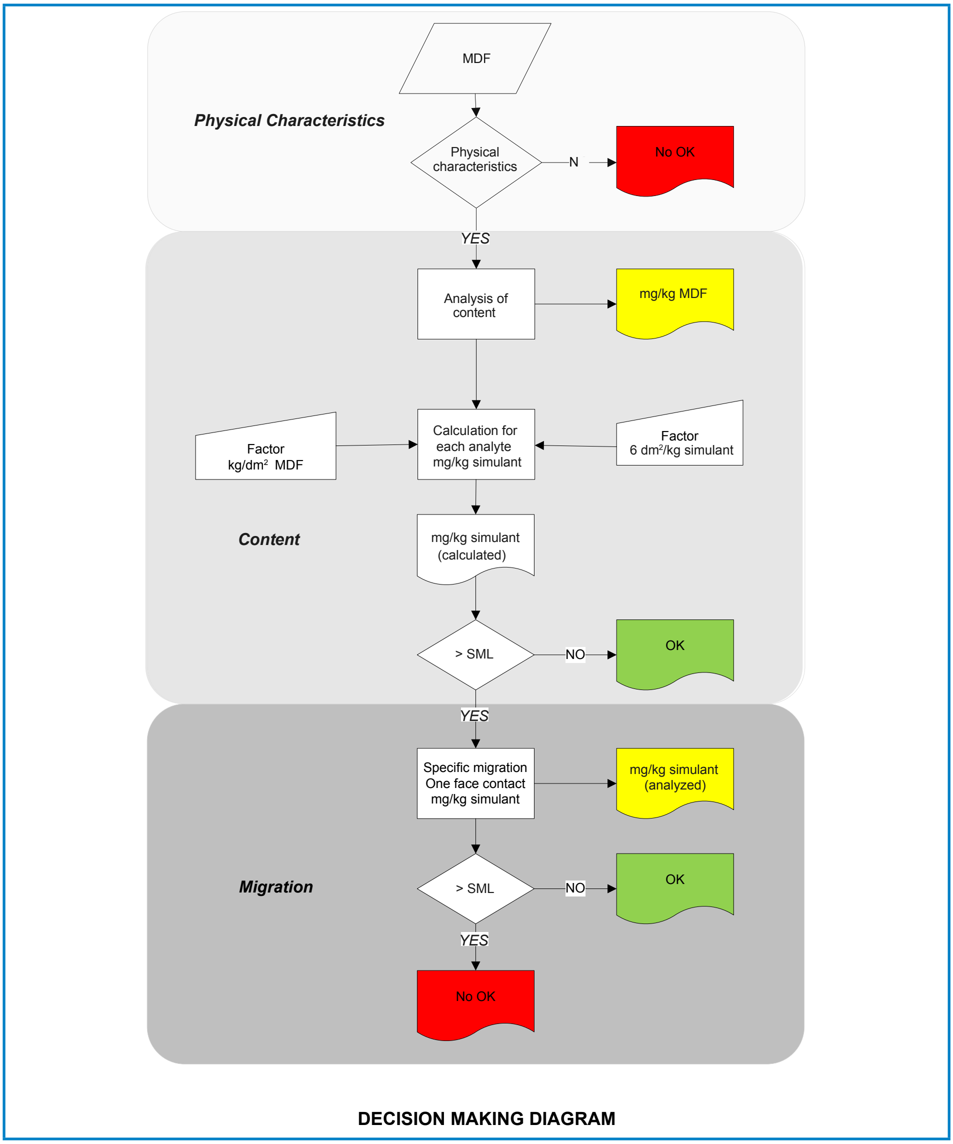

Figure 1. Analytical strategy for conducting migration tests.

4.3 Testing content in the material

The selected analytes were detected in 10 MDF boards (3 Type A, 3 Type B and 4 Type C boards) 2.5 and 3 mm thick, from different manufacturers and made with different types of wood compositions within the ranges mentioned in Table 5.

These three types of boards represent the most frequent wood composition (B) and two extreme examples of coniferous and non-coniferous content (A and C).

All of them fulfil the characteristics stipulated in the specifications in Section 3.2.

Table 5. Composition of the wood blends selected for the application of the analytical strategy

%	A	B	C
Coniferous	100	≥90	≥90
Eucalyptus	0	≤10	0
Poplar	0	0	≤10

The results of the content values of the different analytes selected from the MDF are summarised in Tables 6 and 7, expressed in mg/kg.

Table 6. Results of the aldehyde and terpene content in MDF boards

Parameter	Analytical technique	Content (mg/kg MDF)	Maximum migration calculation/10 (mg/kg food)	Limit (mg/kg food or simulant)
Pentanal	P&T GC-MS	<LD*-0.75	<LD-0.0096	Not established
Hexanal	P&T GC-MS	0.04-0.75	0.0005-0.0096	Not established
Octanal	P&T GC-MS	0.05-0.07	0.00064-0.00089	Not established
Nonanal	P&T GC-MS	0.14-0.61	0.0018-0.0078	Not established
α-Pinene	P&T GC-MS	2.98-29.9	0.038-0.38	Not established
α-Terpineol	P&T GC-MS	1.42-9.96	0.018-0.127	Not established
Caryophyllene	P&T GC-MS	0.30-5.13	0.038-0.065	Not established

*LD: limit of detection.

These compounds were selected due to their presence in the chromatographic profile when determining volatile compounds.

Table 7. Results of the content analysis of different compounds in MDF boards

Parameter	Analytical technique	Content (mg/kg MDF)	Screening. Maximum migration calculation/10 (mg/kg food or simulant)	Limit (mg/kg food or simulant)	Reference
Formaldehyde	HPLC-DAD	57.5-78.0	0.73-0.99	15.0	Regulation (EU) No. 10/2011 (EU, 2011)
Melamine	HILIC-DAD	<6.73-33.4	<0.086-0.426	2.5	
Bisphenol A	HPLC-FLD	<0.35	<0.0045	0.05	
Pentachlorophenol	HPLC MS/MS	<0.11	<0.0014	0.15*	(Council of Europe, 2002)

Table 7. Results of the content analysis of different compounds in MDF boards

Parameter	Analytical technique	Content (mg/kg MDF)	Screening. Maximum migration calculation/10 (mg/kg food or simulant)	Limit (mg/kg food or simulant)	Reference
PAAs	HPLC MS/MS	<0.024	<0.0003	<0.01	Regulation (EU) No. 10/2011 (EU, 2011)
Al	ICP-MS	4.0-33.8	0.051-0.43	<1.0	
Ba	ICP-MS	0.39-1.8	0.0049-0.023	<1.0	
Co	ICP-MS	0.012-0.046	0.000153-0.00059	<0.05	
Cu	ICP-MS	0.04-1.7	0.00051-0.0217	<5.0	
Fe	ICP-MS	0.11-11.1	0.0014-0.1415	<48	
Li	ICP-MS	0.02-0.056	0.000255-0.00071	<0.6	
Mn	ICP-MS	7.9-71.1	0.10-0.907	<0.6	
Zn	ICP-MS	1.1-11.0	0.014-0.14	<5.0	
Pb	ICP-MS	0.009-0.077	0.00011-0.00098	<0.01	
Cd	ICP-MS	0.005-0.050	0.000063-0.00064	<0.002	
Ni	ICP-MS	0.029-0.20	0.00037-0.00255	<0.02	
Cr	ICP-MS	0.023-0.089	0.00029-0.0011	<0.01	
As	ICP-MS	0.031-0.074	0.0004-0.00094	<0.002	(Council of Europe, 2013)
Hg	ICP-MS	n.d.**-0.0004	n.d.-0.000005	<0.003	
V	ICP-MS	0.0004-0.021	0.000005-0.00027	<0.01	
MOAHs (C16-C35)	LC-GC-FID	<2-23***	<0.0255-0.293***	0.50/0.15****	(BMEL, 2020)

*Limit in mg/kg material. This value already constitutes a content limit because it is expressed in mg/kg of material, as it would be compared directly to the value of the content obtained.
**n.d.: not detected.
***This case also includes the results obtained for a board sample that contained water repellents (not suitable for food contact) to check that it was possible to detect this type of substance by means of this determination.
****The limit of 0.50 mg/kg is applied to foods and the limit of 0.15 mg/kg is applied to simulants.

To determine formaldehyde presence in boards, all manufacturers use the method described in the standard UNE-EN ISO 12460-5:2016 (UNE, 2016). This is an extraction method called the perforator method and it is used to measure formaldehyde content in non-laminated and unvarnished wooden boards.

Formaldehyde is extracted from the test samples or specimens by boiling them in toluene at nearly 110 °C and later transferred to distilled or demineralised water. The formaldehyde content in the aqueous solution is determined by photometry through derivatization with acetylacetone (UNE, 2016).

In relation to MOAHs, the results include boards without water-repellents (paraffin-based compounds that cannot be used in food contact boards), but they also include a sample of boards with water-repellents (not suitable for food contact) in order to ascertain whether the analytical method used for MOAHs is able to detect these types of compounds.

The applicant concludes that:

- Some of the selected aldehydes and terpenes are from wood and are present in different quantities, possibly due to their different areas of origin. These compounds are present in quantities that do not have an organoleptic impact.
- The amount of formaldehyde present comes from the wood and the adhesive used to manufacture MDF boards. The values measured are consistent with the quality of low-emissions MDF boards (E-1), which establishes a content limit set by the UNE-EN ISO 12460-5:2016 Perforator method (UNE, 2016) of ≤8 mg CH_2O/100 g dry MDF (≤80 mg CH_2O/kg dry MDF).
- Melamine is one of the aminoplast components used as glue and with the exception of one of the boards analysed (33.4 mg/kg board), its content is very low (lower than 6.73 mg/kg board).
- As expected, due to the composition and manufacturing process of MDF boards, the content of bisphenol A, pentachlorophenol and primary amino acids is below the quantification level.
- The metals detected are present in the wood as trace minerals. For some metals such as Al, Fe and Mn, which have higher values, most of the content is from certain stages in the MDF board manufacturing process (chiping, defibration).
- Given the results displayed in Table 7, it was deemed necessary to determine the specific migration of Mn and MOAHs, as there have been boards in which, on applying the calculation indicated in the analytical strategy (Section 4.2), the calculated migration is higher than the specific migration limit. In the case of MOAHs, it was a board sample with water-repellents (not suitable for food contact) tested to ensure that the analytical method used for MOAHs may be used to detect this type of boards.
- It was also decided to determine the specific migration of aldehydes and terpenes (Table 6), formaldehyde, melamine and aluminium in order to verify the strategy proposed in Section 4.2.

4.4 Specific migration tests

Specific migration tests were performed on a single side given their intended application as packaging for fresh or refrigerated fruit and vegetables that have not been peeled or cut.

4.4.1 Selection of testing conditions

When selecting the testing conditions (time, temperature and relative humidity), the food storage recommendations of the FAO (Food and Agriculture Organisation) listed in Chapter 3 of its "Manual for the Preparation and Sale of Fruits and Vegetables" were taken into consideration.

The storage conditions of the strawberry were chosen of all the listed fruits and vegetables, as it is the most delicate fruit that is frequently consumed: temperature (0 ºC; 0.5 ºC), relative humidity (90-95 %) and time (5-7 days).

Using formaldehyde as the migrant model, tests were initially conducted in controlled (76 and 95 %) and uncontrolled conditions of relative humidity, and two time and temperature conditions (10 days at 40 ºC and 10 days at 20 ºC) were tested, with direct and indirect food contact.

Finally, taking the time and temperature established in Regulation (EU) 2016/1416 (EU, 2016) modifying Regulation (EU) No. 10/2011 (EU, 2011) as reference testing conditions, the migration testing conditions selected were 10 days at 20 ºC, and a relative humidity of 75 % and 90 %. The high humidity conditions seek to replicate the conditions of use of the packages during storage prior to their placement at the point of sale.

4.4.2 Simulant selection

Simulants conventionally used for plastic materials were taken as reference for selecting the simulant to be used in the test (Regulation (EU) No. 10/2011 (EU, 2011) and Regulation (EU) 2016/1416 (EU, 2016)). However, none of the liquid simulants were suitable for testing MDF material, as they induced colour changes in the simulant or deformation of the material in question. Agar was considered as a valid option to simulate contact with fruits (solid physical state and high water content, simulating foods with intermediate or high water activity). Powdered agar (dry and wet) and reconstituted agar were tested, but they were also unsuitable for testing as they led to deformations in the material.

Finally, simulant E (TenaxÒ), a conventional simulant for contact with fresh or refrigerated fruit and vegetables that have not been peeled or cut, which is listed in Regulation (EU) 2016/1416 on plastic materials (EU, 2016) was selected as the only simulant that did not display the aforementioned problems under the selected conditions: 10 days at 20 ºC with relative humidity of 75 % and 90 %.

Additionally, tests were conducted on foodstuffs to verify the appropriateness of the selected simulant. The strawberry was the foodstuff selected for testing as due to its characteristics it is probably one of the most delicate foods that are stored and transported in MDF packaging. It is also a fruit that is consumed without peeling and is of a small size, which implies a high ratio of surface contact with the MDF.

4.4.3 Specific migration tests

Under the selected testing conditions of 10 days and 20 ºC, with relative humidity of 75 and 90 %, specific migration tests of the compounds listed in Tables 8 and 9 were carried out on simulant E. Additionally, specific migration tests for MOAHs were carried out, which have been discussed below.

The migration tests were accomplished according to the general rules laid down in Chapter 2 of Annex V of Regulation (EU) No. 10/2011 (EU, 2011) and the recommendation of the Council of Europe on paper and board materials and articles intended to come into contact with foodstuffs (Council of Europe, 2002).

10 samples of the same types of MDF boards were analysed in order to determine their content. The average value or the maximum and minimum values for metals and MOAHs are displayed.

Table 8. Results of specific migration tests in simulant E for aldehydes and terpenes

Parameter	Analytical technique	Specific migration (mg/kg food or simulant)
Pentanal	GC-MS	<0.2
Hexanal		<0.3
Octanal		1.72
Nonanal		<0.2
α-Pinene		0.2
α-Terpineol		4.63
Caryophyllene		1.41

Table 9. Results of specific migration tests in simulant E

Parameter	Analytical technique	Specific migration (mg/kg food or simulant)	Specific migration limit (mg/kg food or simulant)	Limit reference
Formaldehyde	HPLC-DAD	<0.07	<15	Regulation (EU) No. 10/2011 (EU, 2011)
Melamine	HILIC-DAD	<0.4	<2.5	Regulation (EU) No. 10/2011 (EU, 2011)
Al	ICP-MS	0.009-0.051	1.0	Regulation (EU) No. 10/2011 (EU, 2011)
Mn	ICP-MS	0.0001-0.0006	0.6	Regulation (EU) No. 10/2011 (EU, 2011)
MOAHs	LC-GC-FID	<0.06-0.17	0.15 (simulant)	(BMEL, 2020)

The specific migration of mineral oil aromatic hydrocarbons (MOAHs) was tested using gas chromatography with flame ionisation detection in three samples of boards 2.5 mm thick (one of each type A, B and C). The specific migration of MOAHs was tested at 40 °C for 10 days, using Tenax as a direct contact simulant. The experimental result of the migration was calculated in μg/dm^2 and converted to mg/kg using the conventional conversion factor of 6 dm^2/kg.

It is worth highlighting that the available analytical technique which consists of a prior separation in column chromatography or liquid chromatography and subsequent analysis (GC-FID), is not selective and additionally, MOH mixtures (MOSH and MOAH) contain a high number of compounds and isomers which makes them extremely difficult to analyse and may lead to high variability of results.

Besides, in this specific case, the results include not only boards without water-repellents (paraffin-based compounds that cannot be used in food contact boards) whose results may or may not be below the reference limits, but also a sample of boards with water-repellents (not suitable for food contact) in order to ascertain whether this analytical method used for MOAHs lets us detect these types of compounds.

MOH determination poses an analytical challenge as they may be present as a complex mixture which must be quantified as the sum of all chemical compounds that cannot be analysed on an individual basis. These are complex mixtures that cannot be resolved by chromatography. Additionally, the most commonly used technique (LC-GC-FID) is unable to differentiate the MOSH from other analogous compounds such as POSH (polyolefin oligomeric saturated hydrocarbons). For all of these reasons, the results should be interpreted with caution.

Apart from the specific migration calculations conducted with Tenax as a simulant, migration tests were also conducted on foods. More specifically, the strawberry was used, because that it is the most delicate fruit of those that are frequently consumed.

Migration tests conducted on strawberries consisted of detecting the presence of formaldehyde in strawberries after they remained in the packaging at 5 °C for 7 days. Several units that had been in direct contact with different areas of the packaging were selected and homogenised for the formaldehyde analysis. The analytical method used was high-performance liquid chromatography (HPLC).

No formaldehyde migration from the packaging to the fruit was detected (limit of quantification = 0.4 mg/kg).

Additionally, aluminium and manganese migration in strawberries was analysed by means of inductively coupled plasma mass spectrometry (ICP-MS). In the case of aluminium, it was verified that the result obtained was in line with the estimates derived from the content in the material, but in the case of manganese, no conclusive results were obtained, as manganese content in unpackaged strawberries was at levels ranging from 3.3 to 9.4 mg/kg, with 0.6 mg/kg being the specific migration limit established by Regulation (EU) No. 10/2011 (EU, 2011).

It was not deemed necessary to conduct specific migration tests of other metals, applying the screening strategy described in Section 4.2 of this document, as the maximum specific migration values calculated from the content were considerably below the specific migration limit.

4.5 Other assessments

4.5.1 Organoleptic impact

In order to assess whether MDF boards provoke changes in organoleptic characteristics, the modification of the olfactory-gustatory sensations of the foods due to packaging was assessed according to the standard UNE ISO 13302:2008 (UNE, 2008).

An assessment was conducted of two MDF samples from two different manufacturers and different wood types (A and B), and a reference sample, inert with regard to odour and aroma migration, in contact with uncovered strawberries from the same production batch for 3 days in an odour-free domestic refrigerator under temperature and moisture conditions that are normal for these types of refrigerators.

Generally speaking odour and aroma are often confused and used synonymously, but according to the standard UNE-EN ISO 5492:2010, odour is the "sensation perceived by means of the olfactory organ in sniffing certain volatile substances" whereas aroma is the "sensory attribute perceptible by the olfactory organ via the back of the nose when tasting" (UNE, 2010).

A panel of eight trained tasters ranked the sensory attributes of odour, taste and aroma of the strawberries from 0 to 10, with the results displayed in Table 10. Prior to testing the samples, the tasting panel was trained and validated (Næs and Risvik, 1996).

Table 10. Average values of the tasting panel on the odour, taste and aroma of strawberries in contact with MDF boards

Sample	Green odour	Strange odours	Cut strawberry odour	Acidic taste	Sweet taste	Strange aromas
Sample A	1.16	0.61	3.94	3.34	3.14	0.48
Sample B	2.24	1.00	4.08	3.26	3.26	0.34
Control	1.54	0.52	3.55	3.11	2.90	0.63

No statistically significant differences (ANOVA) were detected by the panel of tasters with regard to the control sample for accepted tastes, odours and aromas as well as for strange ones.

4.5.2 Antibacterial activity

In order to assess the antibacterial activity of MDF boards against *Escherichia coli* and *Staphylococcus aureus*, the method described in the standard ISO 22196:2011 (ISO, 2011) was used. Two samples of MDF boards (A and B) and a reference sample of polypropylene were assessed.

E coli and *S.* aureus suspensions covered with polyethylene for 24 hours at 35 °C were applied to the sample surfaces and subsequently, the number of viable cells was counted in order to determine the variation in the concentration.

E. coli concentration on the polypropylene surface increased from 1.4×10^4 CFU/cm^2 to 6.4×10^5. Conversely, *E. coli* concentration on the surface of the MDF samples decreased below the limit of detection of 1 CFU/cm^2 (Table 11).

Table 11. Surface antibacterial activity against *Escherichia coli*

Sample	Contact time		Growth reduction	
	0 hours	24 hours	Log_{10}	%
Reference (PP)	1.4×10^4	6.4×10^5	-	-
Board A	1.4×10^4	<1.0	>4.2	≥99.99
Board B	1.4×10^4	<1.0	>4.2	≥99.99

In the case of *S. aureus*, its concentration on the polypropylene surface increased from 1.4 x 10^4 CFU/cm^2 to 3.1 x 10^3, but on the MDF sample surfaces, it decreased below the limit of detection of 1 CFU/cm^2 (Table 12).

Table 12. Surface antibacterial activity against *Staphylococcus aureus*

Sample	Contact time		Growth reduction	
	0 hours	24 hours	Log_{10}	%
Reference (PP)	9.3 x 10^3	3.1 x 10^3	-	-
Board A	9.3 x 10^3	≤1.0	≥4.0	≥99.99
Board B	9.3 x 10^3	≤1.0	≥4.0	≥99.99

The applicant indicates that according to a series of works on the bactericidal effect of wood compiled by the European Federation of Wooden Pallet & Packaging Manufacturers (FEFPEB), the antibacterial effect of wood is due to a combination of two effects. On one hand, wood is porous and hygroscopic, and its capillarity affects surface humidity. This has a bacterial capture effect (inner layer penetration) and a drying effect (lower survival of bacteria). On the other hand, in some woods, especially pine, the antibacterial effect may be due to the presence of polyphenols (FEFPEB, 2016a, b, c).

5. Analysed samples

The analytical strategy described in Section 4.2 has been applied to 22 samples of MDF boards. This strategy consists of an initial analysis of the material itself, of the selected analytes along with organoleptic and antimicrobial activity tests. For the analytes, calculations are performed on the basis of the analysed content in the material, and if the calculated value exceeds the migration limit, the specific migration test is carried out.

Thus, 22 samples of MDF boards from 5 different manufacturers (2 from Spain, 1 from Portugal, 1 from France and 1 from Brazil) were analysed over a period of 4 years. The organoleptic and antimicrobial activity tests were conducted on a sample from each manufacturer. The boards had thicknesses of 2.5 and 3 mm, and each of them were made with the woods listed in Table 5 and with a different type of adhesive in each one (of those specified in Section 3.2.2). All the analysed boards fulfilled the characteristics listed in the specifications of Section 3.3, with the exception of one (high MOAH content) which was intentionally chosen to verify the utility of the proposed methodology.

Two thicknesses were selected: 2.5 and 3.0 mm, taking into consideration the most unfavourable case (3.0 mm) as representing the most content per surface unit, and the most commonly used thickness (2.5 mm).

The results are displayed in Tables 13 and 14. The migration results (mg/kg) indicated in the columns "Migration calculation" and "Specific Migration" are expressed for a ratio of 6 dm^2 of material in contact with 1 kg of food.

Table 13. Overview of the results of content analysis in MDF boards and specific migration tests for aldehydes and terpenes

Parameter	Analytical technique	Content (mg/kg MDF)	Maximum migration calculation/10 (mg/kg food)	Specific migration (mg/kg food or simulant)	Limit (mg/kg food or simulant)
Pentanal	P&T GC-MS	<LD*-0.75	<LD-0.0096	<0.2	Not established
Hexanal	P&T GC-MS	0.04-0.75	0.0005-0.0096	<0.3	Not established
Octanal	P&T GC-MS	0.05-0.07	0.00064-0.00089	1.72	Not established
Nonanal	P&T GC-MS	0.14-0.61	0.0018-0.0078	<0.2	Not established
α-Pinene	P&T GC-MS	2.98-29.9	0.038-0.38	0.2	Not established
α-Terpineol	P&T GC-MS	1.42-9.96	0.018-0.127	4.63	Not established
Caryophyllene	P&T GC-MS	0.30-5.13	0.038-0.065	1.41	Not established

*LD: limit of detection.

Table 14. Overview of the results of the content analysis of different compounds in MDF boards and specific migration tests in samples

Parameter	Analytical technique/ Standard	Content (mg/kg MDF)	Screening. Maximum migration calculation/10 (mg/kg food or simulant)	Specific migration (mg/kg simulant)	Limit (mg/kg food or simulant)	Reference
Formaldehyde	HPLC-DAD	57.5-78.0	0.73-0.99	<0.07	15.0	Regulation (EU) No. 10/2011 (EU, 2011)
Melamine	HILIC-DAD	<6.73-33.4	<0.086-0.426	<0.4	2.5	
Bisphenol A	HPLC-FLD	<0.35	<0.0045	-	0.05	
Pentachlorophenol	HPLC MS/MS	<0.11	<0.0014	-	0.15*	(Council of Europe, 2002)
PAAs	HPLC MS/MS	<0.024	<0.0003	-	<0.01	Regulation (EU) No. 10/2011 (EU, 2011)
Al	ICP-MS	4.0-33.8	0.051-0.43	0.009-0.051	<1.0	
Ba	ICP-MS	0.39-1.8	0.0049-0.023	-	<1.0	
Co	ICP-MS	0.012-0.046	0.000153-0.00059	-	<0.05	
Cu	ICP-MS	0.04-1.7	0.00051-0.0217	-	<5.0	
Fe	ICP-MS	0.11-11.1	0.0014-0.1415	-	<48	
Li	ICP-MS	0.02-0.056	0.000255-0.00071	-	<0.6	
Mn	ICP-MS	7.9-71.1	0.10-0.907	0.0001-0.0006	<0.6	
Zn	ICP-MS	1.1-11.0	0.014-0.14	-	<5.0	
Pb	ICP-MS	0.009-0.077	0.00011-0.00098	-	<0.01	
Cd	ICP-MS	0.005-0.050	0.000063-0.00064	-	<0.002	
Ni	ICP-MS	0.029-0.20	0.00037-0.00255	-	<0.02	
Cr	ICP-MS	0.023-0.089	0.00029-0.0011	-	<0.01	

Table 14. Overview of the results of the content analysis of different compounds in MDF boards and specific migration tests in samples

Parameter	Analytical technique/ Standard	Content (mg/kg MDF)	Screening. Maximum migration calculation/10 (mg/kg food or simulant)	Specific migration (mg/kg simulant)	Limit (mg/kg food or simulant)	Reference
As	ICP-MS	0.031-0.074	0.0004-0.00094	-	<0.002	(Council of Europe, 2013)
Hg	ICP-MS	n.d.**-0.0004	n.d.-0.000005	-	<0.003	
V	ICP-MS	0.0004-0.021	0.000005-0.00027	-	<0.01	
MOAHs (C16-C35)	LC-GC-FID	<2-23***	<0.0255-0.293***	<0.06-0.17	0.50/0.15****	(BMEL, 2020)
Organoleptic impact	UNE ISO 13302:2008	No impact				(UNE, 2008)
Bactericidal effect	UNE ISO 13302:2008	Yes				(UNE, 2008)

*Limit in mg/kg material. This value already constitutes a content limit because it is expressed in mg/kg of material, as it would be compared directly to the value of the content obtained.

**n.d.: not detected.

***This case also includes the results obtained for a board sample that contained water repellents (not suitable for food contact) to check that it was possible to detect this type of substance by means of this determination.

****The limit of 0.50 mg/kg is applied to foods and the limit of 0.15 mg/kg is applied to simulants.

Based on the results obtained, and following the proposed analytical strategy of screening described in Section 4.2, it was only considered necessary to conduct specific migration tests for manganese and MOAHs in one sample (based on the result obtained from the material, the estimated migration value exceeded the limit of 0.6 for Mn established in Regulation (EU) No. 10/2011 (EU, 2011)). In the case of MOAHs, only the board that was unsuitable for food contact as mentioned in Section 4.3 exceeded the limit of 0.15 set in the draft modifying the Decree on food contact materials and articles of the German Federal Ministry of Food and Agriculture (BMEL, 2020). Additionally, specific migration tests were also carried out for formaldehyde, melamine and metals, with the results displayed in Table 14.

With regard to organoleptic testing in all cases, the result had no impact and all analysed samples also demonstrated bactericidal effect according to the mentioned test.

Based on the results obtained, the applicant concludes that:

- All the food contact boards analysed fulfil the characteristics listed in the specifications given in Section 3.2. The thicknesses are 2.5 and 3.0 mm.
- The migration results of the tested samples for the selected analytes were within reference limits, in cases where these were available in legal documents or other reference documents. The reference values are derived from those laid down in Regulation (EU) No. 10/2011 for plastic materials (EU, 2011) as well as those included in the documents of the Council of Europe (Resolutions on paper and board, and on metals and alloys (Council of Europe, 2002, 2013)). In the case of tests for aromatic mineral oils (MOAH), the migration level of the 4th German draft legislation on food contact materials (mineral oils) was taken as a reference (BMEL, 2020).
- None of the seven compounds selected due to their possible organoleptic impact (pentanal, hexanal, octanal, nonanal, α-pinene, α-terpineol and caryophyllene) have established specific migration limits. The values obtained are low considering that the result of the organoleptic impact test confirmed the absence of strange odours and tastes from the material into the food. Nevertheless, it is recommended to monitor them in the event that certain limits need to be set in the future.
- All the boards are of E1 quality, which implies formaldehyde extractable content according to the standard UNE-EN ISO 12460-5:2016 (UNE, 2016), of under 8 mg/100 g of dry MDF equivalent to 80 mg/kg MDF. Although the method to calculate specific migration for this formaldehyde content eliminates the need for the experimental determination of specific migration, this test has also been conducted and a very low value was obtained. This analyte has also been directly determined on food (strawberry). No formaldehyde migration from the MDF to the fruit was detected (Limit of quantification= 0.4 mg/kg strawberry).
- With regard to melamine, low values have been obtained and therefore, a board with especially high melamine content (information provided by the manufacturers) has been used to test the methods to determine content and specific migration. In both cases, the result obtained was also below the established specific migration limit.
- As expected, A bisphenol was not present in MDF (Limit of detection= 0.35 mg/kg board).
- Pentachlorophenol, a biocide used some years ago to help preserve wood and currently of

restricted usage, was also not present in MDF (Limit of detection= 0.11 mg/kg board).

- PAAs whose presence may be attributed to the use of epoxy adhesives (not used according to manufacturers), were also not present (Limit of detection= 0.024 mg/kg board).
- The measured metal content values are consistent with metal content in wood, where they are present as trace minerals. The values corresponding to Al, Fe and Mn are higher than their content in wood, probably because they are inevitably included in MDF during the manufacturing process, mainly during chiping and defibration.
- The result of the organoleptic impact study (detecting significant differences that indicate possible migrations of strange odours and tastes from the material to the food) on strawberries demonstrates no impact. This result is consistent with the low content of volatile and semi-volatile compounds with a low odour detection threshold.
- The bactericidal effect determination test shows that b*oth Escherichia coli* and *Staphylococcus aureus* populations had a decrease of ≥4.2 orders of magnitude, reaching levels below the limit of detection after 24 hours when compared with the initial population. Conversely, both *Escherichia coli* and *Staphylococcus aureus* populations increased in the reference material (PP).
- Regarding MOAHs, the expected values denoting their practical absence were obtained. The process of MDF sampling verified that this determination is useful for detecting boards unsuitable for food contact.
- The analytical strategy proposed and summarised in the diagram in Figure 1 has proved to be useful for checking that food contact MDF complies with all specifications related to food safety.

The applicant concludes that no substance has been detected in sufficient quantities to pose a health hazard or to provoke unacceptable changes to food composition or changes in the organoleptic characteristics of foods. Therefore, it considers the analysed MDF boards to comply with the provisions of Article 3 of Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food (EU, 2004).

Conclusions of the Scientific Committee

With the goal of protecting consumer health, Article 3 of Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food, establishes that they shall be manufactured in compliance with Good Manufacturing Practices so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food, or bring about a deterioration in the organoleptic characteristics thereof.

Medium-density fibreboard (MDF) used as a food contact material for fresh or refrigerated fruits and vegetables that are not peeled or cut, consists of a processed material that is manufactured by means of hot pressing and formed of lignocellulosic fibres bonded together with an adhesive and water. The final composition of the product is 88 % wood, 6-7 % an amino-resin that acts as an adhesive, and 5-10 % water, although given that it is a hygroscopic material, its water content may reach values of 13-17 % when stored in conditions of high relative humidity (90 %).

Regarding wood, it is necessary to mention the specific woods that are used in each case, the place of logging, and any other data that may be relevant for assessing the safety of the boards, even when dealing with the by-products of plywood manufacturing or sawmill residue. It is worth establishing a series of specifications that cover, among others, the different types of woods that may be used, the percentages for mixing different woods and the requirements for sustainable logging certification or other quality criteria. The wood type (species) as well as their origin are crucial factors for ensuring the safety of the final product, given that although all woods have a common chemical composition, there are species-based variations in the composition, which are inherent to the natural characteristics of the material (in contrast to synthetic materials created under controlled conditions of production). Additionally, their composition may be affected by environmental conditions which may lead to the presence of contaminants in the raw material.

With regard to the adhesive, its complete composition must be provided, which must be in line with certain specifications on composition and quality and always in accordance with Royal Decree 847/2011. It must be ensured that the inclusion of formaldehyde in the finished product does not render it unsuitable for food use.

With regard to water content, although MDF boards are manufactured with a water percentage of 5 to 10 %, its content may increase depending on the relative humidity of storage of the boards, as in the case of storage coolers which may have a high relative humidity. Therefore, it is necessary that tests and analyses are conducted keeping in mind the representative conditions of use.

Although the documents provided by the manufacturer make no mention of the use of inks or other elements such as paper or plastic coatings, or staples on MDF boards, in the event that these are used, their migration to foods and their safety must be assessed.

It is important that manufacturers establish the specifications of the raw materials used and of the produced MDF boards, and ensure compliance, both in relation to the species of wood, the composition of the material, the dimensions and mechanical properties; and with regard to food safety. This control must be performed at least every time there are changes to raw material supply or the production process, which may entail changes in the composition or characteristics of the boards.

In order to ensure the food safety of the MDF-based articles to be used for contact with fruits and vegetables that have not been cut or peeled, the applicant has proposed a screening of possible volatile migrant substances by means of gas chromatography combined with mass spectrometry, tests of content in the material, specific migration tests, and other determinations linked to organoleptic impact, antibacterial activity, or the presence of mineral oils.

In the view of the Scientific Committee, the proposed analytical strategy of identifying the possible migrant compounds and conducting specific migration tests is correct and constitutes a good starting point for assessing compliance with the requirements established in Article 3 of Regulation (EC) No. 1935/2004 for MDF boards as single-use packaging for fresh or refrigerated fruits and vegetables that are not peeled or cut.

However, the Scientific Committee considers that the selection of substances detected in the raw material screening phase for migration control should not be limited exclusively to substances with organoleptic impact and substances with legal or recommended restrictions in international documents for other food contact materials. The risk assessment must consider all detected substances that may potentially migrate to the food in contact.

The Scientific Committee recommends drawing up a sector-based Guide that outlines a detailed Protocol to be followed in order to demonstrate that these requirements are fulfilled in the process of manufacturing articles from food contact MDF boards, including the aforementioned considerations with regard to the specifications of the raw materials and the safety of the final article.

In any case, the use of MDF boards as a food contact material must be limited to a single use, without being re-used for the same purpose by both industries and consumers.

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