

NEW RULES FOR PLASTIC RECYCLATES IN CONTACT WITH FOOD

GUIDELINES – SECOND EDITION



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On 15 September 2022, the European Commission adopted new EU-wide rules for the safe use of recycled plastics for food contact materials (Commission Regulation No. 2022/1616). These rules will enter into force on 10 October 2022. They apply directly to companies and replace the previous rules of Commission Regulation No. 282/2008. These guidelines explain the partly complex systematics of the new rules, the detailed requirements for recycled plastics and provide guidance for implementation by plastics processors based on practical examples.

BACKGROUND

The associations of the plastics processing industry (GKV and its supporting associations) and the plastics recyclers (BDE, bvse) have long advocated the use of more recycled plastics in plastic products, especially in packaging. Already in 2017, the manufacturers of plastic packaging set themselves the goal of increasing the total amount of recycled plastics in packaging from 400,000 t to 1 million t by 2025 (post-industrial and post-consumer). To achieve this, packaging manufacturers need an additional approx. 530,000 t of post-consumer recyclates in suitable qualities. The technical potential to achieve the goal is in any case available: Provided that customers accept moderate restrictions with regard to the aesthetic properties of the packaging and material efficiency, a total of about 22 per cent (960,000 t) of the raw material demand for plastic packaging can be replaced by recyclates by 2025 - measured against today's qualities.

A major hurdle for the use of more recycled plastics in food contact materials has so far been the high legal requirements. This is because in the EU there are strict requirements for the safety of (new and recycled) plastics in contact with food. This affects, for example, about 44 percent of all plastic packaging, as it is used to transport and protect food and beverages. The requirements are regulated EU-wide in (1.) the EU Framework Regulation No. 1935/2004, (2.) the Commission Regulation on Good Manufacturing Practice No. 2023/2006 (GMP Regulation), (3.) the Commission Regulation No. 10/2011 on plastics in contact with food and (4.) the new Commission Regulation No. 2022/1616 on recycled plastics in contact with food. In the following, the prerequisites of regulations 1. to 3. for the use of recycled plastics are briefly presented, but the focus of these guidelines is on the new regulations of Regulation No. 2022/1616.

I. EU REGULATIONS ON FOOD CONTACT MATERIALS – OVERVIEW

Materials and Articles made from or containing recycled plastic are expected to comply with the general safety requirements of Framework Regulation No. 1935/2004, GMP Regulation No. 2023/2006 and Plastics Regulation No. 10/2011.

GMP Regulation No. 2023/2006 is designed as an implementing regulation for Article 3 of Framework Regulation No. 1935/2004. Like the Framework Regulation No. 1935/2004, it applies on a horizontal level for all food contact materials. The Plastics Regulation No. 10/2011 and the new EU Regulation No. 2022/2016 are individual measures at the vertical level only for plastics.

1. EU Framework Regulation No. 1935/2004

Food contact materials in the EU are subject to the requirements of the Framework Regulation No. 1935/2004, which lays down general safety requirements. Article 3.1 of the Framework Regulation requires that all food contact 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”*.

The Framework Regulation also sets requirements for labelling, record keeping and traceability. Finally, article 5 of the Framework Regulation allows the adoption of individual measures for a group of materials and Articles listed in Annex I, e.g. plastics, paper and board, printing inks, adhesives, varnishes and coatings.

2. Regulation on Good Manufacturing Practice No. 2023/2006

The Commission’s *Good Manufacturing Practice* (GMP) Regulation (No. 2023/2006) sets out the general rules for good manufacturing practice, which include the establishment and implementation of quality assurance and quality control systems and the appropriate documentation of these systems. The GMP Regulation applies to all sectors and all stages of manufacture of the groups of materials and Articles listed in Annex I in the Framework Regulation, except for the manufacture of starting materials.

3. Plastics Regulation No. 10/2011

Commission Regulation No. 10/2011 on plastic materials and articles intended to come into contact with food is the most comprehensive material-specific legislation adopted as a single measure under the Framework Regulation No. 1935/2004 (see above). No other material is subject to such detailed specifications as plastics. The EU Commission has published comprehensive guidance documents on this regulation.

The Plastics Regulation contains provisions on the following aspects:

- Union list of authorised substances that can be used in the manufacture of plastic layers from the plastic materials and Articles described in the scope-positive list;
- restrictions and specifications for these listed substances;
- Total migration limits for plastic materials and Articles;
- Requirements for passing on a declaration of compliance (DoC) and its content;
- Rules for conformity assessment for plastic materials and Articles.
- Rules for handling non-listed substances, preparation of a risk assessment

4. the previous Recycling Regulation

The previous Commission Regulation No. 282/2008, which will be repealed by the new regulation from 10 October 2022, has not fulfilled the hopes placed in it.

Plastics converters and recyclers, together with the food industry, have long campaigned for a revision of the existing, but practically futile, EU requirements of Commission Regulation 282/2008 for recycled plastics in contact with food.

Contrary to what was foreseen in Regulation 282/2008, the EU Commission has not authorised a single one of the now more than 230 recycling processes positively assessed by EFSA. The problem mainly stems from the fact that the Commission had expected authorisation applications for recycling processes to be submitted at company level. However, due to the differences e.g. in input materials (waste) and in order to obtain legal certainty, the recycling companies decided in the past to submit the authorisation applications for the individual recycling plants respectively (see chart). This is how the high number of applications came about.

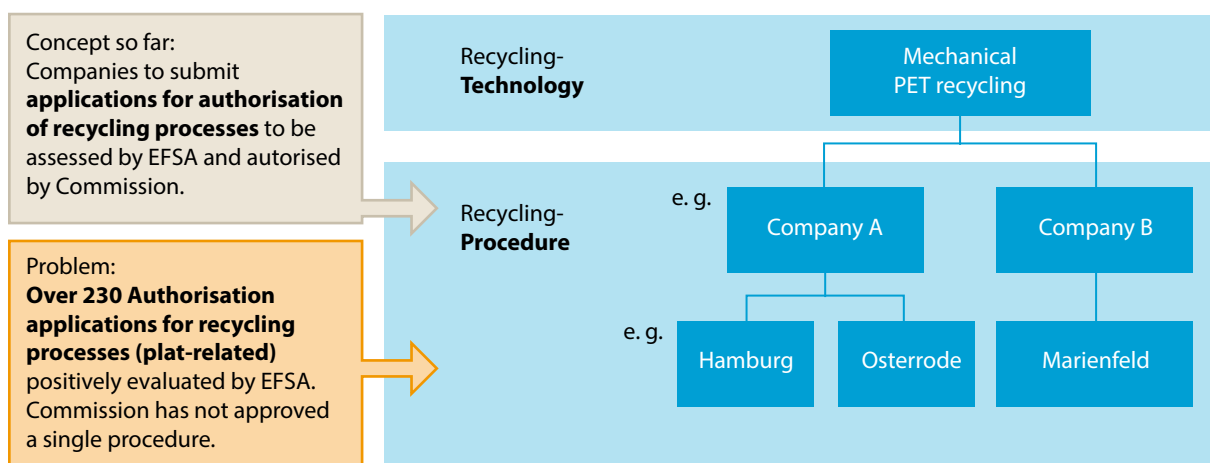


Figure 1: Excessive plant-related approval according to Regulation 282/2008.

Furthermore, a new regulation was also necessary in view of the ambitious circular economy goals, which among other things stipulate minimum recycle use quotas for plastic packaging. Up to now, essentially recycled PET plastics could be used in food packaging. The new regulation should make it possible for plastics other than rPET to be used in contact with food.

The use of recycled plastics has so far been based on national regulations, where they exist¹. There was massive criticism of this system from industry. The Commission was asked to also approve the recycling processes assessed as safe by EFSA.

¹ This was based on the transitional provisions in Article 16 of the Recycling Regulation No. 282/2008, according to which the national provisions on recycled plastic and recycled plastic materials and Articles in force in the Member States remain in force until the date of a Commission decision on authorisation. For the previous authorisation procedure for food contact materials in Germany see [here](#).

II. THE NEW RECYCLING REGULATION

1. background

An analysis of the impact of the new regulations was only possible to a limited extent in the process of drafting the regulation because the Commission did not submit an impact assessment for the extensive and extremely complex new regulations during the three-year lead time. An analysis of why the system of the previous Regulation No. 282/2008 did not work is also missing so far.

The Commission has announced that after the entry into force of the new regulation on 10 October 2022, it will quickly grant authorisations for all recycling processes (mainly for PET) that have been assessed as safe by EFSA.

The Commission has also announced that it will publish guidelines on the new rules.

2. systematics of the new regulations for recycled plastics

The new regulation stipulates that plastic recyclates can in principle only be used in food contact materials if they are processed by means of a

- “suitable recycling technology” or
- of a “novel technology”

were produced (or they are pure substances within the meaning of Annex I of Commission Regulation No. 10/2011). Annex I of the new regulation currently allows for two “suitable” recycling technologies (see page 11 below).

So-called “novel” recycling technologies, on the other hand, must go through an elaborate approval procedure in order to be approved as a “suitable” recycling technology (see page 22 below).

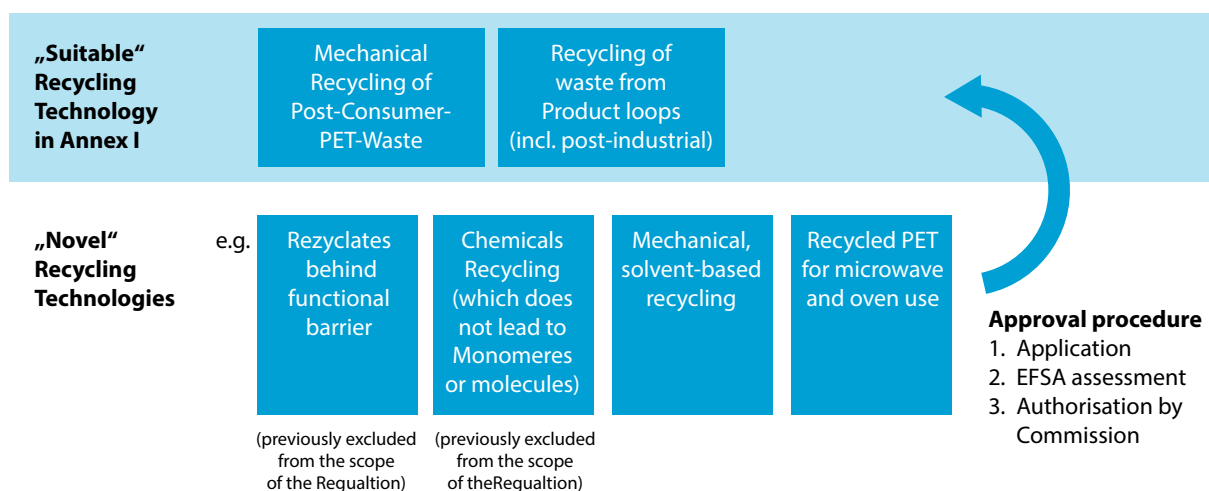


Figure 2: „Novel“ recycling technologies are only to be recognised after a long and elaborate approval process. However, many of the technologies, such as the use of recyclates behind functional barriers and rPET for microwave and oven use, are not „novel“ at all, but have been established for a long time.

Unlike in the past, the Commission hopes that the new regulations will lead to applications for authorisation no longer being made for each individual recycling plant, but for “recycling processes”. In view

of the difficult delimitation issues, however, there is a risk that recyclers and machine manufactures will apply for authorisation for individual plants, as has been the case up to now.

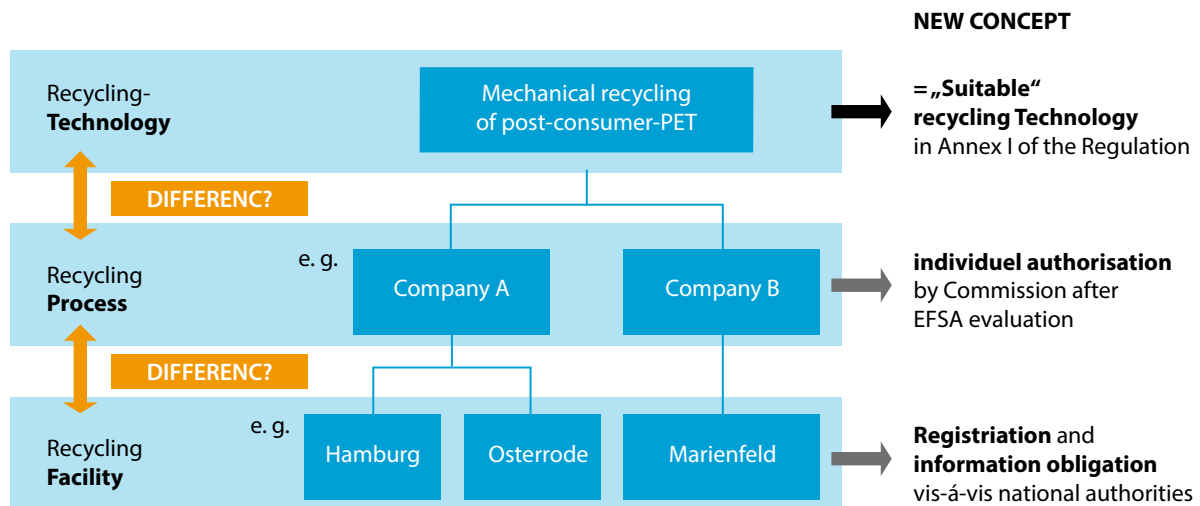


Figure 3: One of the new concepts of the regulation is to distinguish between recycling processes and recycling facilities. Whether this distinction will succeed in view of unclear definitions remains to be seen. Shown here using the example of PET recycling.

3. new definitions

The new regulation focuses on the decontamination process during the recycling procedure, but also contains specifications for the use of the products and waste collection. The following overview shows

the most important terms and refers to the definitions in the regulation. It is important to note that the terms are defined only for the purpose of the regulation and are not, for example, congruent with the terms used in the context of waste law.

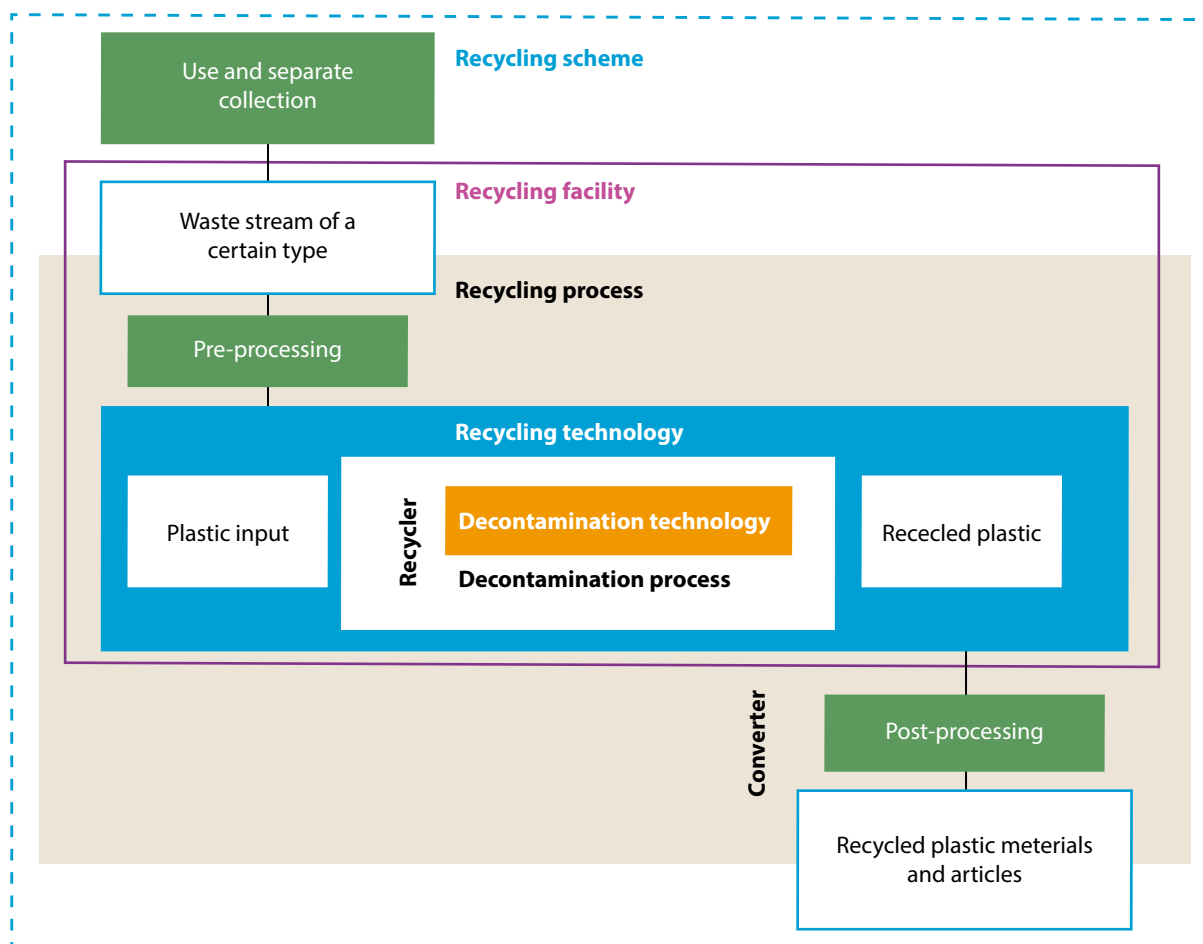


Figure 4: The terms shown are defined in Art. 2 para. 3 of the new regulation (source: Plastics Recyclers Europe: Guidance Document 2022).

The recycling process is again divided into three areas: *pre-processing*, *decontamination* and *post-processing*:

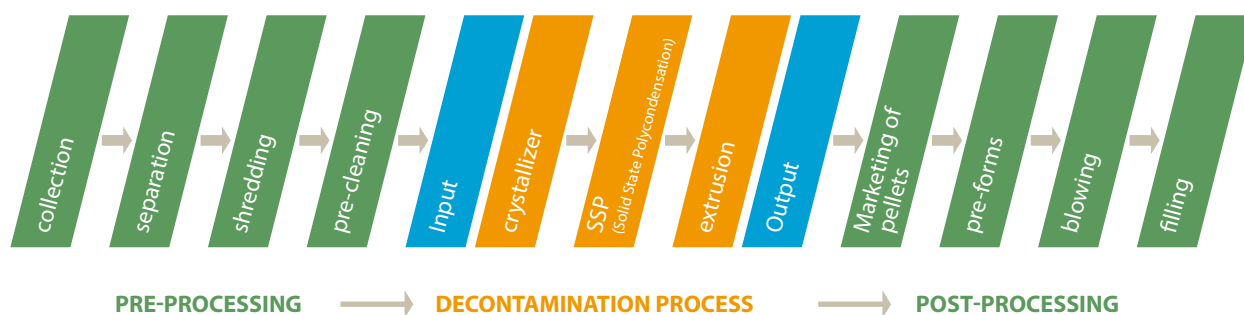


Figure 5: Recycling process in individual representation. Source: European Commission 2022, modified

The necessary need for decontamination depends on input materials.

4. Scope

The regulation applies to plastics that have been produced from waste (= recycled), regardless of whether this waste comes after use of the product (post-consumer) or from production residues (post-industrial). For production residues, which are not waste but a by-product, the requirements of Regulation 10/2011 apply.

The difference between so-called post-consumer recyclates (PCR) and post-industrial recyclates (PIR) is shown in Figure 6 and the distinction between by-products and waste is explained in Figure 7 (see in detail GKV-BDE-bvse Guidelines “Recycled Plastics in Products” 2022).

HOW TO DIFFERENTIATE BETWEEN PCR, PIR AND BY-PRODUCTS?

It depends on where the waste comes from:



Figure 6: Difference between post-consumer recyclate and post-industrial recyclate: The decisive factor is where the recycled plastics come from.

DIFFERENTIATION BETWEEN BY-PRODUCT AND WASTE

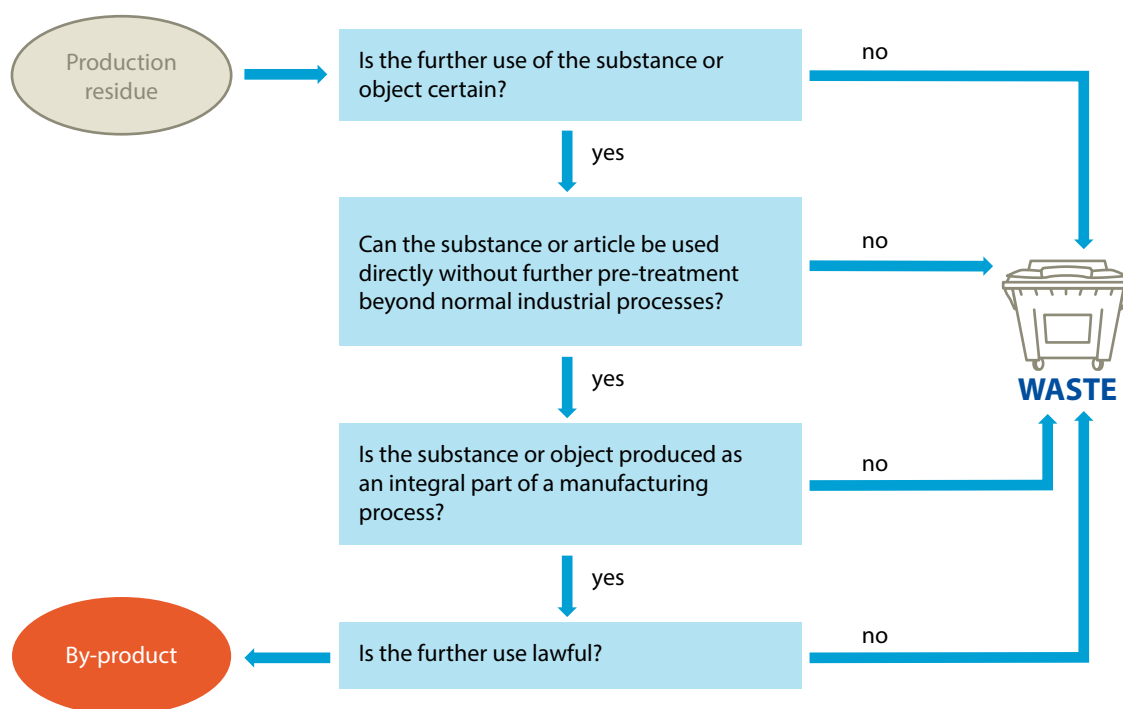


Figure 7: The delineation of when a production residue is considered a waste and when it is considered a by-product is sometimes difficult in practice. These criteria need to be examined.

The Regulation covers the results of all recycling processes, i.e. in principle also recycles obtained from chemical recycling (see recital 8). However, the Regulation does not apply to chemical recycling processes that lead to monomers after a complete depolymerisation, which are regulated in the Plastics Regulation No. 10/2011 (see Art. 1 para. 3 of Regulation No. 2022/1616).

5. suitable recycling technologies

The very abstract regulation only becomes comprehensible through the two suitable technologies. Therefore, the requirements for the production of recycled materials are explained below on the basis of the two suitable technologies.

A technology is considered suitable if sufficient data can demonstrate that the plastic used has been “decontaminated” and that the resulting recycled plastics comply with Commission Regulation No. 10/2011 and Framework Regulation No. 1935/2004 as well as GMP Regulation No. 2023/2006. Based on

the assessments carried out by the authorities under the “old” Commission Regulation No. 282/2008, two recycling technologies are currently considered “suitable”:

(1.) the **mechanical recycling of post-consumer PET waste** and

(2.) the recycling of waste from **closed and controlled product cycles**.

The suitable technologies are listed in Annex I of the Regulation.

The requirements for the input material, the process and the output material as well as the need for an individual authorisation and a so-called recycling scheme are regulated for all suitable recycling processes in annex 1, tables 1 to 5 of the new regulation.

Although some recycling processes are already considered suitable, the parameters and duration of treatment that determine decontamination capability may vary depending on the specific configuration of the recycling process. This means that although the same recycling technology is applied, different parameters may be used, which in the Commission’s view believes may compromise the safety of the recyclates produced. Therefore, these processes require **individual authorisation** (for example, in the case of mechanical PET recycling, see below).

Other recycling technologies, on the other hand, can in the Commission’s view ensure that any recycling process using them will result in safe recycled plastic. Therefore, the assessment of each recycling process using these technologies brings little benefit compared to the burden it imposes on both the companies and the authority. Therefore, **no individual approval** is required for these processes (for example, in the closed and controlled product loop, see below).

According to the regulation, a **recycling scheme** is “an arrangement between legal entities to manage the use, separate collection and recycling of plastic materials and Articles with the objective to limit or prevent their contamination in order to facilitate their recycling” (see Art. 2 para. 3 No. 15 of the regulation). Further details on the recycling scheme are regulated in Art. 9 as well as in Annex 1. The type of recycling scheme permitted for a particular technology is specified in Annex I, Table 1 (columns 8-10) (see also p. 17 f.).

The conditions under which recyclates from these two processes can be used in food contact materials are explained below.

a) Mechanical recycling of post-consumer PET waste

Mechanical recycling of PET beverage bottles is the best known and most widely used process for producing recyclates for food contact. One reason for this is the single-variety collection within the bottle deposit system as well as the established recycling processes and special reprocessing plants.

The requirements of the new regulation for PET recycling result in particular from annex 1, table 1 No. 1, as well as table 2, table 3 No. 3.1 and can be divided into 5 stages along the value chain:

(1.) General requirements for waste collection and pre-processing

The basic requirement according to Art. 6 is that the plastic waste used has been produced in accordance with Regulation No. 10/2011 and originates from one of the following waste streams:

- **Municipal waste** or
- **Food retailing** or
- other **food businesses** if they were intended and used only for contact with food, or
- Waste disposed of under a **recycling scheme** as referred to in Art. 9 para. 6 (applicable to food businesses).

Food businesses are *“any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food”* (Art. 3 No. 2 of Regulation No. 178/2002). Manufacturers of plastic food packaging are also food businesses within the meaning of this provision, because without packaging it is not possible to distribute most foods. Many food safety regulations also relate to packaging, e.g. migration limits and hygiene rules. In addition, the regulations on production waste (see annex I, table 3, point 3.2 and Art. 9 para. 6) would otherwise be meaningless.

Food retailing also belongs to this group of businesses. There is no specific definition in EU law. However, Regulation 178/2002 defines “retail” as *“the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, super-market distribution centres and wholesale outlets”*.

If this waste is collected **together** with other packaging waste or non-packaging fractions of municipal waste (but only with non-hazardous waste and separated from residual waste), the contamination of the collected waste must be “minimised” (see Art. 6 para. 1 c) in conjunction with para. 2 b)). If this waste is collected **separately** (e.g. by deposit system), this requirement does not apply (see there para. 2 a)).

In addition, the plastic waste must be continuously controlled during collection and pre-processing with the help of **quality assurance systems**. The quality assurance systems must be audited by a third party no later than two years after entry into force (see Art. 6 para. 3 in conjunction with Art. 33). Please note that these requirements may be used when applying for a novel technology.

(2.) Special requirements for the input material

The specific requirements for this process are regulated in annex 1 table 1 No. 1 column 5 of the new regulation: According to this, only **post-consumer** PET waste may be used (see above for the demarcation). Furthermore, this PET waste may be used *“with a maximum 5% of materials and Articles that were used in contact with non-food materials or substances”*.

The regulation thus adopts a legally non-binding EFSA recommendation from 2011². When the regulation was drafted, the associations had pointed out that this recommendation is now scientifically outdated, as it has been shown in many cases that the migration limits can be safely met even with higher proportions of non-food contact materials in the input material (see publication of Fraunhofer IVV³). Accordingly, the 5% threshold unnecessarily complicates the use of recycled PET (rPET) from mixed collections in food contact, as its safe compliance requires, for example, the introduction of new marking and sorting procedures. Moreover, it is very difficult to prove compliance with this limit.

(3.) Requirements for the recycling process

PET recycling requires a **specific authorisation** of the recycling process (see annex 1 table 1 No. 1 column 7). The requirements for such a specific authorisation are listed in Articles 17 to 19 and are not further described here.

The Commission has announced that the applications for authorisation of PET recycling processes submitted under the previous Regulation No. 282/2008 and assessed as safe by EFSA – now more than 230 – will be approved quickly after the new Regulation enters into force.

The decontamination plant must be located in a **single recycling plant** (Art. 7 para. 3 a)).

In addition, recyclers must document information on the quality of individual batches, submit a **declaration of compliance** (see Art. 5 Para. 2 in conjunction with Art. 29 para. 1 as well as template in Annex III part A). Art. 29 para. 1 as well as template in Annex III part A) and **label** the containers delivered to the processors (not permanently mounted on vehicles) with⁴ recyclates (see Art. 5 para. 1 to 5). Apart from that, no further specifications and requirements apply to PET recycling (see annex 1 table 1 No. 1 column 8 in connection with Art. 4 para. 4). A so-called *recycling scheme* is also not required here.

According to the **transitional provisions** in Art. 31 para. 1, mechanically produced post-consumer PET recyclates may continue to be placed on the market pending a decision by the Commission if for them

- a valid application for authorisation is available (according to Art. 5 Regulation No. 282/2008) or
- an application for authorisation has been submitted by 10th July 2023⁵ (in accordance with Art. 17 or 22 of the new Regulation).

Recycling facilities must be registered with the Commission and the competent national authorities immediately after the entry into force of the new Regulation (Art. 25).

² EFSA-Opinion of 6th July 2011: <https://www.efsa.europa.eu/en/efsajournal/pub/2184>

³ Recycling of Post-Consumer Packaging Materials into New Food Packaging Applications – Critical Review of the European Approach and Future Perspectives“, Roland Franz and Frank Welle, Sustainability 2022, 14(2), 824: <https://www.mdpi.com/2071-1050/14/2/824>

⁴ Not „containers made of recycled plastic“, as it erroneously says in the German version of the regulation.

⁵ Corrigendum to Commission Regulation (EU) 2022/1616 of 15 September 2022 on materials and articles made of recycled plastic intended to come into contact with food and repealing Regulation (EC) No 282/2008 ([here](#))

(4.) Requirements for the processing of PET recyclates

Converters of PET recyclates should subject the recyclates to **post-processing** and otherwise follow the recycler's instructions during processing (Art. 8).

Restrictions and specifications for the use of recycled PET plastics have to be included in the **labelling** of products made from it according to Article 15 of the Framework Regulation 1935/2004 (Art. 8 para. 2 in conjunction with Art. 5 para.6 of the Regulation). This means that the labelling of products made from recycled PET obtained from a "suitable recycling technology must include a statement that they are not" intended for use in microwave ovens and conventional ovens" (see Annex 1 Table 1 No. 1 column 6). This does not apply to recycled PET obtained from closed and controlled-loop recycling processes and from novel technologies.

Converters must also submit a **declaration of compliance** (see Art. 5 para. 2 in conjunction with Art. 29 para. 3). A corresponding template can be found in Annex III part B.

Where appropriate, they must give instructions to subsequent converters or users regarding the restrictions and specifications (Art. 8 para.1(b) and (c)). In the case of PET recycling, the restrictions already result from the labelling of the product (see above).

Recycled PET plastics may be used for microwave and conventional ovens if it stems from a "novel technology" or a "closed and controlled loop" process.

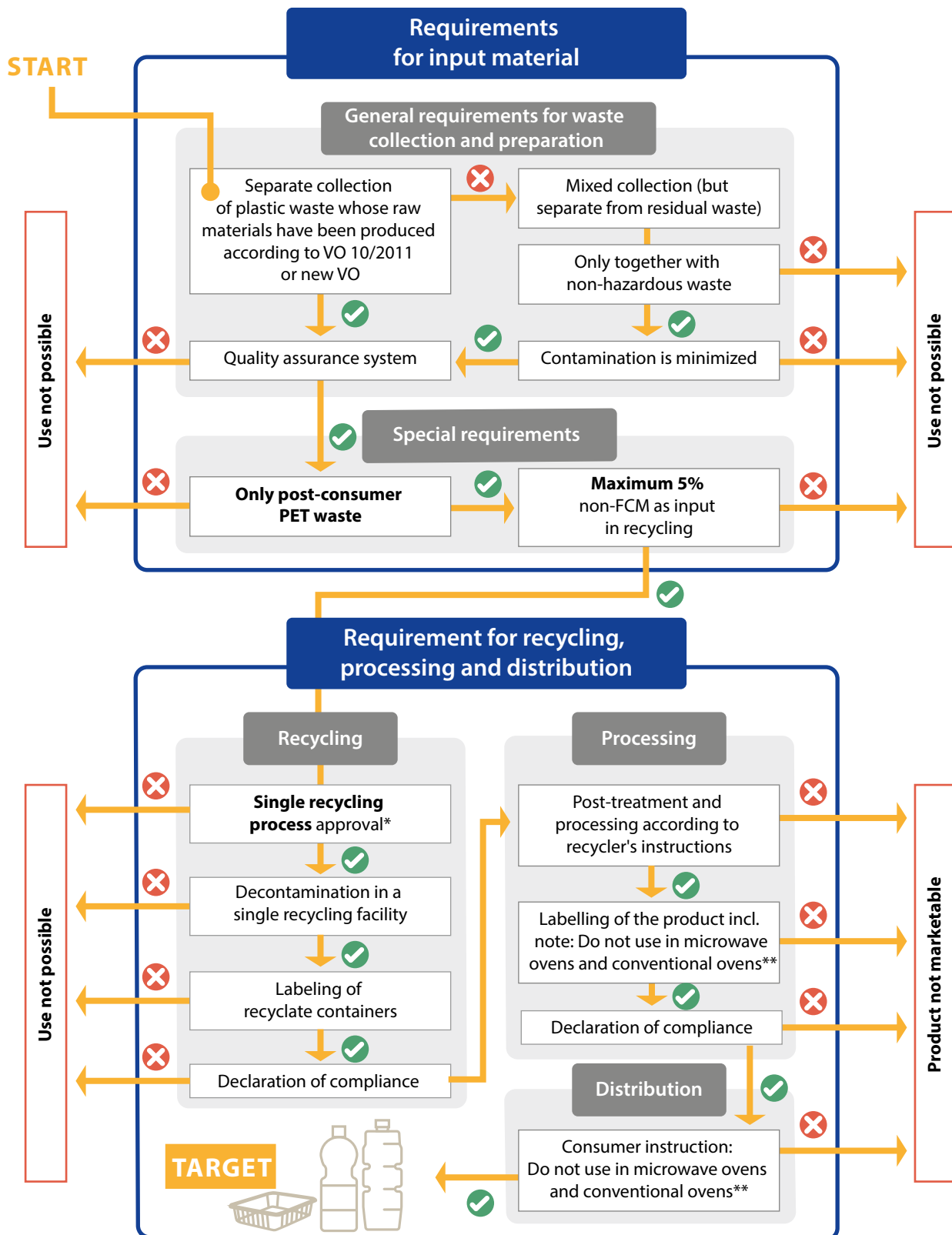
(5.) Requirements for the distribution of products with PET recyclates

Food business operators shall use products made from recycled PET in accordance with the instructions received, i.e. not in microwave ovens and conventional ovens. They shall also communicate instructions to consumers of food packed in packaging containing recycled PET and/or to other food business operators as appropriate. However, here the instruction already results from the labelling of the packaging (Art. 8 para 2, see above).

Retailers of products made of recycled PET plastic that have not yet come into contact with food shall provide appropriate instructions to the users of such products, unless these are already apparent from the labelling affixed to such materials and Articles (Art. 8 para 3, see above).

DECISION TREE – SUITABLE TECHNOLOGY

Post consumer PET recyclates for food contact materials



* See transitional provisions in Art. 31

** This does only apply to recycled PET obtained from a „suitable recycling technology“, not to rPET from “closed and controlled loop” recycling processes and „novel technologies“.

Figure 8: Decision tree - post-consumer PET recyclates for food contact materials

b) Recycling of waste from production cycles

With the help of the second recycling technology classified as suitable, three selected, closed and controlled product cycles can be mapped. In these circuits, the Commission's assessment is that it can

be ensured that contamination of the material, e.g. through misuse by consumers, is excluded. According to Annex 1 Table 3 No. 3.2, these three production cycles are limited to the waste from manufacturing, distribution and catering facilities.



Figure 9: The new regulation allows the use of recyclates from closed and controlled production cycles. This only applies to recyclates from production waste and waste from distribution or catering facilities.

The requirements for the use of recyclates produced from these waste streams differ fundamentally from PET recycling in that a so-called recycling scheme must be used here (see below) and that no *individual approval* is required for the recycling plant.

(1.) Requirements for the input material

Unlike PET recycling, the general requirements of Articles 6, 7 and 8 of the Regulation do not apply here, as they are replaced by the specific requirements of a recycling system in article 9 and annex 1 table 4 (see Art. 4 para.4 (c)).

However, the plastic waste used must also have been produced in accordance with Regulation No. 10/2011 and intended and used for food contact (annex 1 table 1 No. 2 column 3, table 3 No. 3.2).

Further requirements according to annex 1 table 1 No. 2 column 5 are that the input material into the recycling process must be

- made from a **single polymer** or from **compatible polymers**,
- is **not chemically contaminated**, excluding surface residues from food and labelling (annex 1 table 3 No. 3.2),

- was **used under the same conditions of use** (as the target product) or was intended for use under the same provisions, and
- were obtained exclusively from a **closed and controlled product cycle** (production, distribution, catering),
- **excluding collection from the consumer.**

As seen, the regulation only mentions waste from manufacturing, distribution and food service/catering facilities as closed and controlled product cycles (annex 1 table 3 No. 3.2, see above). Examples of production waste generated during manufacturing are listed as *“crushed materials and objects as well as offcuts and leftovers from manufacturing”*. A closed and controlled product loop requires that these materials and Articles have not been made available to consumers *“for use outside the premises and/or control of the facilities participating in the recycling system”*.

(2.) Recycling requirements

The fundamental difference with PET recycling is that this “technology” requires a so-called **recycling scheme** (annex 1 table 1 No. 2 column 10). A recycling scheme is *“an arrangement between legal entities to manage the use, separate collection and recycling of plastic materials and Articles with the objective to limit or prevent their contamination in order to facilitate their recycling”* (Art. 2 para. 3 No. 15). The requirements for a recycling scheme are according to Art. 9:

- Designation of a single legal entity as **“manager”** of the recycling system,
- Inform the national authority and the Commission at least 15 working days before the launch for the purpose of **registration** in the Union Registry (Art. 24),
- a **“single document”** (*“single document”*) for all participating companies with instructions,
- **Waste collection system,**

- All participating businesses maintain a **quality assurance system** in accordance with Regulation 2023/2006 (exceptions for small food businesses in Art. 9 para. 9 b)).

In addition to these requirements of a recycling system, the recyclates produced must be **microbiologically decontaminated** as part of a closed and controlled product cycle (annex 1 table 3 No. 3.2). In order to avoid quality losses, **new plastic** may be **added**. Further requirements, such as scientific **proof of harmlessness to health**, are listed in annex 1 table 4 No. 4.1.

In addition, recyclers must document information on the quality of individual batches, submit a **declaration of compliance** (see Art. 5 Para. 2 in conjunction with Art. 29 para. 1 as well as template in Annex III part A). Art. 29 para. 1 as well as template in Annex III part A) and **label** the containers delivered to the processors (not permanently mounted on vehicles) with recyclates (see Art. 5 para. 1 to 5).

(3.) Processing requirements

The recyclates produced under this recycling system may only be *“intended to be used for the same purpose and use under the same conditions of use as the materials and Articles circulated in the recycling scheme from which the input plastic material was obtained”* (annex 1 table 1 No. 2 column 6). A similar provision, albeit slightly different in wording, is found in annex 1 table 3 No. 3.2 a.E.), according to which the recyclate *“is used only for manufacturing plastic materials and Articles for contact with the same foods and under the same conditions as the collected materials and Articles were intended for, and for which compliance to Regulation (EU) No. 10 /2011 was initially verified”*.

Converters must also submit a **declaration of compliance** (see Art. 5 para. 2 in conjunction with Art. 29 para. 3). A corresponding template can be found in Annex III part B.

At the use stage where contact with food is intended or foreseeable, all materials and Articles used in the recycling system shall be clearly **marked in** a visible, indelible and – for the recycling system – unambiguous manner (Art. 9 para. 5).

(4.) Requirements for the distribution

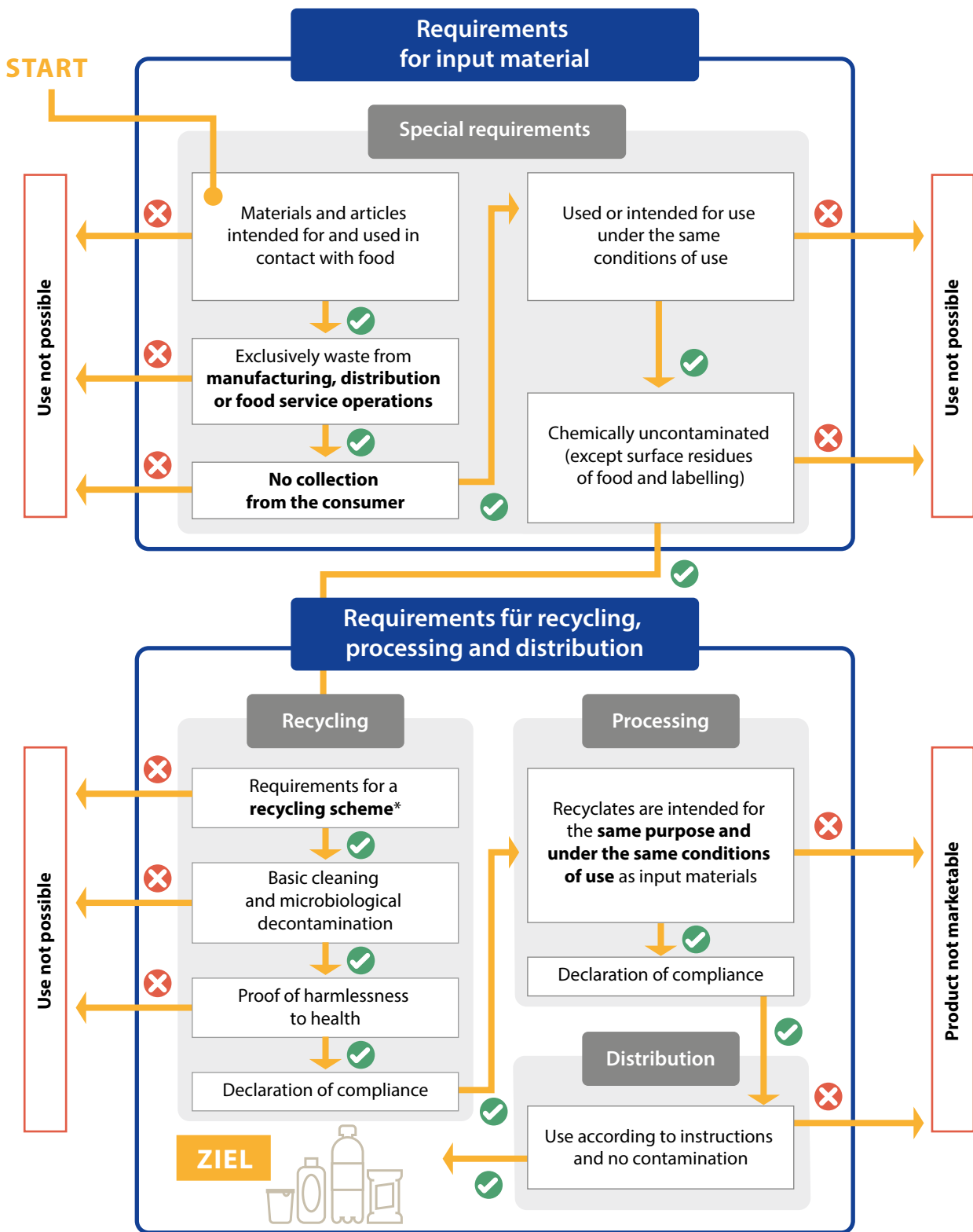
Food businesses using labelled materials and Articles made from these recycled materials must ensure, in accordance with Art. 9 para.6, that they are

- be labelled, used and cleaned in accordance with the recycling scheme manager's instructions,
- are used only for the distribution, storage, display and sale of the food for which they are intended (i.e. repackaging is not possible), and
- not be contaminated with materials and substances other than those permitted under the recycling scheme.

If one of these conditions is not met, the materials or Articles must be disposed of. However, according to Art. 6 para 1 (a), this waste stream may in turn be input material for a closed and supervised recycling scheme.

DECISION TREE – SUITABLE TECHNOLOGY

Recyclates from closed and controlled product loops for food contact materials



* See requirements in Art. 9

Figure 10: Decision tree - recyclates from closed and controlled product loops for food contact materials

1.) *In practice:* recycling scheme for recyclates from production waste

For the production of post-industrial recyclates from production waste from the manufacture of plastic food contact materials, a recycling scheme looks as follows:

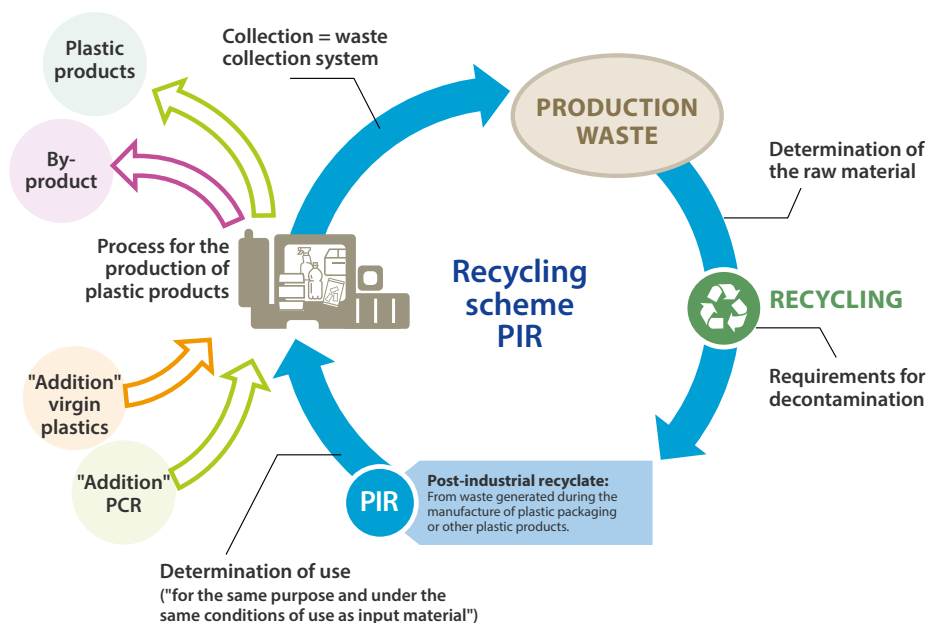


Figure 11: This is what a „recycling scheme“ for post-industrial recyclates looks like.

The application of the strict requirements for a recycling scheme will still raise many questions in operational practice. The following points, among others, are unclear:

- For example, it is unclear whether **several legal entities** actually have to be involved or whether it is not sufficient if a company itself recycles and reuses the production waste, e.g. from the production of food packaging. The requirement for several companies here seems an unnecessary formalism because it does not improve the safety of the recyclate. The instructions under the “single document” could also be given internally within the company through work instructions.
- The requirements that the recyclates may only be used for “the same purpose” or “for contact with the

same food” and “under the same (use) conditions” as the original products are open to interpretation.

- Finally, the question arises why food contact products made from *post-industrial recyclate* actually have to be **labelled**, because these products are no longer part of the recycling system.

It is to be hoped that the Commission will clarify these issues in the announced guidelines.

(2.) In practice: recycling scheme for recyclates from sales returns

For the production of *post-consumer* recyclates from returns from the supply chain, a recycling scheme looks as follows:

Again, questions arise that will hopefully be answered in the Commission guidelines, including: Is labelling of the product made from the recyclate required? The fact that the product is no longer part of the recycling scheme speaks against this.

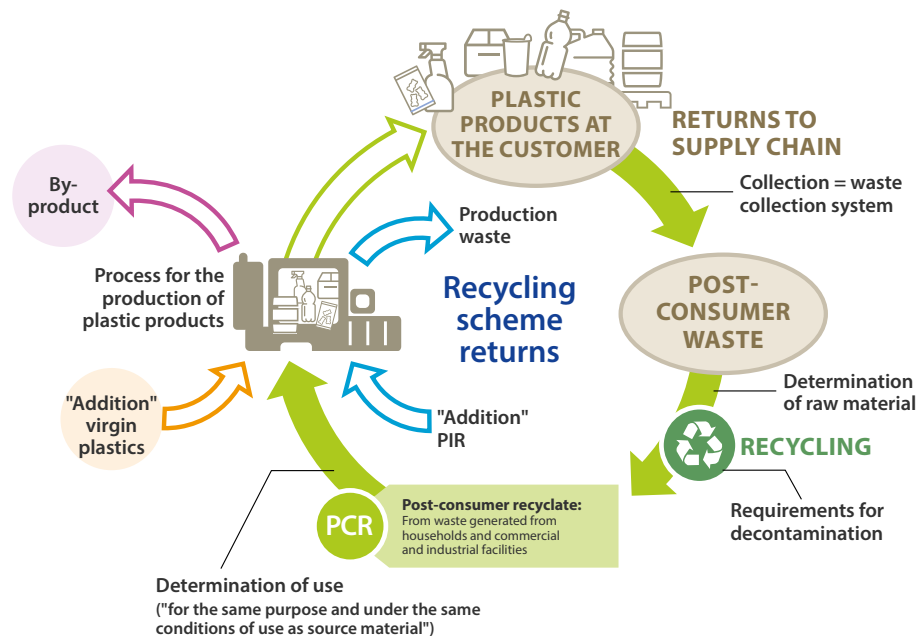


Figure 12: This is what a „recycling system“ for returns from distribution looks like.

6. recyclates from new technologies

Any recycling technology not classified as “suitable” is considered a so-called “novel” recycling technology. Recyclates produced with such “novel” technologies may only be used for food contact under strict conditions. Prerequisites are that

- the recycler (“developer”) notifies the “novel” technology to the competent authority⁶ and the Commission at least six months before the “decontamination facility” is put into operation (Art. 10 para. 1-7) and

- fulfils extensive registration (Art. 11(2)) and information obligations (Art. 11(4-5), Art. 12),
- the competent authority, after an inspection within five months and in the course of regular inspections, has no “concerns” about the operation (Art. 10 para. 8),
- the recycler monitors the input materials as well as the recyclates “by means of a sound sampling strategy” (Art. 13)⁷ and
- there is no negative decision by the Commission (Art. 15).

⁶ The Federal Office of Consumer Protection and Food Safety (BVL) has published the respective competent authorities sorted by federal states: <https://www.bvl.bund.de>

⁷ See in detail: PRE, Guidance document 2022, p. 13 ff.

In the context of a novel recycling technology, the general requirements in Articles 6 to 8 may be derogated from, provided that any derogation is justified (Art. 11 para.3). This allows a much larger waste stream to be used, provided that the recyclates produced from it comply with the requirements of the Framework Regulation 1935/2005 and Commission Regulation 10/2011.

Provided that sufficient data has been collected over time, the Commission may, on its own initiative or at the request of the developer, start the process of an assessment of the novel technology. The process can take up to seven years and is described in Articles 13 and 14. It ends with the Commission's decision on the suitability as an appropriate recycling technology (Art. 15).

STRUCTURE OF THE NEW REGULATION

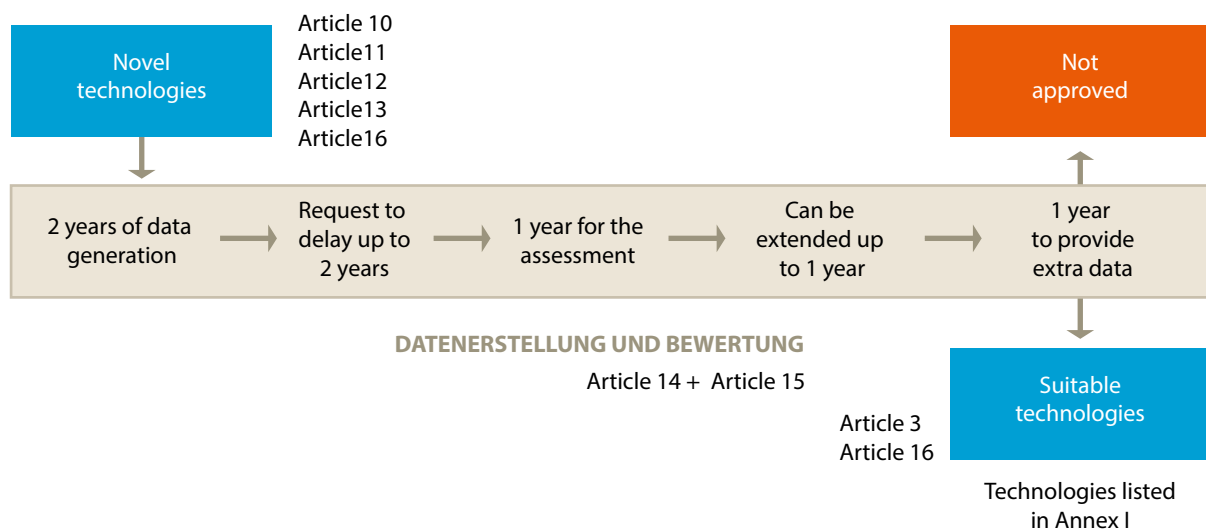


Figure 13: All recycling technologies not classified as „suitable“ have to go through an elaborate and lengthy approval process to be classified as suitable technology. In the meantime, strict regulatory monitoring ensures that recyclates produced with such „novel“ technologies are safe for food contact (source: PRE).

7. recyclates behind functional barriers

Previously, recyclates “*where the recycled plastic is used behind a functional plastic barrier in accordance with Directive 2002/72/EC*” were explicitly excluded from the scope of the Regulation (Art. 1(2)(c) Regulation 282/2008)⁸. This changes with the new Regulation, which does not provide for such an exemption. Such applications are therefore considered to be novel technologies.

The Commission justifies this amendment with reference to an EFSA decision from 2011, according to which it is generally not possible to predict the type of contaminants potentially present in post-consumer plastic waste and thus to ensure that it is not genotoxic. Therefore, the Commission concludes, it is also not possible to ensure that a barrier layer prevents the transfer of potential contaminants (see recital 4).

According to the Commission, the amendment affects “*several hundred recycling facilities*” that have so far used recyclates behind barrier layers (see recital 33, the Regulation is silent on the number of processors). Special transitional provisions in Art. 32 therefore apply to plants that were already operating before the Regulation entered into force: By 10 April 2023, the “developer” shall submit to the competent authority and the Commission

- a list of the facilities and recycling technology together with
- the results of migration tests, challenge tests and/or migration modelling which clearly show that the functional barrier is effective within the meaning of Regulation 10/2011 (Art. 32 para. 1).

In order to avoid a large number of applications for authorisation, the actors involved should come together in consortia (Art. 32 para. 2)⁹. These consortia may also represent several barrier technologies. In contrast to other emerging technologies, slightly weakened monitoring obligations apply (Art. 32 para. 3).

For recyclates behind functional barriers made of materials other than plastic, the requirements in Regulation (EU) No. 10/2011 still apply.

8. General transitional provisions

Recyclates that have not been produced by means of an “appropriate” recycling technology could only be placed on the market until 10 July 2023 “*unless they are manufactured with a recycling installation that is operated for the purpose of development of a novel technology*” (Art. 31 para. 3).

Applications for authorisation for non-“appropriate” recycling technologies and for closed and supervised product loops become invalid (Art. 31 para. 2).

Certain transitional provisions applied to already existing recycling facilities: Existing installations based on a suitable recycling technology are deemed to be put into operation as of 10 December 2022. Installations for the development of new technologies are considered to be in operation from 10 June 2023 (Art. 31 para. 4), in case the corresponding notification (according to Art. 10 para. 2) was made by 10 December 2022. The detailed information requirements (Art. 10 para. 3 and 4) had to be fulfilled by 10 April 2023 (Art. 31 para. 5).

⁸ In Article 13 and 14 of the Plastics Regulation No. 10/2011 there are specifications for functional barriers for multilayer materials and Articles made of plastics.

⁹ The European associations PETCORE and PETSHEET have agreed to jointly prepare the necessary dossiers for a recycling technology in the field of functional barriers and to provide for monitoring, etc.

In addition, food business operators may use legally placed recyclates for the packaging of food and place them on the market until stocks are exhausted (Art. 31 para 6).

On the transitional provisions for mechanical PET recycling, see above. p. 14 (Art. 31 para. 1).

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Gesamtverband Kunststoffverarbeitende Industrie e. V. (GKV)
Gertraudenstraße 20
10178 Berlin
Tel. +49 (0) 30 2061 67 150
Fax +49 (0) 30 3971 22 30
E-Mail: info@gkv.de
www.gkv.de

Editorial

Yvonne Kramer

Responsible for the content

Dr. Martin Engelmann
Dr. Fang Luan

Cover photo

iStockphoto

Design

Ilona Hirth Grafik Design GmbH



Gesamtverband
Kunststoffverarbeitende
Industrie e. V. (GKV)
Gertraudenstraße 20
10178 Berlin
www.gkv.de



BDE Bundesverband der
Deutschen Entsorgungs-,
Wasser- und Kreislaufwirtschaft e. V.
Von-der-Heydt-Straße 2
D 10785 Berlin
www.bde.de



bvse-Bundesverband
Sekundärrohstoffe und
Entsorgung e. V.
Fränkische Straße 2
53229 Bonn
www.bvse.de