

Update on FCM legislation

- revision of EU food contact legislation
- EU legislation on Recycled Plastic FCMs

6th Japanese Food Business Council in Europe

Press and Cultural Center, The Mission of Japan to the EU

Bastiaan Schupp, EC DG SANTE, team leader Food Contact Materials

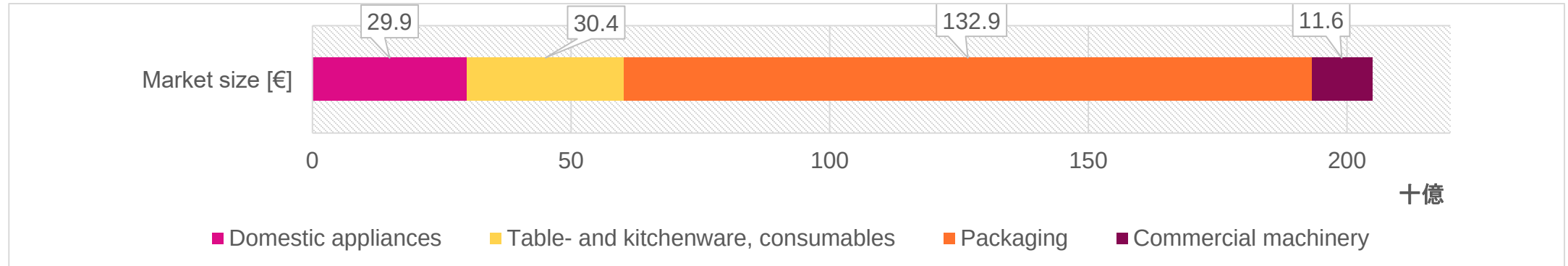
Food Contact Materials - Background



Food Contact materials are **all** materials and articles:

- already in contact with food (e.g. food packaging)
- intended to be brought into contact (kitchenware, food processing equipment)
- that can reasonably be expected to be brought into contact with food or transfer constituents to food under normal or foreseeable conditions of use

Size of the affected industry is considerable ~ € 200 billion / yr



Food Contact Legislation

Regulation (EU) No 1935/2004 on food contact materials and articles

- ‘Basic Act’ – adopted by council and parliament
- applies to all food contact materials
- basic requirements and procedures

Commission implementing legislation on specific materials

- adopted on the basis of Regulation (EU) No 1935/2004
- **Regulation (EU) No 10/2011** on plastic materials
- **Regulation (EU) 2022/1616** on recycled plastic materials
- Also: Ceramic materials, regenerated cellulose, and active and intelligent materials are subject to EU legislation – as are some specific substances (BPA, VCM, nitrosamines)

All other materials are subject to national legislation!



Article 3

Article 3 is considered the main requirement of FCM legislation

Materials and Articles shall not transfer their constituents in amounts that could:

- **endanger human health**
- bring about unacceptable change to the composition of food
- bring about a deterioration in the organoleptic characteristics thereof

Article 3

General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

or

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

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

EU legislation on FCMs

Regulation (EC) No 1935/2004 (objectives: human health and functioning of EU market)
Basic rules on safety, labelling, traceability, inspection and control, authorisation process



Guidance
on plastic FCM &
documentation

**Regulation (EC)
No 10/2011**
on plastic FCM

**Regulation (EC)
2022/1616**
on plastic recycling

**Regulation (EC)
No 450/2009**
on AIM

**Directive
84/500/EEC**
on ceramics

**Directive
2007/42/EC**
on RCF

**Regulation (EC)
No 2023/2006**
on good
manufacturing
practices

**Directive
93/11/EEC**
on nitrosamines

**Regulation (EC)
No 1885/2005**
on epoxy derivatives

**Regulation (EU)
No 2024/3190**
on BPA/bisphenols

**Directive
78/142/EEC**
on VCM

Regulation 284/2011
on plastic
kitchenware

**Recommendation
2019/794**
on FCM controls

**Recommendation
2017/84**
on MOH



Revision of FCM legislation

The revision will likely result in the replacement of Regulation (EU) 1935/2004



Background to revision

- Basic act is approaching 50 years old (originally Directive 76/893/EEC)
 - EU authorised lists of substances since 1980s (RCF) and 1990s (plastics)
 - Rules on lead and cadmium but also old (1984)
 - Substance specific rules (BADGE, BPA, VCM)
 - More recently specific measures being implemented on recycled plastic
- Support from all stakeholders to improve the current EU FCM legislation and for more EU harmonised rules beyond plastics
- JRC ‘baseline’ study published 2016 – FCM industry and national rules
- Evaluation carried out 2017 – 2020 and [published 2022](#)
- Revision of EU FCM rules announced May 2020



Problems identified: Why revise FCM legislation?

- Issues raised
 - Beyond plastics, little or no harmonisation → **lack of functioning of EU market and uncertainty over safety**
 - Harmonisation made difficult by issues with authorised list approach, inc. **lack of assessment capacity and prioritization of substances, up-to-date assessments and lack of focus on the final article**
 - **Exchange of safety and compliance information** in the supply chain is poor and ability to ensure compliance is compromised; enforcement of rules on FCMs is generally poor
 - Rules do not sufficiently take into account the **specificity of SMEs**
 - Rules do not encourage development of safer and more **sustainable alternatives**
- Causes are inherent to the present regulatory system
→ **fundamental change to present system required** to address issues

Primary objectives of the revision

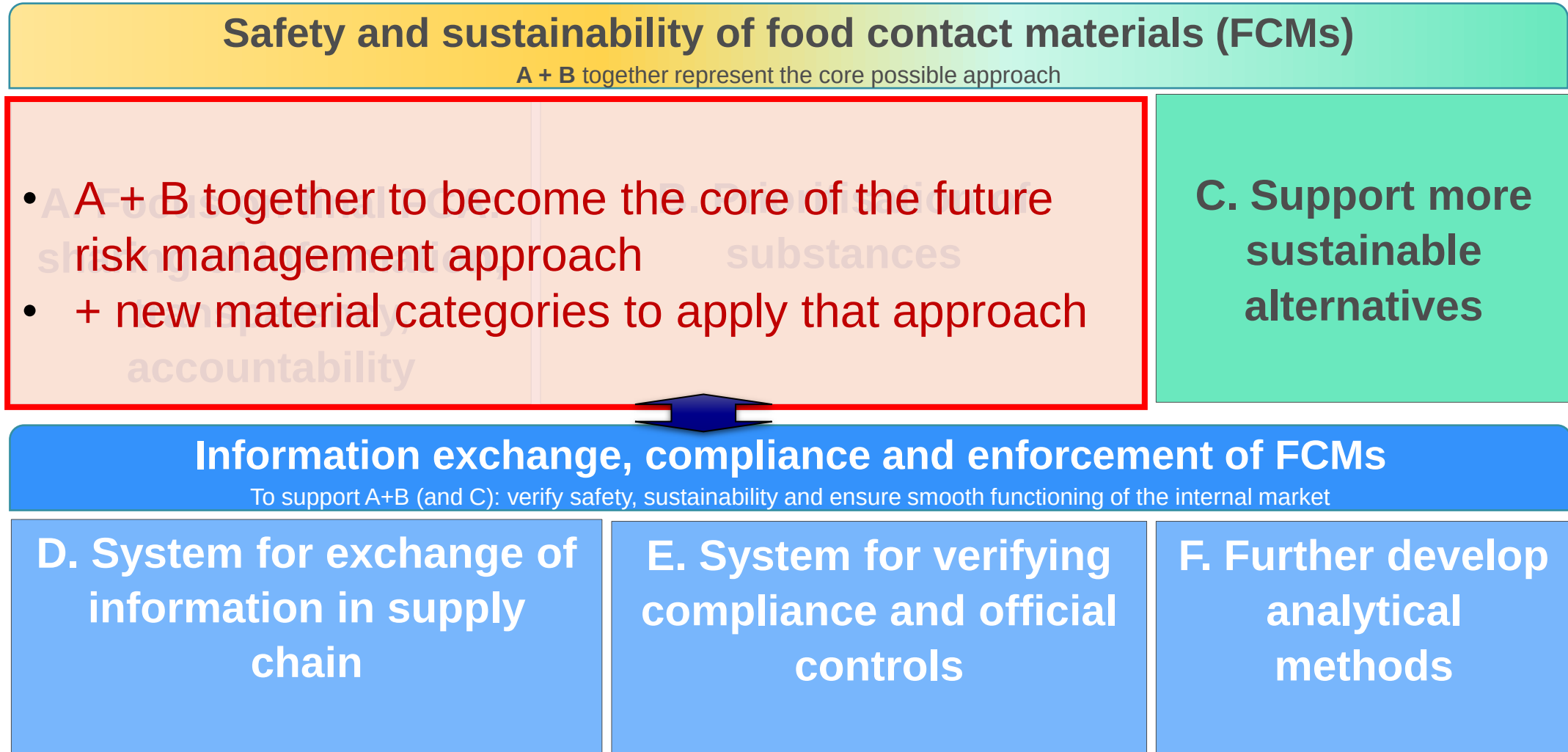
1. Ensure appropriate level of **harmonisation** across all materials
 - improve certainty over **food safety**
 - improve **functioning of the EU market**
2. Make rules more practicable, enforceable and achievable: **Simplification**
3. Achieve **transparency** and ultimately **accountability** regarding (final) materials and articles
4. Improve **competitiveness and legal certainty**

For all primary objectives we keep in mind

- SMEs (particular focus on **traditional** and **artisanal manufacturing**)
- **tools for compliance and enforcement**
- level playing field (including internationally)
- sustainability



EU FCM revision: Main policy themes and pillars



The current work on the revision

- Number of targeted consultations with people who have significant expertise and experience in the field of FCMs
 - Discussion and documentation of experience and ideas and possible solutions
 - Interviews and workshops
 - Experts not representing interests of a particular sector, business or viewpoint but on basis of individual expertise with backgrounds from industry, academia, consumer interests, compliance and enforcement
- Initial focus on pillar A, expanding gradually to other pillars...
- Wider consultation on developments with stakeholders when appropriate
- Finalisation of policy through impact assessment



Pillar A – main elements

1. Business operators to build **complete knowledge on composition of FCM**
 - from moment substances, preparations and materials are declared/ intended for FCM
 - presence of intentional and unintentional substances, throughout the supply chain →
 - → migration potential ('migratable substances') in final food contact materials and articles
 - **details under discussion and to be defined** which business operators must have what knowledge
2. Use of **GMP** to control manufacturing processes
 - better understand processes and improve knowledge on composition of substances, preparations and other intermediate materials declared as suitable for food contact
 - customers only procure substances, preparations and materials suitable for food contact
 - possibility for certification scheme(s) or self-responsibility for validating GMP procedures and/ or materials



Pillar A – main elements

3. Undertake a risk assessment of migratable substances

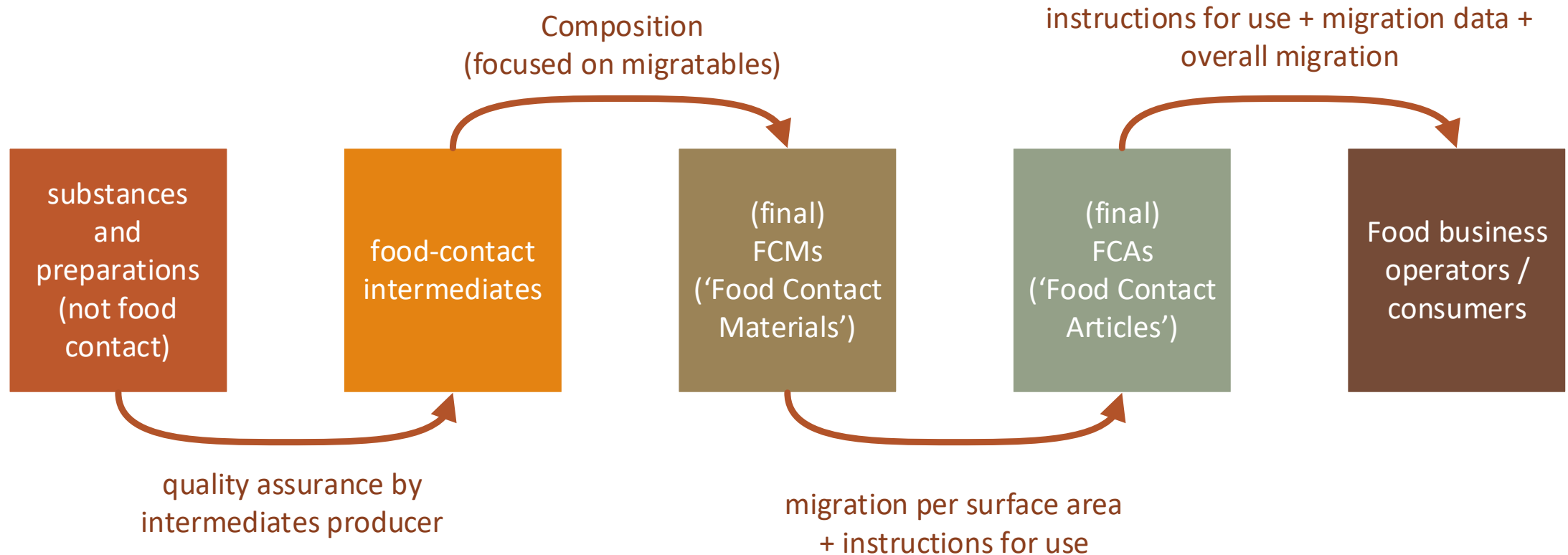
- techniques including analytical verification or migration modelling needed to ensure real migration levels under foreseeable/intended conditions of use do not have an adverse effect on human health
- ensure compliance with specific restrictions (e.g. ban of substance, SML)
- link with Pillar B

4. Make information available

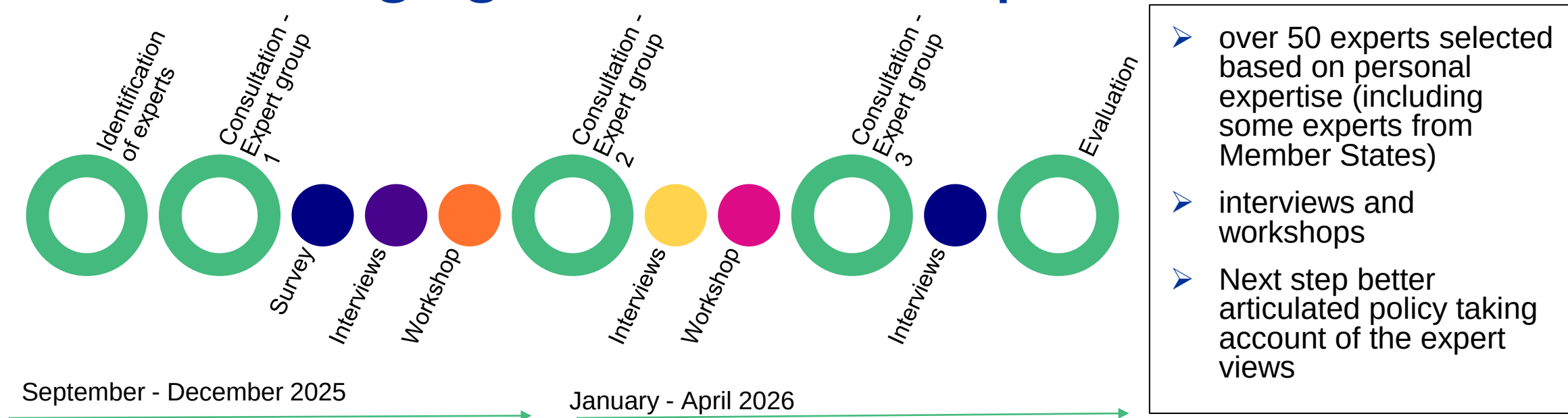
- in full to enforcement authorities
- all information necessary to ensure safety to be passed from business to business, respecting defined legitimate business confidentiality



Pillar A – a view on complete knowledge



Pillar A: engagement with experts



Provisional outcome

- Refined and more detailed views on pillar A and how to attribute responsibilities throughout supply chain;
- Importance of detailed GMP rules highlighted;

and...

- Good basis to further develop pillar A in a practical and regulatory sense;
- Method used to address pillar A lead by single external expert successful and will continue to be used;
- Developments to be shared at a later stage of the process.

next steps (short-term)

Pillar B – substances

- use of substances
- restricted substances
- hazard and risk assessment

Pillar F – novel analytical methods

- non-targeted screening methods (presence and controls of many substances at once)
- bio-assays (direct risk assessment of mixtures)
- finger-printing (special case of screening, highly standardised methods to identify products)

Discussion with expert groups during Q3-Q4, similar to Pillar A work



Important disclaimer!



- The slides describe the ‘aspirations’ of the revision
- These do not necessarily reflect the reality of what will be the final legislation
- Some of these aspirations may not be achieved, or be differently achieved
- Discussions with EFSA, Member States and Stakeholders will be very important
- Success also relies on you!

(plastics) + recycled plastics

EU legislation on FCMs

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'new' plastics: Regulation (EU) No 10/2011

Intentionally used substances

- All substances used to manufacture the plastic
- **must be authorised** (other substances cannot be used)
- subject to scientific opinion of European Food Safety Authority ('EFSA')
- subject to restrictions – e.g. migration limits
- must be of a high degree of purity
- approximately 1000 substances are authorised

non-intentionally added substances (NIAS)

- impurities, reaction products, degeneration products
- no other substances
- subject to risk assessment in accordance with internationally accepted practices
- **responsibility of business operators**
- number of NIAS much larger than authorised substances

Safety assessment of the substance fatty acid-coated nano precipitated calcium carbonate for use in plastic food contact materials

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcetti, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Laurence Castle, Emma Di Consiglio, Roland Franz, Nicole Hellwig, Maria Rosaria Milana, Stefan Merkel, Eric Barthélémy and Gilles Rivière

Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the substance identified by the applicant as 'fatty acid-coated nano precipitated calcium carbonate'. It is intended to be used as a filler in all plastics at up to 5% for contact with acidic food and at up to 40% for contact with all other types of food. Articles made with the substance are intended for long-

authorisation

Table 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecular obtained from microbial fermentation (yes/no)	FRP applicable (yes/no)	SNL [mg/kg]	SNL (7) [mg/kg] (Group restriction on No)	Restrictions and specifications	Notes on verification of compliance
1	12310	0266309-43-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C ₄ -C ₁₂)	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,5-disocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-disocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	triethyl(C ₁₂ -C ₁₃)acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxy group. Molecular weight is 43 Da.	
6	25380	—	triethyl acetic acid (C ₁₂ -C ₁₃), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylacetic acid, salts	yes	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	yes	no	no		(32)		

Regulation (EU) 2022/1616; recycled plastics

The Regulation is to ensure that recycled plastic is safe

- It covers all plastic food contact materials that have recycled content
- recycled content originates from waste

The Regulation requires that:

- **All** recycled plastic **content**...
- in materials and articles **placed on the EU market**...
- that **foreseeably** come in contact with food...
- ...is manufactured with a **suitable recycling technology!**



Regulation of **recycled** plastic food contact materials

Plastic Food Contact materials

(Regulation (EU) No 10/2011)

- Focus: Composition
- Rules on:
 - Substances authorised to manufacture plastics
 - Purity and other compositional requirements
 - Migration and verification of compliance
- Official controls: compliance of **products**

Recycled Plastic Food Contact Materials

(Regulation (EU) 2022/1616)

- Focus: Decontamination
(Compliance with Regulation (EU) No 10/2011 required)
- Rules on:
 - Collection, Decontamination, Use
 - Technologies, Processes, Installations
 - Authorisation (Technologies, Processes)
 - Good Manufacturing Practices
 - Documentation and Registration
- Official Controls: compliance of **production**



Decontamination of Recycled Plastic

Recycled plastic must comply with Regulation (EU) 10/2011

- the quality of the plastic itself should not be a problem; collected plastic must comply

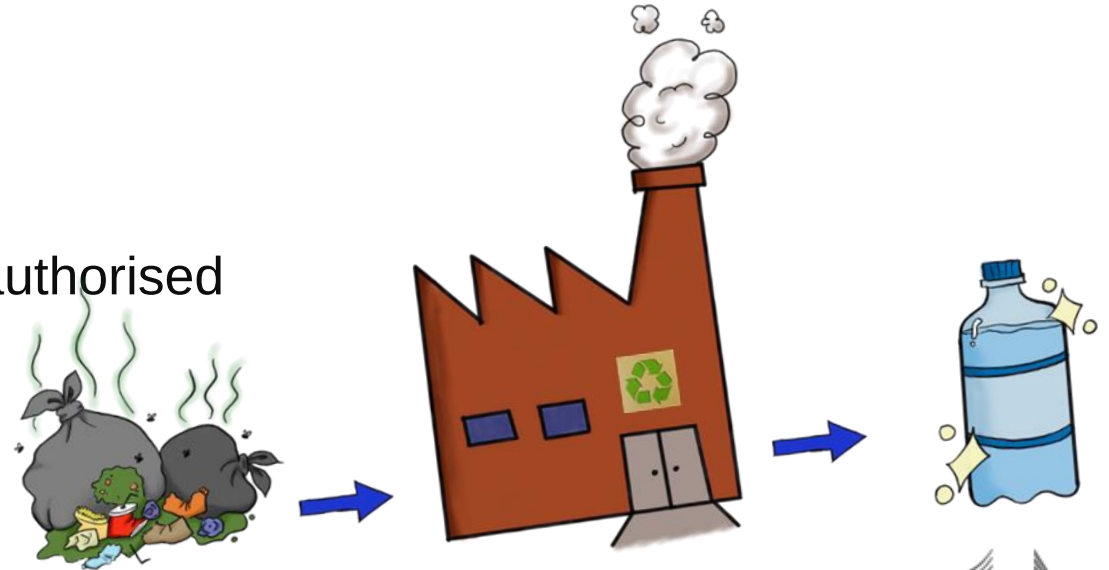
Plastic waste contains contaminants → it needs decontamination

- Contaminants originate e.g. from use, mis-use, cross contamination during collection
- Required amount of decontamination depends on the quality of the waste

Decontamination technology is specifically intended to remove contaminants to make it suitable for food contact

Regulation (EU) 2022/1616

- Strict requirements on collection and recycling
- Decontamination technologies and processes authorised
- Recycling installations are audited
- Presently mostly for PET



Regulatory permission to manufacture recycled plastic

1. Establish **suitable** recycling **technologies** (prove the main principles)
 - development via ‘Novel Technology’ procedure
 - suitability assessment by **EFSA**; established as suitable by **Commission**
 - presently:
 - ‘mechanical PET recycling’
 - ‘recycling from closed and controlled chain’
2. **Authorise** recycling **processes** (specific, detailed implementation)
 - presently only for mechanical PET recycling
 - authorisation procedure
 - evaluation of process by **EFSA**; authorised by **Commission**
3. **Register and Audit** decontamination installations
 - must use an authorised process
 - compliant operation to be audited by **local Competent Authority**
 - ‘compliance monitoring summary sheet’ – summary of good manufacturing practices

Analogy to cooking: ‘process’ vs. ‘installation’ ~ ‘recipe’ vs. ‘kitchen’

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not necessarily represent a final position and (Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which preliminary assessment. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

Safety assessment of the process [redacted], based on [redacted] used to recycle post-consumer PET into food contact materials

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Vittorio Silano, José Manuel Barat Baviera, Claudia Bolognesi, Beat Johannes Brüsche, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Alicja Mortensen, Gilles Riviere, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Laurence Castle, Vincent Dudler, Nathalie Gontard, Cristina Nerin, Constantine Papaspyrides, Cristina Croera and Maria Rosaria Milana

Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEP) deals with the safety evaluation of the recycling process [redacted] (EU register No RECYC1[redacted]), which is based on the [redacted]. The decontamination efficiency of the process was demonstrated by a challenge test. The input of this process is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, mainly bottles, containing no more than 5% of PET from non-food consumer applications. In this technology, washed and dried PET flakes are preheated before being submitted to solid-state polycondensation (SSP) in a continuous reactor at high temperature under vacuum and gas flow. Having examined the challenge test provided, the Panel concluded that the preheating (step 2)

authorisation

COMMISSION IMPLEMENTING DECISION

of XXX

authorising the mechanical PET recycling process ‘process name’ in accordance with Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008¹, and in particular Article 19(1) thereof,

Whereas:

- (1) Regulation (EU) 2022/1616 provides that recycled plastic materials and articles can only be placed on the market if the recycled plastic therein is obtained using a manufacturing process that applies a suitable recycling technology. Post-consumer mechanical PET recycling is such a suitable technology. Recycling processes applying this technology as set out as technology no. 1 in the list of suitable technologies contained in Table 1 of Annex I to that Regulation, require an authorisation by the Commission based on an application to be submitted to the European Food Safety Authority (‘the Authority’). In accordance with Article 31(1) of Regulation (EU) 2022/1616, an application for authorisation submitted under Commission Regulation (EC) No 282/2008² is to be considered equivalent to an application received in accordance with Article 17(1) of Regulation (EU) 2022/1616.

Public Register

of recycling operators, facilities, installations, processes, schemes and novel technologies

Recycling installations (886 matching records)

(note: RIN - 'Recycling installation number'; RFN - 'Recycling facility number'; RON - 'Recycling operator number')

◆ RIN	◆ Name of Recycling installation	◆ Country	◆ RFN	◆ RON
AE6-7HE-3IP	Ravago Recycling Middle East LLC - SPC	United Arab Emirates	AE6-7HE-3FU	AE0-OES-3O5
AE9-HND-1I5	HORIZON TECHNOLOGIES FZC - STARLINGER IV+	United Arab Emirates	AE9-1CK-1FN	AE5-1CK-1OJ
ANG-99C-0I8	Glopol Angola – Indústria, Lda. recoSTAR PET 125 HC IV+ (machine number MA 2014317)	Angola	ANG-6JD-0FS	ANG-6JD-0OQ
AR0-JM4-2IQ	RECICLAR S.A.	Argentina	AR0-JM4-2F0	AR0-JM4-2OG
AT1-1FL-0IG	PET to PET Granulierungsanlage 1	Austria	AT1-61T-0FC	AT1-61T-0OA
AT1-3T5-0I7	Production Line SSP	Austria	AT1-9B3-0FM	AT1-9B3-0OK



Contact:

For all enquiries regarding this register please only use SANTE-FCM-recycling-register@ec.europa.eu and put [DR05] in the subject

Union register of technologies, recyclers, recycling processes, recycling schemes, and decontamination installations

Established in accordance with Article 24 of Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods

List 5: Novel Technology Numbers ('NTN')
version: 1.3 (28 May 2026)

This list contains all presently validated novel technologies notified in accordance with Article 10(2) of Regulation (EU) 2022/1616

This document is part of the Union Register of novel technologies, recyclers, recycling processes, recycling schemes and decontamination installations, established and made public in accordance with Article 24 of Regulation (EU).
Important: This list is drawn up based on registration data that the Commission received since October 2022, to the extent that could be validated by Member States and Commission services.
The Novel Technology dossiers submitted by the developers in accordance with the requirements of Article 10(2) of Regulation (EU) 2022/1616 are listed in tables 5a and 5b below. This includes the presence of a functional and publicly accessible URL to access the Novel Technology reports published in accordance with Article 10(4) and Article 13(4) of the Regulation.

List 5a: Register of Novel Technologies in the EU (note: NTN – 'novel technology number')

Row	NTN	5.1. Novel Technology	5.2. Name of the developer	5.3. Address of the developer	5.4. URL referred to in Article 10(2);	5.5. MSs
1	AT3-7NY-2NE	Intarema + ReFresher	EREMA Engineering Recycling	Unterfeldstrasse 3, 4052 Ansfelden, Upper Austria, Austria	https://erema.sharefile.com/public/share/web-saa1abbf9922e49e396ab105dda4f6760	Austria
2	AT3-0TP-2N7	Rigid Post-Consumer high density polyethylene (HDPE) container recycling	EREMA Engineering Recycling	Unterfeldstrasse 3, 4052 Ansfelden, Upper Austria, Austria	https://erema.sharefile.com/public/share/web-s599fb7763c1c45ad9bd8c9a9fc9b5810	Austria
3	AT1-6NQ-2NH	Starlinger viscotec viscoZERO super-clean process for HDPE	STARLINGER & CO Gesellschaft m.b.H. viscotec	Sonnenuhrstrasse 4, 1060 Vienna, Austria	https://www.viscotec.at/novel	Austria
		Starlinger viscotec viscoZERO	STARLINGER & CO	Sonnenuhrstrasse 4,	https://www.viscotec	

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ongoing amendment to Regulation (EU) 2022/1616

To facilitate the automation of EU Register

- registration will be possible only if identified competent authority in territory

To introduce new compliance documentation

- Declaration 'P' – for pre-processed material; includes reference to certification (new)
- Declaration 'A' – recycled plastic (only small update)
- Declaration 'B' – post-processed recycled plastic (update)
- **Declaration 'C'** – post-processed recycled plastic of final composition (new)

Introduction of **CN codes** (TARIC, mainly for PET), requiring the declarations

Some smaller matters

Expected entry into force late November

Table 6
Documentation requirement upon release for free circulation in accordance with Article 5a(4)

Reference number 6.1 CN codes applicable to PET			Declaration of compliance
ex 3907 61 00	Poly(ethylene terephthalate) having a viscosity number of 78 ml/g or higher, recovered from waste, <i>suitable or intended for food contact use</i>		Declaration P, A or B
ex 3907 69 00	Other poly(ethylene terephthalate), recovered from waste, <i>suitable or intended for food contact use</i>		Declaration P, A or B
ex 3915 90 20	Waste of poly(ethylene terephthalate), <i>intended for food contact use</i>		Declaration P
ex 3923 30 10	Carboys, bottles, flasks and similar articles: of a capacity not exceeding two litres, of poly(ethylene terephthalate), <i>with recycled content suitable for food contact use</i>		Declaration C
ex 3923 30 90	Carboys, bottles, flasks and similar articles: of a capacity exceeding two litres, of poly(ethylene terephthalate), <i>with recycled content suitable for food contact use</i>		Declaration C
ex 3920 62 19	Other plates, sheets, film, foil and strip, of plastics, non-cellular and not reinforced, laminated, supported or similarly combined with other materials, of poly(ethylene terephthalate) of a thickness not exceeding 0,35 mm, <i>with recycled content suitable for food contact use</i>		Declaration C
ex 3920 62 90	Other plates, sheets, film, foil and strip, of plastics, non-cellular and not reinforced, laminated, supported or similarly combined with other materials, of poly(ethylene terephthalate) of a thickness exceeding 0,35 mm, <i>with recycled content suitable for food contact use</i>		Declaration C
ex 3919 10 80	Self-adhesive plates, sheets, film, foil, and other flat shapes, of plastics, in rolls of a width not exceeding 20 cm, of poly(ethylene terephthalate) with recycled content suitable for food contact use		Declaration C
ex 3919 90 80	Self-adhesive plates, sheets, film, foil, and other flat shapes, of plastics, of poly(ethylene terephthalate), with recycled content suitable for food contact use		Declaration C
ex 3923 10 90	Articles for the conveyance or packing of goods, of plastics; boxes, cases, crates and similar articles, of poly(ethylene terephthalate), with recycled content suitable for food contact use		Declaration C
ex 3923 90	Other articles for the conveyance or packing of goods, of plastics; of poly(ethylene terephthalate) with recycled content suitable for food contact use		Declaration C
ex 3924 10 00	Tableware and kitchenware, of poly(ethylene terephthalate) with recycled content suitable for food contact use		Declaration C
ex 3924 90 00	Other household articles, of plastics, of poly(ethylene terephthalate) with recycled content suitable for food contact use		Declaration C

Declaration C, Food Business Operators

- Declaration C must be provided at all marketing stages where recycled plastic is placed on the market and no longer changes composition
- It should not be provided to consumers ('at the retail stage')
- Food business operators will always receive declaration C
- By derogation, food business operators do not need to provide it to distributors and retailers, unless asked
- Note that the same provisions apply to imported food
 - (imported food not subject to TARIC codes on recycled plastic)

(See Article 5a and Article 26a – both newly introduced)

'Article 5a Requirements for compliance documentation

1. At marketing stages other than the retail stage, business operators shall provide a declaration of compliance in accordance with Article 16 of Regulation (EC) No 1935/2004 for materials and articles subject to this Regulation.
2. Business operators shall establish the declarations of compliance referred to in paragraph 1 in accordance with Article 29.
3. Business operators shall only accept plastic materials, articles or food with packaging subject to this Regulation, that are accompanied by the appropriate declaration of compliance.
4. By derogation to paragraph 1, food business operators that use products with recycled content to pack food shall not be obliged to provide a declaration of compliance to retailers and to the distributors supplying to retailers where all the following conditions are met:
 - (a) relevant information and instructions needed for the retailers to ensure compliance with this Regulation and for consumers to ensure the safe use of the products containing recycled plastics are provided through labelling or through other appropriate documentation;
 - (b) any information concerning the recycled content of the products with recycled plastics does not differ from the information contained in the declaration received by the food business operator in accordance with paragraph 1.

In this case paragraph 3 shall not apply.

Upon request from a competent authority, or from a retailer or distributor it supplies to, a food business operator that uses recycled plastic materials and articles to pack food shall provide within ten working days from the request, where the request is made in the context of a control by a competent authority, or otherwise within twenty working days from the request, one of the following declarations of compliance:

- (a) the declaration of compliance that they have received from their supplier;
- (b) a new declaration of compliance issued by them.

5. Business operators shall ensure that supporting documentation to demonstrate that the products that they place on the market comply with the requirements of this Regulation is stored in their documentation systems at the time of issuance of the declaration of compliance. In case of recycled plastic, the documentation shall include all relevant records kept in accordance with Article 7(4).

Supporting documentation shall be made available within ten working days to competent authorities on their request.

6. A declaration of compliance may be provided as a signed digital document, provided that it can be made available without delay as a single document that can be read and printed with commonly available software.

7. The release into free circulation of the following products is subject to the presentation to the customs authorities of the documentation listed in Table 6 of Annex I, under the specified commodity codes:

- a) products containing recycled plastic manufactured with a suitable recycling technology where column 11 of Table 1 of Annex I indicates 'yes', as well as partially pre-processed plastic input, plastic input and recycled plastic intended for use in the manufacture thereof, except packaged food, food processing equipment and appliances;
- b) tableware and kitchenware falling within CN code ex 3924 10 00 and CN code ex 3924 90 00, if that contains recycled plastic;
- c) multi-layer sheets containing at least one layer of recycled PET used behind a functional barrier layer, irrespective of the composition of the barrier layer, as well as plastic input and recycled PET intended for the manufacture of such layers of recycled PET.'



Electronic Registration System

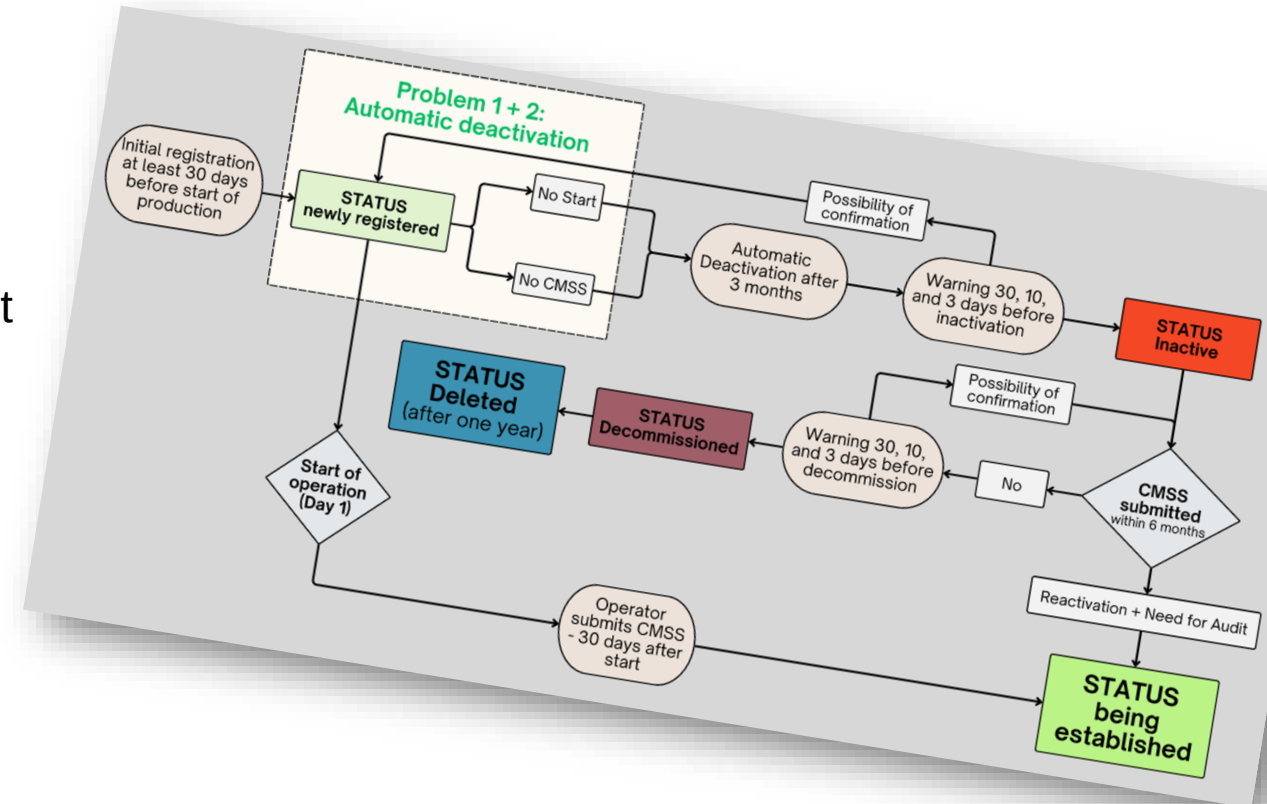
Introduction of an electronic registration system – new workflow

- Administrative support to the Union register - gather all data through one platform.
- Single point of access and interaction for the concerned stakeholders, who become able to directly edit their data
- The electronic registration system is to implement the business logic laid down in the legislation

Accessible by competent authorities from Member States and third countries

- Member States authorities can read all information
- Competent Authorities from both Member States and thirds countries can edit certain information related to the entities located in their territory

Implemented in the text through amendment of articles 24, 25, 26.



Thank you



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