New FCM policies Recycling, Revision

Regional seminar on 'Food Contact Materials and Safety Requirements applicable to Recycled Plastic'

Bangkok, 26 June

European Commission; DG SANTE E.2

1

Three sessions

14:00 – 14:30	Introduction to general policies of the EU green deal, circular economy, chemicals strategy for sustainability – *by Mr Bastiaan Schupp, DG SANTE* *Shortened*
14:30 – 15:20	Presentation of Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods (entered into force on 10 October 2022) - *by Mr Bastiaan Schupp, DG SANTE, joined by Ms Eleni ZAFEIROPOULOU*
15:20 – 15:40	Coffee break
15:40 – 16:10	Safety assessment of mixtures from renewable biological resources – *by Mr Eric Barthelemy, EFSA (online)*
16:10 – 17:10	Revision of FCM legislation *by Mr Bastiaan Schupp, DG SANTE*

2

Relevant Commission Policies

Introduction to the general policies of the EU green deal, circular economy, chemicals strategy for sustainability

3

European Commission

3

4

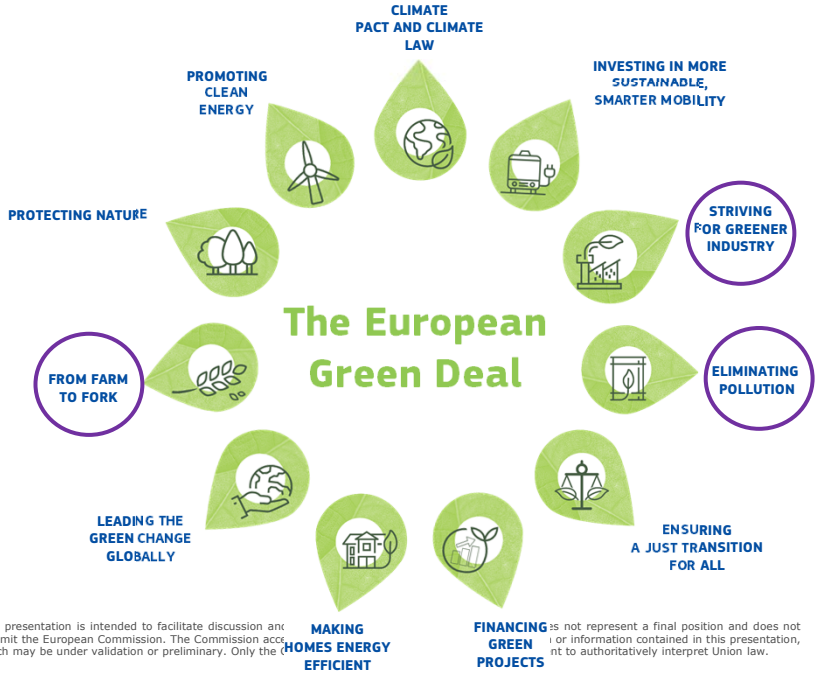
Overcome existential threat to Europe and the world

The European Green Deal is our roadmap for **making the EU's economy sustainable.** This can only happen if we turn climate and environmental challenges into opportunities across all policy areas and making the transition just and inclusive for all.

https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

European Commission

5



European Commission

6

Policies of the European Commission (relevant to FCM)

- 6 European Commission priorities 2019-2024
  - **green deal**, fit for digital ages, economy that works for people, stronger Europe, promoting European way of life, new push for democracy
- Green Deal – many initiatives – directly relevant to FCM legislation
  - policy on packaging waste – is to reduce the use of packaging including food packaging
  - chemicals Strategy for sustainability – affects the use of chemicals
  - sustainable food systems – requires FCM legislation to consider sustainability
- The next presentations (including that from EFSA) should be seen in this context

Framework for sustainable food systems

- Background
  - Currently no dedicated EU framework law on food sustainability similar to the EU framework law on food/feed safety, i.e. General Food Law (R 178/2002)
  - Fitness Check of the GFL (2018) → regulatory framework found largely inadequate to address the new challenges of food sustainability
- Objectives
  - *Set the foundations for the **systemic changes** that are needed by all actors of the food system, including policy makers, business operators and consumers in order to **accelerate the transition to a sustainable EU food system**.*
  - *Promote policy coherence at EU and national level, mainstream sustainability in all food-related policies and strengthen the resilience of food systems.*

Packaging and Packaging Waste Regulation

- Target of 5% reduction of all packaging waste by 2030 vs 2018
- Measures on waste prevention and reuse
  - full recyclability of all packaging by 2030 ensuring recyclability at scale
  - **recycled content targets for plastic packaging**
  - targets on the reuse of certain packaging
  - bans on the use of certain packaging
- All four measures include food packaging
  - food packaging nearly 50% of all packaging waste
- Presently under discussion in Council and Parliament

9

Chemicals Strategy for Sustainability

- The strategy is to:
  - ensure better protection of human health and the environment from hazardous chemicals
  - boost innovation for safe and sustainable chemicals
  - enable the transition to chemicals that are safe and sustainable by design
- **Key objectives relevant to FCM policy:**
  - banning the most harmful chemicals in consumer products - allowing their use only where essential
  - phase out per - and polyfluoroalkyl substances (PFAS) in the EU, unless their use is essential
  - establish a simpler “one substance one assessment” process for the risk and hazard assessment of chemicals

10

Plastic Recycling

Presentation of Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods (entered into force on 10 October 2022)

Content

- Introduction:
  - Why is there specific legislation on plastic recycling for food contact?
  - and why does it apply in full also to foreign operators that export to the EU?
- Outline of Regulation (EU) No 2022/1616 on recycled plastic FCMs
- mechanical PET recycling
  - The obligations of Recyclers
  - The obligations of Competent authorities regarding official controls
- Wrap-up

Objective of this presentation

- To explain you the main principles
- To explain you the logic of the Regulation
- To explain you the main obligations

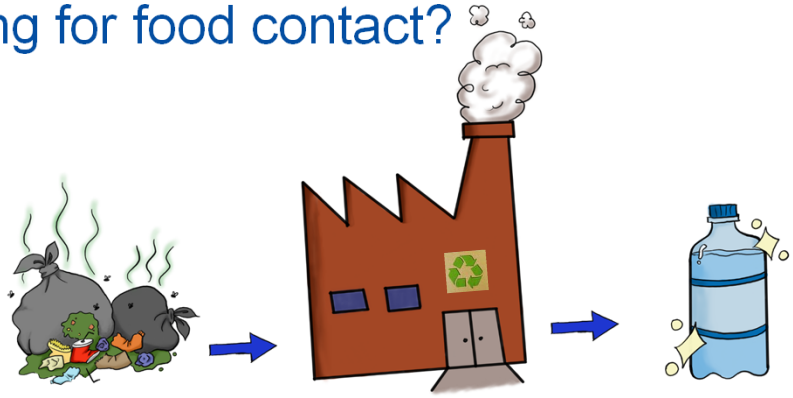
→ objective is not to provide you with a full course…
… rather it is to help you read and understand the Regulation

introduction

Why is there specific legislation on plastic recycling for food contact?

and why does it apply in full also to foreign operators that export to the EU?

Why is there specific legislation on plastic recycling for food contact?



- High level of trust needed – health protection – consumer trust - uptake

15

Waste Plastic

- Waste plastic from contains contaminants
- Origins:
  - manufacture of the plastic
  - intentional use (i.e. from food)
  - potential misuse (e.g. paint, petrol)
  - degradation of the plasic
  - contamination with non food contact plastics (e.g. non-authorised additives)
  - from cross contamination in waste collection
- 'incidental contamination'
  - random presence of substances
  - individually in low amounts
- large amounts of single contaminants
  - e.g. in waste from industrial use

→ the quality of waste plastic should be controlled

- self-control by operators, guidance, standards legislation

- control of the composition of waste:
  - collection / origin of the plastic waste
  - separation and sorting
  - washing and similar operations
- objective of such:
  - to limit the contamination level
- this does not ensure a sufficiently low level of contaminants
  - it could but then would the use of plastic waste for food contact becomes extremely limited

16

Decontamination

- waste plastic contains contaminants

→ it needs decontamination

- required amount of decontamination depends on the quality of the waste
- for FCM:

decontamination technology

=

recycling technology

- Decontamination technology is specifically intended to remove contaminants to make it suitable for food contact
  - technology suitable to remove contaminants
  - up to a level low enough that consumer health cannot be adversely affected
  - and exclude organoleptic concerns
- the level of decontamination must be controlled
  - again the EU uses legislation to ensure that decontamination is sufficient

Ensuring sufficient decontamination

- approach based on toxicology
  - presence of genotoxic substances must be at a very low level
  - unless the presence can be excluded
- Incidental contaminants cannot be identified (or measured)
  - random presence, we do not know what substances to look for
  - could be toxic below detection limits

→ migration limits cannot be used

- Step 1:
  - determine level of contaminants in the input
  - determine level needed for a safe output
- Step 2:
  - design a decontamination process that can lower the input level to the safe output level
  - verify scientifically that it can achieve that its decontamination efficiency is high enough
- **Step 3:**
  - ensure in practice that the decontamination efficiency is achieved
  - laboratory controls of limited value
  - **strict adherence to good manufacturing practices**
- The EU uses legislation to ensure sufficient decontamination
  - Authorisation of recycling processes
  - Official controls (audits) of their functioning

Restrict use of specific recycled plastic

- Not all food contact applications are equally sensitive
  - low sensitivity: dry foods for adults
  - high sensitivity: aqueous/fatty foods for infants
- Plastic intended for low sensitivity applications?
  → Permitted residual contaminant level may be higher without affecting health
- Not all recycled plastics can be used for all applications
  - it is possible to invest less in decontamination for low sensitivity applications
  - it affects the calculations explained on the previous slide
- EU legislation may restrict the use of the plastic
  - depending on the cleaning efficiency of the decontamination process

In summary

- Recycled plastic must have a residual contaminant level that is safe
  - to ensure consumer health as well as the uptake of recycled plastics
- To that purpose EU legislation regulates
  - the waste plastic that can be used
  - the efficiency of the decontamination process
  - the use of the recycled plastic
- The safety of recycled plastic cannot be verified using laboratory techniques
  - strict adherence to good manufacturing practices

→ Regulation (EU) 2022/1616

Two main elements of the EU approach

- Recycling processes must prove their decontamination capability **on paper**
  - EFSA assessments – Commission authorisation – 'regulatory approval'
- Recyclers must show that they operate the process correctly **in practice**
  - Good Manufacturing Practices ('GMP') – Competent Authorities – Audits
- The second point is often overlooked
  - the focus of many is on approval – not on continuous application of GMP
  - role for the competent authorities

Why does the Regulation apply outside the EU?

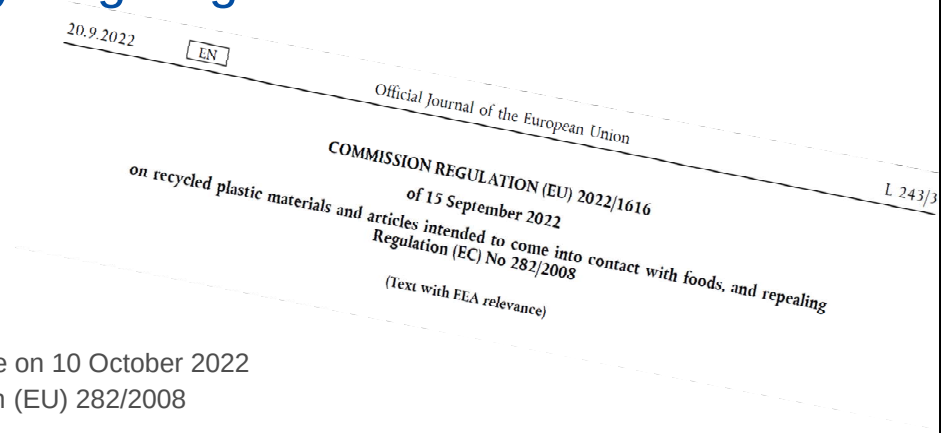
- Of course it only applies to operators exporting to the EU
  - WTO rules: the same rules should apply to operators inside and outside the EU
- Many operators understand EU approvals are required
  - particularly aware of the need of having an EFSA evaluated process
- Obligations placed on Competent Authorities are less easily understood
  - an operator cannot recycle plastics if there has not been an audit of their installation
- the recycler must show in practice they operate the recycling installation correctly
  - the second element of the EU approach

→ obligation on competent authorities

Regulation (EU) 2022/1616

Regulation on recycled plastic food contact materials

New Recycling Regulation



20.9.2022 EN Official Journal of the European Union L 243/3

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 282/2008

(Text with EEA relevance)

- The Regulation
  - it entered into force on 10 October 2022
  - replaced regulation (EU) 282/2008
- see http://data.europa.eu/eli/reg/2022/1616/oj

scope and purpose

- The new Regulation requires that:
  - **All** recycled plastic **content…**
  - in materials and articles that **foreseeably** come in contact with food…
  - is manufactured with a **suitable recycling technology!**
- There are two exceptions:
  - manufacture of **pure** substances listed in Annex I to Regulation (EU) No 10/2011
  - manufacture of recycled content **with a novel technology**

Main Terminology

- The Regulation uses the following technology
  - Technology, Process, Installation
  - Pre-processing, decontamination, post-processing
  - Suitable Technologies and Novel Technologies
- This terminology should be understood in the way the Regulation defines it

Definitions

- Definitions related to →
  - technology
  - process
  - installation
  - recycling
  - decontamination
- To note:
  - definitions in Article 2(3) apply only in the scope of this Regulation
  - facilitate the functioning of this Regulation

(1) → 'recycling technology' means a specific combination of physical and chemical concepts, principles, and practices to recycle a waste stream of a certain type and collected in a certain way into recycled plastic materials and articles of a specific type and with a specific intended use, and includes a decontamination technology;¶

(2) → 'decontamination technology' means a specific combination of physical and chemical concepts, principles, and practices part of a recycling technology which have as primary purpose to remove contamination;¶

(3) → 'recycling process' means a sequence of unit operations that is intended to manufacture recycled plastic materials and articles through pre-processing, a decontamination process, and post-processing, and which is based on a specific recycling technology;¶

(8) → 'decontamination process' means a specific sequence of unit operations which together have as primary purpose to remove contamination from plastic input in order to make it suitable for contact with food, using a specific decontamination technology;¶

(11) → 'recycling installation' means the equipment operating at least a part of a recycling process;¶

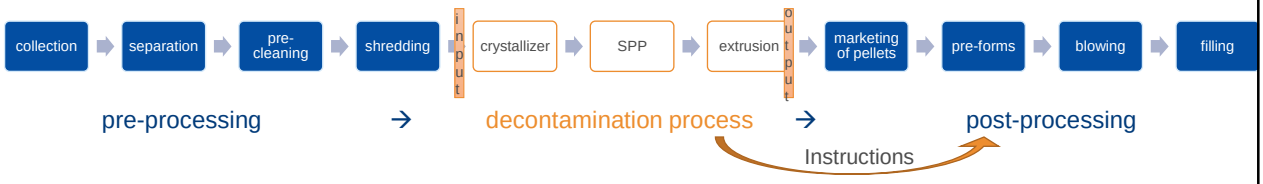
(12) → 'decontamination installation' means specific equipment operating a decontamination process;¶

Technologies, Processes and Installations

- Recycling **Technology**
  - generic concepts, principles and practices to recycle a defined input into a defined output
- Recycling **Process**
  - well described specific sequential operations based on a recycling technology
- Recycling **Installation**
  - **hardware** that actually recycles the plastic using a process
- Three associated procedures to establish safety
  - 'establish' suitable recycling technologies (EFSA + COM)
  - 'authorise' recycling processes (EFSA + COM)
  - 'control' recycling installations (audits) MS Competent Authorities

Processing stages

- Three main stages:
  - pre-processing, decontamination, post-processing
- During decontamination plastic is made suitable for food contact
  - This is what makes it a recycling process under FCM legislation
- Pre-processing is often referred to as ‘recycling’
  - it is insufficient for food contact legislation



29

suitable technologies

- Suitable technologies provide a proven way to decontaminate plastic
  - recycling processes can only be authorised if based on a suitable technology
- Suitable technologies are established on basis of novel technologies
  - the new regulation sets out a procedure to this purpose
- The new Regulation already establishes two suitable technologies:
  - mechanical PET recycling, max 5% non-food consumer waste, **authorisation of processes**
  - recycling from closed and controlled chain, no authorisation of processes, use of scheme

30

Annex I, table 1, laying down *suitable* technologies

(1) Recycling technology number	(2) Technology name	(3) Polymer type (detailed specification in Table 2)	(4) Short description of the recycling technology (detailed specification in Table 3)	(5) Specification of input	(6) Specification of output	(7) Subject to the authorisation of individual processes	(8) Specifications and requirements (reference to table 4)	(9) Derogations (reference to table 5)	(10) Recycling scheme applies
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5% materials and articles not used in contact with food.	Decontaminated PET; additional specifications may apply to output from individual processes	Yes	-	-	
2	Recycling from a closed and controlled chain	All polymers manufactured as primary materials in compliance with Regulation (EU) No 10/2011	Basic washing and microbiological decontamination during remoulding (3.2)	Chemically uncontaminated used materials and articles solely obtained from a closed loop; polymers not collected in mixed form, and/or from consumers	Materials and articles remoulded into the same materials and articles as those originating from the recycling scheme from which the plastic input was obtained	No	4.1		Yes

Establishment of suitable technologies II

- When not in Annex I – novel technology
- Novel technology procedure in Chapter IV of the Regulation
  - novel technology may be used to place recycled plastic on the market
  - subject to strict requirements regarding safety and monitoring
  - subject to notification requirements and reporting requirements
- No further discussion during this seminar

Authorisation of Processes

- For now, only mechanical PET processes require authorisation
- 230+ processes applied for authorisation – authorisations in progress
  - Regulation (EC) No 282/2008 preceded Regulation (EU) 2022/1616 – most applications
  - authorisations expected in Q4 2023
- Slightly different regime for future applications, only by developers
  - individual recyclers can no longer apply

Recycling installations

- They must apply an authorised recycling process
  - unless they use a technology that does not require that
  - unless they are
- They must be registered in public register (which is being established)
  - Article 25
  - notification by business operator 30 days prior to the start date of production
  - have a completed compliance monitoring summary sheet in accordance with Annex II
- They must be audited by competent authority
  - Article 26 compliance monitoring summary sheet to be agreed with competent authority
  - if not within one year, installation is suspended
  - *'The competent authority shall verify whether the information provided in the compliance monitoring summary sheet complies with this Regulation and perform a control of the recycling installation to this purpose in accordance with Article 27.'*

Structure of new Regulation

- **Part 1: basic rules**
  - **1: subject matter, scope and definitions**
  - **2: placing on the market of recycled plastic materials and articles**
  - **3: general requirements for recycling**
- Part 2: assessment and authorisation
  - 4: assessment of novel technologies and establishment of suitable technology
  - 5: evaluation and authorisation recycling processes
- **Part 3: controls of recycling installations**
  - **6: Union register**
  - **7: Official controls**
  - **8: Compliance documentation**
- Part 4: Final provisions
  - 9: Final provisions, transition + barrier materials

- Note:
  - Regulation has 9 chapters
    - No 'part' headers in text
  - In total 32 articles
  - Chapter 4 and 5 longest
  - Seminar covers **bold** parts in more detail

Obligations applicable to mechanical PET Recycling

As well as to other authorised recycling processes but at present there is only mechanical PET recycling

Obligations

- Obligations on the supply chain (mostly on recyclers)
  - Article 4-8 of the Regulation (chapter II and III)
  - Annex I
  - Authorisation Decision
  - Obligations regarding controls (Chapter VI, VII, VIII)
- Obligations on competent authorities
  - mostly in Article 26-28 (Chapter VI, VIII)

Obligations in the main text, Chapter II

- Article 4: *Requirements for recycled plastic materials and articles*
  - requires for mechanical PET recycling the use of a recycling installation based on an authorized recycling process
  - transitional provision: if applied for authorisation before 10 July 2023, the process may be used on the basis of the application until a decision on authorisation is available
- Article 5: *Requirements for documentation, instructions and labelling*
  - Compliance documentation
  - labelling of containers with recycled plastics
  - instructions to down stream operators including to converters and users

Obligations in the main text, Chapter III

- Article 6: *Requirements for collection and pre-processing*
  - plastic originates only from municipal waste, only compliant with Regulation (EU) 10/2011, and is separately collected
  - sets out what separate collection is (in essence not from general waste, but from a separately collected fraction of recyclable materials)
  - **requires certification of material originating from pre-processing stages** (relevance outside EU)
- Article 7: *Requirements for decontamination*
  - link to Annex I and authorisation, decontamination at single recycling facility,
  - installation and operation corresponds to authorised process, repository of records
  - it is operated as described in the compliance monitoring summary sheet established in accordance with Article 26.
- Article 8: Post-processing and use of recycled plastic materials and articles
  - essentially follow and pass-on instructions from recyclers

39

Obligations in Annex I

(1) Recycling technology number	(2) Technology name	(3) Polymer type (detailed specification in Table 2)	(4) Short description of the recycling technology (detailed specification in Table 3)	(5) Specification of input	(6) Specification of output	(7) Subject to the authorisation of individual processes	(8) Specifications and requirements (reference to table 4)	(9) Derogations (reference to table 5)	(10) Recycling scheme applies
1	Post-consumer mechanical PET recycling	**PET (2.1)**	Mechanical recycling (3.1)	**Only PET PCW containing maximum 5% materials and articles not used in contact with food.**	**Decontaminated PET; additional specifications may apply to output from individual processes**	Yes	-	-	
2	Recycling	All polymers	Basic washing and	Chemically	Materials and	No	4.1		Yes

2.1	PET	1	polyethylene terephthalate polymer made by the polycondensation of the comonomers ethylene glycol and terephthalic acid or dimethyl terephthalate, of which the polymeric backbone contains up to 10 % w/w other comonomers listed in Table 1 of Annex I to Regulation (EU) No 10/2011, such as isophthalic acid and diethyleneglycol

Column 5: the type of input that the recycling technology can decontaminate, where

— PCW: 'post-consumer waste' means plastic waste collected in accordance with Article 6;

— FG: 'food-grade' means plastic that was as primary material compliant with Regulation (EU) No 10/2011;

— 'Non-food PCW' means packaging that was not used to package food and may not have been manufactured in full compliance with Regulation (EU) No 10/2011 and other post-consumer plastic materials which were not intended for contact with food;

— 'Non-food %' (% w/w) means the maximum amount of non-food PCW present in the input;

40

Obligations in the Authorisation Decision

- Decisions are legal acts
  - they complement the Regulation
  - applicable only to one process
  - **forthcoming - still in draft status**
  - fields in green – process specific

Article 3

Specific requirements on the use of the authorised process

1. The decontamination process applied as part of the 'XXXX' process described in chapter 3 of the opinion shall fully correspond to the part of the process described in the subsection 'Decontamination and production of recycled PET material' of that chapter, comprising all main steps of that part of the process as described in the opinion, including any unit operations that are part of these steps or which are in between these steps if any.

   The decontamination process shall also correspond with its detailed description as further described and outlined in the application dossier which was provided to the authority to obtain this authorisation and to which the authority assigned reference number EFSA-Q-20xx-xxxx (further referred to as 'the dossier').

2. The pre-processing and post-processing parts of the recycling process may be configured or applied differently from the description in the opinion, provided that the resulting input to the decontamination process meets the specifications defined for the input in the opinion, as well as Article 6 of Regulation (EU) 2022/1616 and Annex I thereto, and the output is used in accordance with the respective specifications set out in Article 8 of Regulation (EU) 2022/1616 and Annex I thereto, as well as with Article 4 of this Decision.

Article 4

Requirements on the operation of a recycling installation using the process

A recycling installation based on the process and its operation shall meet the following requirements:

1. The decontamination installation that is applied to manufacture the recycled PET placed on the market fully corresponds with the decontamination process referred to in Article 3(1).
2. The plastic input meets the requirements set out in Article 6 of Regulation (EU) 2022/1616 and the specification set out in column 5 of table 1 of Annex I to the Regulation for post-consumer mechanical PET recycling and shall meet the specifications for the input described in chapter 3 of the opinion.
3. The operation of the decontamination installation applying the decontamination process shall be controlled to ensure that each critical step operates under conditions at least as severe as the conditions defined for the challenge test.
4. The output material meets the requirements set out in column 6 of table 1 of Annex I to the Regulation, and may be used up to 100% recycled content for the manufacturing of the following materials and articles:
   - all materials and articles for long-term storage at room temperature, with or without hotfill; and,
   - in contact with all types of foodstuffs, including drinking water,
5. The recycler using this process monitors that:
   - the recycling process is operated according to paragraph 3; and that,
   - each batch of recycled plastics has been obtained in accordance with the requirements of this Decision.
6. The recycler included a Declaration of Compliance in accordance with Article 29 and Part A of Annex III to Regulation (EU) 2022/1616 with each batch of recycled plastic it places on the market, or in accordance with Part B if it performs post-processing operations prior to the placing on the market of the recycled plastic.

   This Declaration of compliance includes at least the following instructions to converters and users further down the supply chain, including end users:
   - Appropriate references to the restrictions set out in paragraph 4;
   - 'not for oven or microwave use'

41

Obligations regarding controls

- Article 24: recycling installations, facilities, and operators must be on EU register
  - register is being established – please help us in ensuring correct data
- Article 25: Registration procedure for <u>installations</u>
  - recyclers to register 30 day prior to the start of production to competent authority in territory where the are located and to commission and have CMSS
  - CMSS: compliance monitoring summary sheet, Annex II
- Article 26: Agree with competent Authority the CMSS
  - within 1 year after start of operation – otherwise installation is suspended
- Article 27: Official controls in accordance with Regulation (EU) 2017/625
  - using audit in particular
- Article 28: non-compliance of plastics
  - if it has not been properly produced it is not compliant and needs to be taken off the market
  - limited direct (e.g. analytical) control of compliance, very bad quality or non-compliance with Regulation (EU) 10/2011

42

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42

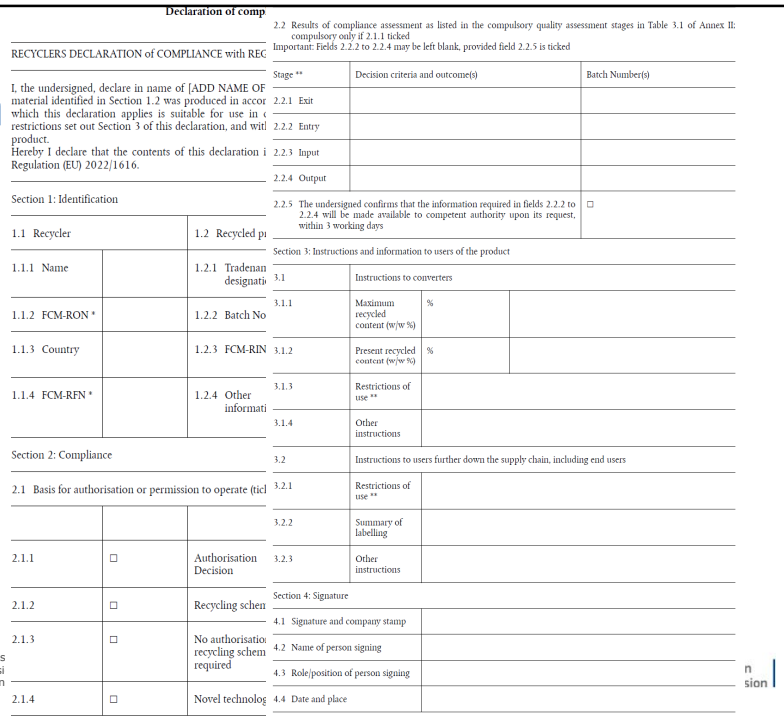
Register

- Draft versions of the Registers are presently being published for checking correctness
  - **still contain errors!**
  - https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/plastic-recycling/resources-plastic-recyclers_en
  - Three registers so-far:
    - Installations
    - Facilities
    - Operators

Row	RIN	1.1. Name of recycling installation	1.2. Member State	RFN	RON
1	AUS-30S-0I1	Martogg - building "B" - Vacurema Advanced 1512T	Australia	AUS-16U-0FS	AUS-0QL-0OT
2	AUS-12J-0IG	Martogg - building "B" - Vacurema Advanced 1714T	Australia	AUS-16U-0FS	AUS-0QL-0OT
3	AUS-6TT-0ID	Martogg - building "B" - Vacurema Advanced 2018	Australia	AUS-16U-0FS	AUS-0QL-0OT
4	AUS-3EG-0IU	PET Extruder recoSTAR 330 and 2 viscoSTAR 120	Australia	0	0
21	IND-0PV-0IK	Langgeng_deCON	Indonesia	IND-48D-0FA	IND-48D-0O8
22	IND-787-0I4	PT Veolia Services Indonesia - Phase I	Indonesia	IND-5FJ-0FH	IND-5FJ-0OF
23	IND-4XH-0IG	Starlinger iV+ process 1_Srichakra Telangana	Indonesia	IND-2GS-0F0	IND-2GS-0OT
24	IND-7XP-0IH	Starlinger iV+_Ganesha ECOPET BtB Building	Indonesia	IND-5TX-0FC	IND-9G6-0O9
25	ISR-6WX-0I2	rPET (Aviv Shalam) Ltd	Israel	ISR-6UA-0F2	ISR-91M-0OD
26	JAP-5HZ-0IA	UTSUMI_EREMA Basic	Japan	JAP-1DZ-0FB	JAP-1DZ-0O9
27	JAP-0LO-0I0	UTSUMI_Starlinger deCON	Japan	JAP-1DZ-0FB	JAP-1DZ-0O9
28	KOR-1GY-0IB	DY POLYMER	Korea	KOR-1GY-0FM	KOR-1GY-0OK
29	MAL-4ES-0IH	Dialog_Starlinger iV+	Malaysia	MAL-211-0FG	MAL-211-0OE
30	MAL-5I2-0I9	SUMILON ECO PET SARL LOT # 98-99,TANGER, MOROCCO	Malaysia	MOR-6JP-0F6	MOR-4ZK-0O8
31	MEX-48V-0I0	Greenpet S.A. de C.V.	Mexico	0	MEX-9KB-0O9
32	MEX-1HY-0IO	RECOSTAR PET 125 HC IV+	Mexico	MEX-1HY-0F4	0
33	MEX-1HY-0IO	RECOSTAR PET 125 HC IV+	Mexico	0	0
34	NIG-382-0I9	Alef_Starlinger iV+ (Alef Recycling Company Ltd)	Nigeria	NIG-382-0FK	NIG-5NA-0OM
35	NIR-8TY-0I2	Greiner Packaging Ltd Starlinger deCON 1 technology.	Northern Ireland	IRE-2UC-0FP	CZE-2GB-0OT
36	OMA-5XP-0IM	Sapphire	Oman	OMA-1DS-0FA	OMA-2AE-0OH
37	TAI-3QJ-0IH	Derchia_deCON	Taiwan	TAI-328-0FO	TAI-328-0OM
38	THA-1XC-0I1	EcoBlue Limited	Thailand	THA-285-0FP	THA-285-0ON
39	THA-582-0IR	Production Line EX1	Thailand	THA-0JS-0FS	THA-0JS-0OQ
40	THA-259-0I2	Royce_Starlinger iV+ process	Thailand	THA-6WH-0F8	THA-6WH-0O6

Compliance documentation

- Declaration of compliance must be provided per batch, using a template
  - Annex III part A, template for recyclers
  - Annex III part B, template for converters (will be most used)



Declaration of comp

RECYCLERS DECLARATION of COMPLIANCE with REC

I, the undersigned, declare in name of [ADD NAME OF material identified in Section 1.2 was produced in accor which this declaration applies is suitable for use in restrictions set out Section 3 of this declaration, and with product.
Hereby I declare that the contents of this declaration i Regulation (EU) 2022/1616.

Section 1: Identification

1.1 Recycler		1.2 Recycled p	
1.1.1 Name		1.2.1 Tradenan designati	
1.1.2 FCM-RON *		1.2.2 Batch No	
1.1.3 Country		1.2.3 FCM-RIN	
1.1.4 FCM-RFN *		1.2.4 Other informati	

Section 2: Compliance

2.1 Basis for authorisation or permission to operate (tick

2.1.1	☐	Authorisation Decision
2.1.2	☐	Recycling schen
2.1.3	☐	No authorisatio recycling schem required
2.1.4	☐	Novel technolog

2.2 Results of compliance assessment as listed in the compulsory quality assessment stages in Table 3.1 of Annex II: compulsory only if 2.1.1 ticked
Important: Fields 2.2.2 to 2.2.4 may be left blank, provided field 2.2.5 is ticked

Stage **	Decision criteria and outcome(s)	Batch Number(s)
2.2.1 Exit		
2.2.2 Entry		
2.2.3 Input		
2.2.4 Output		
2.2.5 The undersigned confirms that the information required in fields 2.2.2 to 2.2.4 will be made available to competent authority upon its request, within 3 working days		☐

Section 3: Instructions and information to users of the product

3.1	Instructions to converters		
3.1.1	Maximum recycled content (w/w %)	%	
3.1.2	Present recycled content (w/w %)	%	
3.1.3	Restrictions of use **		
3.1.4	Other instructions		
3.2	Instructions to users further down the supply chain, including end users		
3.2.1	Restrictions of use **		
3.2.2	Summary of labelling		
3.2.3	Other instructions		

Section 4: Signature

4.1 Signature and company stamp	
4.2 Name of person signing	
4.3 Role/position of person signing	
4.4 Date and place	

Guidance

- available on website

DRAFT GUIDANCE TO ANNEX II AND III TO REGULATION (EU) 2022/1616

Version: 0.5.1. 22 February 2023

A Quality Assessment ('QA') stage is to refer to a specific operation in the recycling process during … f material resulti…

This docu… Annex II authorities…

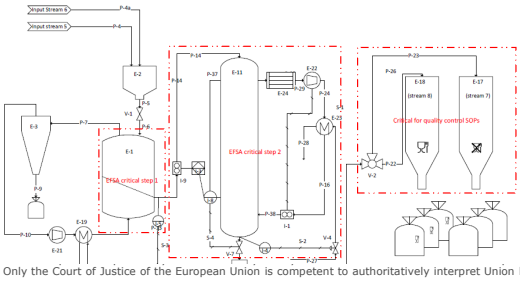
manu… turi… operat…

Figure…

1.1 Identification of the recycling installation

Installation name	This name should correspond on the EU Register
Applied recycling technology in accordance with Annex I	
EU Register number (recycling installation number, 'RIN')	
Facility Address	

Figure 4: Piping and instrumentation diagram c… installation. The steps/operations deemed crit… marked with a red box



European Commission

Official Controls Regulation

Regulation (EU) 2017/625

of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities…

Unit G4, DG SANTE

Bangkok seminar meeting, 26 June 2023

European Commission

OCR establishes a horizontal framework with principles on official controls for the entire agri-food chain

- Article 1: Subject matter and Scope
- Article 3: Definitions
- Article 4: Competent authorities
- Article 14: Methods and techniques
- Articles 28-31: Delegation of certain tasks of the competent authorities
- Article 120: Commission controls in Third countries
- Article 138: Actions in the event of established non-compliance

47

47

Subject matter and scope [Art.1]

Art. (1) (2) (a):
'This Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at Union level or by Member States, to apply Union legislation, in the areas of:

(a) Food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and ***the manufacture and use of materials and articles to come into contact with food****;…'*

FCM: same principles, same level of safety

48

48

Competent authorities [Art.3, 4, 5]

Art. (3) (3):

'competent authorities means':

- Central responsible authorities of Member States
- Other authorities to which the responsibility was conferred
- **Corresponding authorities of third country**

Art. (4): Designation, **notification to the Commission (including delegated bodies)**

Art. (5): Obligations

Competent authorities [Art.5]

- Effectiveness appropriateness
- Impartiality , Quality , Consistency
- Absence of conflict of interest
- Laboratory capacity
- Staff
- Facilities and equipment
- Legal powers
- Access
- Contingency plans

Art.(5): Obligations

Art.(6),(8), (11), (12), (13):
Internal audits
Confidentiality
Transparency
Documented procedures
Written records

Delegation of tasks [Art.28-33]

Delegating authority

- Written form
- Tasks
- Conditions

Arrangements for coordination

Delegated body

- **Impartiality**
- Free from conflict of interest

- Expertise
- Equipment
- Infrastructure

Staff

- Qualifications
- Experience
- Number

Accreditation

Delegation of tasks [Art.28-33]

Obligations of CAs and delegated bodies & persons

Delegating authority [Art.33]

- Organise inspection & audits, considering accreditation audits
- Full or partial **withdrawal** of delegation: failure to perform, to remedy, **independence/impartiality**
- Other reasons

Delegated body or person [Art.32]

- Communicate the outcome regularly and when asked
- Immediately inform of non compliances
- Access, cooperation, assistance to CAs

Official Control Techniques [Art.14]

Art. (3) (30) :

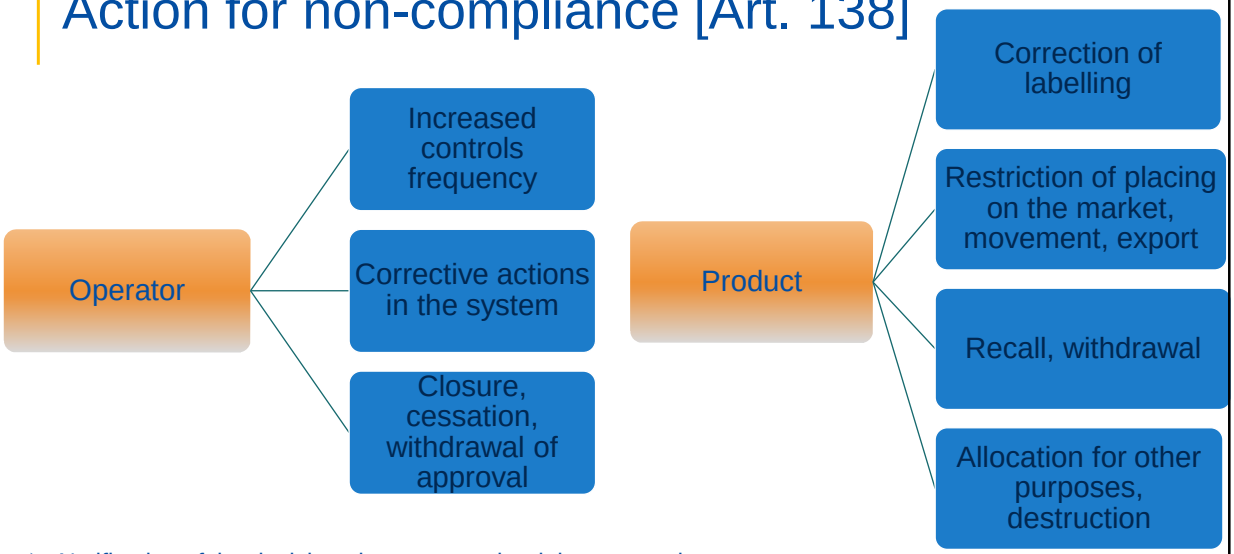
*'**Audit** means*

A systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;'

Audit [new section in revision of OCR Guidance]

- subject of controls is an activity such as a procedure or a management system;
- assessment with regard to its suitability to systematically achieve compliant outcomes;
- a broader and systematic assessment of different stages of a process;
- goes beyond the verification of compliance with specific requirements, but also examines whether predefined outcomes – objectives – are achieved.

Action for non-compliance [Art. 138]



- Notification of the decision, the reasons, the right to appeal
- At operator's expense
- Prohibition of delegation of decisions on tasks relevant to measures of Art. 138

Commission Controls in Third countries [Art.120]

- Legislation
- Organisation, powers, independence, supervision
- Staff training
- Resources
- Control procedures and systems
- Situation, outbreaks, notification procedures
- Assurances regarding compliance or equivalence

Request of information beforehand on:

- Info on Control systems [Art.125]
- Written records of controls

55

wrapping up

56

Main messages

- We can recover plastic from wasted and use it in contact with food
- There are two controls to ensure sufficient decontamination
  - Approval – the technology / process / installation shall demonstrate its capability
  - Control – Operators must ensure that capability in their operations
- There are obligations applicable to recyclers that must be met
  - in the Regulation, in its Annexes, and in an authorisation decision
  - obligations also apply to exported plastic waste to be recycled in the EU
- Competent Authorities in the territory of a recycled have also tasks
  - the Official Control Regulation applies

What did we not explain?

- The use of recycling schemes, and suitable technology 2
  - less relevant in an international context
- The novel technology procedure (Chapter IV)
- Authorisation of recycling processes (Chapter V)
- On many other provisions we could not go in-depth
- There are further obligations that we therefore did not cover!

The Commission provides resources

- https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/plastic-recycling/resources-plastic-recyclers_en
- Language versions in .docx format of:
  - Compliance Monitoring Summary Sheet (i.e. Annex II)
  - Declaration of Compliance (i.e. Annex III A, B)
- Guidance on the above mentioned documents
- Resources for registration
  - in case of problems: SANTE-FCM-RECYCLING-REGISTER@ec.europa.eu
  - A list of competent Authorities + National information (EU only)
- Detailed (official) guidance under preparation
  - DRAFT guidance on Annex II and III already available – also for feedback

FCM Revision

On-going revision of the FCM legislation

Revision of FCM legislation

- The European Commission is presently revising food contact legislation
- The revision may lead to a major change in the regulation of FCMs in the EU
- The main subject of the Revision is Regulation (EC) No 1935/2004
- However, also Regulation (EU) NO 10/2011 and National legislation affected

FCM revision approach

1. Evaluation of FCMs (completed) — 2018 - 2022
2. Define main policy themes and broad initial solutions — 2022
3. **Refine solutions and define more detailed policy options** — 2023
4. Assess feasibility and impact of policy options — 2024
5. Conclude on preferred policy options — 2024 and beyond
6. Work towards legislative proposal

Challenges (summarised from evaluation)

- **Safety** is **insufficiently** defined at EU level for most FCMs (lack of harmonisation)
- **Safety** of migrating substances is **not transparent** – is an FCM actually safe?
- Public authorities have **insufficient capacity** to
  - **risk assess** all **substances**
  - **harmonise** and manage **specific FCM** rules under the present system
  - comprehensively **enforce compliance** and safety in accordance with current rules
- Specific detailed **rules** with **ever increasing complexity** – problems may be left in fog
- The **use of** certain **chemicals** is increasingly **no longer** accepted
- **Environmental challenges** call for more sustainable production and use
- **New products** are entering the market that **challenge present categories**

Objectives of the Revision ('aspirations')

- Strengthen Article 3 – **FCMs are to be inert** – migration to be the exception
  - and as migration is unavoidable, it shall not adversely affect food safety/quality
  - rules to encourage **inherently safer FCMs** – 'limits' no longer driving force
  - rules to drive innovation towards safer materials
- Ensure we can effortlessly know **that a final material is safe**
- Keep **new rules** simple, practicable, enforceable and **achievable**
- Ensure there is **full harmonisation**, level playing field, including imports
- Ensure **high level of transparency** over composition and sustainability

(***inherent safety:*** *materials have been produced fewer substances with particular hazardous properties, so less controls such as limits are needed)*

EU FCM revision: Main policy themes and pillars

Safety and sustainability of food contact materials (FCMs)

A + B together to become the core of the future risk management approach + new material categories to apply that approach

A. Redress focus onto final material

- Better define the level of safety required, [illegible] final FCM articles and migrating
- Cluster into broader material types (synthetic polymers, paper and board, composite, active)

B. Prioritisation of substances

- Define rules for the risk assessment of all [illegible]
- Tiered approach:
  - Tier 1: generic risk (hazard) based (CMRs, EDs, PBTs and vPvBs)
  - [illegible]
  - Tier 3: Self-assessment by business operators of more benign substances

- A + B together to become the core of the future risk management approach
- + new material categories to apply that approach

C. Supporting more sustainable alternatives

- Ensure fewer hazardous chemicals
- Prioritise more sustainable use of FCMs
- Coherence and support to other EU rules on sustainability, including packaging and food

Information exchange, compliance and enforcement of FCMs

To verify safety, sustainability and ensure smooth functioning of the internal market

D. Improving quality and accessibility of supply chain information

- Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a DoC for all FCMs
- Digitalisation to help businesses, including SMEs to ensure compliance and for Member States to enforce

E. System for verifying compliance and undertaking of official controls

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment

F. Analytical methods

- Migration testing rules
- Analytical methods (i.e. for official controls)
- Further development of test methods and technical standards as required

65

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65

A: shifting focus on final materials

What does this mean?

- Producers of final FCM to have full knowledge on '*migratables*'
  - They become fully accountable
- All '*migratables*' to be risk assessed
  'migratables':
  substances that can foreseeably migrate into food under foreseeable conditions of use
- Difference between NIAS and IAS to disappear
  NIAS/IAS:
  '(non) intentionally added substances'
  (term originates from R 10/2011)

66

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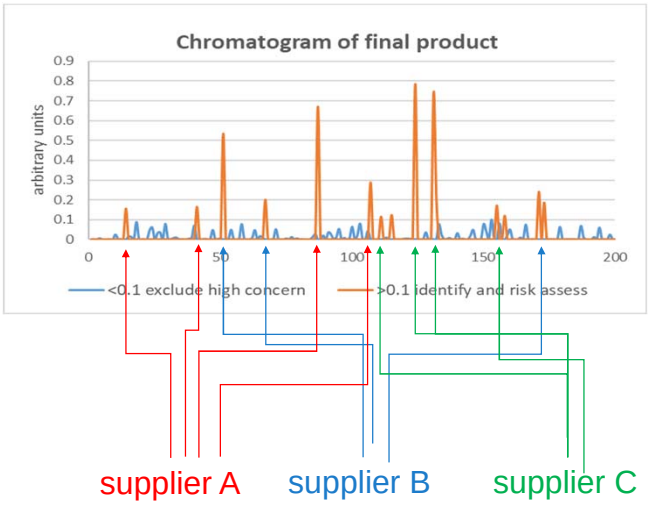
66

A: In practice

- **<u>If</u>** the **final** producer were to make a 'forest of peaks' style chromatogram:
- They would need to be able to explain all peaks give rise to safe migration level
- Information can't come from (present) analytical techniques **(→F)**
- Information to come from suppliers as shown on right→



A: Legislation would consider

<u>What information to provide?</u>

- All substances in product with migration potential above cut-off
- Exclude presence of certain categories (tier 1 substances)
- risk assessment **(→B)**

<u>How to provide it</u>

- supporting documentation
- via IT system **(→D)**
- keeping information up to date

  (it is to be provided 'continually')

<u>Data management</u>

- definition of IT system
- data
  - ownership
  - formats
  - storage
- **rules for handling proprietary data**

A: shifting focus on final materials

Accountable for final material

- all substances that may migrate are known by the producer of the final material or article
  - the maximum migratable quantity is known (GMP required)
  - substances have been risk assessed
  - no difference between NIAS and IAS
- the information is provided by the supply chain

Drivers

- Inherent safety:
  Producers have reason to keep materials clean and simple
- Simplification:
  No detailed rules on starting-substances and supply chain needed
- Transparency:
  It is immediately clear what migrates from a specific FCM, and in what amount

Barriers

- Information flow
  final producer depends on supply chain
- confidential information
  commercial practices prevent transfer of certain information on composition

B: Prioritisation of substances

What does this mean?

- Substances are no longer prioritised for risk assessment and risk management purely on the basis of the need to authorise their use in the manufacture of FCMs
- Rather, ‘migratables’ should be assessed according to a number of criteria including identified hazardous properties, use, migration, exposure, grouping and combination effects, vulnerable populations, essentiality
- Different levels of risk assessment and possible risk management depending on these criteria

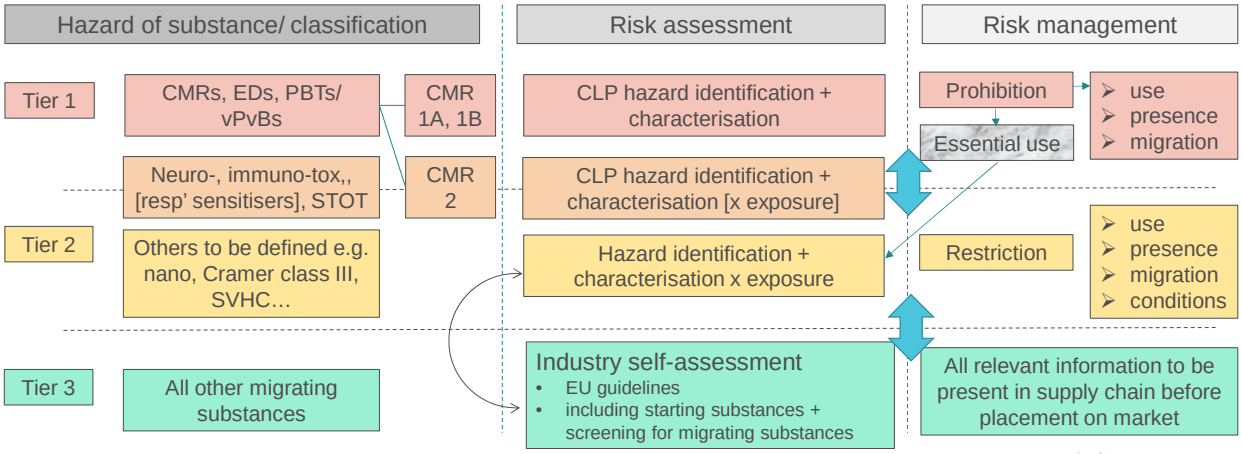
B: Prioritisation of substances

Drivers

- Prioritisation / resources
  - Harmonisation (more materials)
  - Focus on final material (more substances)
- Commission policy on substances of concern/ most hazardous substances
- 'One Substance One Assessment' (1S1A)
- Inherent safety
- Need to include updated scientific knowledge

B: Prioritisation of substances

A basic tiered system…



B: Prioritisation of substances

Where should the information come from?

- Supply chain/ business operators
  - Information on starting substances and other migrating substances via screening
  - Toxicological information, migration data, risk assessments
- EFSA (existing data and risk assessments)
- ECHA
  - Information on substances registered under REACH, substances under evaluation and those of concern, risk assessments on drinking water materials etc
- Member States
  - National lists and existing risk assessments
- One Substance One Assessment principle should apply
  - transparency and access to data

B: Prioritisation of assessment of substances

Essential use of FCM substance

- In principle for tier 1 substances for which a generic risk approach would be taken
- A specific risk assessment of the substances in question (taking into account migration, exposure etc) would be required
- An evaluation of alternatives would be required
- Criteria need to be laid out in accordance with the principles agreed across chemicals legislation (awaiting Commission output as part of CSS)
- Decision making body: Commission and/ or Member States? Agencies?

applying A+B to specific material groups

Simplification of material groups

- Main Materials
  1. Synthetic organic type materials (plastics, rubbers, coatings, inks, adhesives, …)
  2. Natural organic type materials (wood, fibres, plant-based)
  3. Inorganic based materials including metals
- Special materials (made from 1, 2 and 3)
  4. Active and Intelligent materials
  5. Recycled materials
  6. Composites (paper, multi-material)

Grouping is done on the basis of a high similarity in applicable rules i.e. if substances can be regulated in the same way, they will be in the same group. Grouping is not to set different safety standards, rather to reflect similarities between the groups and practicable and achievable approaches for RA and RM

75

Lists of authorised substances or positive lists

- Presently the central element
  - both at EU and national level
- Authorisation of tier 2 substances likely to be very specific to use
  - no lists according to the present model
  - lists may have role in transition to new model
- Tier 3 substance used on basis of risk assessment by business operators
  - no lists according to the present model
  - present lists may have role in starting point for risk assessment + transition
- Potentially a limited use of positive lists in material groups
  - List of suitable natural materials
  - List of certain inorganic compounds (mostly as a derogation to migration limits)
  - Essential use

76

Summary pillar A+B

- A: putting the focus on the final materials
  - migratable substances need to be known and risk assessed
  - below a certain (to be defined) level only presence of Tier 1 substance needs excluding
  - information on composition to be delivered by supply chain
- B: prioritising the assessment of substances
  - tier 1: generic rules to apply to the use of most hazardous substances
  - tier 2: risk assessment by public Authorities – width of tier depends on capacity
  - tier 3: more benign substances assessed by business operators
  - OSOA applies – risk assessment to be available
- Rules on specific materials define how A+B are applied in practice

Pillars C+D+E

- C – Sustainable alternatives: Study to be launched in 2023
- D + E in summary
  - to facilitate information exchange on composition (‘migratable substances’)
  - to facilitate access to information on risk assessment
  - to facilitate enforcement
  - Study launched in 2022

F: Analytical methods

- Present: focus on enforcement of migration limits under OCR
  - in practice, only a very limited number of substances is routinely subject to verification of compliance by competent authorities on the basis of analytical methods
  - in many cases methods do not exists, or accreditation does not exist
- Future:
  - lower importance of migration testing **(→A)**
  - rules to be made specific to the tiered approach **(→B)**
    - **Tier 1: confirm absence**
    - **Tier 2: the present approach?**
    - **Tier 3: screening**
  - consider novel approaches (e.g. screening / finger printing approaches)
  - rework migration testing (Annex III + V to R 10/2011) to become generally applicable

Important Disclaimer

- The previous slides describe the ‘aspirations’ of the revision
- These do not necessarily reflect the reality of what will be 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

How will we work?

- Step 1: discussion paper to support work and on which elaboration/ options required
  → based on view of Commission Services
- Step 2: Possible focus/ expert groups for main pillars (A, B, and F)
  - pillar C + D and E subject to separate studies
- Step 3: Such groups to refine and steer the discussion paper
  → add their view
- Step 4: Consolidate views in revised discussion paper
- Step 5: Commission to continue impact assessment on basis of that paper
- Step 6: Discussion and assessment on policy options (IA)
- Step 7: Final report (SWD) → basis for Commission proposal

How will we work? Discussions

- We will encourage discussions on alternative solutions
- The objective of the revision will be leading
  - High level of safety, transparency, prioritisation, harmonisation
- Solutions need to be implementable in practice
  - e.g. if solution requires resources that are not available, it is not a solution
  - if it takes time to implement a solution that is not necessarily an issue
- Experts will be welcome to disagree
  - but will be asked for alternative approaches if they do so ;-)

Thank you

Happy to receive questions/discuss…