Novel packaging films and textiles with tailored end of life and performance based on bio-based copolymers and coatings.

D. 5.5 Report on Food packages health & safety assessment

This project has received funding from the Bio Based Industries Joint Undertaking under the European Union's Horizon 2020 research and innovation programme under grant agreement No 837761

Grant Agreement No:	837761	**Project Acronym:**	BIOnTop
Project Title:	**Novel packaging films and textiles with tailored end of life and performance based on bio-based copolymers and coatings**		
Funding scheme:	BBI-JU-Horizon 2020 – Research & Innovation Action		
Project Coordinator:	AIMPLAS		
Lead Beneficiary	ARCHA		
Start date of the project:	01.06.2019	**Duration of the project:**	48 months
Deliverable:	**D.5.5 Report on Food packages health & safety assessment**		
Contractual delivery date:	**31.05.2023 (deadline as stated in the DoA)**		
Actual delivery date:	**23.05.2023**		
Type of Deliverable	R (Document, Report)		
Dissemination level:	PU (public)		
Authors:	ARCHA (Francesca Braca)		
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Version:	**1.0**		

History of changes

Version	Author	Date	Comments
0.1	ARCHA	08.05.2023	First draft
0.2	ARCHA	13.05.2023	Second draft with the addition of information on the analyses performed on films from secondary raw materials, paragraph 7.8
1.0	ARCHA	22.05.2023	Final version for submission

Acronyms

BBI-JU	Bio-Based Industries Joint Undertaking
D	Deliverable
EU	European Union
EC	European Commission
FCMs	Food Contact Materials
H2020	Horizon 2020
IAS	Intentionally Added Substances
NIAS	Not Intentionally Added Substances
OML	Overall Migration Limit
SML	Specific Migration Limit
WP	Work Package

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Executive summary

The main goal of BIOnTop is to deliver novel bio-based biodegradable packaging based on versatile copolymers and coatings that optimally preserve the packed products but also resources (packaging based on significantly >85% renewable resources, partly produced from by-product biomass and recyclable). BIOnTop packaging are compatible with a broad range of packaging applications' requirements and multiple EoL options.

Accordingly, one important objective of BIOnTop project is the evaluation of the end-users safety assessment by quantifying the total and the specific migrations of the new developed packaging for the final application as food packaging: different plastic types as rigid and flexible packaging of food contact materials are verified in terms of their chemical migrations from packaging materials into simulants.

According with BIOnTop Consortium and current procedures and Regulations, the migration tests are carried out on developed packaging to validate the BIOnTop demonstrators, both flexible and rigid, according to Regulation 10/2011 and further updates and modifications for food contact and the overall and specific migration tests are performed.

1 Introduction

All materials and articles intended to come into contact with foods are regulated by general principles, in addition to specific rules, when existing, at the National and/or EU level.

The packaging materials must be in compliance to Regulation (EC) No 1935/2004. Specifically, those made of plastic materials must comply to (EU) No 10/2011 and further amendments.

The assessment of the new materials and packaging is fundamental to verify their safety for the consumers in terms of migrations of hazardous substances and molecules from the material to the food products: one important objective of BIOnTop project is the evaluation of the end-users safety assessment by quantifying the total and the specific migrations of the new developed packaging for the application as food packaging.

Plastic materials for food contact, e.g. packaging trays and films (lids, pouches) and also nets, fall within the scope of the Framework Regulation (EC) No 1935/2004, which provides the harmonized legal framework by setting out general principles and safety requirements for all kinds of food contact materials (FCM).

More specifically, food contact materials and articles made of plastics are covered by the Regulation (EU) No 10/2011 (and further updates and modifications). It sets out rules on the composition of the plastic FCMs by establishing a positive list of substances approved for use in the manufacture of plastic FCMs ('Union list') and lays down migration limits (a generic overall migration limit as well as specific migration limits for individual substances).

Compliance with regulatory demands is essential for putting new packaging materials on the market.

2 Description of the document and pursue

This report described the tests carried out to evaluate the compliance of the BIOnTop packaging with the EU and National Legislations for food contact material. These tests are performed on plastic substrates protected with the coatings developed during BIOnTop project.

2.1 WPs and Tasks related with the deliverable

This deliverable is related to WP5 and specifically to the activities described in Task 5.5 Food packages health & safety assessment.

Task 5.5 Food packages health & safety assessment

Leader: ARCHA. Partners involved: those who processed/used materials to provide info & samples

The present activity aims at performing a health & safety risk assessment on new developed products. ARCHA will assess the chemical safety and food regulatory compliance of selected representative final packaging materials developed within the project considering the regulatory requirements for food contact materials set out by the EC Regulation No 1935/2004 and, more specifically, the Plastics Regulation (EU) No 10/2011. The mass transfer properties of the selected materials will be assessed using conventional and realistic methods for migration evaluation. This will be achieved by studying the migration of a range of representative molecules already present in the basic polymer(s) but also of substances not been added for a technical reason during the production process, "non-intentionally added substances" (NIAS), such as impurities, reaction and degradation and decomposition products. Migration tests will be performed according to EC 10/2011 and establishing analytical methods based on gas- and liquid chromatography (GC and HPLC) coupled with suitable detection systems, i.e. mainly mass spectrometry.

Due to the similarity in terms of performed activities between Task 5.5 and Task 6.5, the main paragraphs describing the concept of the migration assessment, the legislative context and the official testing methods are described both in this deliverable D 5.5 and in deliverable D 6.4.

3 Migration assessment for food packaging

Foods are exposed to contact materials including cutlery and dishes, containers, processing machine, and packaging materials during all steps passed from farm to fork (Simeneau, 2008; EC, 2004)[1]. Food industry has been conducting research and development activities on food packaging to increase shelf life, keep the food quality at optimum level, attract consumer interests, and reduce waste. A package material for any type of food should minimize aroma and flavor losses, constitute an excellent barrier for gas and water, provide a perfect hermetically sealed seam, as well as have good mechanical properties.

Food contact materials including food packaging are generally based on paper, metal, ceramic, aluminium, lacquers and coating, and plastic (Krochta, 2007; Driscoll & Rahman, 2007)[2][3].

Food packaging is used to increase shelf life, to keep food quality at optimum level, to attract consumer interest, to facilitate the sale and distribution (Robertson, 2012)[4].

The degree of the final product quality and safety, and consumer expectations from the ergonomic features of the package affects the acceptance criteria of a package material. A package material for any type of foods should minimize aroma and flavor losses, constitute an excellent barrier for gas and water, provide a perfect hermetically sealed seam, as well as have a good mechanical properties and offer chemical and biological protection against contamination (Simeneau, 2008). Glasses, metals, paper, ceramic, and plastics are the most used materials for food packages. Glasses are inert packaging material and its shows heat resistance to thermal processing has advantages of providing good strength under compression and heat. Glasses as well as metals like steel and aluminium act a barrier to gases, water vapor and aromas. Paper based packaging materials produced from wood pulp, rags, and other waste have been reported to be used since the seventeenth century. Ceramic type packaging materials including glass and pottery are produced at high temperatures from non-metal inorganic material produced by high temperatures (Krochta, 2007; Driscoll & Rahman, 2007). Plastic packaging materials are made up from polymers by adding additives, processing aids, catalysts, and plasticizers.

Chemical components of packaging materials may migrate into foods when they contact with them. This type of transfer is called as chemical migration, which is a mass transfer operation. Diffusion the macroscopic movement of molecules from high to low concentration is the main mechanism in migration. The migrated chemicals from packaging materials can be originated from the substances used in their formulation and also from interactions between different ingredients, degradation products or from the presence of impurities in the raw materials. The duration of the contact between the material and food, temperature profile during interaction and the physicochemical behavior of the packaging material are the main drives for the migration (Simeneau, 2008).

[1] Simeneau C. 2008. Food Contact Materials (Chapter 21), in Comprehensive Analytical Chemistry. 1st ed., D. Barcelo (ed), Elsevier, Amsterdam.

[2] Krochta, 2007 Krochta J.M. 2007. Food Packaging, in Handbook of Food Engineering, 2rd ed, D.R. Heldman and D.B. Lund (ed), Taylor and Francis.

[3] Driscoll R.H. & Rahman M.S. 2007. Types of packaging materials used for foods, in Handbook of Food Engineering, 2rd ed, D.R. Heldman and D.B. Lund (ed), Taylor and Francis, pp.917-938.

[4] Robertson, 2012 Robertson G.L. 2012. Food packaging: Principles and Practices, 3 rd ed, CRC Press.

Keeping consumer health safe, components of food contact materials shall not migrate into the foods. Therefore, substances used in the manufacture of the packaging materials are regulated with maximum limits that may migrate into foodstuffs without causing any health concerns. To analyze migrated chemicals, food simulants are used to test migration in the scope of compliance with regulations. Sophisticated equipment such as liquid and gas chromatography equipped with mass spectrometry and inductively coupled plasma mass spectrometry have been used successfully for migration analysis so far.

Migration from packaging materials is a diffusion process that is subject to the normal laws of physics. Consequently, the conditions of use of polymers will influence the levels of migration that may be expected from them. Migration increases with:

- increased time of contact
- increased temperature of contact
- intimacy of the contact
- foodstuffs that interact strongly with the packaging and have a high solubility for the migrant(s).

Migration decreases with:

- only indirect contact
- low diffusivity (‘inert’) packaging materials
- presence of an inert barrier layer

4 Legislative context

The legislative context for the packaging materials that come in contact with food is presented below:

- Regulation (EC) No 1935/2004[5] states that food contact materials shall be safe and they shall not transfer their constituents into the food in quantities that could endanger human health, change the composition of the food in an unacceptable way or deteriorate the organoleptic properties of foodstuffs.
- Commission Regulation (EU) No 10/2011[6] is a specific measure of Regulation (EC) No 1935/2004 and establishes the specific rules for plastic materials and articles to be applied for their safe use. This Regulation is applicable as from 1 May 2011.
- Regulation (EC) No 882/2004[7] includes quality standards for laboratories entrusted by the Member States with the official control of foodstuffs.
- The GMP Regulation (EC) No 2023/2006[8] contains the basic principles of good manufacturing practice in the area of food contact materials.
- Directives 93/8/EEC and 82/711/EEC[9] containing the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs as well as 85/572/EEC containing the list of simulants remain applicable until 31/12/2012. As of 01/01/2013 they are replaced by Regulation (EU) No 10/2011.

In addition, Annex I of Commission Regulation (EU) No 10/2011 contains the Union list of authorized monomers, additives, polymer production and other starting substances. There are 885 authorized food contact material substances in the list. These listed substances called as “Intentionally Added Substances (IAS)” can be used to manufacture plastic materials, with the restrictions and specifications established in the list.

The contamination of foods due to the release of chemicals from packaging materials can be originated from the substances used in their formulation (IAS) but also from interactions between different ingredients, degradation products or from the presence of impurities in the raw materials (so called “Non Intentionally Added Substances-NIAS”).

The components from food contact materials must not migrate into the foods in unacceptable quantities. Therefore, substances used in the manufacture of FCMs are regulated with maximum limits that may migrate into foodstuffs without causing any health concerns.

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[5] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

[6] Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

[7] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

[8] GMP Regulation (EC) No 2023/2006 contains the basic principles of good manufacturing practice in the area of food contact materials.

[9] Directives 93/8/EEC and 82/711/EEC containing the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs as well as 85/572/EEC containing the list of simulants remain applicable until 31/12/2012. As of 01/01/2013 they are replaced by Regulation (EU) No 10/2011.

The migration of the substances present in the packaging material must not exceed 2 different limits:

1. the Overall Migration Limit (OML) is applicable to the total of migrant substances
2. the Specific Migration Limit (SML) refers to individual substances or groups of substances.

According to the Regulation, plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2) as overall migration limit.

SML are set for individual authorized substances based on toxicological evaluation.

The specific migration limit (SML) is a maximum permitted amount of a substance in food. This limit should ensure that the food contact material does not pose a risk to health. It should be ensured by the manufacturer that materials and articles not yet in contact with food will respect these limits when brought into contact with food under the worst foreseeable contact conditions. Therefore, compliance of materials and articles not yet in contact with food should be assessed and the rules for this testing should be set out.

Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I of the Regulation 10/2011. Those specific migration limits (SML) are expressed in “mg of substance / kg of food”. For substances for which no specific migration limit or other restrictions are provided in the same Annex I, a generic specific migration limit of 60 mg/kg shall apply.

The food simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with a single food or specific groups of foods are set out in point 3 of Annex III to Commission Regulation (EU) No 10/2011.

5 Official testing methods

In the scope of BIOnTop project, plastic type for food contact materials are analysed and migration tests are carried out for the quantification of the total migration. For the experimental activity the general applied Standard method is EN 1186:2002 series (Materials and articles in contact with foodstuffs – Plastics). All these methods deal with overall migration test, providing the main procedures and calculations to assess the total migration from each different simulant, temperature and contact time condition. Below the applied Standards are listed:

- EN 1186-1:2002 Part 1: Guide to the Selection of Conditions and test methods for Overall Migration
- EN 1186-3:2002 Part 3: Test methods for Overall Migration into Aqueous Food Simulants by Total İmmersion
- EN 1186-12:2002 Part 12: Test methods for Overall Migration at Low Temperatures
- EN 1186-14:2002 Part 14: Test methods for 'Substitute tests' for Overall Migration from Plastics İntended to come into contact with Fatty Foodstuffs using test Media İso-Octane and 95% Ethanol.

The EN 13130[10] sstandard deals with specific migration (Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants).

[10] EN 13130-1:2004 Materials and Articles in Contact with Foodstuffs — Plastics Substances Subject to Limitation. Part 1: Guide to test methods for the Specific Migration of Substances from Plastics to Foods and Food Simulants and the Determination of Substances in Plastics and the Selection of Conditions of Exposure to Food Stimulants.

6 Laboratory testing for overall and specific migration tests

The guiding principle in the EC Directives on plastics, is that migration testing should mimic actual and foreseeable conditions of use, and this includes taking into account the physical state of the packaged food (or material) and the nature/extent of this contact.

Migration from packaging materials is a diffusion process that is subject to the normal laws of physics. Consequently, the conditions of use of biodegradable polymers and packaging will influence the levels of migration that may be expected from them, especially in terms of temperature and duration of the storage and the usage.

The procedures used to bring and maintain the plastic in contact with the food simulant, procedures used for both overall migration and specific migration, are described in the EN 1186 series of standards.

According to EN 1186 the following steps must be followed to provide the overall migration performance and verify the compliance with the limit (below 10 mg/dm^2), as described in the next paragraphs.

6.1 Identification of the polymer type

For BIOnTop specimens, the identity of the used polymer or substrate is always known thanks the information provided by the Partners and the migration test is carried out.

6.2 Surface area calculation of test specimen

For the calculation of the surface area, the surface area can be seen as the sum of all the areas that make up the food contact surface of the article. Empirical methods can be used to calculate the surface area by placing the article on a piece of millimetric or plain paper of sufficient size. The paper is then wrapped around the contour of the article and cut to size. The contact area is then calculated by either counting the area based on millimetric measurements or by weighing the paper and converting the weight to the surface area.

6.3 Rules on testing conditions

Type of contact: total immersion or article filling: according to the type of article the test is performed by total immersion.

Single use article testing: according to the final type of usage of developed packaging (single use), one migration test is carried out.

Simulants: to determine migrated chemicals into food either for specific or total migration, analysis is performed in food simulants, not actual foodstuffs. Food simulants are used as substitutes for food due to the complexity and variety of foodstuffs, simplification of chemical analysis, and make comparable results between different laboratories.

There are five simulants described in the legislation for plastic (EU 10/2011):

- 10% ethanol (v/v) in aqueous solution (simulant A),
- 3% acetic acid (w/v) in aqueous solution (simulant B),
- 20% ethanol (v/v) in aqueous solution (simulant C),
- 50% ethanol (v/v) in aqueous solution (simulant D1),
- vegetable oil (simulant D2),
- poly(2,6-diphenyl-p-phenylene oxide, particle size 60-80 mesh, pore size 200 nm, commonly named as Tenax) (simulant E).

The selection of the simulants for the specific final applications of the food packaging is performed according to the specifications provided by the Regulation:

- Food simulants A, B and C are used for hydrophilic foods.
- Food simulant B is used for acidic foods with pH below 4.5.
- Food simulant C is used for alcoholic foods with an alcohol content of up to 20 %.
- Food simulants D1 and D2 are assigned for lipophilic foods.
- Food simulant D1, D2, and E are used for alcoholic foods with an alcohol content of above 20 %, for fatty foods, and for dry foods, respectively.

For demonstration of compliance for plastic materials and articles not yet in contact with food, that is the case of BIOnTop developed packaging, both flexible and rigid, the tests must be carried out with three different food simulants: **simulant A, B and D2 (together with a simulation with water)**. And simulant D2 can be substituted with iso-octane for technical reasons: the quantification of the total migration with vegetable oil is a very difficult and with high uncertainty on the quantification step.

6.3.1 Time-temperature exposure conditions

Migration experiments must be conducted under standardized conditions of contact time and temperature to get the worst scenario for the labelling information on the maximum temperature of use. In addition, time and temperature conditions should be in accordance with the relevant legislation (Regulation EU 10/2011), on the basis of the specific function of the packaging article(s).

The foreseeable conditions of use as regard contact time are presented in Table 1 and as regard contact temperature in Table 2.

The Regulation affirmed that if it is found that carrying out the tests under the combination of contact conditions specified in Table 1 and Table 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

In addition, for contact times above 30 days at room temperature and below, the specimen has to be tested in an accelerated test at elevated temperature for a maximum of 10 days at 60 °C.

Contact time in worst foreseeable use	Test time
t ≤ 5 min	5 min
5 min < t ≤ 0,5 hour	0,5 hour
0,5 hours < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours
1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
Above 30 days	See specific conditions

Table 1. Contact time of the overall migration test.

Conditions of contact in worst foreseeable use	Test conditions
Contact temperature	Test temperature
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C (*)
121 °C < T ≤ 130 °C	130 °C (*)
130 °C < T ≤ 150 °C	150 °C (*)
150 °C < T < 175 °C	175 °C (*)
T > 175 °C	Adjust the temperature to the real temperature at the interface with the food (*)

(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

Table 2. Contact temperature of the of the overall migration test.

The total migration of BIOnTop developed packaging is allowed to proceed for 10 days at 40°C, as worst condition and simulation of long-lasting contact of food at room temperature.

Hence, packaging samples with negative results provided under the previous conditions (not passed test) are tested under less rigorous conditions (i.e. for 3 days at 40°C and for 24 hours at 40°C).

6.4 Preparation of laboratory samples and procedure for overall migration tests

Dust has been removed by wiping the sample with a lint-free cloth or brushing with a soft brush. All the specimens have been weighted before starting the tests. The three test specimens for the total migration test are tested separately in different containers (glass beaker) and tested by immersion.

The experimental set-up must limit the evaporation that occurs during the exposure phase. The volume or weight of the simulant is recorded following the completion of the test.

6.4.1 Test protocol by immersion

Materials:

- 3 beakers (cylindrical flask) of diameter as narrow as possible whilst accommodating the width of the article (usually 500 ml and 800 ml long necks have been found adequate),
- 3 glass or tightly fitted aluminium foil covers.
- Thermostatic oven with monitoring of the temperature
- Solution of each simulant in sufficient amount for the test.

Procedure:

Take 3 beakers (cylindrical flask) of diameter as narrow as possible whilst accommodating the width for containing 3 articles together fully exposed.

Take 3 samples and be sure that the height of the sample is below at least of 1 cm from the surface of the simulant inside the beaker when you fill in the container.

Prepare the solution of each simulant according to the detailed concentrations and equilibrate at the test temperature, previous their use.

Fill the beaker with the simulant equilibrated at the test temperature to a volume able to submerge at least the entire “food contact surface area” of the test specimen (1 cm of the handle can be included if desired).

Immerse the specimen, covering the top of the beaker with a glass plate or hour glass or aluminium foil in order to reduce the loss of the simulant by evaporation. Add blank sample for each simulant to check the dry mass of the simulant itself at the end of the test which has to be subtracted from the solid residue of each sample, accordingly.

When temperature reaches testing temperature, start the timer to assess the time for contact as established for the test.

At the end of the test, remove the test specimens from the simulant.

Determine the weight of the dry solid residues from simulant at constant weight to assess the weight of the substances migrated from the packaging for each single specimen. The food simulant from each test specimen has to be evaporated to dryness (steam bath to reduce the volume and then in oven 105°C)

and the mass of the non-volatile residue was determined and expressed as mg/dm^2 of surface area exposed to the food simulant.

For all migration tests, the final overall migration is reported as the mean of a minimum of three determinations on separate test specimens.

6.4.2 Specific migration tests

The objective of this analytical test is to evaluate the maximum permitted amount of a given substance released from a material or article into food or food simulants. In this case, the evaluation of the general restrictions for plastic materials and articles collected in the Annex II of the Regulation (EU) No 10/2011 and related to metals and volatile organic compound (primary aromatic amines) and several selected chemical components.

The conditions have been selected according to the Annex III related to food simulants (table 2) and Annex V on compliance testing (Chapter 2) of the mentioned Regulation in order to cover the usage of the final material.

7 Tested samples and experimental results

All partners involved in the study of the production of BIOnTop film and rigid packaging (AIMPLAS, BIO-MI, INSTM, PLANET) provided the samples to ARCHA for the determination of the migration properties and to assess the compliance with the Regulation (EU) No 10/2011.

For all migration tests, the final overall migration is reported as the mean of a minimum of three determinations on separate test specimens.

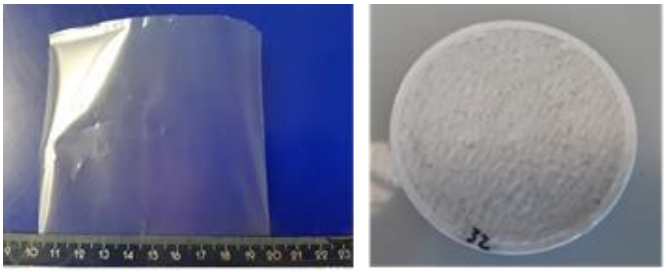
On the compliant residues obtained from the overall migration tests, the specific migration tests are performed for the optimised samples in the following conditions:

- for film formulations, the specific migration test is performed after 10 days at 40°C,
- for tray formulations, the specific migration test is performed after 24 hours at 40°C.

In the following paragraphs, all the obtained results are described.

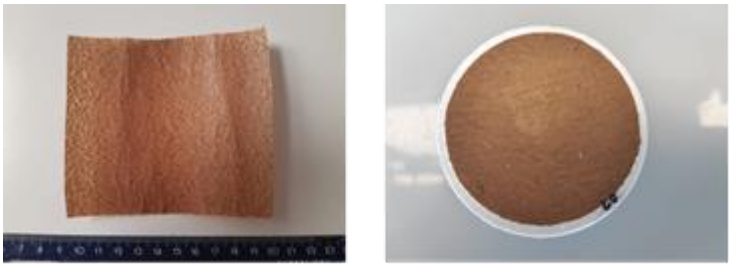
7.1 Overall migration results on the first film and tray formulations (sent by INSTM, May 2022)

In the picture below, Figure 1 and Figure 2, the pictures of "Film – formulation n. 2" and "Tray – formulation n. 1" showing on the left the sample as it is and on the right the residual after migration, respectively.



Film - formulation n. 2

Figure 1. Picture of Film – formulation n. 2 (on the left the sample; on the right the residual after migration).



Tray - formulation n. 1

Figure 2. Picture of Tray – formulation n. 1 (on the left the sample; on the right the residual after migration).

In the Table 3, the results of the total migration tests performed on the abovementioned samples are provided.

Samples	Simulant	Test conditions	Total migration (mg/dm²) (Limit = 10 mg/dm²)	STD DEV
Film - formulation n. 2	Water	10 days at 40°C	4,8	0,7
	Ethanol (10% v/v)		6,5	1,0
	Acetic acid (3% w/v)		9,2	0,4
	Vegetable oil		7,4	0,5
Tray - formulation n. 1	Water		8,9	0,4
	Ethanol (10% v/v)		**15,6**	1,6
	Acetic acid (3% w/v)		**51,8**	5,2
	Vegetable oil		**46,5**	3,9

Table 3. Results of the total migration of "Film - formulation n. 2" and "Tray – formulation n. 1" (10 days at 40°C).

The sample called "Film – formulation n. 2" is compliant with the total migration limit.
The sample called "Tray – formulation n. 1" is not compliant with the total migration limit (red values in the table).

7.2 Overall migration results on the optimised film and tray formulations (sent by AIMPLAS and INSTM, March 2023) - 10 days at 40°C

In the pictures below, the pictures of "Film – formulation n. 1 & 2" and "Tray – formulation n. 1 & 2" are provided.

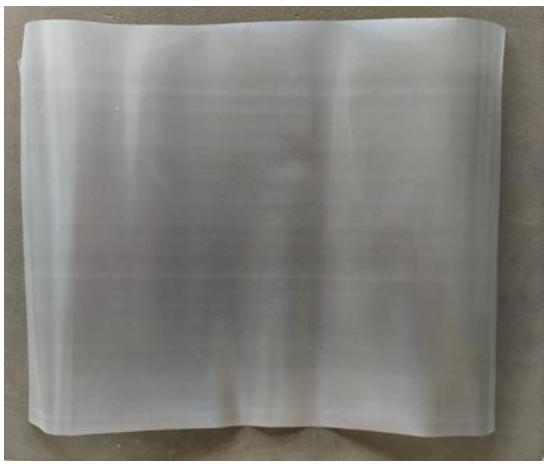


Figure 3. Picture of "Film – formulation n. 1".

Figure 4. Picture of "Film – formulation n. 2".

Figure 5. Picture of "Tray – formulation n. 1".

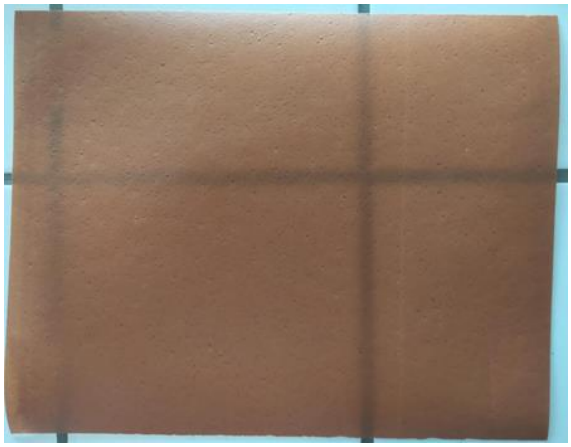


Figure 6. Picture of "Tray – formulation n. 2".

In Table 4 and Table 5, the results from the overall migration tests of the film and tray formulations developed during the last period of the project are provided.

The conclusions on these samples for the overall migration tests are:

- Both formulations for Trays don't comply with the total migration limit (red values in the table), except for the migration in iso-octane performed on "Tray – formulation n. 2"
- Both formulations for Films comply with the total migration limit.

Sample	Simulants	Exp. conditions	Total average migration (Limit = 10 mg/dm^2)	STD DEV
Tray - Formulation n. 1	Water	10 days at 40°C	**21,5**	2,8
	Acetic acid (3% w/v)		**30,7**	4,6
	Ethanol (10% v/v)		**35,6**	2,4
	Iso-octane		**12,6**	2,1
Tray - Formulation n. 2	Water		**37,4**	2,1
	Acetic acid (3% w/v)		**41,5**	6,1
	Ethanol (10% v/v)		**40,3**	4,7
	Iso-octane		8,8	0,9

Table 4. Results of the total migration of "Tray - formulation n. 1" and "Tray – formulation n. 2" (10 days at 40°C).

Sample	Simulants	Exp. conditions	Total average migration (Limit = 10 mg/dm^2)	STD DEV
Film - Formulation n. 1	Water	10 days at 40°C	0,9	0,1
	Acetic acid (3% w/v)		2,1	0,2
	Ethanol (10% v/v)		1,1	0,3
	Iso-octane		0,4	0,3
Film - Formulation n. 2	Water		0,6	0,1
	Acetic acid (3% w/v)		1,5	0,2
	Ethanol (10% v/v)		0,9	0,1
	Iso-octane		0,9	0,2

Table 5. Results of the total migration of "Film - formulation n. 1" and "Film – formulation n. 2" (10 days at 40°C).

Both films formulations can be used for all the application in contact with food considering all types of food and temperature of contact T ≤ 40°C and contact time ≤ 30 days, according to Regulation (EU) No 10/2011.

7.3 Overall migration results on the optimised tray formulations (sent by INSTM, March 2023) - 3 days at 40°C

The same samples called Tray – formulation n. 1 & 2 described in Paragraph 7.2 are tested under different experimental conditions, by decreasing the time of the contact with simulants: 3 days at 40°C is considered the first less aggressive condition to be applied.

In Table 6, the results from the overall migration tests of the tray formulations developed during the last period of the project are provided.

The conclusions on these samples for the overall migration tests are:

- "Tray – formulation n. 1" doesn't comply with the total migration limit (red values in the table) for water and Acetic acid; for the contact with ethanol, the obtained result is borderline; the isooctane migration is compliant
- "Tray – formulation n. 2" doesn't comply with the total migration limit (red values in the table), don't comply with the total migration limit (red values in the table), except for the migration in isooctane.

Sample	Simulants	Exp. conditions	Total average migration (Limit = 10 mg/dm^2)	STD DEV
Tray - Formulation n. 1	Water	3 days at 40°C	**11,0**	1,8
	Acetic acid (3% w/v)		**18,2**	1,4
	Ethanol (10% v/v)		9,6	0,4
	Isooctane		7,6	0,5
Tray - Formulation n. 2	Water		**16,2**	0,9
	Acetic acid (3% w/v)		**21,1**	3,0
	Ethanol (10% v/v)		**14,4**	1,6
	Isooctane		5,9	1,0

Table 6. Results of the total migration of "Tray - formulation n. 1" and "Tray – formulation n. 2" (3 days at 40°C).

Even if both formulations are not compliant under the less aggressive condition (3 days at 40°c), it's important to notice that all the migrations results are decreased compared with the "10 days" tests.

In the next Paragraph 7.4, the duration of the total migration tests for these samples has been decreased more, till 24 hours, to verify how long the duration of the compliant contact could be.

7.4 Overall migration results on the optimised tray formulations (sent by INSTM, March 2023) – 24 hours at 40°C

The same samples of Tray – formulation n. 1 & 2 described in Paragraphs 7.2 and 7.3 are tested under different experimental conditions, by decreasing the time of the contact with simulants: 24 hours at 40°C is considered less aggressive condition to be applied.

In Table 6, the results from the overall migration tests of the tray formulations developed during the last period of the project are provided.

The conclusion on these samples for the overall migration tests is that both samples called "Tray – formulation n. 1" and "Tray – formulation n. 2" comply with the total migration limit.

Sample	Simulants	Exp. conditions	Total average migration (Limit = 10 mg/dm^2)	STD DEV
Tray - Formulation n. 1	Water	24 hours at 40°C	7,0	0,6
	Acetic acid (3% w/v)		8,2	0,9
	Ethanol (10% v/v)		7,1	0,4
	Isooctane		6,8	0,7
Tray - Formulation n. 2	Water		8,2	1,1
	Acetic acid (3% w/v)		9,3	0,6
	Ethanol (10% v/v)		6,6	0,6
	Isooctane		5,2	0,7

Table 7. Results of the total migration of "Tray - formulation n. 1" and "Tray – formulation n. 2" (24 hours at 40°C).

Both tray formulations can be used for the application in contact with food considering all types of food and temperature of contact T ≤ 40°C and contact time ≤ 24 hours) according to Regulation (EU) No 10/2011.

7.5 Specific migration results on the optimised film formulations (sent by AIMPLAS, March 2023) – 10 days at 40°C

For the film formulations, the residues from the overall migration tests are analysed for the quantification of the concentration of specific chemicals and molecule to assess if the migrated concentrations comply with the single specific limits defined in Regulation (EU) No 10/2011.

The used simulant is the food simulant B (Acetic acid (3% w/v)) because acidic conditions are the most favourable to extract metals. If the samples pass the test using this simulant, the material will be able to be in contact with all types of food. To cover any long-term storage at room temperature or below, the test is performed during 10 days at 40 °C. The results obtained are presented in Table 8.

	Simulant B (Acetic acid 3%) - 10 days at 40°C		Limits (Regulation EU 10/2011) (mg per kg of product)
	Film - formulation n. 1	**Film - formulation n. 2**	
Barium	< 0,1	< 0,1	1
Cobalt	< 0,02	< 0,02	0,05
Copper	< 0,1	< 0,1	5
Iron	0,56	0,75	48
Lithium	< 0,1	0,11	0,6
Manganese	< 0,1	< 0,1	0,6
Zinc	1,3	1,8	25

Table 8. Specific migration results of "Film - formulation n. 1" and "Film – formulation n. 2" (10 days at 40°C).

According to the obtained results on heavy metal migration, the film demonstrators are able to be in contact with all food types in periods of long storage at room temperature or below.

Plastic materials and articles must not release **primary aromatic amines**, in detectable quantities in food products or food simulants. The detection limit is 0.01 mg of substance per kg of product or food simulant. The detection limit applies to the sum of primary aromatic amines released (as for heavy metals, the used simulant is the food simulant B (Acetic acid (3% w/v)) because acidic conditions are the most favourable to extract primary aromatic amines). If the samples pass the test using this simulant, the material will be able to be in contact with all types of food. To cover any long-term storage at room temperature or below, the test is performed during 10 days at 40 °C. The results obtained are presented in Table 9.

	Simulant B (Acetic acid 3%) - 10 days at 40°C		Limits (Regulation EU 10/2011) (mg per kg of product)
	Film - formulation n. 1	Film - formulation n. 2	
Primary aromatic amines	< 0,01	< 0,01	0,01

Table 9. Specific migration results on Primary aromatic amines of "Film - formulation n. 1" and "Film – formulation n. 2" (10 days at 40°C).

According to the obtained results on primary aromatic amines, the film demonstrators are able to be in contact with all food types in periods of long storage at room temperature or below.

In addition, several chemical substances and groups of substances are quantified to ascertain their absence and to verify their compliance with the specific limits. In the Table 10, the experimental results are provided. The used simulant is the food simulant A (Ethanol 10% v/v).

	Simulant A (Ethanol 10%) - 10 days at 40°C		Limits (Regulation EU 10/2011) (mg per kg of product)
	Film - formulation n. 1	Film - formulation n. 2	
Phosphate	< 0,02	< 0,02	0,05
Vinyl chloride	< 0,01	< 0,01	0,01
Acrylamide	< 0,01	< 0,01	0,01
Methacrylamide	< 0,01	< 0,01	0,01
Vinyl acetate	< 0,1	< 0,1	12
Acetaldehyde	< 0,2	< 0,2	6
Formaldehyde	< 0,1	< 0,1	15
Isocyanate	< 0,01	< 0,01	0,01
Acrylic acid	< 0,5	< 0,5	6
Methacrylic acid	< 0,5	< 0,5	6
Terephthalic acid	< 1	< 1	7,5
Caprolactone	< 0,01	< 0,01	0,05
Phthalates	< 1	< 1	60

Table 10. Specific migration results on several chemicals of "Film - formulation n. 1" and "Film – formulation n. 2" (10 days at 40°C).

According to the obtained results on several selected chemicals (e.g. Phthalates, Aldehydes, acrylic and vinyl chemicals…), the film demonstrators are able to be in contact with all food types in periods of long storage at room temperature or below.

7.6 Specific migration results on the optimised tray formulations (sent by INSTM, March 2023) – 24 hours at 40°C

For the tray formulations, the residues from the overall migration tests are analysed for the quantification of the concentration of specific chemicals and molecule to assess if the migrated concentrations comply with the single specific limits defined in Regulation (EU) No 10/2011, as performed for the films.

The used simulant is the food simulant B (Acetic acid (3% w/v)) because acidic conditions are the most favourable to extract metals. If the samples pass the test using this simulant, the material will be able to be in contact with all types of food. The specific migration test is performed after 24 hours of contact (due to the total migration results) at 40 °C. The results obtained are presented in Table 11.

	Simulant B (Acetic acid 3%) - 24 hours at 40°C		Limits (Regulation EU 10/2011) (mg per kg of product)
	Tray - formulation n. 1	**Tray - formulation n. 2**	
Barium	0,3	0,18	1
Cobalt	< 0,02	< 0,02	0,05
Copper	1,02	1,25	5
Iron	3,4	4,5	48
Lithium	0,21	0,19	0,6
Manganese	0,19	0,33	0,6
Zinc	4,9	5,6	25

Table 11. Specific migration results of "Tray - formulation n. 1" and "Tray – formulation n. 2" (24 hours at 40°C).

According to the obtained results on heavy metals migration, the tray demonstrators are able to be in contact with all food types in periods of long storage at room temperature or below.

Plastic materials and articles must not release **primary aromatic amines**, in detectable quantities in food products or food simulants. The detection limit is 0.01 mg of substance per kg of product or food simulant. The detection limit applies to the sum of primary aromatic amines released and the used simulant is the food simulant B (Acetic acid (3% w/v)) because acidic conditions are the most favourable to extract primary aromatic amines. If the samples pass the test using this simulant, the material will be able to be in contact with all types of food. The specific migration test is performed after 24 hours of contact (due to the total migration results) at 40 °C. The results obtained are presented in Table 12.

	Simulant B (Acetic acid 3%) - 24 hours at 40°C		Limits (Regulation EU 10/2011) (mg per kg of product)
	Tray - formulation n. 1	Tray - formulation n. 2	
Primary aromatic amines	< 0,01	< 0,01	0,01

Table 12. Specific migration results on Primary aromatic amines of "Tray - formulation n. 1" and "Tray – formulation n. 2" (24 hours at 40°C).

According to the obtained results on primary aromatic amines, the tray demonstrators are able to be in contact with all food types in periods of long storage at room temperature or below.

In addition, several chemical substances and groups of substances are quantified to ascertain their absence and to verify their compliance with the specific limits. In the Table 13, the experimental results are provided. The used simulant is the food simulant A (Ethanol 10% v/v).

	Simulant A (Ethanol 10%) - 24 hours at 40°C		Limits (Regulation EU 10/2011) (mg per kg of product)
	Tray - formulation n. 1	Tray - formulation n. 2	
Phosphate	0,04	0,03	0,05
Vinyl chloride	< 0,01	< 0,01	0,01
Acrylamide	< 0,01	< 0,01	0,01
Methacrylamide	< 0,01	< 0,01	0,01
Vinyl acetate	< 0,1	< 0,1	12
Acetaldehyde	0,5	0,8	6
Formaldehyde	< 0,1	< 0,1	15
Isocyanate	< 0,01	< 0,01	0,01
Acrylic acid	< 0,5	< 0,5	6
Methacrylic acid	< 0,5	< 0,5	6
Terephthalic acid	< 1	< 1	7,5
Caprolactone	< 0,01	< 0,01	0,05
Phthalates	< 1	< 1	60

Table 13. Specific migration results on several chemicals of "Tray - formulation n. 1" and "Tray – formulation n. 2" (24 hours at 40°C).

According to the obtained results on several selected chemicals (e.g. Phthalates, Aldehydes, acrylic and vinyl chemicals…), the tray demonstrators are able to be in contact with all food types in periods of long storage at room temperature or below.

7.7 Evaluation of Not-Intentionally Added Substances (NIAS)

To finish with the assessment, the evaluation of non-intentionally added substances (NIAS) present in the material by extraction is carried out. The main objective is to evaluate the risk of the presence of non-listed, toxic or not evaluated substances in the materials, such impurities or degradation/reaction products that potentially could migrate to the packed food.

The extraction from the demonstrators is performed by Microwave Assisted Extraction (MAE) with acetonitrile and / or dichloromethane, achieving the complete disintegration of the materials.

The analyse of the volatile and semi-volatile fractions and semi-quantification of the found substances are performed using different chromatography techniques such GC for Volatile and semi volatile fraction. The extraction and determination are carried out following the parameters in Table 14.

	Semi-volatile compound	Volatile compound
Sample weight	1 g	
Extraction	Microwave assisted extraction (MAE)	
Extraction solvent	Acetonitrile or Dichloromethane	
Final volume	100 ml	20 ml
Sample preparation analysis		
Injection volume	1 µL	1 mL
Carrier gas	Hydrogen 2 ml/min	
Oven	40 °C (3min), 5 °C/min up to 100 °C (3min), at 10 °C/min up to 280 °C (3min)	
Detector	Scan 50-650 m/z in EI+	
Injector	Split (1:10) 250 °C	
Method of analysis and identification	Comparison of mass spectra with NIST library (match greater than 700). Calculation of the elemental composition of the substance (empirical formula) and of the strongest fragment ions (mass error < 3 mDa)	
Equipment and tools	Gas Chromatograph with Mass Detector	

Table 14. Experimental conditions for extraction.

The detected substances in the “Film – formulation n. 1” and “Film – formulation n. 2” are presented in the Table 15; the detected substances in the “Tray – formulation n. 1” and “Tray – formulation n. 2” are presented in Table 16.

Volatile compounds			Film - Formulation 1		Film - Formulation 2	
rt (min)	**Substance**	**CAS**	**Prob**	**Area**	**Prob**	**Area**
2,4	Chloroform	67-66-3	81	285	65	73
5,93	Ethyl benzene	100-41-4	42	58	18	35
10	limonene	138-86-3	20	53	32	146
15,15	triacetin	102-76-1	56	29	66	118
16,08	tetradecane	629-59-4	50	40	29	78
17,61	methyl-3-2-methoxyphenyl propanoate	C11H14O3	50	490	27	354
Semi volatile compounds			**Film - Formulation 1**		**Film - Formulation 2**	
rt (min)	**Substance**	**CAS**	**Prob**	**Area**	**Prob**	**Area**
13,43	lactide	95-96-5	27	4702	40	1670
17,86	cyclododecane	293-96-9	8	48	12	120

Table 15. Substances found in the Film – formulation n. 1 & 2.

Volatile compounds			Tray - Formulation 1		Tray - Formulation 2	
rt (min)	**Substance**	**CAS**	**Prob**	**Area**	**Prob**	**Area**
2,1	acetic acid	C2H4O2	16	78	25	150
2,87	4-methyl ciclohexanol	C7H14O	18	41	34	69
5,93	ethyl benzene	C8H10	34	20	16	112
8,76	caproic acid	C6H12O2	62	103	36	55
9,13	pentyl furano	C9H14O	77	218	80	302
9,25	pseudocumol	C9H12	23	32	21	58
13,14	dodecane	C12H26	29	47	33	40
15,15	triacetin	C9H14O6	52	154	41	162
16,08	tetradecane	C14H30	29	47	36	59
18,61	hexadecane	C16H34	30	29	45	33
Semi volatile compounds			**Tray - Formulation 1**		**Tray - Formulation 2**	
rt (min)	**Substance**	**CAS**	**Prob**	**Area**	**Prob**	**Area**
1,92	propanenitrile	C3H5N	82	260	89	160
17,86	cyclododecane	C10H20	3	31	12	96
23,17	hexadecanoic acid	C16H32O2	68	36	55	180
27,23	tributyl acetylcitrate	C20H34O8	92	50	78	125

Table 16. Substances found in Tray – formulation n. 1 & 2.

7.7.1 Risk assessment of the found substances

The risk assessment of the identified candidate compounds (see Paragraph 7.7) has been performed according to the strategy proposed by Plastics Europe[11]. The risk assessment has focused on the substances that are present in the BIOnTop demonstrators.

The presence of these substances in Food Contact Materials (FCMs) and in the positive lists has been verified. Their presence in those lists means that their use in FCMs is known and in some cases even their toxicity has been evaluated and a Specific Migration Limit (SML) has been set in order to protect consumers' health when the substance is present below that limit. In the case of the non-listed or non-evaluated substances, on the one hand, the classification of the substances as chemical contaminants according to the European Regulation on chemical products, has been analysed.

The Regulations require that, for the commercialization of a substance, the possible health hazards that these may cause have been studied. The classification in the CLP Regulation (Classification, Labelling and Packaging) responds to the United Nations Globally Harmonized System (GHS) for the classification and labelling of chemical products. Prior to this classification, applicants must submit a CLP notification providing their studies. Similarly, under the REACH Regulation, companies must register the substances they market, collecting and evaluating the information on the properties and dangers of these substances.

On the other hand, the individual toxicological information available in the registration dossiers submitted to ECHA has been compiled, namely the NOAEL (No Observed Adverse Effect Level) from which a TDI (Tolerable Daily Intake) and a self-derived SML (SML-NOAEL) have been calculated.

SML-NOAEL (mg/kg) = 60 (kg body weight) x TDI (mg/kg body weight/day) / 1 kg food/day
TDI (mg/kg body weight/day) = NOAEL (mg/kg body weight/day) / assessment factor

For EU FCMs, the typical convention is to calculate the TDI by dividing the NOAEL obtained from an oral sub chronic (90 days) study with a default assessment factor of 100.

Finally, for those substances for which such information is not available, their structural toxicity has been clustered by considering three levels of toxicity:

- Low (class I): Substances with a simple structure and for which there are efficient metabolic routes, which suggest a low level of oral toxicity. Exposure threshold in humans 1.8 mg / kg body weight / day.
- Intermediate (Class II): Substances with less harmless structure than Class I, but which do not contain structures that suggest toxicity similar to Class III substances. Human exposure threshold 0.54 mg / kg body weight / day.

[11] Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (https://plasticseurope.org/wp-content/uploads/2021/11/risk-assesment-of-non-listed-substances-and-non-assesed-substances.pdf)

- High (Class III): Substances with a structure that cannot be predicted to be safe or to suggest significant toxicity or to have reactive functional groups. Exposure threshold in humans 0.09 mg / kg body weight / day.

Out of this exposure threshold and considering the default assumption that in Europe an adult person consumes 1 kg of packaged food every day, a self-derived SML (SMLTTC) has been calculated.

The above risk analysis has been carried out on the detected substances with a **probability > 70** of those found above, summarised in the next Table 17, both in the Films and trays formulations. In the Table 18, the Risk information for detected substances, for films and trays demonstrators are provided.

Volatile compounds			Film - Formulation 1		Film - Formulation 2	
rt (min)	**Substance**	**CAS**	**Prob**	**Area**	**Prob**	**Area**
2,4	Chloroform	67-66-3	81	285	75	73
Volatile and semi-volatile compounds			**Tray - Formulation 1**		**Tray - Formulation 2**	
rt (min)	**Substance**	**CAS**	**Prob**	**Area**	**Prob**	**Area**
9,13	pentyl furane	C9H14O	77	218	80	302
1,92	propanenitrile	C3H5N	82	260	89	160
27,23	tributyl acetylcitrate	C20H34O8	92	50	78	125

Table 17. Substances with probability > 70, found in Films and Tray – formulations.

Compound	CAS	FCM Regulation	SML (mg/kg)	Classified or notified hazards	SML_{NOAEL} (mg/kg)	Structural toxicity	SML_{TTC} (mg/kg)
Chloroform	67-66-3	-	-	NOAEL oral route 34 mg/kg bw/day. According to the notifications provided by companies to ECHA in REACH registrations s suspected of causing cancer, is suspected of damaging the unborn child and causes skin irritation (CMR)	20,4	**High (Class III)**	**0,09**
Pentyl furane	3777-69-3	-	-	NOAEL oral route 13,93 mg/kg bw/day. There is no harmonised classification and there are no notified hazards by manufacturers, importers or downstream users for this substance	8,36	High (Class III)	0,09
Propanenitrile	107-12-0	Ordinance of the FDHA - Annex 10 - Part B	0,01	NOAEL oral route 63,45 mg/kg bw/day. According to the classification provided by companies to ECHA in REACH registrations this substance is fatal if swallowed, is fatal in contact with skin, is toxic if inhaled, is a highly flammable liquid and vapour, causes serious eye irritation, may cause damage to organs through prolonged or repeated exposure and is harmful to aquatic life	38,07	High (Class III)	0,09
Tributyl acetylcitrate	77-90-7	Regulation (EU) No. 10/2011	60	NOAEL oral route 100 mg/kg bw/day. According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified	60	Low (Class I)	1,8

Table 18. Risk information for detected substances, for films and trays demonstrators.

The found substances with high structural toxicity and toxicity threshold need to be quantified and their compliance with the derived SML verified: in BIOnTop demonstrators, the presence of these substances has been identified (by NOAEL or TTC) and therefore their compliance has been validated by migration testing and their presence has been quantified below the not detectable value (0.01 mg/kg) for all samples.

Non-listed substances for which has been established for a low hazard level (in BIOnTop trays, Tributyl acetylcitrate), the self-derived SML by TTC of 1.8 mg/kg has been proved verified.

7.8 Total migration on films from secondary raw materials

As defined within Task 5.6 “Films from secondary raw materials”:

“A comparison with the virgin materials will be made in terms of properties to validate if the reuse of the films in similar applications could be technically feasible, although it is currently hindered by food contact legislations (unless working in a close collection system or after the certification of the overall recycling chain by challenge test which would not make sense at TRL5). To that end, also migration tests will be made on these materials in task 5.5.”

Accordingly, the total migration is also assessed on the materials obtained from different cycles of recycling. ROMEI, after performing the recycling of the tray packaging materials, provided the samples to ARCHA, as it is defined during the last meeting of the project. Furthermore, BIO-MI after performing the recycling of the film packaging materials, provided the samples to AIMPLAS and then to ARCHA, as it is defined during the last meeting of the project (Dusseldorf, May 11, 2023).

All these results will be provided in the final technical report to allow to carry out the test with 10 days as duration of the contact (or lower, if the samples don’t pass under this condition), at 40°C with simulant A, B and iso-octane.

8 Conclusions

In terms of the H&S assessment of packaging products, the study provided the results for migration tests performed on different selected formulation and, in particular, on 4 selected plastic demonstrators. To evaluate the H&S aspect of these packaging, the total migration of the BIOnTop Films and Trays formulations, flexible and rigid packaging, is carried out and this Deliverable 5.5 describes all the obtained results.

The tests are performed accordingly to the Regulation (EU) No 10/2011 to verify the compliance with the Overall Migration Limit of 10 mg/dm^2 in several simulants and with different experimental conditions, in terms of time of contact and exposure temperature to assess the condition for the final application as food packaging. In addition, the specific migration in the same experimental conditions of the passed overall migration tests has been performed.

The main conclusions and the main results are:

- **For flexible packaging (Film – formulation n. 1 & 2)**: the total migration results are compliant with the limit by performing the tests at 40°C for 10 days of contact with all tested simulants. Accordingly, the packaging can be applied for food packaging application for contact times above 30 days at room temperature (or below) as real use.
- **For rigid packaging (Tray – formulation n. 1 & 2):** the total migration results are compliant with the coating with limit by performing the tests at 40°C for 24 hours of contact with all tested simulants. Accordingly, the packaging can be applied for food packaging application for contact times below 24 hours at room temperature (or below) as real use.
- From the specific migration tests, a risk assessment has been carried out for substances identified in the selected demonstrators with a confidence level higher than 70 %. The found substances have to be taken into account when assessing the suitability of the material for food contact. Especially substances with a high toxicity or which are not listed in FCM legislation, or toxicity studies are not available. The applicable SML obtained in the performed risk assessment must be verified for each substance.
- the total migration is also under assessment for the materials obtained from different cycles of recycling, both for films and trays formulations (these results will be provided in the final technical report).

9 Bibliography

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- EN 1186-1:2002 Part 1: Guide to the Selection of Conditions and test methods for Overall Migration
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