PRIMUS

Guidance report on recyclate-related standardisation: PRE 1000 and food contact materials

Task 1.2

PRE 1000: One EU standard to determine the quality and general product safety of recyclate

Task 1.3

Beyond general product safety towards Food Contact Material Status

Funded by the European Union's Horizon Europe Programme under Grant Agreement No. 101057067

DISCLAIMER

ACKNOWLEDGEMENT

The PRIMUS project is funded by the European Union's Horizon Europe research and innovation programme under grant agreement N° 101057067.

Project Data			
Project Acronym	PRIMUS		
Project Title	Reforming Secondary Plastics to Become the Primary Raw Material Choice for Added Value Products		
Grant Agreement number	101057067		
Call identifier	HORIZON-CL4-2021-RESILIENCE-01		
Topic identifier	HORIZON-CL4-2021-RESILIENCE-01-10 Paving the way to an increased share of recycled plastics in added value products		
Funding Scheme	RIA – Research and Innovation Actions		
Project duration	36 months (From 1 May 2022)		
Coordinator	VTT		
Website	https:// primus-project.eu		
Deliverable Document Sheet			
Deliverable No.	1.2		
Deliverable title	Guidance report on recyclate-related standardisation - PRE1000 and food contact materials		
Description	The document aims at providing a guidance on the use PRE1000 tool and on the process on how to reach a food contact approved HIPS recyclate following the requirements of Regulation (EU) No 2022/1616.		
WP No.	WP1		
Related task	T1.2 – PRE 1000: One EU standard to determine the quality and general product safety of recyclate Task 1.3 - Beyond general product safety towards Food Contact Material Status		
Lead Beneficiary	11 - PRE		
Author(s)	Mathilde Taveau (PRE) Andromeda Scoppio (PRE)		
Contributor(s)	Jarkko Saarinen (UEF)		
Type	R		
Dissemination L.	Public		
Language	English – GB		
Due Date	31/10/2024	Submission Date	29/10/2024

Version	Action	Owner	Date
V.0.1	First draft	PRE	30/09/2024
V.0.2	Reviewed	VTT	

Table of Contents

List of Figures

List of Tables

GLOSSARY

Acronym	Definition
ADCA	Azodicarbonamide
CA	Competent Authority
CMSS	Compliance Monitoring Summary Sheet
EC	European Commission
EEE	Electrical and Electronic Equipment
ELV	End-of-life vehicles
EPR	Extended Producer Responsibility
EU	European Union
GCMS	Gas Chromatography-Mass Spectrometry
HIPS	High Impact Polystyrene
LCMS	Liquid Chromatography-Mass Spectrometry
NTN	Novel Technology Number
PET	Polyethylene terephthalate
POP	Persistent organic pollutants
PVC	Polyvinylchloride
REACH	Registration, Evaluation, Authorization and restriction of CHemicals
SHVC	Substance of very high concern
UV	Ultraviolet

EXECUTIVE SUMMARY

The PRIMUS project plays a crucial role in advancing the objectives of the European Strategy for Plastics, with a specific focus on increasing the volume of safe and high-quality recycled plastics entering the European market. This report serves as a comprehensive guide on the standardization of recyclates, focusing on compliance with chemicals legislation using the PRE 1000 tool, and addressing the development of food contact materials.

The PRE 1000 tool, developed by Plastics Recyclers Europe (PRE), is an industry standard for monitoring substances in recycled plastics. It has been validated within the PRIMUS project through testing on recyclate samples, further confirming its reliability. The tool simplifies compliance with regulatory requirements by enabling recyclers to effectively monitor over 300 Substances of Concern (SoC) and ensure that materials meet legislative requirements, such as the ones reported in the REACH, POPs, and RoHS regulations.

The report provides an in-depth explanation of the PRE 1000 methodology, from product definition, to sampling, and analysis of SoCs. It outlines how recyclers can use this tool to assess substances within recycled plastics efficiently, reducing the need for costly, complex, and lengthy chemical analysis. Using handheld XRF devices and additional chemical analysis when required, the PRE 1000 tool offers a cost-effective solution for recyclers to demonstrate compliance with EU regulations.

Additionally, the report serves as guidance on achieving food contact-approved High Impact Polystyrene (HIPS) recyclate in line with Regulation (EU) No 2022/1616. This regulation controls the use of recycled plastics in food contact materials, expanding upon previous legislation to accommodate advancements in plastic recycling technologies. The document details the steps necessary for recyclers to obtain approval for food contact materials, including requirements on plastic waste collection, decontamination processes, and the difference between suitable and novel recycling technologies.

Hence, the report provides valuable insights into the use of the tool and the broader regulatory landscape regulating recyclates and food contact materials in Europe.

PRIMUS PROJECT

PRIMUS project is dedicated to significantly contribute to the goals of the European Strategy for Plastics and enhance the amount of quality and safe recycled plastics that enter the European markets. PRIMUS is a project funded by the Horizon Europe in the following call: *HORIZON-CL4-2021-RESILIENCE-01-10: Paving the way to an increased share of recycled plastics in added value products (RIA).* PRIMUS is a 3-year project with a total budget of 7 M€. PRIMUS has 10 partners.

PRIMUS will actively engage with the plastics value chain stakeholders and innovatively develop novel methods and technologies to significantly increase the circularity, and production and use of sustainable, safe, and quality recyclates in added value products. The main technological focuses are on advanced mechanical recycling coupled with broad analytics and novel pretreatment methods for removal of hazardous substances and counteracting degradation. PRIMUS will produce 4 demonstrations where new added value products will be made from recycled and upgraded non- or underutilized plastic waste streams from waste electronics and electrical equipment (WEEE) and end-of-life vehicles (ELV). The four demo products will be automotive interior parts, automotive cooling circuits and its elements, a food contact application refrigerator, and a closed-loop demonstration of washing machine seals.

The project aims at establishing EU widely accepted and transparent procedures to control quality and safety of recyclates, especially for the waste streams containing hazardous substances like brominated flame retardants. The framework related work will include broad engagement of the European plastics sector and recyclers, but also the society, citizens, and communities as well as consumers. Safety and trackability back to origin, traceability, are consistent and overlapping themes in PRIMUS. PRIMUS will not only technically and industrially support the uptake of recyclates in products but will also address and support the concerns of the society and enhance the uptake of products that have recycled content.

1 INTRODUCTION

1.1 Scope

This document serves as a guidance report on the standardization of recyclates in compliance with chemicals legislation, using the PRE 1000 tool, and the development of food contact materials. It also provides information on how to use the PRE 1000 tool and outlines the process for achieving food contact-approved HIPS recyclate in accordance with the requirements of Regulation (EU) No 2022/1616.

1.2 Contributions of partners

The following Table 1 Table 1. Partners´ contributions depicts the main contributions from participant partners in the development of this deliverable.

Participant short name	Contributions
PRE	PRE-1000: ONE EU STANDARD TO DETERMINE THE QUALITY AND GENERAL PRODUCT SAFETY OF RECYCLATE: • Development & validation ACHIEVING FOOD CONTACT HIPS RECYCLATES: • Expertise in Regulation (EU) No 2022/1616 and novel technology 'path' to produce recyclates to be intended to come in contact with food.
UEF	DEVELOPMENT AND VALIDATION OF SAMPLING PROTOCOL IN COLLABORATION WITH VTT AND PRE • Quantification of mass-spectrometry data for direct mass spectrometric BFR analysis in plastics (published in ACS Omega 2024 ; https://doi.org/10.1021/acsomega.4c04059) • Manuscript about the developed sampling protocol was submitted for evaluation to the peer-reviewed scientific journal *Waste Management* in September 2024

Table 1. Partners´ contributions

1.3 Structure

- **Section 1:** Contains an overview of this document, providing its Scope, Audience, and Structure.
- **Section 2**: Focuses on the PRE-1000 tool and its use as a standard to determine general product safety of the recyclates.
- **Section 3** : Delves into the topic of producing recyclates that are intended to come in contact with food, as well as Regulation (EU) No 2022/1616.

2 PRE-1000: ONE EU STANDARD TO DETERMINE THE QUALITY AND GENERAL PRODUCT SAFETY OF RECYCLATE

The PRE-1000, a standard for monitoring of substances in recycled plastics, was initially developed by the industry association Plastics Recyclers Europe (PRE) and has been employed within the PRIMUS *consortium* in the context of tests on specific samples of recyclate, leading to a further validation of the standard and method. More detailed information can be found in the sections below.

2.1 Background: Legislative requirements for substances in recyclates

Recyclers are companies that purchase waste and place a product on the market. They need to ensure that the material that they place on the market is compliant with product regulation and fulfill the end of waste criteria of the Waste Framework Directive. Within the product legislation, there are extensive requirements on substances, and the PRE 1000 method was developed to enable recyclers to produce legally compliant material, in a cost-effective manner. This method is meant to be integrated into the quality control procedure already present at recyclers' facilities.

In the context of recycled plastics and throughout this document we will refer to 'Substances of Concern (SoC)' as the ones that are either: listed as REACH Substances of Very High Concern (SHVCs), covered under relevant[1] REACH restrictions, Persistent organic pollutants (POP) substances, and the ones under Restriction of Hazardous Substances (RoHS) directive. The existing legislative and regulatory framework sets the following requirements on SoC:

- Any recycler placing a substance or mixture on the market must inform its customer if there is an SVHC present within the material above its regulatory cutoff value.
- If such an SVHC is present above the cutoff value and has been included in the Authorization list[2], authorization must be applied for when supplying the market with this material in the form of a substance or mixture.
- Materials must be compliant with the POPs Regulation, which includes a number of substances relevant to plastics with frequently more stringent limit values than those in the REACH Regulation.
- In case a substance is present that is covered by a REACH restriction, the conditions of the restriction must be analysed and it must be determined if the material itself needs to comply or articles produced thereof by customers. For example, should cadmium be present in a non-PVC material at a concentration

[1] Restrictions not applicable to plastics are excluded (e.g., content limit for lead in jewelry).
[2] Within the REACH legislation, some SVHC are prioritised and are placed in the 'Authorisation' list, which includes substances for which the application for authorisation is needed for their use on the market.

exceeding 0.01% this can legally be placed on the market by a recycler, however the subsequent article manufacturer is obliged to ensure that the concentration limit of 0.01% is respected. As such it would be appropriate to inform the customer of the presence of this element.

- Similarly, material that is supplied to the Electrical and Electronic Equipment (EEE) sector itself does not need to, strictly speaking, be compliant with the RoHS Directive, as the obligation falls on the manufacturer of EEE. However, this sector demands supplier specification that the material supplied is "RoHS Compliant".

2.1.1 The need for an effective screening: Role of PRE-1000

The aforementioned requirements result in the need to verify compliance of the material across over 300 substances. Analytical quantification of all these substances would be prohibitively expensive and, in many cases, not feasible[3]. Some laboratories have developed screening approaches, that do not necessarily give exact quantification but can give confidence that the substances are not present above their regulatory limit values. Such screening approaches are more economical, though still quite broad in their spectrum.

2.2 About PRE-1000

2.2.1 Product definition

The voluntary industry standard provides guidance for companies on how to specify their products based on input waste and output polymer (blend) and complete the standard for each of these defined products.

2.2.2 Sampling and sampling preparation

The standard explains one method of sampling and sample reduction based on the standards that have been developed for WEEE recyclers (EN 50625 series). Alternative sampling may be performed if the recycler can justify that this provides an equally representative sample.

In terms of sample preparation, a strong departure is made from the EN 50625 series in the sense that the PRE 1000 requires recyclers to produce extruded plaques from their material. This was done, because recyclers that followed the EN 50625 standard series noticed great heterogenicity in the results that they receive from analytical laboratories, following the sampling method described therein.

This heterogenicity was mainly since analytical laboratories tend to be extremely economical and environmentally conscious and when supplied with a sample of several hundred flakes take a much smaller subsample for the analysis to reduce

[3] For example, the substance "Fatty acids, C16-18, lead salts" CAS 91031-62-8 is not quantifiable. GC-MS technology would reveal the presence of the fatty acid component and ICP-MS (or XRF) would reveal lead. However, it is not possible to determine if these substance components are present within the plastics material as such or whether the fatty acid component is there due to a zinc (or other metal) fatty acid complex and the lead is present in the form of a lead pigment.

solvent use. When 10 – 20 flakes are taken there is a certain probability that one flake will contain functional levels of a brominated flame retardants (e.g., 8-15%) that willskew the results and would not be representative of the sample. By homogenization of the material with an injection moulding machine or equivalent apparatus to produce a plaque before analysis, this problem is overcome, and a representative sample is obtained.

2.2.3 PRE-1000 Tool

2.2.3.1.1.1 Properties screening

When preparing the PRE 1000 specification PRE made an inventory of all Substances of Concern (SoC), that includes all SVHCs, all substances under relevant3 REACH restrictions, all relevant POP substances, all RoHS substances. This originally resulted in a list of 240 entries, which has expanded over time as legislation has evolved and the standard thus updated.

For each substance, PRE carried out an analysis to determine if the SoC can be present in plastics recyclates above the regulatory limit values by looking at the following properties:

Property	Explanation
Phys-chem Properties	Certain substances cannot be present in thermoplastics products due to their phys-chem properties. For example, benzene has a boiling point of 80.09 ˚C. As all thermoplastics melt at a temperature that is higher than this the substance would volatilize before the polymer melts. Introduction of such a substance into an extruder would have significantly adverse effects on the production process.
Technical Function	Certain substances such as ADCA (cas: 123-77-3) are added to plastisol (a mixture of PVC powder and plasticizer. The mixture is heated until PVC melts and encapsulates the plasticizer and ADCA, whereupon the material is heated and ADCA undergoes thermolysis to produce a gas. The resulting material is a PVC foam without ADCA. Other examples include monomers and curing agents. Such substances cannot be present in the waste
Additivation Rate	Certain substances such as UV benzotriazole stabilizers are part of a plethora of substances that achieve the same functionality in plastics material. The amount needed within individual articles will be low. As such a mix of shredded articles will not contain any of these substances above their respective regulatory limit. The same applies to certain pigments/dyes. As such they are excluded from consideration.

Polymer Specificity	Certain additives are polymer specific. In the event the product stream does not contain this polymer, it may be excluded from consideration.
Absence Historic Use	A thorough search was carried out to determine if substances have been used in the past. In the event that there is no indication that a substance was used in polymeric material in the past, the substance is excluded from consideration.
Proof of Absence	Through this standard PRE aims to collect sufficient analytical test reports to determine if a substance may be reasonably be expected to be absent from certain product streams. When sufficient test reports have been collected for a particular waste stream proving absence of the substance or presence below a regulatory limit value, the substance can be removed from consideration.

The approach results in a much more manageable list of substances that require attention of recyclers implementing PRE 1000.

2.2.3.1.1.2 XRF Analysis

The remaining substances that can be present within plastics, and thus plastic waste, typically contain certain elements that can be detected through handheld XRF devices that have a modest to high investment cost (e.g. 30,000 EUR) and a low marginal cost for each use (e.g. cents). While these devices cannot give an indication as to which molecule such elements are attached to, they can be used to calculate whether it is possible for a certain substance to be present above its regulatory limit value.

By utilizing this XRF screening approach the number of substances that need to be tested for can be reduced further or, potentially with extremely good results, (e.g. for recyclate derived from household packaging) be completely avoided.

2.2.3.1.1.3 Chemical Analysis

Should it not be possible to exclude the presence of certain substances based on the work done by PRE and the XRF screening, chemical analysis is the last resort. However, the cost for testing of this more limited number of substances will be radically lower than a proper analysis of all SoC. A combination of GCMS and LCMS is specified to ensure detection of more volatile lighter compounds and less volatile higher molecular weight compounds.

2.2.3.1.1.4 Key take-aways

- The PRE 1000 standard enables plastics recyclers to obtain the necessary information for general product regulation requirements related to SoCs (i.e., REACH and POP regulation) and remain complainant with the existing legislation.

- The PRE 1000 method provides an easy-to-use tool (excel file) that allows a first and quick monitoring of SoCs. It allows plastics recyclers to use with confidence the PRE-1000 tool to demonstrate compliance with the chemical's legislation.
- When properly implemented the PRE 1000 standard should be considered a solution to ensure fulfilment of article 6.1(d) of the WFD, i.e., the End-of-Waste criteria relating to not having an overall adverse effect on human health and the environment.

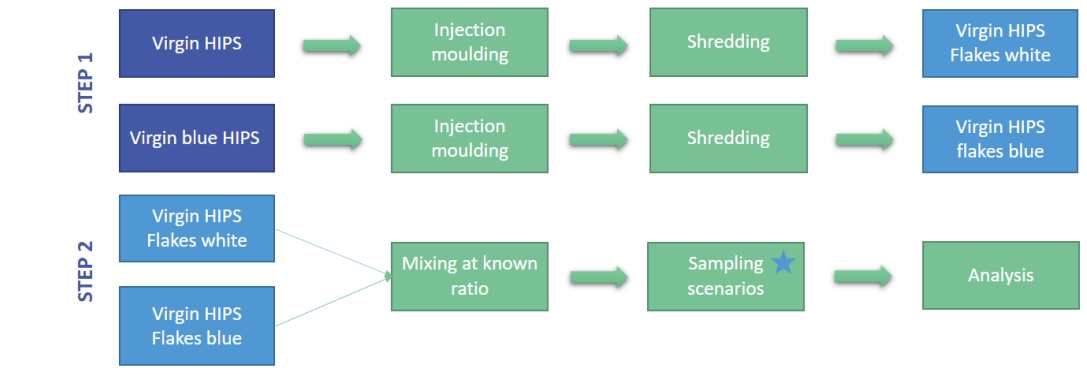
2.3 Validation of PRE-1000 during PRIMUS

The PRE-1000 standard also suggests specific sampling protocols and sample preparation methods. In this context, to ensure the results provided by the PRE-1000 tool were accurate, work has been undertaken in the PRIMUS project to validate the approach. The aim was to test and validate different sampling scenarios and compare the analysis results to find the most robust method.

Such study was carried out as shown in Figure 2:

- **Visually:** to determine which sampling strategy gives the most homogeneous output.
- **Analytically:** the different output from the different sampling strategies are analytically tested to identify whether the concentration of the output matches the one of the input.

Figure 2 also illustrates how performing only an injection moulding step was not sufficient to obtain a representative sample. For instance, if the blue flake would contain a contaminant, it will not be spread evenly on the samples and therefore might lead to wrong interpretation. The study has shown that the most promising sampling preparation in term of representativeness and cost-efficiency is a compounding step followed by an injection moulding step.



★ **Scenario for defining the best sampling strategy**

- Flakes → injection moulding → dog bones → analysis
- Flakes → extrusion → granulates → injection moulding → dog bones → analysis
- Flakes → cryogenic grinding →analysis
- Flakes → cryogenic grinding →extrusion → granulates → injection moulding → dog bones → analysis

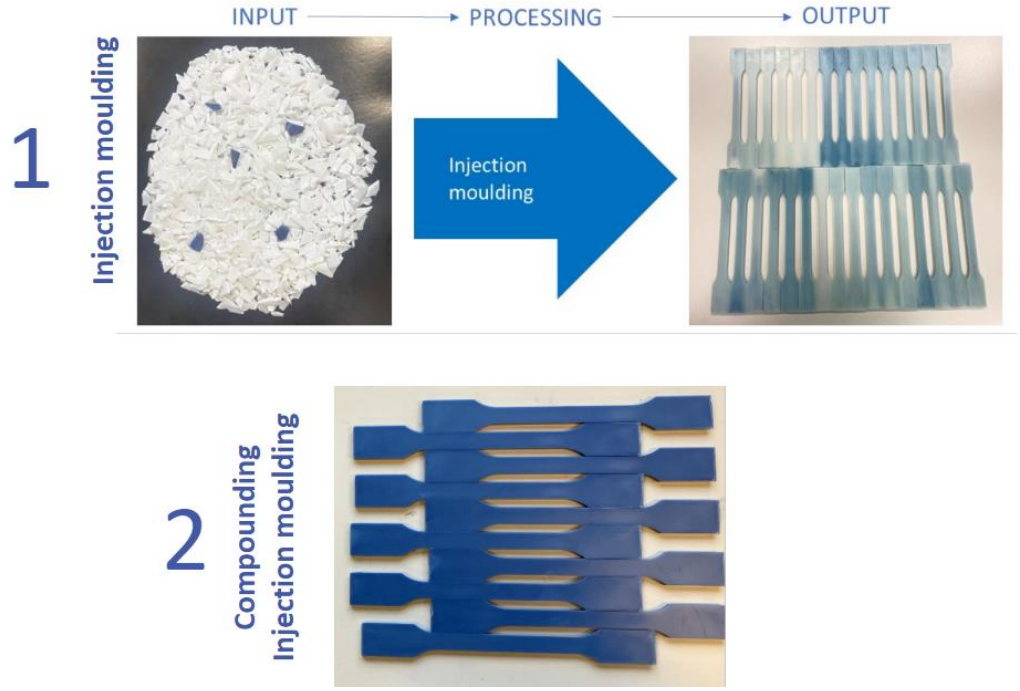


Figure 2. (Top) schematic representation of the experimental plan to carry out the sampling study.

Moreover, validation of the PRE-1000 tool has been carried out according to the following method:

1. Selection of the samples
2. Analytical results on the recycled plastics samples
3. XRF results on the samples
4. Comparison of the data

The PRE 1000 has been validated based on the analytical tests and XRF performed on the samples. All samples for which a signal was recorded via the analytical tests (i.e., detecting a SoC) have not been excluded in the PRE 1000 tool, leading to the correct conclusion. As the PRE 1000 has implemented some intervals of confidence to ensure that the substances with a concentration near the threshold would not be excluded, two samples, despite not having any signal via analytical test, have not been excluded.

3. ACHIEVING FOOD CONTACT HIPS RECYCLATES

One of the demonstrators of the PRIMUS project is to recycle the HIPS present in the liner of the refrigerator to use it for the same purpose. The liner of a refrigerator is a food contact part as it is intended to come into contact with foods.

The present section aims at providing background information on the Regulation (EU) No 2022/1616 *on recycled plastic materials and articles intended to come into contact with foods*. Additionally, the document will guide the reader on how to complete the necessary steps to fill in an application for rHIPS for food contact.

3.2. Regulation (EU) No 2022/1616

3.2.3. Introduction

On 10th October 2022, Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods, was repealed by Regulation (EU) No 2022/1616 broadening its original scope. In the last decade, the plastics recycling industry introduced a variety of new processes and techniques to recycle plastics intended to come into contact with foods. The progress achieved by the industry outpaced the narrow legal framework of Regulation (EC) No 282/2008, to a point where new approvals could no longer be granted being outside the framework to assess the safety of such recycling processes.

Regulation (EU) No 2022/1616 on recycled plastic materials and articles intended to come into contact with foods lays down rules on:

- the placing on the market of recycled plastic food contact materials,
- the development and operation of recycling processes producing recycled plastic to be used in contact with foods,
- the use of recycled plastics intended to come into contact with foods,
- the manufacture of materials and articles in which recycled plastic is used behind a functional barrier.

It introduces two pathways to obtain approval for food contact materials: the suitable technology addressing already evaluated processes, and the novel technology addressing processes that have not been assessed yet.

3.2.4. Scope of the Regulation

- **Any plastic that has been produced from a waste input is in the scope of the Regulation.**

Both pre-consumer and post-consumer recycled plastics are within the scope of the Regulation. Where offcuts and scraps have reached the waste status they are under the scope of this Regulation, otherwise they are subject to Regulation (EC) No

10/2011. To define whether the material is pre-consumer waste or by-product (non-waste), the following guidelines from the Circular Plastic Alliance can be followed.

- **All recycling processes are in scope (e.g. mechanical, dissolution and chemical).**

In case a chemical recycling process produces substances included in the Union list of authorised substances in accordance with Article 5 of Regulation (EU) No 10/2011, the Regulation does not apply.

3.2.5. Definitions

The Regulation introduces new definitions in *Article 2*. To understand the Regulation, it is important to understand how those definitions are interlinked and their meaning (see Figure 1).

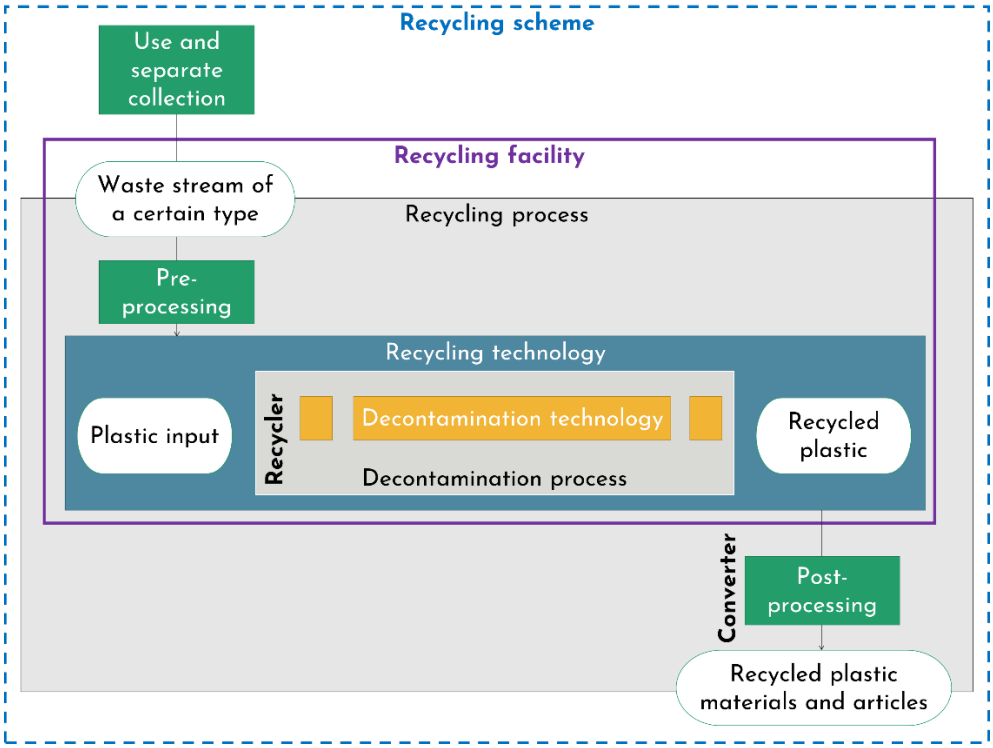


Figure 2: Definitions introduced in the Regulation

The focus of the Regulation is on the decontamination process; definitions, as well as the overall assessment, have been written from this angle. The **pre-processing** activities correspond to comminution, cleaning and washing operations. The resulting material is the **plastic input**. The latter is the material entering the decontamination unit. In the Regulation, a **recycled plastic** is defined as the output of the **decontamination technology**.

3.2.6. Requirements on plastic waste

Article 6 sets requirements for both collection and pre-processing activities.

The **input plastic waste originates only** from one of the following waste streams:

- Municipal waste, or
- food retail or
- other food businesses if it was only intended and used for contact with food,or
- waste discarded from a recycling scheme in accordance with *Article 9(6)*.

Furthermore, the plastic waste must have been previously manufactured in accordance with Regulation (EC) No 10/2011 and is separately collected as defined in *Article 6 (2)*.

In addition to the requirements on the material origin, the plastic waste must be controlled throughout collection and pre-processing **by means of quality assurance systems**. The quality assurance systems must be audited by a third-party maximum two years after entry into force.

Please note that these requirements can be derived from when applying for a novel technology.

3.2.7. Suitable and novel technologies

The Regulation defines two types of technologies: the **suitable technologies** and the **novel technologies**. To properly apply the food contact Regulation, one must define whether its recycling technology is categorized as a suitable or a novel technology. Consequently, it is essential to understand the difference between both technology types, as defined in the Regulation.

3.2.7.1.Difference between suitable and novel technologies

A technology is considered **suitable when sufficient data has been generated to demonstrate that the plastic input has been decontaminated and the resulting recycled plastics comply with Regulation (EC) No 10/2011 and Regulation (EC) No 1935/2004**[4]. Based on the evaluations done by the Authority in accordance with Regulation (EC) No 282/2008, mechanical recycling of PET and product loops in a closed and controlled chain are considered as suitable recycling technologies. The suitable technologies are listed in Annex I of the Regulation.

[4] Commission Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).

Any technology that is not yet considered suitable, is listed as novel. In fact, additional data is necessary to determine whether the decontamination technology can produce a recycled plastic in compliance with Regulation (EC) No 10/2011 and Regulation (EC) No 1935/2004.

Once the process of the novel technology has been completed, the suitability of the technology will be assessed. Should the assessment result in a positive opinion, the novel technology becomes a suitable technology. The list in Annex I is then amended to include the latter.

3.2.7.2.Decision tree

To assist the reader in finding whether its recycling technology is suitable or novel, the decision tree can be applied (see Figure 2). To facilitate the understanding, the structure of the *Annex I* of the Regulation has been replicated in Annex I of this document.

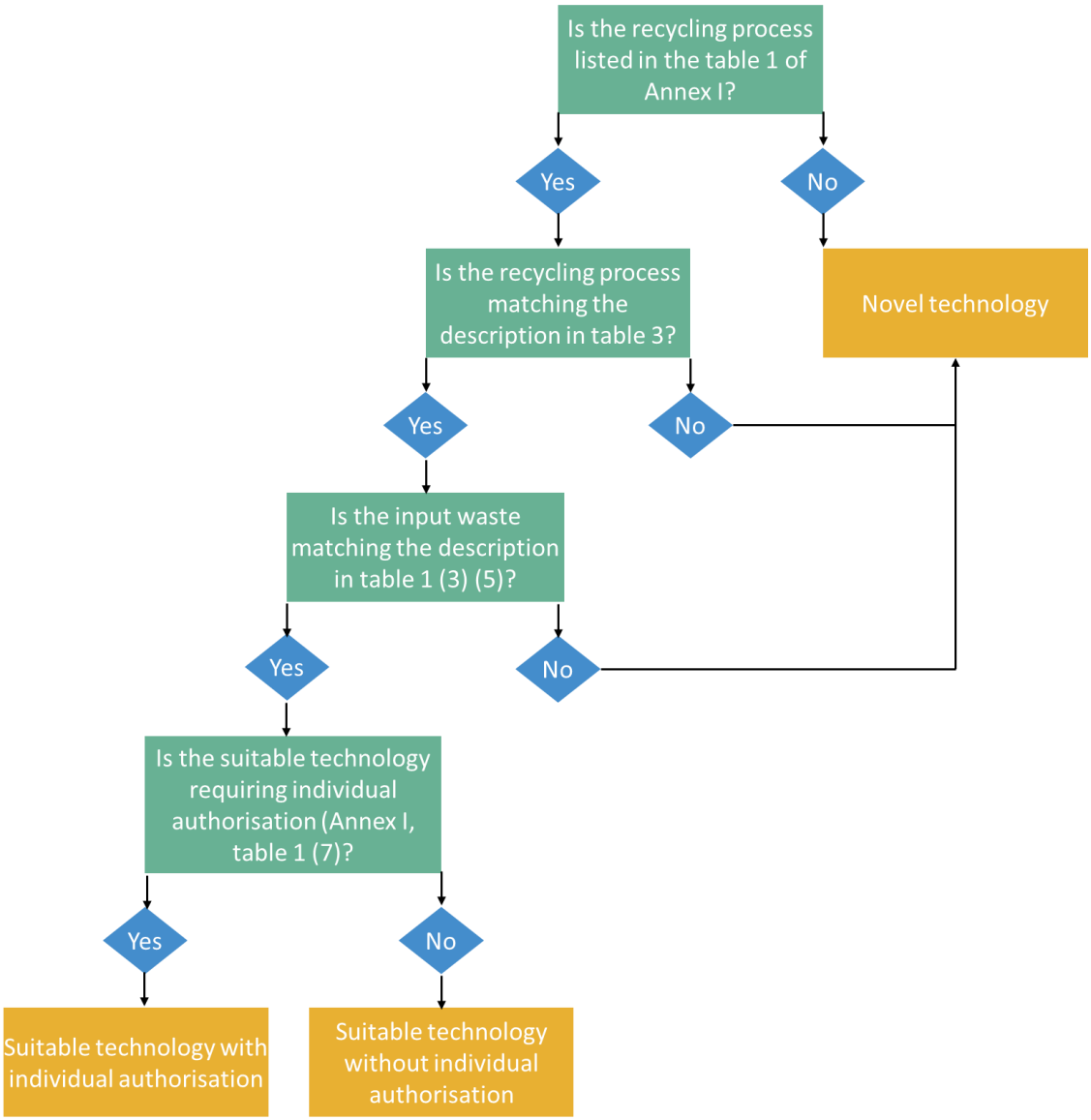


Figure 3: Decision tree, suitable or novel technology?

When applying the decision tree to the specific case of the rHIPS, it can be stated that the recycling process belongs to a novel technology. Consequently, the next section focuses on a guidance for novel technology application and especially considering the rHIPS to be used in a refrigerator liner.

3.3. How to apply for novel technology?

The novel technology section is linked with the *Chapter IV* of the Regulation (EU) No 2022/1616.

3.3.3. Overview of the process for application

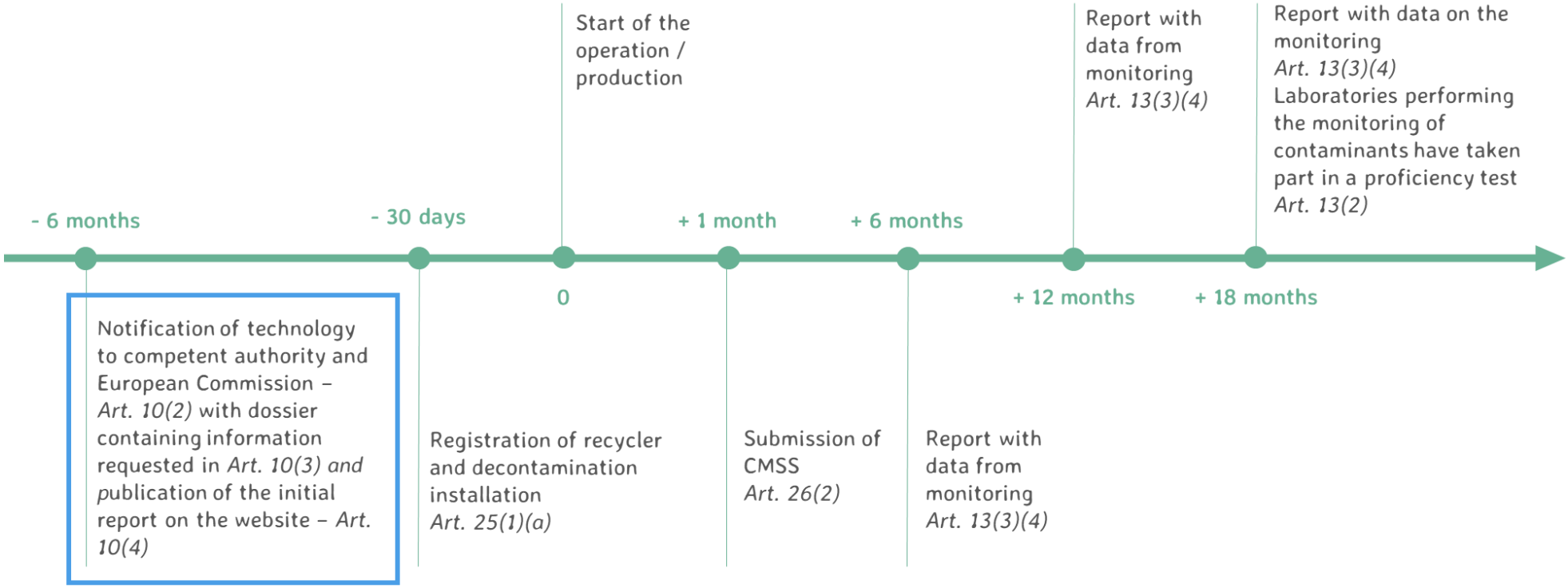


Figure 4: Timeline novel technology application.

The timeline above describes the process to apply for novel technology. The process can split in two distinct categories:

- Notification period.
- Monitoring period.

3.3.4. Notification

3.3.4.1. Developer

The actor defined as the developer is the owner of the application. If several partners are involved in the development of the technology, only one should act as the developer. A machine manufacturer or an industry association can act as the developer.

At least six months prior to the start of the operation of the first decontamination installation, the developer must notify the CA and the Commission of the novel technology.

3.3.4.2. Formal notification

The notification, submitted by the developer, should contain the following:

- Its name
- Address
- Contact persons
- Name of the novel technology
- A summary of the novel technology (not exceeding 300 words)
- Uniform Resource Locator ('URL') where the biannual reports will be published
- Names and addresses or numbers of any recycling facilities at which the development of the technology is foreseen to take place.

The notification also requires an initial report. The content is described in *Article 10(3)*. The initial report must be published on the developer website and may omit some confidential information.

3.3.5. Notification report

3.3.5.1. Sampling strategy

The monitoring of the contaminants is focused on the decontamination technology input and output. For the initial report, the sampling must be performed on **all** the input batches and corresponding output batches. Once sufficient data has been

collected and stable results are obtained, the **sampling frequency can be reduced**. A report must be written on the sampling strategy justifying the chosen method and frequency.

For the case of the rHIPS, the material has been taken before the decontamination unit, as sorted HIPS flakes and after the decontamination unit, as rHIPS pellets. A sample has been taken from different big bags and combine in one sample that has been sent to the laboratory. The same process has been repeated from the corresponding batch in output.

3.3.5.2. Monitoring of contaminants: Analysis and sample preparation

The residual contaminants must be assessed in the plastic input and in the corresponding recycled plastic. Contaminants include substances that have a molecular weight between 0 and 1000 Da. If the concentration of contaminants in output is below the Limit of Quantification (LoQ), the monitoring of the output may be replaced with one or more studies to determine the residual contaminant level in a limited number of output batches with analytical methods with a lower LoQ. The goal is to obtain real data to calculate the decontamination efficiency achieved in the decontamination installation (Figure 3).

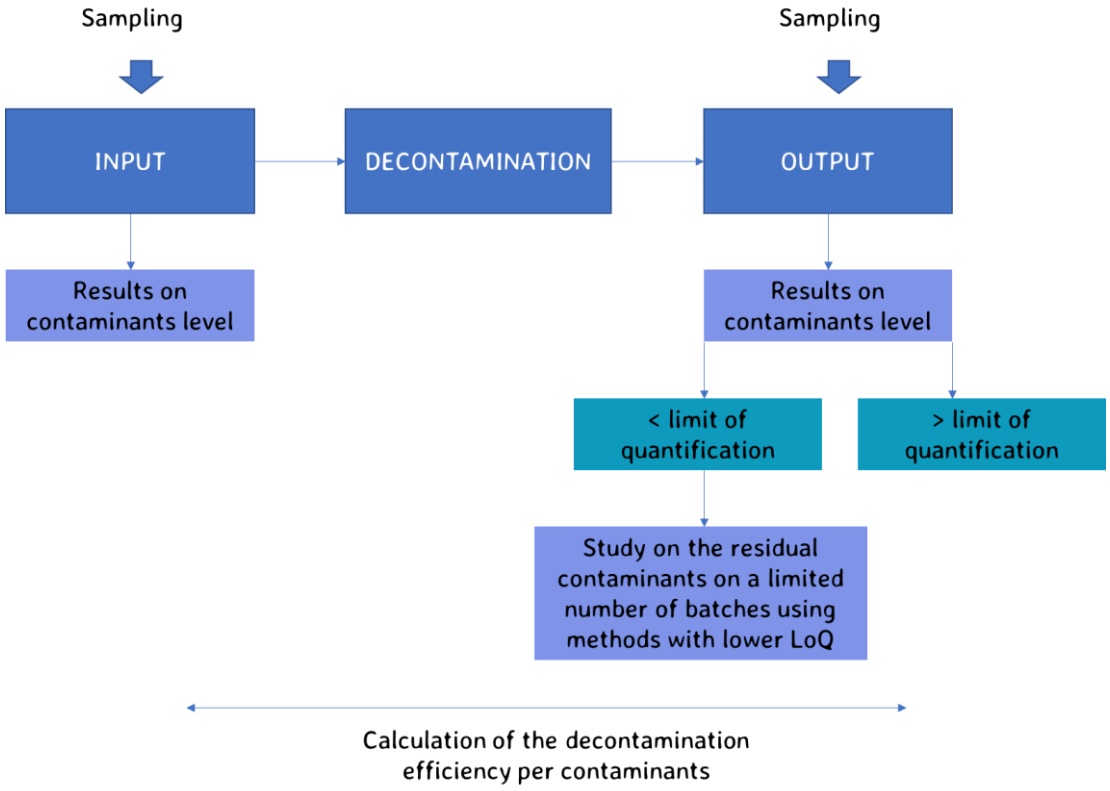


Figure 5: Analysis on contaminants level to define the decontamination efficiency.

Preliminary screening of NIAS present in plastic samples was conducted with gas chromatography-mass spectrometry (GC-MS). HIPS flakes/granulates/sheets were cryogenically ground with a Retsch ZM200 ultracentrifugal mill using liquid nitrogen and a 0.5 mm sieve. The samples were dried in an oven at 60 °C overnight to remove any excess moisture. Next, the powdered plastic samples (100 mg) were extracted with 2 ml of 2-propanol (HPLC) in 10 ml sealed bottles using ultrasound-assisted extraction (60 °C / 60 min). The supernatant was filtered with a 0.2 µm polytetrafluoroethylene syringe filter and analysed using a Bruker Scion 456 GC equipped with a Rxi-5Sil MS column by Restek (30 m × 0.25 mm × 0.25 µm). The gas chromatograph (GC) was coupled to a high-resolution Bruker timsTOF mass spectrometer via a Bruker GC-APCI interface, enabling identification of the analytes based on their accurate masses, fragmentation patterns and Kovats retention indices. Additionally, the GC was equipped with a flame ionization detector (FID) and the relative abundance of species in the extraction liquids was evaluated by comparing the GC-FID peak areas. All measurements were conducted in a split injection mode with a split ratio of 1:10.

Please note that as per October 10th, 2024, laboratories that perform the monitoring of contaminants must take part in a proficiency test. The purpose is to ensure that the methods are aligned and generate comparable results.

Based on the results obtained, the developer must provide extensive reasoning, based on scientific data generated on your process, demonstrating that the novel technology can manufacture recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004.

3.3.5.3. Migration testing

3.3.5.4. Challenge test

Challenge test data will need to be submitted to state the decontamination efficiency of the novel technology.

A challenge test consists of the following procedure:

- Taking washed and dried flakes (from the polymer studied).
- Contamination with surrogates. The surrogates must be substances whose polarity and molecular weight are representative of possible contaminants of concern.
- Determination of initial concentration of surrogates.
- Decontamination process of the material spiked with surrogates.
- Determination of final concentration of surrogates.
- Calculation of the decontamination efficiency.

3.3.5.5. Process flow

The process flow must be defined in the report and especially the information on the input material, recycling process and output material.

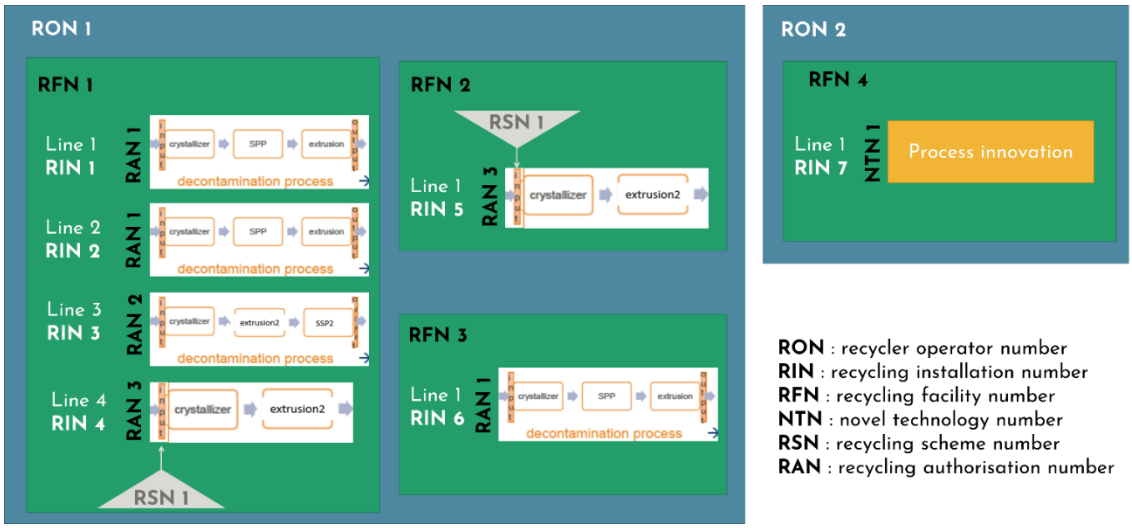
	Input	**Recycling process**	**Output**
General	The type, mode of collection and origin of the input material.	The specific combination of physical and chemical concepts, principles and practices used to decontaminate that input material.	The type and the intended use of the recycled plastic materials and articles.
rHIPS case	HIPS from the refrigerator. Material collected via EPR schemes. The liner of the refrigerator was previously a food contact material produced in accordance with Regulation (EU) No 10/2011.	Mechanical recycling of HIPS includes grinding, washing, sorting, extrusion.	rHIPS intended to be used in the inner liner of refrigerators.

3.3.6. Submission phase

The developer sends the finalized dossier to the competent authority of the Member State where the Developer is located. The competent authority will then have 5 months to review the dossier. Only after the competent authority has given its approval, the production and placing on the market of the recycled plastic into a food contact application can start. Contact from the competent authority can be found on this page.

3.3.7. Registration

The novel technology needs to be registered via the European Commission's website. During the registration, the notification dossier must be submitted through this website as well. This process is meant to establish the Novel Technology Number (NTN) once the notification report has been approved. The NTN is related to the technology. Therefore, it is also necessary to register the recycling operator, facility and installation that will run this novel technology. This corresponds to the registration forms for, respectively, RON, RFN and RIN.



3.3.8. Monitoring

Every 6 months, the recycler must provide data on the monitoring of the contaminants to the developer as well as a reasoning on the overall safety of the recycled plastic (*Article 12 (3)(f)*).

The monitoring of contaminants should follow the same process than for the notification report. However, it is important to implement the monitoring in a regular routine to gather several datasets to be able to submit the data every 6 months.

The Compliance Monitoring Summary Sheet (CMSS) must be completed. The template is provided by the developer as it may be modified compared to the reference document stated in the Regulation.

3.3.9. Assessment from the Authority

After the submission of minimum 4 reports, the Authority will assess the technology.

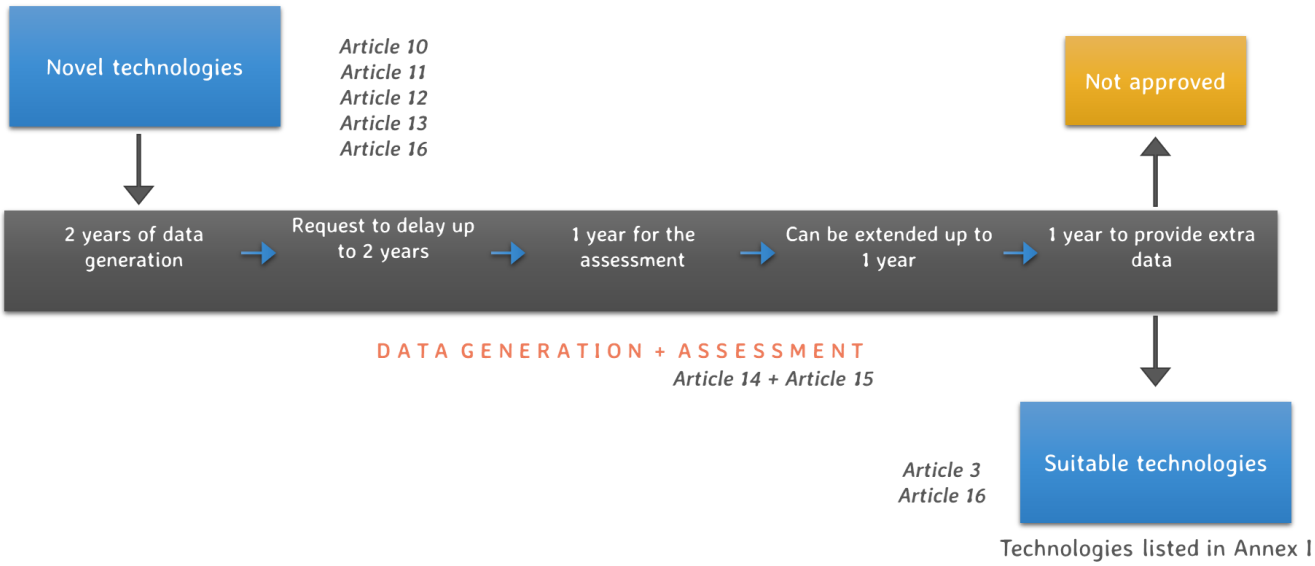


Figure 6: From novel to suitable technology.

Should the assessment be successful, the Authority will define the novel technology as a suitable technology.

4. CONCLUSIONS AND DISCUSSION

4.2. Summary of achievements

Regarding the PRE 1000 standard, the study conducted within the PRIMUS project focused on validation of the tool and its sampling protocol. Different sampling scenarios were tested visually and analytically to determine the most robust and homogeneous methods. It was found that only performing injection moulding was insufficient for producing representative samples for the analysis. The best method was identified as a combination of compounding followed by injection moulding, ensuring greater sample representativeness and cost-efficiency. Then, the PRE-1000 tool was validated using analytical tests and XRF results on recycled plastic samples. These tests ensured that substances of concern (SoCs) were correctly identified and not excluded by the tool. Indeed, by cross-checking the list of substances provided by the PRE-1000 and the signals from the analytical tests, it was determined that substances near concentration thresholds were not wrongly excluded. Even samples without signals were 'flagged' by the tool, ensuring the accuracy of conclusions. Overall, the study confirmed the reliability of the PRE-1000 tool and established an optimal sampling method and standard for analyzing recycled plastics.

Finally, one of the demonstrators of the PRIMUS project is to recycle the HIPS present in the liner of the refrigerator to be put back in new refrigerators, where this liner is a food contact part and as such it is intended to come into contact with foods after its recycling. Concerning this, extended information was given in this document to navigate the complex Regulation (EU) No 2022/1616 *on recycled plastic materials and articles intended to come into contact with foods*. The main achievement was in this case the creation of a guidance document to be used by the reader to gain knowledge on how to complete the necessary steps to fill in an application for rHIPS for food contact.