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EUPC COMMENTS TO THE DRAFT COMMISSION IMPLEMENTING REGULATION (EU) ON RECYCLED PLASTICS MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODS

EuPC thanks for the opportunity to comment and provide its view on the proposed draft Implementing Regulation on recycled plastics materials and articles intended to come into contact with foods.

EuPC is willing to discuss the radical changes that will affect existing industry practices. In particular, we would like to shed light on the impractical applicability of some of the proposed rules. In particular,

- the introduction of rules for functional barriers,
- the protection of confidential information which would have to be made publicly available,
- the uncertainty on the timing for authorization granting,
- the lack of a sound impact assessment,
- the lack of clear rules for authorization of single processes.

In the attached document, we have reported detailed examination of the draft and we have identified the points that we consider critical for our industry.

PREAMBLE/ARTICLE/ANNEX	COMMENT
[GENERAL COMMENT]	This Regulation is a complete overhaul of the current legislation, and it is expected to have a significant impact on all stakeholders, especially Small and Medium Size Enterprises (which are largely represented by EuPC), and converters that use recycled plastics for manufacturing finished food contact materials and articles. Investments in expertise and in analytical equipment will be significant. The impact on availability of recycled plastics, price, competitiveness in the global market, resources necessary for compliance vs. benefits, are not taken in consideration. We believe that an impact assessment should be carried out before adopting the Regulation as it has been carried for the production of Regulation no. 282/2008, that will be repealed by the Regulation at issue. In addition, as the Regulation is rather complex and several points are open to interpretation; we would suggest publishing guidelines for a correct interpretation and application of the Regulation

(1) As part of the 2015 circular economy action plan2, the Commission identified the increase in plastic recycling as an essential prerequisite for the transition to a circular economy and committed to address this sector in a targeted way	The "New Circular Economy Action Plan For a cleaner and more competitive Europe" reads: **4.3. Creating a well-functioning EU market for secondary raw materials.* *Secondary raw materials face a number of challenges in competing with primary raw materials for reasons not only related to their safety, but also to their performance, availability and cost.* The question is whether the Commission considered availability and cost of the input/output of recycled plastic in developing the draft. New rules have an impact on costs, and, again, an impact assessment should be carried out to evaluate the costs vs. benefit of the proposed legislation.
3. *Also scraps and off-cuts were being recycled, and functional barriers were used to contain contaminated recycled plastic* …	It is confusing to mention scraps & offcuts and functional barriers in the "whereas" and not mentioning how these concepts are managed under the new regulation. Does the use of scraps and off-cuts qualify as recycling or not? Are they in or out of scope? Would the use of scraps and off-cuts it be considered a closed loop process or not? The above questions stem from the fact that scraps and offcuts often require some kind of process to make them usable, for example washing, milling, wind sifting and/or processing to form pellet with vacuum treatment. Since "scraps and offcuts" and "functional barriers" are only mentioned here together, one could understand that the new regulation treats them as equivalent. It is not clear whether they are out of scope or both "new technologies", thus requiring an application. It should be clarified how "scraps and offcuts" are treated in the Regulation.
It is, therefore, appropriate to replace Regulation (EC) No 282/2008 with new rules covering all those existing recycling technologies which cannot adequately be regulated by Regulation (EU) No 10/2011 as well as capable of covering future recycling technologies.	Functional barrier cannot be considered a "Novel Technology" since it has been applied for more than 15 years without evidence of risk. Barrier layer (A/B/A) is the most common structure used in rPET food tray containers. If this technology would have to be assessed by EFSA as a novel technology, this will result in many hundreds of applications filed before EFSA, which will require considerable resources and long timing to be processed. In our opinion laminating recycled plastics with functional barrier qualifies as a post-processing operation rather than a novel process.
(5) As plastic waste should always be decontaminated (…)	The recovered product to be used in FCM must comply with 10/2011. It may require a decontamination process unless the final process demonstrates that the finished FCM complies with the said Regulation

(8) it is not necessary to require the authorisation of individual recycling processes applying the closed-loop recycling technology as for all those processes the introduction of contaminants in the chain is sufficiently controlled to ensure that the only contamination of the plastic input can be removed with the simple washing and heating processes needed in any case for the remoulding of the materials	This wording suggests that washing constitutes always part of closed-loop recycling technologies (which includes the decontamination technology). However, EFSA has delivered positive opinions on closed-loop recycling processes that do not include washing, in which decontamination of the plastic is ensured through other processes that include high temperatures remoulding. Therefore, we suggest to re-word the sentence as "*sufficiently controlled to ensure that the only contamination of the plastic input can be removed with other processes that may include washing, combined with heating processes needed in any case for the remoulding of the materials"*
(10) the rules on compliance set out in Regulation (EU) No 10/2011 should not apply to residual incidental contamination *To ensure the same level of safety of recycled plastic materials and articles, they should be of the same composition as plastics manufactured in accordance with Regulation (EU) No 10/2011, and comply with the restrictions and specifications, such as migration limits, laid down that Regulation*	The way the sentence is formulated suggests that the residual contamination is not subject to Art. 19 of Reg. 10/2011, as it should be. Is this point linked to NIAS, and if so, how? The hierarchical relationship between this Regulation and Regulation (EU) 10/2011 is not clear. Does the first prevails over the second? This would imply that "novel technologies" should not be regulated by Reg. (EU) 10/2011. Is this the intention of the Commission? If a plastic FCM contains a non-authorized substance behind a functional barrier, and it is recycled and used in direct contact with food, the recycled plastic food contactmaterial or article is not in compliance with the requirements of article 4 point 2. How would the Commission handle these situations and who would be responsible within the supply chain?
(12) While such instructions should be transferred via documentation, plastic materials may not be easily recognisable as requiring a special treatment. To prevent mistakes and to facilitate controls, recycled plastic should therefore be labelled in a clearly legible way to ensure it is	Why special labels apply to recyclate? The care needed for handling recyclate is not different from other plastic materials. Recyclate does not need "special treatment", it requires the same care as any virgin material. The persons receiving the truck from the recycler does not care about dosing. They just store the material in the appropriate silo, while the persons setting the dosing in the control room cannot see any label. Also, the percentages written on a label might be higher than the amount a manufacturer intends to use in the product, and this is more likely to create confusion and cause mistakes rather than prevent them.

correctly used during post- processing in accordance with the instructions from the recycler	If a purchaser of recyclate needs a special label to handle the recyclate properly, he can and should specify this with his supplier.
(12) While Regulation (EC) No 1935/2004 lays down specific rules for the labelling of materials and articles to inform users on their appropriate use, such rules do not exist regarding the post-processing of decontaminated plastic	Labelling rules do not exist for recycled plastics, not only for decontaminated, we suggest to replace "decontaminated " with "recycled"
(13) "To ensure that plastic materials and articles are subject to conditions throughout the recycling process that ensure their safety and quality, and to facilitate enforcement and the functioning of the supply chain, rules (...)"	While 282/2008 applies to the recycling process providing a decontamination to fulfill the obligations of the use of the material in contact with food, this Regulation addresses issues in the value chain, and especially falling under WFD 2008/98/EC. We consider these requirements out of scope of DG Santé. Users of recycled FCM plastics cannot be held responsible of the management of waste, upstream in the value chain, for which only the public authorities in charge of waste may act.
(14) "to ensure clarity and uniform application of a recycling scheme, only one entity should be responsible for managing its overall functioning and it should be responsible to provide all participating operators with binding directions"	We do no not see how a single entity may be responsible for operations carried out in different Member Sates, and possible outside the EU. This concept is also elaborated later.
(16) "Moreover, to ensure trust, public knowledge and scrutiny on technologies that are being developed, it is important that the reports of such monitoring are made public regularly."	This suggests that innovative technologies which may be protected by confidentiality, and for which the competent authority does not have neither the time, nor the data for assessment, will be judged by the general public, and that the confidentiality must be lifted. To what extent then commercial secret is protected? In addition, as this Regulation falls under the remit of Reg. 1935/2004, its purpose should be "to ensure the effective functioning of the internal market […] whilst providing the basis for securing a high level of protection of human health and the interests of consumers". This does not include public information or building consumers' trust. Regulation (EU) 625/2017 on official controls requires that the reports of monitoring shall be available upon request of the Competent Authorities, rather than public.
(19) it is appropriate to lay down that only the business operator who developed the recycling	What happens if the operator who developed the recycling business runs out of business (merged or acquired by other companies, dismiss production of the technology etc.)? Is the simple listing in the repository sufficient

process, and not any recycler using it, may apply for authorisation	for recyclers using the technology to continue to operate, and, in this case, what happens if these recyclers make upgrading, changes or other modifications of the technology, that the authorization's holder can't anymore require? Moreover: if the application of a functional barrier falls under a technology to be authorized, does the Commission expect that the manufaturer of the lamination lines act as authorization holders?
(22) To ensure that recycled plastic and recycled plastic materials and articles are used appropriately and in a traceable manner by converters and food business operators, a declaration of compliance should be provided to accompany batches of recycled plastic, in order to establish the identity of the recycler, the recycled origin of the plastic, and to provide instructions to the converters and final users regarding its use. To ensure that that document can be understood in a uniform manner by anyone who receives it, operators should be required to use a pre-defined template	The term "Declaration of Compliance" is confusing, because it is the same term as employed in (EU) 10/2011, but the "required content" given in the draft annexes do not contain all information required by (EU) 10/2011. A complete Declaration of Compliance (DoC), covering both the requirements of (EU) 10/2011 and issues relating to this regulation shall be provided for each recycled food contact plastic, material or article to the recipient preferably prior to first delivery, so that the legal entity receiving can determine if and how the material can be used. DoCs are to be renewed only when their content changes or the recipient requests a new version. This is important because the personnel qualified to review DoCs are generally not directly involved in logistics. As is common between industrial partners, delivery documentation should identify the recycled plastic (product designation), the batch number and provide any data relevant to the specification. In the case of recycled plastic this would include a confirmation that the applicable DoC applies, but not repeat the contents of the DoC. Since (EC) 1935/2004 came into force, food contact materials and articles have been working under a one-up, one-down traceability system. This one-up, one-down traceability system is a key point of audits, both 3rd party audits according to various standards (ISO 9001, ISO 22000 or BRC) and those done by competent authorities. It is not clear from this "whereas" if this system will be maintained, or additional granularity in the traceability is required and, if so, what is the reason behing such requirement
(25) "This Regulation requires that certain waste management operators involved in the collection of plastic, as well as those involved in further operations as part of pre-processing, set up a certified quality assurance system to ensure the quality and traceability of the plastic input"	It is not clear whether the hierarchical relationship between this Regulation and the WFD and if the first prevails over the second and hence is considered as *lex specialis*.
Article 1 on subject matter and scope	1. Should we assume that the use of recycled plastics behind a functional barrier falls now within the definition of "*novel technology*"? If this is the case, it will create an unmanageable high number of requests to EFSA, unlikely to be processed in time compatible with business practices. The validation of

	functional barriers should remain under the responsibility of products' manufacturers, perhaps other solutions may be considered to keep them under control, such as specific guidelines. We would like to pint out that (i) functional barriers are safely used for more than 15years, so that they can hardly qualify as "novel", and (ii) the use of a functional barrier does not imply decontamination, and therefore , again, should not be seen as a "novel technology" 2. It is not clear whether recycling processes that originate oligomers or pre-polymers (that are not addressed in the list of Reg. 10/2011) are in the scope of this Regulation 3. What is the place of chemical recycling (pyrolysis, hydrolysis, etc.) in the regulation? What about recycling processes based on depolymerisation technologies? 4. Does art. 1(a) include plastic waste deriving from scraps and off-cuts? If this is the case, do these by-products need to undergo decontamination and authorization procedures set by the new Regulation?. Which of the following situations would fall under 10/2011 and which under the new recycling regulation? - Off-cuts and scrap regrinded within the same company (other location) and used on the original plant. - Off-cuts and scraps reprocessed and regrinded by third party and used at the original site. - Off -cuts and scarps originated in one site and reprocessed in another site of the same company - Off-cuts and scraps which are taken back from customers - Off-cuts and scraps taken back from the market (both pre-industrial and post-industrial) 5. Are special processes employed to make scraps and offcuts usable, such as washing to remove cutting fluids or solid state polycondensation to increase the molecular weight (counteracting hydrolytic degradation that occurred in processing) "closed loop" processes or would they need to be authorized under the new regulation? Please also refer to comments to whereas (3) and Annex I
Article 2 on definitions	The draft fails to address the principle of recycling from waste until FCM compliance, while several stakeholders are involved in the whole process, even across borders. The Commission has indicated that these definitions have to be read only in the context of this Regulation, but in part they override the definitions of WFD.

Art 2(2)(3) 'competent authorities', and 'audit', as laid down in Article 3 of Regulation (EU) 2017/625 of the European Parliament and of the Council.	In case of importation of recycled plastics from Countries outside the EU, competent authorities located outside the EU may not have the resources, expertise or legal mandate that they would need to audit and monitor recycling installations according to EU expectations and deadlines. If this regulation prevented imports from third Countries, it would also prohibit the import of food as well, and may result into a barrier to trade, in contrast with WTO rules
Art 2(3)	The article fails to address the definition of "*contamination*" and of "*decontamination*", which is required to further specify decontamination process, technology, etc., as well as "*incidental contamination*". Other related definitions are therefore unclear. The definition of "decontamination" is generic: even a light washing can be considered a decontamination according to this definition. Does "*decontamination"* correspond to the extrusion with vacuum technology or the combination of the extrusion/vacuum AND the functional barrier? Definition of "*post-processing*": does the conversion of flakes into pellets qualify as post- processing? Definition of "*recycler*": will a converter operating extrusion of recycled plastic in a A/B/A (with functional barrier) sheet qualify as a recycler? In addition, a definition of "*closed loop"* is missing, as well as the definition of *"novel technology"*
Art 2(3)(4) 'recycled plastic' means plastic resulting from the decontamination process of a recycling process and plastic resulting from subsequent post-processing operations and that is not yet transformed into recycled plastic materials and articles;	This definition is rather confusing and is interfering with the definition of recycling laid down by WFD and PPWD. There is a regulatory inconsistency.
Art 2(3)(5) 'recycled plastic materials and articles' means food contact materials and articles in their finished state that contain recycled plastic;	This definition is inconsistent with the legislative framework on waste. The finished state is a concept which is not defined (also in Art 2.3.(10)). ISO 14021:2016: *Recycled Content: proportion, by mass, of recycled material in a product or packaging. Only pre-consumer and post-consumer materials shall be considered as recycled content.* Pre-consumer is considered a recycled plastic, but there is no mention in the Regulation. Moreover, there is a need to include chemical recycled plastics in the recycled plastic definition

Art 2(3)(7) Plastic input.. means the plastic materials resulting from pre-processing which are entered into a decontamination process	Is the plastic input defined as post-consumer plastic waste the product coming from bales, or it corresponds to the product after removal (manual or automatic) of non-food items? Annex 1 table 1 defines the specifications of post-consumer mechanical PET recycling as Only *PET PCW containing maximum 5% materials and articles not used in contact with food.* In line with this definition, how the Regulation considers multilayers polyesters, polyolefin and EVOH materials present in a waste stream, trays and tubes? Are they suitable for mechanical recycling if they contain more that 5% of non-food contact, as long as the whole input stream would be max 5% non-food contact?
Art 2(3)(15) 'recycler' means any natural or legal person who applies a decontamination process	A recycler is an entity who also performs a pre-processing operation and not only the decontamination process. This regulation applies to all entities who carry out or perform one step of a recycling process not only who perform the decontamination process. For this reason all these entities qualify as recyclers. It will be helpful to use a different definition for entities who perform the decontamination process and leave the definition of "recycler" to all entities involved in the actua "recycling process"
Art 2(3)(19) 'batch' means a quantity of plastic of the same quality, and produced using uniform production parameters at a certain manufacturing stage, stored and contained to exclude mixing with other materials or contamination, and designated as such by a single production number	We suggest to use "unique alphanumeric code" instead of "single production number", as this would be more comprehensive and closely reflets the current industrial practices
Art 3 Suitable recycling technologies	By defining what a recycling technology is, this regulation is imposing rules on WFD. Also, it can be legally challenged the fact that the definition of mechanical recycling is not listed in the main body of the Regulation but only in the Annex.
Art 3(2) (d) A suitable recycling technology shall be distinguished from other recycling technologies based on the following properties: […] *(d) the need or absence thereof for the evaluation and authorisation of recycling processes applying that technology, and the criteria therefore*	We wonder whether there may be examples of recycling processes that are completely equivalent, except for the need or absence for evaluation and authorization. This point can be either clarified or removed.

Art. 3(3) Where a suitable recycling technology may be implemented through different recycling processes and that the capacity of each of those processes to recycle waste into recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 may vary, each recycling process shall be individually authorised by the Commission in accordance with Article 19(1) ('the authorisation').	It is not clear when a recycling process needs to be authorized, on top of the authorization of the recycling technology. Please specify up to which level the capacity may vary as to require (or not require) the process to be authorized The consequences of the change of status by the developer of the technology who owns the authorization (for example, if it runs out of business) are not clear, especially versus those business partners that rely on the authorization.
Chapter II – Placing on the market of recycled plastic and recycled plastic materials and articles	The title of the chapter refers to recycled plastic (intermediate) and recycled plastic materials and articles (final articles). However, article 4 only refers to final articles and not to the intermediates
Art. 4(2) The compositional requirements and requirements on compliance set out in Chapter II and Chapter V of Regulation (EU) No 10/2011 shall apply to recycled plastic materials and articles. Those rules shall not apply to potential residual incidental contamination present in recycled plastic materials and articles (concept repeated under Preamble 10)	The final article (plastic material that contains recycled plastic) needs to be in compliance with 10/2011 (chapter II and V). To assure that compliance it is important that information is shared in the supply chain trough a DoC according to Annex IV. Information on potential migrants with restrictions (SML, QM and/or in column 10), substances Annex 2, and potential genotoxic substances play a vital role in the compliance assessment of the final article. It is also important to perform the compliance assessment as early as possible in the supply chain. When we now look at the DoC template for recycled plastic (recycler and converter), it does not contain this information. How can one guarantee compliance of the final article, containing recycled plastic, without information? The disparity of treatment between *incidental contamination* and *residual incidental contamination* appears not sufficiently explained and justified. The language used in this Article seems to suggest that rules such as Art. 19 of Reg. 10/2011 do not apply to incidental contaminants. Is this the intention of the Commission?

Art. 4(4)(a) Where the recycled plastic materials and articles are manufactured using a suitable recycling technology, the following requirements are met: (a) where relevant, the recycling process used to manufacture the recycled plastic materials and articles has been granted an authorisation	Please clarify whether the Commission believes that the use of functional barrier in A/B/A structures falls under 4(4)(a) (and in such case whether it is relevant obtaining an authorization) or under 4(5), or in none of the above. Please clarify whether the processes already assessed by EFSA up to the date of entry into force of this new Regulation, and having received a positive opinion (in accordance to Reg. 282(EC) 2008) can be placed on the market
Art 5(1) 1. Individual batches of recycled plastic or recycled materials and articles shall be subject to a single document or record regarding their quality, and shall be identified by a unique number and the name of the manufacturing stage from which they originate	Suggest to use "unique alphanumeric code" instead of "Unique number" (see comment to art 2(3)(19))
Art 5(2) Recycled plastic placed on the market shall be accompanied by compliance documentation in accordance with Article 29	Does it mean that there is no obligation for compliance documentation for the final article (recycled plastic material or article)?
Art 5(3)(b) the percentage by weight of the plastic content that originates from recycling.	If this percentage refers to the recycled plastic in the finished product, for recyclers this provision may not be applicable as the composition of the material may be the result of the development of formulations at the converter's place. Such percentage, when applicable, is established in supplying agreements, so that we fail to understand why it should be restated in labels
Art 5(3)(c) the maximum percentage by weight of the recycled plastic that final recycled plastic materials and articles containing the recycled plastic may contain, if this is less than 100%;	This provision is unclear and rather confusing as it suggests that 100% recycling is achievable in all conditions, for all application, which is not always true. If this information is included on a label or delivery document, as it can confuse the operators in the shop floor, it may be better part of the Declaration of Compliance. The converter using the recycled plastic is responsible for deciding on dosing for the intended product, which will often be significantly less than the maximum. The personnel of the converter should not receive conflicting instructions

Art 5(3((d) (d) a brief summary of any other instructions provided in the documentation in accordance with paragraph 2.	We fail to understand why this is needed: personnel handling the containers are not experts in food contact compliance. It should be allowed to use bar codes or QR codes to provide information
The labels referred to in paragraph 3 shall be at all times clearly legible and be located at a visible place on the packaging.	The word "packaging" should be better "container", in line with 5(3)
Art 5(4)(4) The labels referred to in paragraph 3 shall be at all times clearly legible and be located at a visible place on the packaging.	Why is this mandatory as the Declaration of Compliance serves the purpose? Moreover, this is a provision ruling the management of waste or the management of material/articles which have exited the waste status, which is not in scope of this Regulation. Or, at least, it is disproportionate, as does not serve the purpose of the regulation as the label does neither decontaminate nor increase FCM compliance.
Art 5(5) Restrictions and specifications in labelling	This requirement is already included in the declaration of compliance. Can the Commission explain why it is repeated in this Regulation?
Art 6 Requirements for collection and pre-processing	This lays down rules for waste collection, changing actual practices and affecting the existing collection and sorting scheme. These provisions are out of scope of 1935/2004 from which 10/2011 is derived and from which 282/2008 has been drafted. Especially by *specifying (c) the plastic waste is subject to separate collection,* the Regulatory Impact assessment with WFD and PPWD has not been performed leading to inconsistencies and implementation, changing the scope of the regulation. In addition, for household packaging, what implementation of traceability should be done in Countries that mixes packaging (e.g. France in the "yellow bin")?
Art 6(1)(a) and (b) : Waste management operators that participate in the supply chain of plastic input shall ensure that the collected plastic waste meets the following requirements: (a) the plastic waste originates only from municipal waste, or from food retail or other food businesses if it was only intended and used for contact with food, (b) the plastic waste originates only from plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011 or	How can this be guaranteed for example for coloured PET bottles for non-food use? In the development of colour and additive masterbatches for non-food, the requirements from 10/2011 are often not taken in consideration. How Article 6(1)(b) ties with the 5% rule set in Annex 1?

recycled plastic materials and articles manufactured in accordance with this Regulation	
(d) the presence of plastic materials and articles that are different from the plastic for which the decontamination process is intended, including caps, labels and adhesives, other materials and substances, and remaining food is reduced to a level specified in the requirements for the plastic input provided by the recycler and which shall not compromise the achieved level of decontamination.	The level of non-plastic materials is provided by the recycling technology rather than the recycler. The recycler can only communicate such an information
Art 6(2)(b)(i) the collection system does not collect waste likely to contain hazardous substances;	The sentence sets an obligation that cannot be verified. Moreover, the word "likely" suggests the obligation may or may not apply. Overall, the sentence is very weak and of doubtful use. What is the definition of "dangerous"? How does this tie with REACH or CLP? Where household packaging is all collected in the same bin (e.g. detergents containers with food grade plastics), how this can be implemented? How traceability ensured?
Art 6(3)(b) be certified by an independent party	We do not believe that a binding regulatory measure can mandate for obligations that are operated by private businesses. Will the existing certifications still be valid? If so, what level of certification? What periodicity?
Article 7 Requirements for decontamination 1. The plastic input and output of the applied decontamination process shall meet the specifications set out in column 3, 5, and 6 of table 1 of Annex I for the relevant recycling technology and, as applicable, the specific criteria set out in the authorisation	Is the plastic input defined as post-consumer plastic waste coming from bales, or after removal (manual or automatic) of non-food items?

Art. 7(3)(a) The decontamination installation shall meet the following requirements: (a) it is located at a single recycling facility, which is organised so as to ensure that no new contamination of recycled plastic or recycled plastic materials and articles can occur;	We do not see any reason related to the efficiency of the decontamination or safety of the finished products for which the decontamination installation shall be located in a single recycling facility, as long as storage and transportation of , e.g., PET pellets are operated under GMP
Art 8(2) 2. Food business operators shall use recycled plastic materials and articles in accordance with the instructions received in accordance with Article 5(5). *They shall communicate relevant instructions to consumers of food packed in such materials and articles, and/or to other food business operators, where relevant*	Is it the information the same than those provided for in Annex III section 3, e.g. "do not use in microwave"? If so, it would be worth making reference to such Annex here
Art 9 Requirements for the operation of recycling schemes *Art 9(1)A single legal entity shall act as the manager of a recycling scheme, and shall be*	Is the term "recycling scheme" referred to closed loops only, or covers other systems? In the former case, why not just using the term "closed loop"? In the latter case: which other schemes are covered? It is necessary to define the boundaries of the recycling scheme. For example, if the plastic to be recycled is collected by a retailer in several Countries across the EU (and maybe outside the EU), how it can be that one single legal entity outside the retailing company is deemed responsible for the whole scheme? (This would also apply if the retailer is the responsible legal entity, but converting is made in different locations). This provision in general does not fit the rules of chain of custody in genuine business on material, for which the recycling of waste may occur in one MS and the decontamination is carried out by another legal entity, which is based in a different MS. What happens if one of the scheme's stakeholders withdraws, and it is replaced by another equivalent (e.g. changing the converting company, or modifying the sales point of a retailer where the plastic to be recycled is

responsible for the overall functioning of the recycling scheme.	collected): will this lead to a new notification? Will the scheme allow a single function (e.g. providing plastics to be recycled to the scheme) be performed by more than one stakeholder? And if so, what happens if one of these stakeholders withdraws, or a new one enters the scheme: will this imply new notifications?
Art 9(4) A waste collection system shall be part of a recycling scheme	This means that the responsible body for the recycling process must also take responsibility for the waste management and waste collection, which can be considered out of scope of the Regulation Unclear what it is intended by waste collection.
Art 9(5) All materials and articles used subject to a recycling scheme shall bear a marking registered in the Union register established in Article 24. That marking shall be clearly visible, indelible and unique to the recycling scheme.	This provision seems to say that every individual article in a waste stream should be marked with a marking for further recycling, hence it seems to imply the inclusion to shredded flakes which also will have to be marked individually. This is unapplicable and unpractical.
Art 9(6) ...marking ...(a) they are labelled, used and cleaned in accordance with instructions obtained from the manager of the recycling scheme; *(b) they are used only for the purpose of distribution, storage, display and sale of the foods which they are intended for;* *(c) they are not contaminated with materials or substances other than those permitted by the recycling scheme.*	This means that the producer of an article must know for which application the article will be used. This information is not necessarily disclosed by the customer who may however demand technical specifications to the supplier, manufacturing FCM material with or without its own decontamination process. In particular. For Art 9(6)(c), how will the food business ensure that materials are not contaminated with materials or substances other than those permitted by the recycling scheme? This needs to be addressed in specific guidelines (if ever possible).
Art 9(9)(b)	Which criteria a business operator should meet in order to qualify as a "small food business operator"?
Art 10 Requirements for the development of a novel technology *Art. 10(1)Several developers may independently develop novel technologies at the same time ... a single legal entity shall represent these operators or organisations.*	This provision clearly stands against the principle of competitive innovation and may be considered as unfair competition or illegal trade agreement.

Art. 10(2): at least four months prior…	Does this mean that business operators placing in the market A/B/A structures with functional barrier have to inform the authorities four months prior placing them in the market? What happens with the structures already existing in the market?
Art 10(2) Uniform Resource Locator (URL) locating the report to be published in accordance with Article 13(3)	See comments to Article 13(3) and 13(4).
Art10(2): Art 4(2)(b)	Art. 4(2)(b) does not exist
Art 12 (3)(c) information on estimated residual incidental contamination present in the output of the decontamination process taking the decontamination efficiency into account, including that of potentially remaining genotoxic and endocrine disrupting substances and substances referred to in Article 13(4)(a) of Regulation (EU) No 10/2011, even if their occurrence is below the limit of their detection of the applied analytical techniques	Residual incidental contamination that falls below the detection limit cannot (by definition) be detected, therefore no information can be provided on it. The requirement is inapplicable and, as such, lacks of legal certainty and places unacceptable liabilities on manufacturers.
Art 13 Monitoring and reporting of the contamination level	Which methods and analytical tools should be used? Which contaminants should be monitored (volatile, non-volatile, inorganic)? How does this tie with NIAS? This article is hardly applicable unless and until harmonised methods to compare results are developed. Use of several different approaches by each supplier (different tools, different analytical conditions) would inevitably lead to confusion Does the Commission have intention to require the EURL to develop methods and analytical guidelines?
Art. 13 A recycler operating a decontamination installation in accordance with Article 11 shall monitor the average contaminant level by sampling each batch of plastic input and the corresponding decontaminated output batch.	In the PET sheet industry, a batch could consist of a few kg of material; how can one perform a monitoring process input/output on such small scale? There should be a minimum size of the sample which would trigger the monitoring (regardless whether composed by one or more batches)

Art 13(2) 2. Recyclers shall provide the developer at least every six months with the data forthcoming from the monitoring and their updated reasoning in accordance with Article 12 (3)(f) if that has changed on the basis of the data	For existing technologies that did not fit into the scope, will it be possible to use historical/existing data?
Art 13(3)(d) fate of contamination	The requirement is unclear, in particular in relation to the expectation of the Commission on this provision on who should be in charge of this stage. The provision seems to imply that someone in the recycling chain should investigate where the contaminants end up. This requirement is inapplicable.
Art. 13(3) and 13(4)	The article violates the purpose of the Regulation no. 1935/2004, which does not deal with public information or building of consumers' trust, and mandates for disclosure of confidential business information, jeopardizing competitiveness
Art 14	The lead time for introduction of a new technology is very wide, from minimum 2 to maximum 7 years. With this lead time it will be more convenient for investors to develop new technologies outside the EU. This should be reduced to avoid impact on competitiveness of the European industry
Art 14.1. When the Commission considers there is sufficient data available on a novel technology, it may on its own initiative request the Authority to assess that technology, ...	It is not clear when "sufficient data" are reached, in particular what principles and criteria would govern the Commission's consideration. This paragraph leads to legal uncertainty. Businesses investing resources in developing new technologies shall have the certainty that the technology is evaluated in a well-defined timeframe, therefore the Commission should be bound to request EFSA an assessment within a defined period
Art 14(2)	What happens if the Commission does not respect the deadline? The article should include the right of applicant to act legally to protect its investments
Art 14(3) The Authority shall assess the suitability of the decontamination technology that the novel technology applies taking into account the recycling technology as a whole.	This means that the Authority will assess waste management, waste collection, recycling scheme, public authorities etc... in the process, while the purpose of the assessment should be limited to ensure decontamination requirements for FCM. Moreover, in the case of a decontamination of a waste, the Authority will assess the principle of final recovery as defined in WFD, leading to an automatic End of Waste for which the Authority has no mandate. The Authority will most likely exceed its mandate, rendering the assessment unfeasible.

Art. 15 Decision on the suitability of a novel technology	The article misses the fact a decision may be challenge. A procedure for an administrative appeal on this decision must be described as regulatory best practices (similar to Article 19).
Art 15(1) other legitimate factors	This is unclear; please make examples of which factors other than safety the Commission intends to adopt in its decision on compliance of the technology.
Art 16(1) … even if the technology has been considered suitable	The way this provision is formulated appears vague: there must be compelling evidence that the technology is unsuitable, otherwise the paragraph is open to respond perception issues.
Art 16(2) when necessary, the Commission may consult the Authority	The change of the conditions for placing on the markets should be based on evidence of risks, therefore the Commission should be bound to consult EFSA.
Art. 16 (3) The Commission may specify deadlines before which those actors shall provide the required information or reports	For such request, deadlines must be specified in the text and not left for interpretation.
Art. 17 To obtain authorisation of an individual recycling process, the natural person or legal entity that developed the decontamination process of the recycling process, either exclusively for its own purposes as a recycler or for the sale or licensing of recycling or decontamination installations to recyclers, 'the applicant', shall submit an application in accordance with paragraph 2	It is not clear up to which extent the authorized technology can be modified by the process holder without the process become eligible for authorization. Who is responsible to decide when the recycling process needs authorization? This ambiguity is not resolved in the whole draft Regulation and the consequence can be that the same technology can originate several different processes that have different cleaning efficiency.
Art. 18 The Authority shall publish an opinion within a time limit of six months...	The issue of publishing an opinion is today issue; which actions the Commission intends to adopt to shorten the time of publication of the Decisions? The draft does not specify what happens if the Authority fails to publish the opinion within the timeframe
Art. 19 Authorisation of an individual recycling process	The article misses the fact a decision may be challenged. A procedure for an administrative appeal on this decision should be described as regulatory best practices as in Article 15. What about recycling processes that have already obtained a positive opinion by EFSA, will they continue to be allowed?

Art.20 (1) (2) The Authority shall publish detailed guidelines, following the agreement with the Commission, concerning the preparation and the submission of the application	These guidelines should be published before or at the same time of the entry into force of the Regulation, to avoid disruptions in the application process
Art 21 The granting of an authorisation of a recycling process shall not affect the civil and criminal liability of any business operator in respect of the authorised recycling process,	We request more clarification: under which legal basis can this article apply? A procedure for appeal should at the minimum be provided.
Art 21(5) The authorisation holder shall immediately inform the competent authority in the territory where it is established and the Commission of a situation under which it can or will no longer assume its responsibilities as authorisation holder	We need to understand what happens to the recyclers to whom the technology has been licensed, if the authorization holders run out of business. Is the registration sufficient to continue to use the technology?
Art 22 request for the modification of an authorization by the authorization holder	Up to which extent a recycler can modify the technology before it becomes eligible for a modification of the authorization? What happens if the authorization holder does not want to request the modification operated by the user of the technology? Is the recycler allowed to require such modification, and in that case, does the technology qualifies for a novel technology?
Art 26(3) If the competent authority does not inform the Commission that compliance is established within one year from the start date of the production of recycled plastic in the decontamination installation, the status of the registration in accordance with Article 24(2), point (g), shall be changed to 'suspended'	The whole FCM control system suffers from lack of resources from control authorities, we think that it is not fair linking the suspension of a recycling process (with implications on investments and jobs) on actions that do not depend on the recyclers. The suspension may only come from clear and controlled non-compliance rather than lack of actions from authorities. What happens if a Member State defaults or delays?
Art. 27 Official controls of recycling installations	Who is handling the controls, with what powers? This article lacks precision and seems to be unapplicable as such. The controls should be organised according to a specific scheme and by competent bodies recognised either at EU level or at MS level.
Art 29 Declaration of compliance	See comments to "whereas" (22)

	Recyclers should confirm compliance of each batch or delivery, but there is no need to provide a long "declaration of compliance" with each delivery, as processes under control deliver the same quality of the recyclate. The delivery documentation must identify the material and the batch numbers and confirm that the specifications are fulfilled, including compliance. This is normal practice in industry. The declarations are often generated automatically, without physical signature, which goes against the modern computer-based paperless practices. A continuous issuing of declarations of compliance represent a heavy burden for recyclers, and no benefit for the converters. If a new version of the DoC is provided for each shipment the converter would need to check for "hidden" changes each time, while the recycler should be obliged to actively inform and alert the converter that a change occurred, by issuing an updated DoC when a change occurs. There should be a requirement that recyclers and converters (supplier and customer) should agree on a specification and that any deviation from the specification must be alerted to the converter. Typically the specification would include food contact compliance, labelling, recyclate content as well as other aspects like pellet size, colour, packaging etc. The advantage of having an agreed specification is that it would make the supplier liable for deviations also under commercial law. Such arrangements are common in industry operating under ISO 9001. DG SANCO's idea of providing complicated DoCs with (usually) the same content with each delivery does not help. The person checking the DoC is liable to oversee changes "snuck in" after the 100th delivery. It's better to update the DoC only when the content changes and confirm compliance with the current DoC for each delivery.
Art. 30	The regulation has no transitional period. The transitional period should be at least 12 month longer that the period required by the Commission to deliver the authorization under the Regulation
Annex I and Annex II	This Annexes can be seen a guidance for the application of the Regulation. We believe that the Commission may consider the publication of them in a separate Guidance, rather than introducing into the Regulations. This would allow easier adaptations and modifications in the future.
Annex I – Table 1	There is not a definition of *closed loop*, there should be one in the main body of the Regulation.

	On the specification of input stream for mechanical recycling, the maximum 5% not used in contact with food is calculated on post-consumer waste bales or on the shredded input to decontamination? If chemical recycling is considered a "suitable technology" it should be inserted in this Annex Also, it should be clarified whether the Commission expects that functional barriers in A/B/A structures are listed under Table 1. We have already expressed our opinion that these structures should continue to be regulated under Reg. 10/2011
Annex I Table 3: Detailed description of the decontamination technology- 3.1 Mechanical recycling	The definition of mechanical recycling usually refers to operations that aim to recover plastics via mechanical processes (grinding, washing, separating, drying, re-granulating and compounding), thus producing recyclates that can be converted into plastics products, substituting virgin plastics. This is a wider definition that those referred in point 3.1, which should be better referred a "decontamination through mechanical recycling" instead. Moreover, 3.1 refers to "molecular weight not decreased": this is in general not true as some change, possibly decrease, of molecular weight may occur, although not compromising the properties of the polymer. A black-and-white definition in the text of the regulation will imply that even a small and insignificant decrease of the mol. weight would exclude polymers from the definition. Moreover, a definition of mechanical recycling, should be better addressed in the main body of the Regulation rather than in the Annex
Annex I Table 3- 3.2 closed loop	Closed loop are not limited to food distribution chain or catering services, there are also closed loop where plastics are recovered from scraps of industrial premises, recycled and then sold again to industrial premises, or in food contact applications outside the loop. These systems should be included. Moreover, the language adopted in this definition can be interpreted as plastics recycled in closed loop cannot be sold in applications outside the closed loop (exiting the loop). This should be allowed instead. If scraps and offcuts fall in the scope of this Regulation, shouldn't closed loop also cover processes to make scraps and offcuts usable?
Annex I table 4.1 (b) and (c)	*Re-use* is not in the scope of this Regulation, therefore these points should be deleted.
Annex I Table 4.1 (f)	Please provide a definition of "*degeneration products*".

Annex III- A template for the declaration of compliance	We find the form for the declaration of compliance very complex. Moreover, requiring a DoC for each batch represent an extremely heavy administrative burden, and it is not technically justified by recycling processes that are in control and deliver products with constant quality. Declarations of Compliance should be issued for each product containing recyclate (plastic, material or article) but not for each individual delivery thereof. DoCs are to be updated when changes occur or on customer request. A DoC for a recycled plastic product must comply with all DoC requirements in (EU) 10/2011 Delivery documents should confirm that the current DoC applies. Section 2.2: please explain the reason why the converter should have access to the QC data other than those agreed with the supplier. What is the benefit? This section, in addition, is not about compliance, and should be placed in the specifications document rather than in the DoC. Section 3.1: the requirement is unclear. The only reasonable requirement should consist in the max quantity, if different from 100%, of recycled plastic that should be used by the converter to meet potential restrictions set in the authorization (if they exist). Section3.2: this is not applicable as the recycler does not have information on the final application.
Annex III - B template for the declaration of compliance	If the material contains only recycled plastics how can there be any additions of substances with SMLs and how can the recycled plastic be equal to 100%? What is 1.3.4. Reg. Number? RIN is not needed, as Supplier of supplier is normally Confidential business information Traceability should be one-up one-down. The only batch number needed is the batch number of the delivery included in the delivery document. 2.1.5 is likely not needed because the converter must already confirm (EC) 1935/2004. 2.1.6 is likely not needed because the converter must already confirm (EU) 10/2011 The information in section 3 is important and should be included in a DoC, but the tabular form shown here is not adequate to cover all the information that customers typically need to use a food contact material properly.

	For example, the time and temperature may depend on the food type. Customers need to know if they must conduct tests and if so, for which substances.