



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



D6.4 Report on Food packaging for nets and textile solutions health & safety assessment



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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, **tea bags and net roll** in particular, according to Regulation (EU) No 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 Regulation (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 and as tea bags, specifically.

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).

The 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 tea bags with the coatings developed during BIONtop project.

2.1 WPs and Tasks related with the deliverable

This deliverable is related to WP6 and specifically to the activities described in Task 6.5 Food packages health & safety assessment for nets and textile solutions.

Task 6.5 Food packages health & safety assessment for nets and textile solutions

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

ARCHA will perform migration tests on the textile packaging as described in task 5.5.

For easier reading, here below, Task 5.5 is also provided.

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 6.4 and in deliverable D 5.5.



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)²³.

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).

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

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*, 2nd 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*, 2nd 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.



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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 1935/2004⁵ 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 10/2011⁶ 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 882/2004⁷ includes quality standards for laboratories entrusted by the Member States with the official control of foodstuffs.
- The GMP Regulation (EC) No 2023/2006⁸ contains the basic principles of good manufacturing practice in the area of food contact materials.
- Directives 93/8/EEC and 82/711/EEC⁹ 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.

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 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 Immersion
- 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 Intended to come into contact with Fatty Foodstuffs using test Media Iso-Octane and 95% Ethanol.

The EN 13130¹⁰ series 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/dm²), 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 linear density of the yarn is used to calculate the surface area that make up the food contact surface of the article. The contact area is then calculated by weighing the sample 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 (Tea and coffee, in particular), that is the case of BIONtop developed packaging, both nets and textiles, the tests must be carried out with two different food simulants: **simulant B and C (together with a simulation with water)**. In addition, as requested from SIOEN, also **simulants A and D2** are considered to achieve the widest application for this kind of packaging. During the project, simulant D2 has been 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 No 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.



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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
$t \leq 5 \text{ min}$	5 min
$5 \text{ min} < t \leq 0,5 \text{ hour}$	0,5 hour
$0,5 \text{ hours} < t \leq 1 \text{ hour}$	1 hour
$1 \text{ hour} < t \leq 2 \text{ hours}$	2 hours
$2 \text{ hours} < t \leq 6 \text{ hours}$	6 hours
$6 \text{ hours} < t \leq 24 \text{ hours}$	24 hours
$1 \text{ day} < t \leq 3 \text{ days}$	3 days
$3 \text{ days} < t \leq 30 \text{ days}$	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
$T \leq 5 \text{ °C}$	5 °C
$5 \text{ °C} < T \leq 20 \text{ °C}$	20 °C
$20 \text{ °C} < T \leq 40 \text{ °C}$	40 °C
$40 \text{ °C} < T \leq 70 \text{ °C}$	70 °C
$70 \text{ °C} < T \leq 100 \text{ °C}$	100 °C or reflux temperature
$100 \text{ °C} < T \leq 121 \text{ °C}$	121 °C (*)
$121 \text{ °C} < T \leq 130 \text{ °C}$	130 °C (*)
$130 \text{ °C} < T \leq 150 \text{ °C}$	150 °C (*)
$150 \text{ °C} < T < 175 \text{ °C}$	175 °C (*)
$T > 175 \text{ °C}$	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 nets and textiles is performed for 5 minutes at 100°C (and keeping the system at room temperature for 30 minutes) for the application as tea bags and for 10 days at 60 °C to cover also other possible application of these packages.

Hence, packaging samples with negative results provided at the previous conditions are tested under less rigorous condition (i.e. for 10 days 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 is determined and expressed as mg/dm² 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) N° 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.

6.4.3 Evaluation of Not-Intentionally Added Substances (NIAS)

The evaluation of non-intentionally added substances (NIAS) present in the material by extraction has to be 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 tested material has to be disintegrated during an extraction phase and the analyses 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.

6.4.4 Risk assessment of the found substances

The risk assessment of the identified candidate compounds is performed according to the strategy proposed by Plastics Europe¹¹. 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-

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>).



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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.

$$\text{SML-NOAEL (mg/kg)} = 60 \text{ (kg body weight)} \times \text{TDI (mg/kg body weight/day)} / 1 \text{ kg food/day}$$

$$\text{TDI (mg/kg body weight/day)} = \text{NOAEL (mg/kg body weight/day)} / \text{assessment factor}$$

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.
- 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 is carried out on the detected substances with a **probability > 70** of the detected substances for the final “Net roll for tea bags” demonstrator.



7 Tested samples and experimental results

All partners involved in the study of the production of BIONtop nets and textiles packaging (AIMPLAS, ASU, CENTEXBEL, SIOEN, SILON) 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. The applied experimental conditions are:

- Immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes,
- Immersion at 60°C for 10 days of contact,
- Immersion at 40°C for 10 days of contact.

On the final residues obtained from the overall migration tests, the specific migration tests are performed for the optimised samples for tea bags, after immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes.

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

7.1 Overall migration results on the first monofilament yarn formulations (sent by SIOEN, March 2022) – 10 days at 40°C and boiling simulant for 5 minutes

In the Figure 1, the pictures of net formulations tested in the first trial for the assessment of the total migration of monofilament yarn formulations are provided.

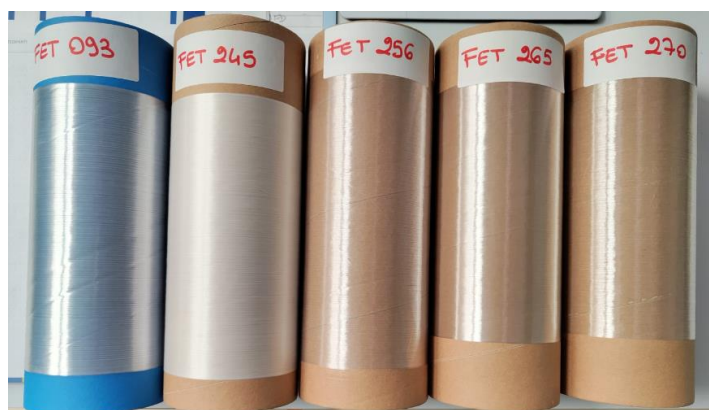


Figure 1. Picture of the tested net formulations.

In the Table 3, the results of the total migration tests performed on the abovementioned samples with experimental conditions used as for 10 days at 40°C, are provided.

Samples	Simulant	Test conditions	Total migration (mg/dm ²) (Limit = 10 mg/dm ²)	STD DEV
FET 093 (PLA / PCL)	Water	10 days at 40°C	3,5	0,5
	Ethanol (10% v/v)		7,6	1,1
	Acetic acid (3% w/v)		11,6	0,8
FET 245 (PLA / PCL / TPS)	Water		7,4	0,7
	Ethanol (10% v/v)		6,8	1,4
	Acetic acid (3% w/v)		9,6	1,1
FET 256 (PLA / PCL / PVOH)	Water		2,1	0,2
	Ethanol (10% v/v)		3,7	0,5
	Acetic acid (3% w/v)		7,7	0,9
FET 265 (PLA / PCL / PEG)	Water		6,6	0,5
	Ethanol (10% v/v)		12,4	0,7
	Acetic acid (3% w/v)		17,6	2,4
FET 270 (PLA / PCL / PEO)	Water		9,5	0,8
	Ethanol (10% v/v)		8,2	0,6
	Acetic acid (3% w/v)		14,7	2,2

Table 3. Results of the total migration of nets formulations (10 days at 40°C).



By applying the contact conditions for 10 days at 40°C:

- the samples called “FET 245 (PLA / PCL / TPS)” and “FET 256 (PLA / PCL / PVOH)” are compliant with the total migration limit.

- the samples called “FET 093 (PLA / PCL)”, “FET 265 (PLA / PCL / PEG)” and “FET 270 (PLA / PCL / PEO)” are not compliant with the total migration limit (red values in the table).

In addition, the experimental conditions are changed for the tea / coffee application by putting the specimens under immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes: the Table 4, the results of the total migration tests performed on the abovementioned samples are provided.

Samples	Simulant	Test conditions	Total migration (mg/dm ²) (Limit = 10 mg/dm ²)	STD DEV
FET 093 (PLA / PCL)	Water	Immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes	1,5	0,2
	Ethanol (10% v/v)		2,1	0,5
	Acetic acid (3% w/v)		6,7	0,8
FET 245 (PLA / PCL / TPS)	Water		1,8	0,5
	Ethanol (10% v/v)		1,9	0,4
	Acetic acid (3% w/v)		5,8	0,7
FET 256 (PLA / PCL / PVOH)	Water		1,6	0,5
	Ethanol (10% v/v)		3,7	0,6
	Acetic acid (3% w/v)		5,5	0,5
FET 265 (PLA / PCL / PEG)	Water		1,7	0,5
	Ethanol (10% v/v)		3,2	0,4
	Acetic acid (3% w/v)		7,5	1,2
FET 270 (PLA / PCL / PEO)	Water	1,3	0,6	
	Ethanol (10% v/v)	2,6	0,3	
	Acetic acid (3% w/v)	6,3	1,0	

Table 4. Results of the total migration of monofilament yarn formulations (Immersion in boiling simulant for 5 minutes).

By applying the contact conditions for immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes, all the tested samples are compliant with the total migration limit.



7.2 Overall migration results on the first coated textile formulations (sent by CENTEXBEL, March 2022) - 10 days at 60°C and 40°C

In the Figure 2, the pictures of coated textile formulation tested in the first trial for the assessment of the total migration is provided.



Figure 2. Picture of the tested textile formulation.

In the Table 5, the results of the total migration tests performed on the abovementioned sample with experimental conditions used as for 10 days at 60°C and 40°C, are provided.

Samples	Simulant	Test conditions	Total migration (mg/dm ²) (Limit = 10 mg/dm ²)	STD DEV
PLA HOTMELT COATED TEXTILE SAMPLE	Water	10 days at 40°C	3,5	0,7
	Ethanol (10% v/v)		4,8	0,8
	Acetic acid (3% w/v)		7,1	1,0
	Water	10 days at 60°C	6,0	0,5
	Ethanol (10% v/v)		5,5	1,2
	Acetic acid (3% w/v)		11,4	0,8

Table 5. Results of the total migration of coated textile formulation (10 days at 40°C and 60°C).

By applying the contact conditions for 10 days at 40°C, the sample called “PLA HOTMELT COATED TEXTILE SAMPLE” is compliant with the total migration limit.

By applying the contact conditions for 10 days at 60°C, the sample called “PLA HOTMELT COATED TEXTILE SAMPLE” is not compliant with the total migration limit only for acidic food.

7.3 Overall migration results on the oriented net formulation (sent by AIMPLAS, February 2023) - 10 days at 40°C

In the Figure 3 below, the picture of the “oriented net” sample is provided.



Figure 3. Picture of “Oriented net”.

In Table 6, the results from the overall migration tests of the oriented net formulation developed during the last period of the project are provided.

Sample	Simulants	Exp. conditions	Total average migration (Limit = 10 mg/dm ²)	STD DEV
Oriented net	Water	10 days at 40°C	0,9	0,1
	Acetic acid (3% w/v)		1,4	0,2
	Ethanol (10% v/v)		0,7	0,2
	Iso-octane		5,9	0,9

Table 6. Results of the total migration of “Oriented net” (10 days at 40°C).

The “oriented net” sample can be used for all the application in contact with food considering all types of food and temperature of contact $T \leq 40^{\circ}\text{C}$ and contact time ≤ 30 days, according to Regulation (EU) No 10/2011.



7.4 Overall migration results on the tea bags formulations (sent by ASU, January 2023) – 5 minutes, boiling temperature

Samples of tea bags, coated with alginate and filled in with tea and without tea, are provided by ASU for the assessment of the total migration by immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes: this is considered the most appropriate condition to be applied. In the Figure 4 below, the picture of the “tea bags” sample, both filled in and empty, is provided. In Table 7, the results from the overall migration tests of the tea bags are provided.

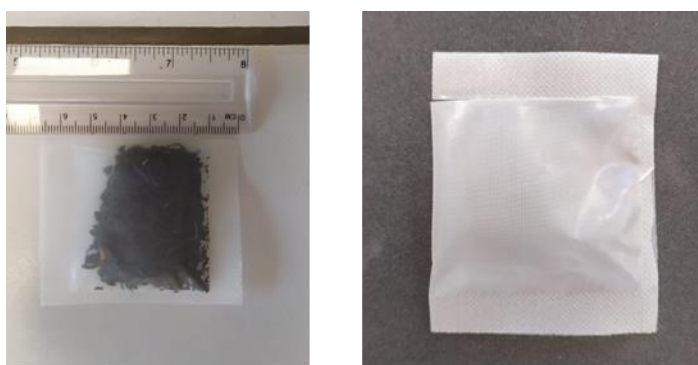


Figure 4. Picture of “tea bags”.

Samples	Simulant	Test conditions	Total migration (mg/dm ²) (Limit = 10 mg/dm ²)	STD DEV
Tea bags with tea inside	Water	Immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes	225,2	3,5
	Ethanol (10% v/v)		234,2	3,9
	Acetic acid (3% w/v)		283,8	5,2
Tea bags without tea (1 st migration)	Water		53,1	1,5
	Ethanol (10% v/v)		43,3	1,0
	Acetic acid (3% w/v)		49,3	1,2
Tea bags without tea (2 nd migration)	Water		25,1	3,6
	Ethanol (10% v/v)		19,6	2,4
	Acetic acid (3% w/v)		26,5	2,2
Tea bags without tea (3 rd migration)	Water	2,9	0,3	
	Ethanol (10% v/v)	2,5	0,2	
	Acetic acid (3% w/v)	2,8	0,4	

Table 7. Results of the total migration of “Tea bags” (immersion in boiling simulant for 5 minutes).

The infrared spectrum of the residues migrated during the first and second steps is related to alginate edible coating as compared in Figure 5 (the pink line is the IR spectrum of the second migrated residue, the black line is the alginate IR spectrum). From the third migration step, a very small amount of residue

is migrated in the simulant and it is not possible to acquire the related spectrum: in any case, the experimental result of the total migration is compliant with the limit.

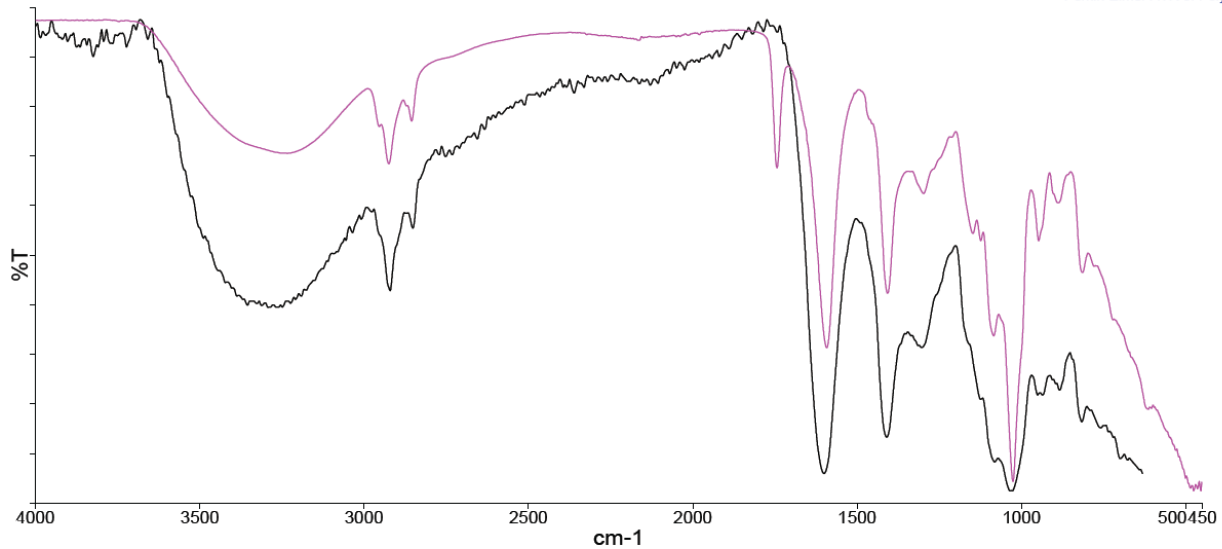


Figure 5. Infrared spectra of migrated residue, compared with the alginate spectrum.

In the first sample, the “Tea bags with tea inside”, the very high migration is due to the tea itself.

In the second and third samples, “Tea bags without tea (1st migration)” and “Tea bags without tea (2nd migration)”, the high migration values are due to the alginate coating applied on the bag.

The sample of “Tea bags without tea (3rd migration)” is compliant with the limits at the third migration step and can be used for the application in contact with food considering the specific application at high temperature with short time contact (5 minutes) according to Regulation (EU) No 10/2011.



7.5 Overall migration results on the “Net roll for tea bags” formulation (sent by SIOEN, April 2023) - 5 minutes, boiling temperature and 10 days at 40°C

In the Figure 6 below, the picture of the “Net roll for tea bags” sample is provided. In Table 6, the results from the overall migration tests of the “Net roll for tea bags” sample developed during the last period of the project are provided from the experiments made by immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes.

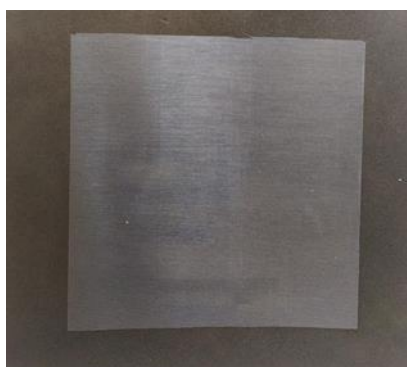


Figure 6. Picture of “Net roll for tea bags”.

Sample	Simulants	Exp. conditions	Total average migration (Limit = 10 mg/dm ²)	STD DEV
Net roll for tea bags	Water	Immersion in boiling simulant for 5 minutes and keeping the system at room temperature for 30 minutes	4,3	0,7
	Acetic acid (3% w/v)		2,1	0,5
	Ethanol (10% v/v)		3,1	0,3
	Ethanol (20% v/v)		2,9	0,1
	Iso-octane		0,7	0,1

Table 8. Results of the total migration of “Net roll for tea bags”, 5 minutes, boiling temperature.

The “Net roll for tea bags” sample is compliant with the limits and can be used for the application in contact with food considering the specific application at high temperature with short time contact (5 minutes) according to Regulation EC 10/2011.

In Table 9, the results from the overall migration tests of the “Net roll for tea bags” sample developed during the last period of the project are provided from the experiments made by 10 days as contact duration and at 40°C as applied temperature.



Sample	Simulants	Exp. conditions	Total average migration (Limit = 10 mg/dm ²)	STD DEV
Net roll for tea bags	Water	10 days at 40°C	6,2	1,1
	Acetic acid (3% w/v)		5,4	0,6
	Ethanol (10% v/v)		3,8	0,5
	Ethanol (20% v/v)		4,6	0,3
	Iso-octane		2,2	0,3

Table 9. Results of the total migration of “Net roll for tea bags”, 10 days at 40°C.

The “Net roll for tea bags” sample can be used for all the application in contact with food considering all types of food and temperature of contact $T \leq 40^{\circ}\text{C}$ and contact time ≤ 30 days, according to Regulation (EU) No 10/2011.



7.6 Specific migration results on the “Net roll for tea bags” formulation (sent by SIOEN, April 2023) - 5 minutes, boiling temperature

For the “Net roll for tea bags” formulation, 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 with two contact conditions: 5 minutes, boiling temperature. The results obtained are presented in Table 10.

	Simulant B (Acetic acid 3%) - Boiling simulant for 5 minutes	Limits (Regulation EU 10/2011) (mg per kg of product)
Barium	0,25	1
Cobalt	< 0,02	0,05
Copper	1,4	5
Iron	3,6	48
Litium	< 0,1	0,6
Manganese	0.15	0,6
Zinc	4,8	25

Table 10. Specific migration results on heavy metals of “Net roll for tea bags” (5 minutes, boiling temperature).

According to the obtained results on heavy metal migration, the “Net roll for tea bags” demonstrator is able to be in contact with all food types in periods of 5 minutes, boiling temperature.

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.

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 with two contact conditions: 5 minutes, boiling temperature. The results obtained are presented in Table 11.



	Simulant B (Acetic acid 3%) - Boiling simulant for 5 minutes	Limits (Regulation EU 10/2011) (mg per kg of product)
Primary aromatic amines	< 0,01	0,01

Table 11. Specific migration results on Primary aromatic amines of “Net roll for tea bags” (5 minutes, boiling temperature).

According to the obtained results on primary aromatic amines migration, the “Net roll for tea bags” demonstrator is able to be in contact with all food types in periods of 5 minutes, boiling temperature.

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 12, the experimental results are provided.

	Simulant B (Acetic acid 3%) - Boiling simulant for 5 minutes	Limits (Regulation EU 10/2011) (mg per kg of product)
Acrylamide	< 0,01	0,01
Methacrylamide	< 0,01	0,01
Vinyl acetate	< 0,1	12
Acetaldehyde	< 0,2	6
Formaldehyde	< 0,1	15
Acrylic acid	< 0,5	6
Methacrylic acid	< 0,5	6
Terephthalic acid	< 1	7,5
Caprolactone	< 0,01	0,05
Phthalates	< 1	60

Table 12. Specific migration results on several chemicals of “Net roll for tea bags” (5 minutes, boiling temperature).

According to the obtained results on several selected chemicals (e.g. Aldehydes, acrylic and vinyl chemicals...), the “Net roll for tea bags” demonstrator is able to be in contact with all food types in periods of 5 minutes, boiling temperature.



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 by identifying the presence of non-listed, toxic or not evaluated substances in the materials, such as 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. The analysis of the volatile and semi-volatile fractions and semi-quantification of the found substances are performed using different chromatography techniques such as GC for Volatile and semi-volatile fraction. The extraction and determination are carried out following the parameters in Table 13. The detected substances in the “Net roll for tea bags” are presented in the Table 14.

	Semi-volatile compound	Volatile compound
Sample weight	1 g	
Extraction	Microwave assisted extraction (MAE)	
Extraction solvent	Acetonitrile	
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 13. Experimental conditions for extraction.

Volatile compounds				
rt (min)	Substance	CAS	Prob	Area
2,4	Chloroform	67-66-3	81	264
5,93	Ethyl benzene	100-41-4	42	58
10	Limonene	138-86-3	20	53
Volatile and semi-volatile compounds				
rt (min)	Substance	CAS	Prob	Area
1,92	Propanenitrile	107-12-0	78	322
13,43	Lactide	95-96-5	27	5210

Table 14. Substances found in the “Net roll for tea bags”.



7.7.1 Risk assessment of the found substances

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. The risk analysis has been carried out on the detected substances with a **probability > 70** of those found above, summarised in the next Table 15, for the “Net roll for tea bags” sample. In the Table 16, the Risk information for detected substances, for Net roll for tea bags is provided.

Volatile compounds				
rt (min)	Substance	CAS	Prob	Area
2,4	Chloroform	67-66-3	81	264
1,92	Propanenitrile	107-12-0	78	322

Table 15. Substances with probability > 70, found in “Net roll for tea bags” sample.

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
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

Table 16. Risk information for detected substances, for “Net roll for tea bags” sample.

Both found substances are characterised by high structural toxicity and toxicity threshold need to be quantified and their compliance with the derived SML verified: in BIONtop net 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.



8 Conclusions

In terms of the H&S assessment of BIONtop nets and textile solutions, the study provided the results for migration tests performed on different selected formulations and, in particular, on 3 net demonstrators, called “Oriented net formulation”, “Tea bags formulation” and “Net roll for tea bag”. To evaluate the H&S aspect of these packaging, the total migration of the BIONtop net formulations is carried out and this Deliverable 6.4 describes all the obtained results.

The tests are performed accordingly to the European Regulation (EU) No 10/2011 to verify the compliance with the Overall Migration Limit of 10 mg/dm² 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 Oriented net formulation:** 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 “oriented net” packaging can be used for all the application in contact with food considering all types of food and temperature of contact $T \leq 40^{\circ}\text{C}$ and contact time ≤ 30 days, according to Regulation EC 10/2011.
- **For Tea bags formulation:** In the first sample, the tea bags with tea inside, the very high migration is due to the tea itself. In the second and third samples, Tea bags without tea (1st migration) and Tea bags without tea (2nd migration), the high migration values are due to the alginate coating applied on the bag. The sample of tea bags without tea is compliant with the limits at the third migration step and can be used for the application in contact with food considering the specific application at high temperature with short time contact (5 minutes) according to Regulation EC 10/2011.
- **For Net roll for tea bags:** The “Net roll for tea bags” sample tea is compliant with the limits and can be used for the application in contact with food considering the specific application at high temperature with short time contact (5 minutes) and temperature of contact $T \leq 40^{\circ}\text{C}$ and contact time ≤ 30 days, according to Regulation (EU) No 10/2011.
- 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 has been verified for each substance.



9 Bibliography

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- EN 1186-14:2002 Part 14: Test methods for 'Substitute tests' for Overall Migration from Plastics intended to Come into Contact with Fatty Foodstuffs using test Media Iso-Octane and 95% Ethanol.
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