

State-of-Play / Timeline

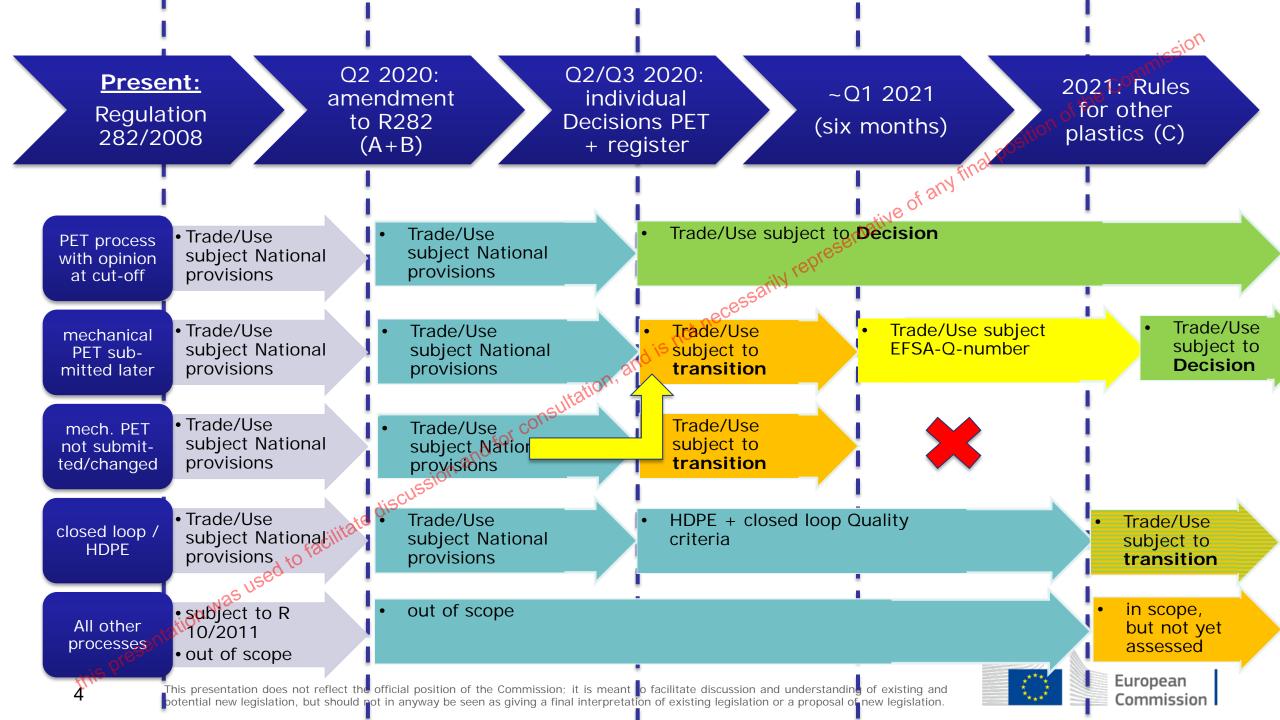
- November / December 2019 Consultation
- Large number of comments received from MS and INDesign
 - Call for clarification, no calls for substantial changes
- New text more or less finished, clarified but not substantially changed
 - presently redrafting as amending act recitals
- Early March: Internal consultation Commission Services
 - legal check + environmental legislation
- Early April: Consultation with you whether ready for SC later that month
- After vote: Decisions on individual applications, followed by 2nd phase



Objective for today

- Discussion on main clarifications
 - mostly in first part of the text
- Discussion on various matters on which we need to understand your position
- Discussion on CMSS Consultation early March





Clarifications to Text

The main clarification based on your comments (and those of industry)



Definitions (main clarifications)

- Recycling process: input is recycled to produce plastic suitable for food contact
- Plastic input: waste plastic possibly cleaned an processed + post-use and primary materials
- Converter: Converts the plastic is subsequent step in the supply chain
- Mechanical Recycling Process: polymeric chains not intentionally changed (new)
- Batch: quantity of plastic produced under same conditions and controls packaged suitable for storage and has unique number (new)



Article 3a(1)

- not changed (requirement for quality assurance)
- b) plastic input: contamination clarified
- c) quality assurance from firstonsultation point of sorting of sorting

 Traceability added

 This presentation was used to facility and the sentation was use

This presentation does not reflect the official position of the Comr potential new legislation, but should not in anyway be seen as givin

- the plastic input to the recycling process shall meet the following quality criteria:
 - it shall originate only from plastic materials and articles that previously have been recycled in accordance with this Regulation or which have been manufactured in accordance with Regulation (EU) No 10/2011; and.
 - it shall originate only from plastic food contact material used by consumers or food business operators and their supply chain; and,
 - it shall be collected with a waste collection system that is designed and organised to minimise incidental contamination with plastics used for purposes other than for contact with food, and with chemicals and plastics from other waste streams.

Plastic materials input from aused for other purposes than contact with food, and plastic input originating from any other source than consumers or food business operators-nonfood and/or industrial origin and incidental contaminants, shall not be present except asonly be present as contaminants in minor and unavoidable amounts. The amount of incidental contamination in that plastic shall also be minimized and unavoidable. If an authorisation is applicable to a process, the maximum level of incidental contamination and the composition of the input materials shall be in accordance with that set out in the authorisation.

- (c) For the purpose of point (b) the collection of the input materials shall be controlled by means of a certified quality assurance system throughout the whole collection chain from the first point of sorting onwards. Article 3, 4, 5, 6, and 7 of Regulation (EC) No 2023/2006 as well as point B of the Annex to that Regulation shall thereto apply mutatis mutandis to all those stages of the collection chain of plastic input
- e)(d) Traceability shall be an essential element of the quality assurance system required under point (c); to this purpose it shall be possible to determine the source of each batch.

Article 3a(2)+(3)

- (2)(f) clarification of wording
- (3)(a) added
 - deleted from Article 9a(1)(ii)

the recycling process does not add any substances not already present in the input material to the recycled plastic, which that are not listed in Annex I to Regulation (EU) No 10/2011 whiless subject to aunless in accordance with a derogation set out in Article 6 tof that Regulation.

- 3. Administrative conditions:
 - (a) the recoveler has notified the responsible competent authority and the Commission of the date at which the operation of the recycling facility will start at least 10 working days prior to that date;
 - (a)(b)The recycler, recycling facility and, if any, the authorisation holder are registered in the Union register of recycling processes for food contact materials and the listed information is up to date;

used to facilitie



Article 3a(4) - new point on monitoring

 This should make clear it is not the CA's who are responsible for monitoring Conditions on Monitoring of contaminant levels

If monitoring of contaminants levels in input and/or recycled materials is required under the applicable authorisation, if any, or when a monitoring programme in accordance with Article 12a is in place, the following conditions shall also be met:

- a) The data that is required in accordance with the authorisation or the programme is collected and submitted; and is not collected and submitted;
- b) the analytical equipment required for the monitoring is present at the recycling facility, or the recycler shall have arrangements in place to ensure that the required analytical work is done off-site such as in a central lab or by a third party;
- c) disamples are collected in agreement with the authorisation or the monitoring programme, as appropriate, and;
 - the activities carried out to ensure condition a-c are met, are subject to and part of the quality assurance system referred to in point 1 of this Article.

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- Article 5a will be dealt with separately in its own amendment

 Relevance for implementation of updated CEIMTERPRESENTED.

Article 9a CMSS – very few comments

- What about already operating facilities?
- Only one MS says: 'delete the whole Article this is not our responsibility'
 - It is considered that this work has been done by EFSA
 - > we need to ensure that the actual process agrees with what was assed by EFSA
 - → the audit system is the only way to ensure the plastics are safe in practice
- 'validation date unclear
- we consider the procedure and timing therefore largely accepted



- Article 10; Official Control

 We will apply separate wording for the control of a receycling facility and the control of converters
- New wording for laboratory testing; and is not necessarily
 during controls and is during controls apply the CMSS as starting point for audits (retained unchanged)
 - [omit chemical verification] When poor quality of a batch of recycled plastic is observed or suspected, audit techniques or inspections of the operation of the process shall be prioritized with a purpose to establish or identify the cause of the poor quality of the batch and to take remedial action, where required supported by physical of chemical verification of the quality of the recycled plastic contained in the batch, such as with laboratory techniques.

Article 10a non-compliance of recycled plastic

- Article 10a is left largely unchanged, but, wording is clarified
 - 1. If, during an audit or other control activity in accordance with Article 10(1) a recycler cannot demonstrate that a batch of recycled plastic placed on the market in accordance with Article 3 was manufactured in compliance with Articles 3, and 3a of this Regulation, with any controls set out in the CMSS, and/or with the authorisation, if applicable, that batch shall be considered as not being obtained from an authorised process and therefore be considered non-compliant.
 - 2(c) wording clarified to ensure consistency with Article 9a (CMSS)
- Yet undefined:
 - What togo at converters; does that need defining?
 - What to do with packaged foods



- Article 10b (suspension of use): duplication point 1 and 4 removed

 Article 11 (labelling): added reference to Article 12 (DoC): reference

Article 12a; analytical monitoring programmes

- Very diverse comments many from industry and related to the science rather than the procedure
- Would a recycler need to monitor anyway, out of a monitoring programme?
 - → No, unless EFSA says so, or they put this as a control in the CMSS



Article 13 + 14 (Transition)

Small corrections and clarifications only

• We will check when final text is ready, as overall consistency needs ensuring.

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Specific Matters

Requiring your views

consultation, a.



All Processes no longer subject to National Provisions

- Presently all non-Authorised processes are subject to National provisions; this will change
 - Is it sufficiently clear all processes in scope will be under EU legislation?
- Three cases:
 - Processes out of scope use already subject to Regulation (EU) No 10/2011, no change
 - Mechanical PET recycling are being authorised, so Union responsibility
 - other processes— will become subject to Article 3a and require registration, but no further National rules will apply
 - velosed-loop, HDPE, mechanical recycling not PET



- Drafting consistency, CA or MS

 When a business operator or other actor needs to contact/communicate via an authority, is this
 - to their competent authority, or to their Member State
- Present wording not entirely consistent but isn't too bad
- However, what is preferred?
 - Member State: only in Article 7(3)
 - Competent Authority: dominant use (just a few cases)



The CMSS procedure in Article 9a

 Just to be sure, this is how we will implement it

the recycler shall provide the compiled summary sheet to the responsible competent authority within one month from the start date;

the competent authority of a Member State that receives the compiled summary sheet shall without delay verify whether the information provided in the summary sheet complies with this Regulation and with the requirements of Annex III; as part of this verification the competent authority shall perform an audit of the recycling facility;

when the competent authority concludes that the information indicated in the summary sheet is not correct or the operation of the recycling facility is not in agreement with this Regulation and the It shal authorisation, the recycler shall without delay update the submitted summary sheet, and/or change the process or its operating conditions; step (iii) of this procedure shall than be repeated;

when the competent authority concludes that the operation of the recycling facility is in compliance it shall notify the recycler and the Commission thereof; when this conclusion is not reached within 6 months following the first reception of the summary sheet, the competent authority may suspend the operation of that facility. In this case, the use of the authorisation by the recycler of an authorised process shall also be suspended in accordance with Article 10b, and the competent authority shall request the Commission to indicate the suspension of the operation in the Union Register.

upon receiving the notification of compliance from a competent (vi) authority, the Commission shall indicate the validation date in the entry in the Union Register applicable to the recycling facility.

(vii) If the competent authority did not notify the Commission of compliant operation within one year after the start of the operation of the facility the use of the authorisation at that recycling facility shall be sion suspended automatically.

this presentation was used to facilitate discussiv This presentation does not reflect the official posit potential new legislation, but should not in anyway

proced

recycli

set out-

Functional Barrier materials

- So-called A-B-A materials
 - Outside layers A made of virgin materials
- Inside layer B made of recycled material but no decontamination requirement
 Problematic for two distinct reasons
- - Safety is unproven in particular after thermoforming what about genotoxic contaminants?
 - Mechanical PET recycling processes likely cannot decontaminate ABA flakes efficiently, or at least this is unproven



Provision 3a (1)(b)(iii) on waste collections

- (iii) it shall be collected with a waste collection system that is designed and organised to minimise incidental contamination with plastics used for purposes other than for contact with food, and with chemicals and plastics from other waste streams.
- This provision implies that FCM needs to be collected separately from non-FCM
- In many MS post consumer recyclables are collected together, FCM + domestic non-FCM, several materials of
- discussion
 - Does this imply separate FCM collection, or allow for sorting post-collection? Consumers get additional bin?
 - relevance for paper and board



DoC provision

Article 12 **Declaration of Compliance**

- 1. In addition to the requirements of Article 9-15 and Annex IV of Regulation (EU) No 10/2011, the declaration of compliance of recycled plastic materials and articles shall contain the information laid down in Part A of Annex I to this Regulation.
- 2. In addition to the requirements of Article 9-15 and Annex IV of Regulation (EU) No 10/2011, the declaration of compliance of recycled plastic shall contain the information laid down in Part B of Annex I to this Regulation.
 - To what extent can a recycler declare compliance with Regulation (EU) No 10/2011, taking into account the (updated!) requirements for a DoC in Article 15 and Annex IV?

PART A

ADDITIONAL INFORMATION IN THE DECLARATION OF COMPLIANCE FOR RECYCLED PLASTIC MATERIALS AND ARTICLES

The written declaration referred to in Article 12(1) shall contain the following additional information:

- . One of the following declarations applicable:
 - (a) A declaration that only recycled plastic from an authorised recycling process has been used listing the EC Register number of the authorised recycling process.
 - (b) A declaration that a percentage recycled plastic from an authorised recycling process has been used listing the EC Register number of the authorised recycling process.
 - (c) A declaration that a percentage recycled plastic from a recycling process not subject to authorisation has been used
- Any specifications and conditions of use under which the material or article shall be used to ensure that it meets the requirements of this Regulation and Regulation (EC) No 1935/2004

PART B

ADDITIONAL INFORMATION IN THE DECLARATION OF COMPLIANCE FOR RECYCLED PLASTIC

- The written declaration referred to in Article 12(2) shall contain the following additional information: confirmation that the recycled plastic was manufactured in compliance with Article 3 and 3a of this Regulation, including the EU registry number of the Recycling process.
- Any specifications and conditions of use under which the recycled plastic shall be used to ensure that it meets the requirements of this Regulation and Regulation (EC) No 1935/2004.
- Any labelling in compliance with Article 11, or instructions for such labelling directed at the manufacturers of recycled plastic materials and articles.
- 3. The declaration that a quality assurance system according to Section B of Annex to Regulation 2023/2006 is in place.



Changes to CMSS

cion and for consultation,



Compliance Monitoring Summary Sheet of the Commission

- Significant changes not because of comments, but rather observations
 - align it with the workflow of an auditor/inspector
- It will contain 4 main sections;
 - Identification
 - Written Declaration
 - General information on the facility and the process
 - Specific information on main process steps



Section 1: Identification

- Recycling facility
- Recycling operator
- Applicable Authorisation Decision (if any)
- Additional responsible staff at recycling facility

Section 2

- Does not change
- Two written statements
 - Explanation in operators words on how the process ensures compliance
 - Explanation why the process corresponds to the one Authorised by EFSA

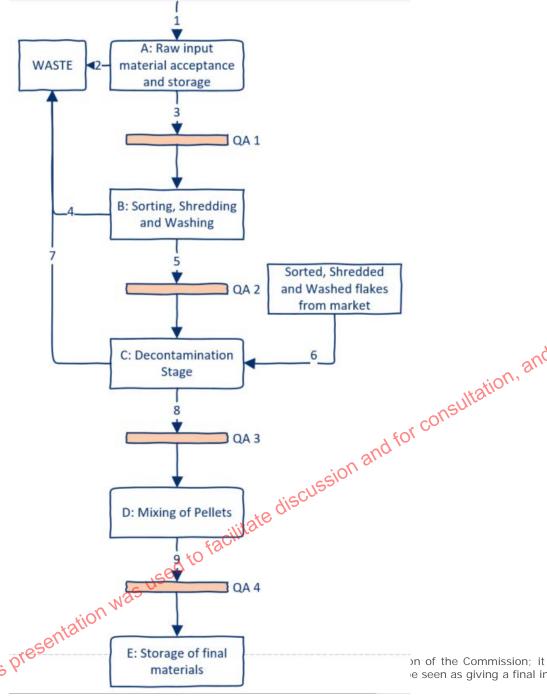
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Section 3: General information on the facility and the process

- New: Description of facility/site and site perimeter
- New: On-site operation stages description + block diagram
 - including QA sections
- List of documents with numbers
- Batch definitions
- List of records

- Decontamination process schematic
 - R&ID, in accordance with ISO 10628-1:2014
- Restrictions on decontamination
 - Critical parameters
 - Restrictions
 - Use and labelling of output

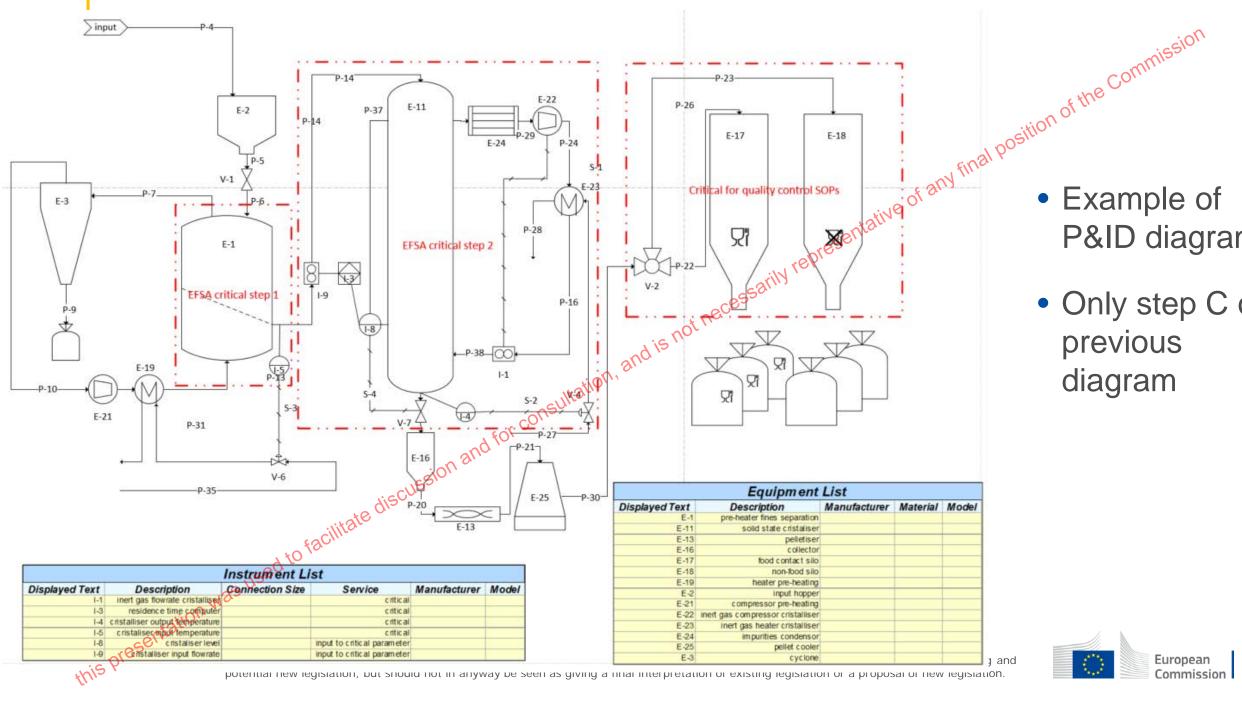




Stage Number	Name	Description	Average Processed Tonnage
A	Raw material acceptance and storage	At this stage the quality of the input material delivered by the suppliers is verified by means of certificates and testing.	10.000 tonnesyr
В	Sorting, Shredding and Washing	At this stage the input material is taken from storage and coloured PET, foreign plastics and materials are sorted out, the remaining bottles are shredded, and a hot caustic wash takes place.	9.500 tonnes/yr
С	Decontamination stage	Decontamination stages as described in the EFSA opinion	6.000 tonnes/yr
D	Mixing of pellets	Pellets are mixed to achieve food contact grade material with 50% virgin material	10.000 tonnes/yr
Е	Storage of final materials	Big bags with premixed pellets are stored until shipment to clients	10.000 tonnes/yr
Stream Number	Name (CP)	Description	Average Stream size
1	Raw input from	Trucks with bales of bottles arrive from suppliers	10.000 tonnes/yr
s not ne	Rejected raw material	Rejected bales found unsuitable for recycling	500 tonnes/yr
3	Accepted raw material to sorting	Raw material transferred from raw material storage to sorting and washing operations	9.500 tonnes/yr
4	Waste materials	Sorted and washed out out foreign plastic, metals, labels and dirt and contamination	4.500 tonnes/yr
5	Cleaned PET flakes	PET flakes transfer to Decontamination stage, includes storage in big bags	5.000 tonnes/yr
6	Input flakes bought on market	Conventionally recycled are procured on market and are recycled using the decontamination stages	1,000 tonnes/yr
7	Decontamination losses – non food recycled PET	Material processed in the decontamination stage at process settings unsuitable for food contact	1,000 tonnes/yr
8	Decontaminated unmixed food- grade PET	PET pellets decontaminated under conditions compliant with the critical parameters.	5,000 tonnes/yr
9	Virgin PET from supplier	Virgin PET pellets	5,0000 tonnes/yr

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P&ID diagram

 Only step C of previous diagram



Section 4: QA activities at each QA section

- Description of stage and batch
- Description of QA Objective:
 - e.g. to ensure that the raw material meets specifications
 - e.g. to ensure the critical parameters where met
- Decision Criteria
 - e.g. non-food consumer waste < 5%
 - e.g., \$\frac{1}{2} \geq 265 C for over 60 minutes while vacuum is maintained

- Test or monitoring procedure
 - reference to SOPs
- Procedure for rejected material
 - Reference to SOPs
- List and location of relevant testing equipment
- Training procedures



What to expect?



Time-line on progress of amendment (phase 1)

- Next few weeks
 - finalisation + internal consultation
 - Consultation on renewed CMSS also with Industry
- Late March, early April, consultation on draft text, decision
 - go for vote in SC (27 April) based on your feedback
 - or further discussion in W6 (11 May) and SC (23 June)
- Preparation of individual decisions after vote on amendment, votes after adoption of the amendment
- 2nd Stage

