ΑΑΔΕ
Ανεξάρτητη Αρχή Δημοσίων Εσόδων

ΓΧΚ/Β΄ Χ.Υ. Αθηνών

Σκόπιμη και μη προσθήκη ουσιών στα υλικά σε επαφή με τρόφιμα: Αξιολόγηση επικινδυνότητας σε πλαστικά και ανακυκλωμένα πλαστικά και χαρτί/χαρτόνι

Intentionally and non-intentionally added substances in food contact materials: Risk assessment of plastics, recycled plastics and paper/board

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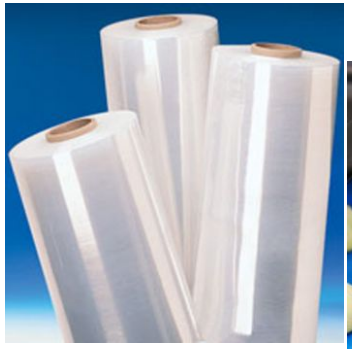
Introduction



Plastics FCM: dominant role in the global economy and consumption

Legislative framework:

EFSA: Risk assessment of chemical substances intended to be used in plastics FCM

European Commission : European legislation on FCM e.g. Reg. (EC) 1935/2004 for all FCM and Reg. (EU) 10/2011 for plastics FCM. No harmonised legislation for paper and board as FCM

Greek Food Code: Article 24 - requirements for paper and board as FCM

Introduction

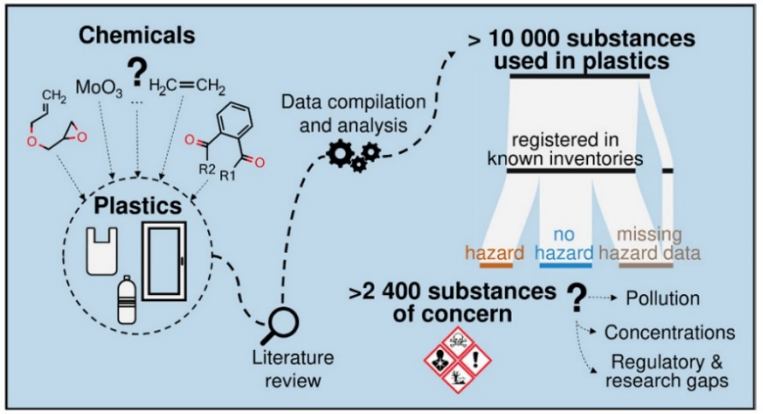
Intentional added substances (IAS): **monomers, additives, polymer production aids**

Non Intentional added substances (NIAS): **reaction, break down products produced during polymerization, conversion and use of plastics**

Only risk assessed and authorized IAS can be used in plastics FCM

Risk assessment:

The likelihood of damaging effects on human health shall be examined



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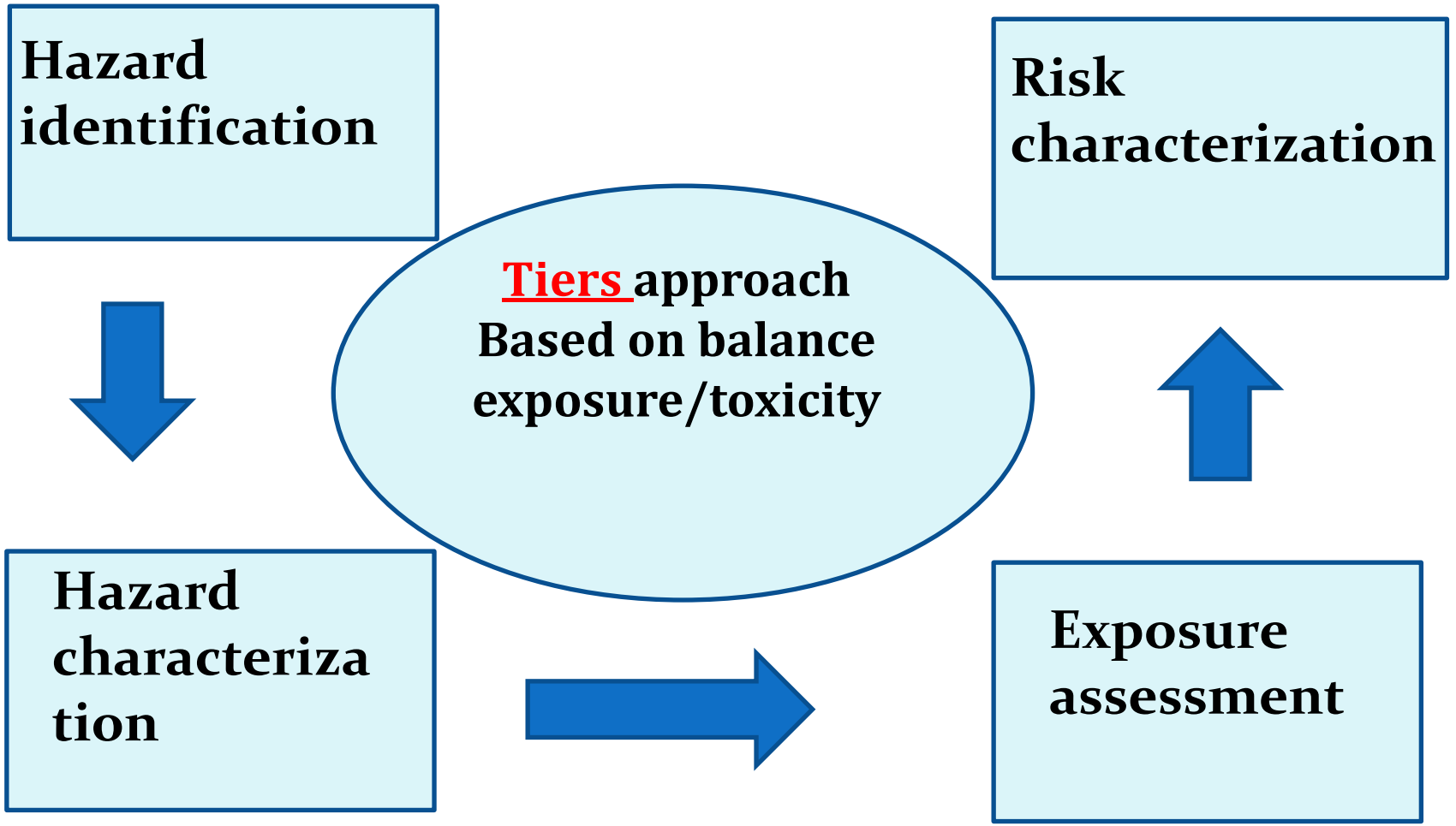
IAS: Risk Assessment pillars



IAS: Toxicological assessment – *Hazard identification and characterization*

Hazard: ***Inherent property of chemical substance having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent.***

A process designed to *determine the possible adverse effects* of a chemical to which an organism, system, or (sub)population could be exposed.

Aims:

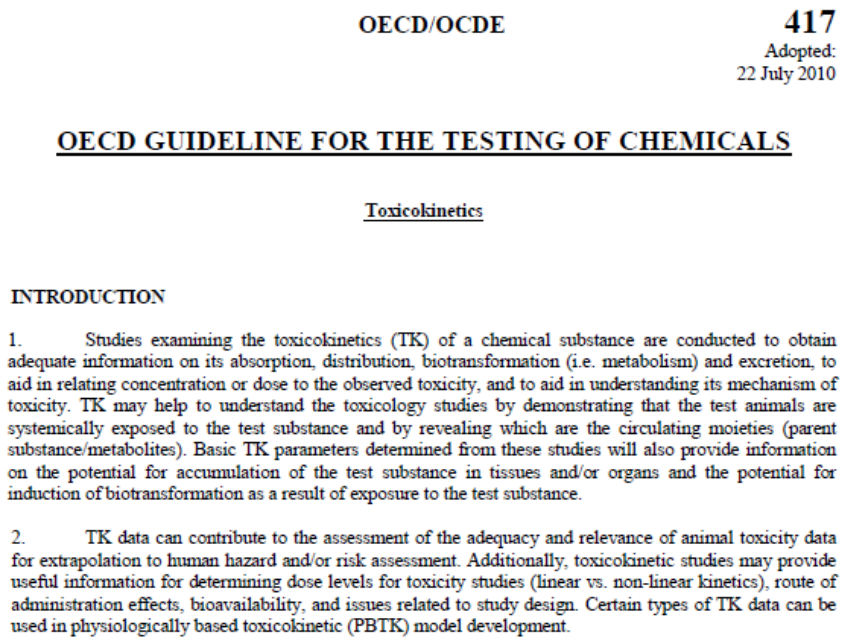
- **to define a dose without appreciable health risk**
- **to provide input for risk characterization of current exposures or of reduced exposures resulting from different actions.**
- **to guide the selection of the approach to the risk assessment**

IAS: Toxicological assessment – *Hazard identification and characterization*

Toxicological studies/tests - quantitative. "In vitro" – "in vivo : experiments with animals"

Dose- response to establish a reference point/point of departure (e.g. NOAEL, LOAEL, BMDL)
Uncertainty factors are applied to NOAEL/LOAEL/BMDL
of laboratory animals to derive safe concentrations in feed based on feed consumption

Tiers approach:



OECD/OCDE 417
Adopted:
22 July 2010

OECD GUIDELINE FOR THE TESTING OF CHEMICALS

Toxicokinetics

INTRODUCTION

1. Studies examining the toxicokinetics (TK) of a chemical substance are conducted to obtain adequate information on its absorption, distribution, biotransformation (i.e. metabolism) and excretion, to aid in relating concentration or dose to the observed toxicity, and to aid in understanding its mechanism of toxicity. TK may help to understand the toxicology studies by demonstrating that the test animals are systemically exposed to the test substance and by revealing which are the circulating moieties (parent substance/metabolites). Basic TK parameters determined from these studies will also provide information on the potential for accumulation of the test substance in tissues and/or organs and the potential for induction of biotransformation as a result of exposure to the test substance.

2. TK data can contribute to the assessment of the adequacy and relevance of animal toxicity data for extrapolation to human hazard and/or risk assessment. Additionally, toxicokinetic studies may provide useful information for determining dose levels for toxicity studies (linear vs. non-linear kinetics), route of administration effects, bioavailability, and issues related to study design. Certain types of TK data can be used in physiologically based toxicokinetic (PBTK) model development.

The studies required depend on the migration of the substance

NIAS: Toxicological assessment:

Hazard characterization

- ***Screening methods – in silico (Q)SAR - read across: known chemical structure***
- **Threshold of Toxicological Concern (TTC) - Cramer Classes I, II and III**

IAS: Chemical assessment

Identity: Name, chemical structure, Mm, Mm distribution, manufacturing details, purity, impurities e.t.c

Physical and chemical properties: melting point, boiling point, decomposition temperature, solubility e.t.c.

Intended uses: Type of polymers (e.g. POs, PET), level of use, manufacturing conditions, foods, conditions of use.

Migration: Overall, specific migration of IAS, simulants, conditions, modelling

Migration of NIAS: simulants, conditions, modelling

Content of IAS: additives

Paper and Board FCM

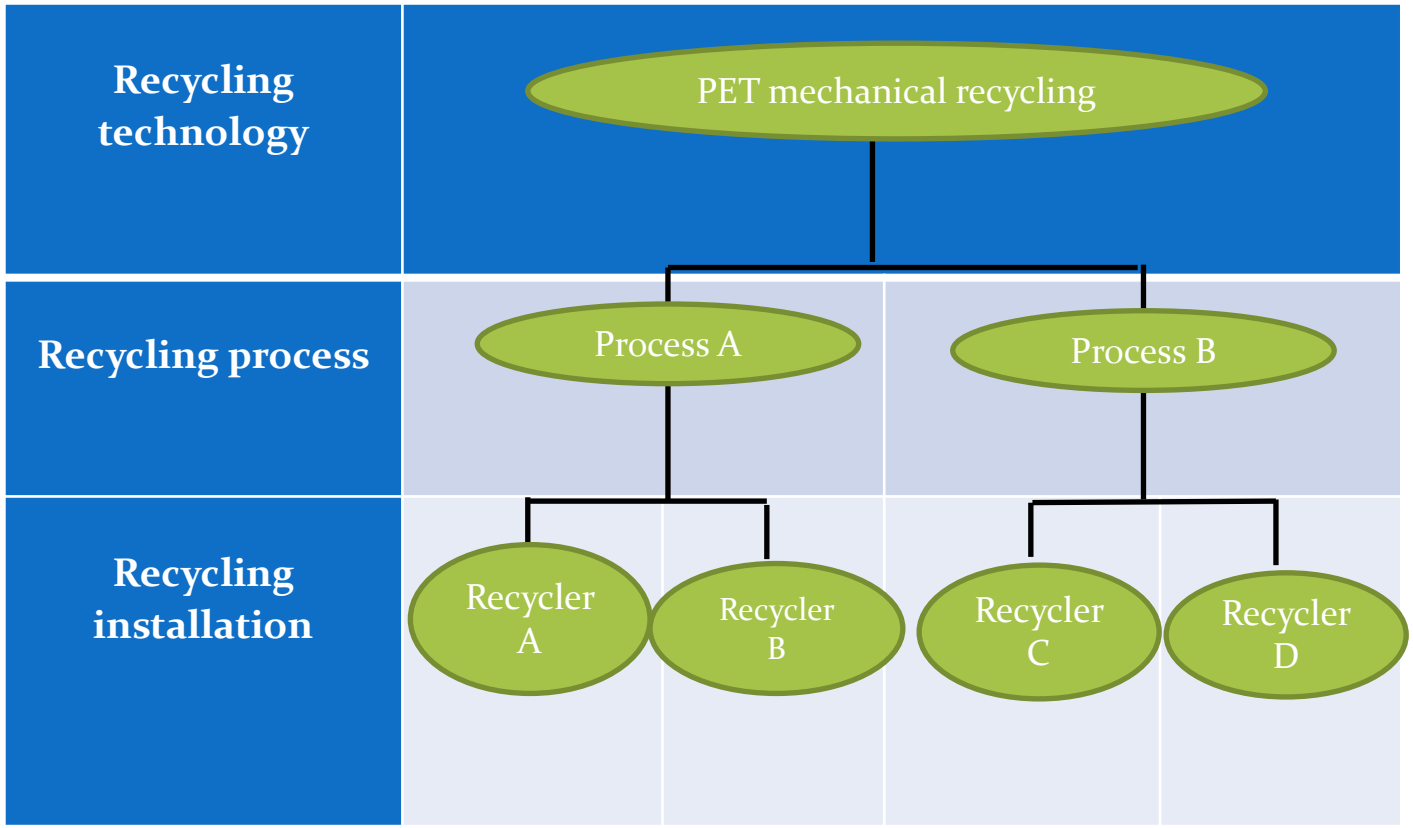
- **Non harmonised**
- **Risk assessment at member state level**
- **CoE: Resolution - Technical Guide on paper and board used in food contact materials and articles, 2021**
  - ***Part I, Council of Europe Resolution CM/Res (2020)9 on the safety and quality of materials and articles for contact with food***
  - ***Part II, Technical guide on paper and board in food contact materials and articles***
  - ***List of substances – tests to check the suitability for food contact***
- **Migration tests for volatiles and semi-volatiles for contact with dry foods**

Recycled FCM Plastics

- **Plastics: According to (EC) 282/2008 risk assessment by EFSA of individual recycling installations -recyclers and authorization.**
- **New Regulation (EU) 2022/1616 repeals (EC) 282/2008**
- **Risk assessment of processes (developers of equipment) - not installations**
- **Contamination of input waste - Type of collection**
- **Evaluation of decontamination efficiency of the process – challenge test**

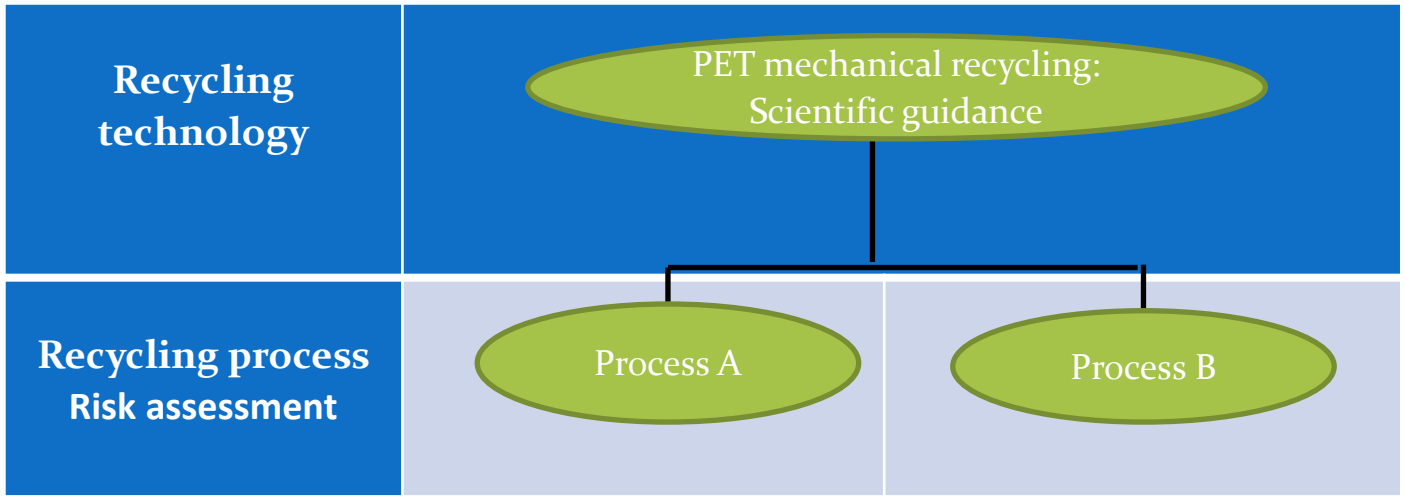
Recycled FCM Plastics

New!!



Recycled FCM Plastics: Risk assessment

EFSA



Recycled FCM Plastics

Article 3. Suitable recycling technologies

A recycling technology shall be considered suitable if it is shown to be capable of recycling waste into recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 and are microbiologically safe. Listed in Annex I

Characterised by:

- **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;**
- **the need or absence thereof for the evaluation and authorisation of recycling processes applying that technology, and the criteria therefore.**

All recycled plastic content intended for FCM is manufactured with a suitable recycling technology except for using in the production of pure substances and the use of novel technologies (new!!).

Recycled FCM Plastics: Suitable technologies

Annex I

Table 1

List of suitable recycling technologies

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Recycling technology number	Technology name	Polymer type (detailed specification in Table 2)	Short description of the recycling technology (detailed specification in Table 3)	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes	Specifications and requirements (reference to Table 4)	Derogations (reference to Table 5)	Recycling scheme applies
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances.	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	Yes	-	-	No
2	Recycling from product loops which are in a closed and controlled chain	All polymers manufactured as primary materials in compliance with Regulation (EU) No 10/2011	Basic cleaning and microbiological decontamination during remoulding (3.2)	Chemically uncontaminated plastic materials and articles produced from a single polymer or from compatible polymers which were used or intended for use under the same conditions of use and solely obtained from a product loop which is in a closed and controlled chain, and excludes collection from consumers	Remoulded materials and articles intended to be used for the same purpose and under the same conditions of use as the materials and articles circulated in the recycling scheme from which the plastic input was obtained.	No	4.1	-	Yes

20.9.2022 EN Official Journal of the European Union

Recycled FCM Plastics

Chapter IV (art. 10-16). Novel technologies

Examples: mechanical recycling of polystyrene, mechanical recycling of PET for use at high temperatures, mechanical recycling of Polyolefins

- **Notification and registration in the EU list of novel technologies and operation prior to the evaluation.**

- **Extensive reasoning, and scientific evidence and studies, compiled by the developer, demonstrating that the novel technology can manufacture complying recycled plastic FCM, with microbiological safety, including a characterisation of contaminant levels in the plastic input and in the recycled plastic, a determination of the decontamination efficiency (at pilot or industrial level), migration tests and reasoning for meeting those requirements.**

- **A summary proposing evaluation criteria to EFSA for its potential future evaluation of recycling processes that apply the novel technology.**

Recycled FCM Plastics

Chapter IV (art. 10-16). Novel technologies

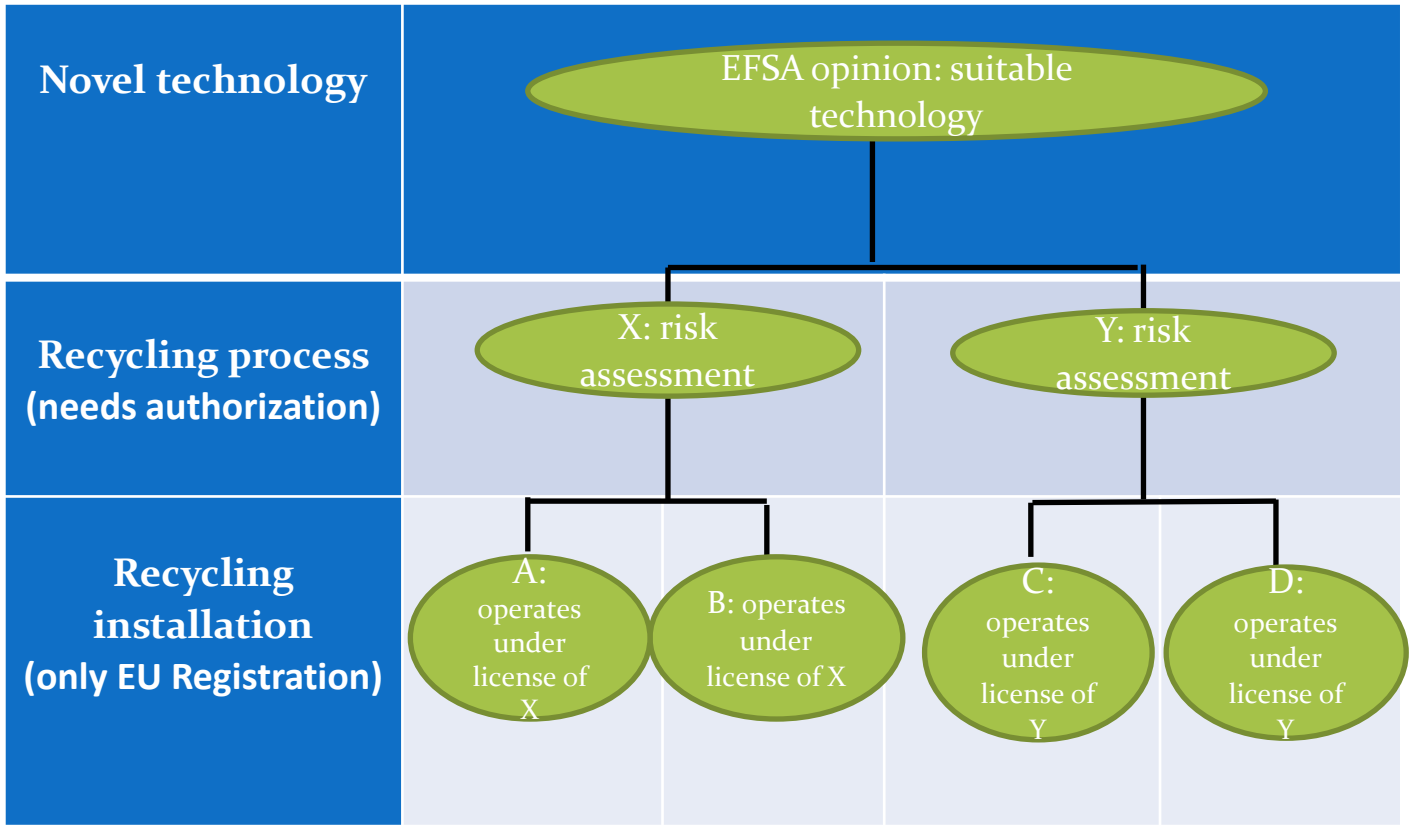
Monitoring and reporting of contamination levels of input and output – sampling strategy

- **Output: regular monitoring/ testing for residual contaminant levels with analytical methods of sufficiently low LODs performed by competent laboratories (participation in proficiency testing schemes).**

- **Recyclers shall provide the developer at least every 6 months with the data forthcoming from the monitoring and their updated reasoning**

Recycled FCM Plastics

Novel technologies



Recycled paper and board

Critical parameter: initial contamination

Recycling technologies: Decontamination efficiency??

Presence of compounds marker: diisopropyl naphthalene DIPN – BisphenolA

Council of Europe: functional barriers

Recycled paper and board

Greek Food Code

- **Recycled paper and board can be used only in contact with dry foods or with other foods behind a functional barrier**
- **Use at high temperatures is not permitted**
- **Risk assessment based on internationally recognized protocols for NIAS (post use contamination, reaction and break down products)**
- **Declaration of compliance: ratio of recycled paper and decontamination process**
- **Effectiveness of functional barrier**
- **Relevant documentation – test reports υψηλής θερμοκρασίας**

Thank you for your attention!