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| **Ref.** | **Date/Name/Org.** | **Comments** |
| **796** | **Date/Time:** 2020/09/01 18:45  **Type:**  BehalfOfAnOrganisation  **Org. type:**  National NGO  **Org. name:**  LandesSportBund Niedersachsen e.V.  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  Mit Blick auf das Infill-Material von Kunstrasenplätzen ist OPTION B unter gesamtheitlicher Berücksichtigung von ökonomischen, sozialen und ökologischen Gesichtspunkten aus Sicht des LSB Niedersachsen die ausgewogenste und nachhaltigste Variante.  Folgende Argumente sehen wir dabei als zentral an:  • OPTION B reduziert die hohe Komplexität sowie die Unsicherheit für Sportvereine und -verbände und Kommunen und ist daher die sportorganisationsfreundlichste Variante.  • Sie weist einen ausreichend langen Übergangszeitraum auf, der allen Betroffenen (Sportanlagenbetreiber und -nutzer, Kunststoffrasenindustrie) die Möglichkeit gibt, sich auf die kommenden neuen Bedingungen einzustellen.  • Bereits heute werden in Deutschland Kunststoffrasenplätze entsprechend den durch OPTION B erst in der Zukunft eintretenden Bedingungen (ausschließliche Verwendung nicht-synthetischer Füllstoffe) gebaut und betrieben.  • OPTION B erfordert während des Übergangszeitraums keine ungeplanten Investitionen in bestehende Kunststoffrasenplätze.  • Sie vermeidet Vorgaben für kostenintensive Risikomanagementmaßnahmen (RMMs).  • OPTION B verringert die Anzahl von Kunststoffrasenplätzen, die nach Auslaufen der Übergangsfrist mit neuen Bedingungen umgehen müssen, auf eine minimale Menge. |
| **Specific information 1:**  Zu 1b.  • Ja, am Ende der sechsjährigen Übergangszeit werden ausreichend viele alternative Kunststoffrasensysteme zur Verfügung stehen, die ohne Füllstoff (der der Definition von Mikroplastik entspricht) sportfunktional tauglich sind. Bereits jetzt werden in Deutschland fast ausschließlich Kunstrasenplätze ohne polymere Füllstoffe gebaut.  • In Deutschland müssen keine Kunstrasensysteme vor dem Ende ihrer erwarteten Lebensdauer ersetzt werden. Die Nachfüllung nach Eintreten des Inverkehrbringungsverbots kann bei bestehenden Kunststoffrasenplätzen bis zum Ende der Lebensdauer durch Bestände des bisherigen Füllstoffs sowie durch ersatzweise Nachfüllung mit alternativen Füllstoffen (u.a. auch Quarzsand) erfolgen.  • Zum Punkt, ob „Kunststoffrasensysteme in Hallen anders behandelt werden sollten als Kunstrasensysteme im Freien?“ liegen dem LSB Niedersachsen keine Informationen vor.  Zu 1c.  Die OPTION C verursacht kurzfristig nicht-budgetierte Kosten (für einfache Risikomanagementmaßnahmen) und mittelfristig hohe, ebenfalls nicht-budgetierte Kosten (für anspruchsvolle Risikomanagementmaßnahmen) für Sportanlagenbetreiber. Es wird daher eine Beeinträchtigung der begrenzten Handlungs- und Finanzierungsmöglichkeiten von Vereinen und Kommunen erwartet. Sie sieht ferner faktisch keine Übergangszeiträume vor.  Fazit: OPTION C stellt keine sportorganisationsfreundliche Alternative zu den OPTIONEN A und insbesondere B dar. |
| **SEAC Rapporteurs response:**  Vielen Dank für Ihre Kommentare.  Diese erfordern keine Änderung der SEAC Stellungnahme. |
| **797** | **Date/Time:** 2020/09/01 18:50  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  It is well accepted that a widespread distribution of microplastics is detrimental to the environment and the human and animal health.  Nevertheless there are a lot of technical applications which provide a huge benefit for health, safety, saving resources and energy where the exposure and the end-of-life conditions are efficiently controlled.  Furthermore, it needs to be pointed out that Non-European suppliers should not gain competitive advantages because they need not to follow the new regulations and neither industry nor the authorities are able to prove that they use materials which are restricted within the EU. |
| **Specific information 2:**  A general transition period of at least 10 years shall be foreseen for all polymers covered by the catch-all clause in paragraph 6 because industrial and professional users (in particular SME's) are very often not aware about the microplastics restriction. In many cases they do not even know that such microplastic materials are present in the products they purchase. A restriction could result in severe performance, quality and safety losses and could even jeopardise the business of such downstream users. After entry into force of the new regulation they need to seek for alternative materials for products they already used since decades.  Furthermore, polymers proven to have no adverse effects to human health should be exempted (e.g. PTFE)  Furthermore the use of such microplastic containing materials should also be exempted for professional users (e.g. maintenance tasks) |
| **Specific information 6:**  The reporting requirements for derogated microplastics are not feasible. These requirements present a high burden in particular for SME's and it is very doubtful that those companies will receive the information about the presence and the identity of the microplastics from the supply chain. It would be sufficient that the EU manufacturer or importer reports the overall volumes. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  The information contained in your submission does not seem to warrant a change to the opinion. |
| **798** | **Date/Time:** 2020/09/01 18:55  **Type:**  BehalfOfAnOrganisation  **Org. type:**  National NGO  **Org. name:**  NABU (Naturschutzbund Deutschland) e.V.  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  Founded in 1899, NABU (Nature And Biodiversity Conservation Union), is one of the oldest and largest environment associations in Germany. The association encompasses more than 770,000 members and sponsors, who commit themselves to the conservation of threatened habitats, flora and fauna, to climate protection and energy policy. NABU's main objectives are the preservation of habitats and biodiversity, the promotion of sustainability in agriculture, forest management and water supply and distribution, as well as to enhance the significance of nature conservation in our society. For several years, NABU has been working on the issue of microplastics and its ecological and social implications. In 2018, NABU published a study on microplastics and synthetic polymers in cosmetic products, laundry detergents and cleaning agents, conducted by the research institute Fraunhofer UMSICHT. In 2020 NABU will publish a new study on (mikro)plastic emissions in agricultural environments.  NABU strongly supports the current regulation process on the restriction of intentionally added microplastics. The releases of intentionally added microplastics pose a risk to the environment that is not adequately controlled and thus justify a restriction under EU regulation. However, further adjustments (related to lower size limit, regulation of sport pitches, criteria on biodegradability, stronger reporting requirements, shorter transitional periods) have to be made in order to ensure that the restriction actually reduces emissions of microplastics to the environment and minimises risks for human lives in the best way possible. |
| **Specific information 1:**  a) Biodegradability  NABU supports a distinction between persistent and (easily) biodegradable polymers in general, as the persistence of a substance is crucial for its environmental impact. But as ECHA itself states in the annex to the proposal (Annex to the Annex XV Restriction Report, B.1.2.1.): “There are no international standardised higher tier test targeted for determining the half-life of plastics in different environmental compartments (freshwater, marine environment, soil or sediment).” As the restriction proposal targets the reduction of microplastics in all these different environmental compartments as freshwater, marine environment, soil or sediment, it is not comprehensible why ECHA proposes such a broad derogation for so called biodegradable microplastics. As long as there are no reliable and standardised test methods including the marine environment, every application or product group must be reviewed separately: Which environment(s) do the microplastics in the specific application or product group pass or end up in? Is a reliable standard of biodegradability available that complies with the specific environmental compartment(s) the microplastics pass or end up in? Does the polymer biodegrade fast enough? Is it guaranteed that the polymer fully biodegrades (100%) in the required time period and under “real life” conditions? Are additives and their toxicity taken into account? Etc.  NABU therefore proposes to formulate – considering the locations of release and changing environments – specific exemptions for application or product groups instead of a general derogation for biodegradable polymers as suggested in the ECHA’s first proposal.  b) Sports pitches  NABU considers the restriction of the use of microplastics in synthetic turfs as a necessary measure to reduce the emission of microplastics into the environment. For Germany, sport pitches are estimated to be the 5th biggest source of microplastics emissions (Fraunhofer UMSICHT 2018).The regulation should cover all different types of synthetic turfs, i.e. not only football pitches as the most prominent example but also tennis courts, equestrian facilities, etc.  Since user instruction and technical measure cannot fully prevent emissions, microplastic infills should be fully replaced by non-plastic alternatives, i.e. mineral or organic materials (e.g. sand, cork), both on existing sites (after a transition period) and on planned sites. For the time of the transition period, physical barriers can avoid emissions.  Regarding alternative materials, cork, besides its biodegradability, is an environmental- and climate-friendly material. The careful use of cork oaks is the guarantee for the preservation of centuries-old cultural landscapes. In addition to the cork production, they are important as pasture and arable land, for hunting and firewood extraction and as a unique habitat for a variety of endangered animals and plants. At the same time, they are an indispensable basis of life and economy for the people of the region. In this sustainable system, cork oaks are not only a supplier of raw materials, they also protect the soil from erosion, increase rainwater harvesting and store carbon dioxide, especially when they renew their bark.  Besides cork, other materials should be taken into account. The use of natural grass needs to become an alternative to synthetic turf again. Objections against natural grass concerning maintenance and time of availability need to be re-evaluated. The same applies for ecological benefits of natural grass, e.g. sealing of soils, compared to synthetic turf.  c) ---  d) Lower size limit  Polymer nanoparticles <100nm pose a particular threat as they are more easily absorbed by living cells. In order to minimise this threat, nanoplastics must be included in the ECHA regulation, since a specific EU wide ban on nanoplastics does not exist. Therefore, NABU supports the RAC position that a lower size limit for microplastics is not appropriate – both from a risk and an enforcement perspective. Including all polymer nano- and microparticles in the scope of the regulation provides clear guidelines for companies, prevents discussions on analytical barriers to measure the size of particles and fibres, and minimises the risk of substituting microplastics with nanoplastics in order to avoid regulation. The fact that industry has been strongly pushing for omitting polymer particles <100nm shows that companies might simply replace microplastics >100nm with nanoplastics causing continued or even worse environmental pollution and health threats to human and other living beings.  e) --- |
| **Specific information 4:**  Calculations by the EEB (2020) show that no relevant decrease in microplastics emissions would be achieved within the first five years after EiF as a consequence of the too long transitional periods. Due to their ability to persist and accumulate in the environment, the release of microplastics should be minimised without any further unnecessary delay. The precautionary principle has to be the guiding principle for the definition of transitional periods. |
| **Specific information 6:**  Current barriers for the transition towards a circular economy of plastics show that full transparency of the quantity and quality of plastics used is key for creating high-grade material cycles and avoiding downcycling, incineration and disposal. The same applies for the regulation of microplastics where comprehensive reporting is needed in order to be able to follow and minimise microplastic emissions and to ensure full biodegradability of microplastics emitted according to appropriate certification standards if the use of microplastics is really required. Therefore, the ECHA regulation should set reporting requirements according to which companies need to, within 12 months after the entry into force of the restriction, sent the identity of the polymer(s) used in the previous year, a description of the use of the microplastic, the quantity of microplastics used in the previous year, and the quantity of microplastics released to the environment. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  SEAC rapporteurs cannot comment on issues within RAC’s remit.  We refer to the final opinion for SEAC’s nuanced view on the lower size limit.  The other information contained in your submission does not seem to warrant a change to the opinion. |
| **799** | **Date/Time:** 2020/09/01 18:58  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Business Machine and Information System Industries Association  **Org. country:**  Japan | **Comments on the SEAC draft opinion:**  Instructions for use and reporting measures as such do not directly support the ultimate goal of having less intentionally added and released primary microplastics controlled. Especially the reporting obligation will represent a significant economic burden to industry while the expected benefits are seen as questionable. Therefore, we urge the Committees to avoid and hence recommend removing this measurement from the REACH restriction proposal.  The initial and fundamental objective of the proposal has been to restrict intentionally added and released microplastics. As toner is not intended to release microplastics we appreciate to have these applications not addressed by the ban measurement. However, for any of this use cases the other two regulatory measures are currently proposed. As none of this use cases are designed to release microplastics into the environment, we are asking the committee to completely exclude toner from all three regulatory measures.  If the commission cannot accept above our comments, we propose following compromise resolution.  1. It should be allowed for representatives including OR and manufacturers outside of EU, on behalf of downstream users, to send to ECHA in the format required by Article 111 of REACH for the reporting of overseas businesses that do not have a base in EU.  2. The lowest limit for the reporting information on uses and releases of microplastics should be provided.  Reason: The target of the report is products that do not have the intentional environmental release of microplastics that are not forbidden to sell, and the amount of environmental release is expected to be extremely small compared to the amount used. The target of the report should be a cutoff value, for example, a usage amount of 10t/year or more.  3. The due date for the reporting should be changed from "by 31 January" to "by 30 June" because of the following reasons:  The reasons:  When many products contain many microplastics to be reported, it is difficult to complete the reporting to ECHA by the end of January. Similar to these requirements proposed in EU, Chemical Data Reporting (CDR) of the United States is mentioned as an example of another country requesting a report on a wide variety of substances, but the CDR reporting due date is the end of September. |
| **Specific information 5:**  Toner products should be removed from the scope of provision of relevant ‘instructions for use and disposal’.  Our toners are not classified as hazardous classifications so generally there is no change in labels after launch. If the toner products are needed to change the labelling, the manufactures need the additional cost for this changing.  There is no environmental emission of microplastics (=toners) under the normal use condition of machines and there is already a mechanism in which toner remaining in used cartridges is retrieved and properly processed so we strongly believe that there is extremely low possibility that users dispose used toner cartridges to the environment. Therefore, there is no benefit of reduction of environmental emission by proposed labelling. |
| **Specific information 6:**  Toner products should be removed from the scope of reporting information on uses and releases of microplastics because of the environmental emission is extremely low level.  If the commission cannot accept, we propose following compromise resolution described in General comment section.  1. It should be allowed for representatives including OR and manufacturers outside of EU, on behalf of downstream users, to send to ECHA in the format required by Article 111 of REACH for the reporting of overseas businesses that do not have a base in EU.  2. The lowest limit for the reporting information on uses and releases of microplastics should be provided.  Reason: There are many suppliers in the EU region, and we think that it is unreasonable to understand all of them, including the suppliers whose amounts of all microplastics are close to zero. As with EU-REACH registration, it should be set to 1 ton. For example, in the case of toner products, there is no environmental emission of toners (=microplastics) under the normal use condition of machines and there is already a mechanism in which toner remaining in used cartridges is retrieved and properly processed so we strongly believe that there is extremely low possibility that users dispose used toner cartridges to the environment.  3. The due date for the reporting should be changed from "by 31 January" to "by 30 June" because of the following reasons:  The reasons:  When many products contain many microplastics to be reported, it is difficult to complete the reporting to ECHA by the end of January. Similar to these requirements proposed in EU, Chemical Data Reporting (CDR) of the United States is mentioned as an example of another country requesting a report on a wide variety of substances, but the CDR reporting due date is the end of September. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  For the objectives of instructions for use and disposal and reporting, please refer to the SEAC opinion and the Background Document (B 2.2.1.4 and B 2.2.1.5). The options you are raising are also discussed there.  The information contained in your submission does not seem to warrant a change to the opinion. |
| **800** | **Date/Time:** 2020/09/01 19:06  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Finland  **Company name confidential: Yes**  **Attachment:**  <redacted>  **Privacy comment:**  To protect new product development and commercial interest | **Comments on the SEAC draft opinion:**  Proposal to restrict “intentionally added microplastics” has supportable intentions, but it has several concerns that require attention and as such, the proposal should not be accepted in its current state.  The scope of the restriction is wide and unclear. With no numerical identifiers, covering all solid “polymers within the meaning of Article 3(5) of Regulation (EC) No1907/2006”, the proposal creates ambiguity to which restricted substances are under the scope which in turn adds an unknown amount of substances to Annex XVII. Restriction should be based on certain strictly defined substances and their uses and if there is an unacceptable risk to human health or the environment. Current proposal includes also polymers (often in small concentration), where the risk to human health or the environment is negligible.  We consider that SEAC does not demonstrate their argument when stating “Targeting the placing on the market and use of a substance or mixture is a tried and tested approach in restriction proposals. SEAC notes however that due to the wide targeting of the restriction, certain elements need to be discussed more in-depth.” Neither “polymer” nor “microplastic” can be identified as a substance. Such approach of restricting wide chemical groups with multiple exemptions does not satisfy the concept of legal certainty, which requires that the legal text must be definite and clear. Based on the Committee draft opinions, it seems that the proposed restriction does not meet the aforementioned requirement.  The main error of assessment was made in the definition, when “polymers” were considered nearly equal to the term “microplastic”. SEAC compiles the Dossier Submitters reasoning: “A first important thing to note is that there does not seem to be a consensus on what the term ‘plastic’ means. Since REACH already contains a definition of the term ‘polymer’ and the term ‘plastic’ is deeply connected to it, the Dossier Submitter decided to use REACH Article 3 point 5 (i.e. definition of ‘polymer’) as the basis for the proposed restriction.” (p. 19 of the draft opinion).  This decision of the Dossier Submitters does not recognise the essential differences between “polymers”, “plastics” and “microplastics” which does not accurately define the restriction proposal. While SEAC accepts this decision as “clear, practical and pragmatic approach” (p. 19), there are still legislative shortcomings, the socio-economic impacts are not understood especially when stating that the industry´s previous requirement of listing substances to be restricted, is “very impractical”.  If practicality indeed is accepted to run over legality, then the proposed restriction should be amended accordingly. Such a position would contradict the wording of the REACH Art. 68.1 requesting the Dossier Submitter to address the risk of a “substance”.  ECHA’s chosen approach demonstrates that the current proposal may be extending the restriction process to areas where the legislator did not mean it to be used. The burden of proof to demonstrate unacceptable risk and risk being not adequately controlled, lies within ECHA for each individual substance (REACH Art. 69.1).  By creating new regulatory definitions with such abovementioned deficits and thus creating significant burden for the industry also on those substances which do not pose the risk as the restriction is described to be targeted against, ECHA could be exceeding its authority. |
| **Specific information 1:**  a) It is already clear that the criteria established in Appendix X of the proposal in all environments, although following the OECD guidelines are strict when regarding the relevance on the actual microplastics concern. As plastic-replacing materials are being developed from for example wood-based polymers, these may not pass the biodegradability criteria while still being an evolution towards sustainable future and renewable materials and even as biodegradable as the natural polymer that it is made of, i.e. tackling the same concern of the proposed restriction.​  In practice, the proposed approach will block biodegradable alternatives and development of sustainable substitutes for plastics. If natural materials that are biodegradable in nature, such as banana peel and wood, cannot fulfill the proposed biodegradability criteria, it is obvious, that there are multiple sustainable and non-harmful biobased substances that will be blocked with the proposed criteria. Biodegradation criteria should be amended. Biodegradability test should allow the use of appropriate reference material. In case of chemically modified natural polymers, the reference material should be the closes natural polymer or natural material available. For example, the biodegradation of a product that is made from kraft lignin by chemical modification should be compared to the biodegradation of certain enzymatically extracted lignin grade. In addition, the compost environment be allowed to replace the tests in soil environment in order to gain results in shorter time and to use the limited biodegradability testing facilities more efficiently. The European industry is also indirectly obliged to perform a large number of new studies to identify the targeted substances, especially regarding the complex biodegradability criteria and the lack of existing studies. With the known low availability of laboratory biodegradability testing capacity, this would take years for the industry to have its polymers studied based on the newly established criteria.​  Detailed proposal to amend the restriction text is provided on Annex I of Comment submitted via section IV of ECHA’s comment platform.​ |
| **Specific information 5:**  Both Para. 7 and 8 are applied (also) to industrial downstream users, and this creates disproportionate requirements for these downstream users, when obligated to quantify and identify possible microplastics from substances and mixtures supplied by the manufacturer or importer of the substances and mixtures. The obligation should be targeted to manufacturers and importers. |
| **Specific information 6:**  The reporting obligation (Paragraph 8) is seen as unjustified and disproportionate burden for the industry. The obligation is proposed to be deleted or amended to exclude natural polymers or industrial sites. Industrial sites are under the strict obligations of IED 2010/75/EU, and to avoid double regulation, no additional burden on reporting should be applied. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  It is important to note that polymers are explicitly defined as substances under REACH (article 3, point 5).  SEAC rapporteurs cannot comment in issues that are within RAC’s remit.  The limited information you provided does not warrant the requested change to the opinion. |
| **801** | **Date/Time:** 2020/09/01 19:10  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  European DIY Retail Association (EDRA)  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  The European DIY Retail Association (EDRA) is the voice for the home improvement industry in Europe. It was founded in 2002 by the French (FMB) and German (BHB) DIY retail associations. Today EDRA represents 140 home improvement companies in Europe either through its country associations or as direct members. These members include the top 3 European players by net turnover: ADEO, Kingfisher & OBI as well as 27 of the top 30 players in Europe.  On the proposal:  • EDRA questions that a REACH restriction can be used for such a wide group of non-biodegradable polymers with a criterion on morphology, physico-chemical properties and persistence in the environment.  • EDRA also stresses the need for scientific evidence on the hazards and risks associated with intentionally added microplastics to justify the restriction proposal. In particular, CEFIC is currently working on a project called ‘ECO49” that aims to develop methodologies for assessing environmental risks from microplastics. ECHA should wait for the results of this project and other similar experiences before carrying on with this restriction proposal.    On the scope:  • The scope covers an enormous amount of products and It would virtually cover whoever uses any solid polymer particle by itself or incorporated in any mixture.  • Concerning the lower size limit, EDRA argues that a lower size limit below 100nm would cause serious problems from analytics and technical possibilities. Indeed, the testing methods under 100nm are not reliable today. For this reason, EDRA supports the SEAC’s recommendation to have a lower size limit of 100nm. However, this limit should be a recommendation and not a specification.  • The definition of microplastic considers that all polymers are plastic while it is not the case. Under these conditions non plastic substances fall under the scope of the proposal, which is a problem.  • The definition refers to “solid polymers” and thus does not seem to include the “semi solid polymers” or “soft polymers” which are also synthetic polymers and could also release some micro fragments of plastics. As a consequence, clarity is needed on what is a solid polymer. A an example, are the latexes or encapsulated polymers made of soft plastics covered by the definition?!  • It lacks clear criteria that could help the microplastic users to decide if they are ‘in’ or ‘out’.  • if economic operators want to benefit from the exemption for biodegradable polymers, they have to prove that their polymers are indeed biodegradable by submitting their test results to ECHA. However, we should keep in mind that there are many conflicting methods to assess biodegradability of polymers. So the test results should be interpreted with caution.  On labeling:  • Today, labels bear a lot of information, sometimes even making it difficult for customers to read. For this reason, EDRA recommends that economic operators have the liberty to choose how they want to communicate information on microplastics to customers (e.g. pictograms, online means like QR codes,…). Besides, today most paint labels are already bearing information on how to clean brushes and rollers.  • Regarding paints, the CEPE (paint industry) has already been working on providing information to consumers on how to use paintbrush and rollers in order to avoid pollution (see guidance in attachment).    On reporting:  • EDRA wishes to challenge the reporting obligation as it will only create massive administrative burdens and cost while not providing any evidence for the effectiveness of the ’Use and Disposal’ information :  • Indeed, if for instance over a period of time as a result of the obligation to inform on use and disposal’ the number of consumers /professionals complying with the guidance on paint and roller cleaning would have increased by 20 % and so did reduce the release of microplastics this will not be visible with the reporting figures. As these figures nly indicates the amount of microplastics used (by industrials) or sold (to consumers).  In addition, the reporting obligation will be uneasy to comply with as retailers are facing difficulties to collect information from the upstream actors on their product composition for confidentiality reasons  As a result, this way of reporting does not allow for solid conclusions on the release of microplastics; it only shows the volumes of microplastics used or sold.  • While the core objective of this restriction is to avoid the further accumulation of microplastics in the environment, a regular survey on the behavior of consumers concerning ‘use and disposal’ would give an outcome that would give more insight on the effect of the objective (e.g. does the consumer clean the brush or let it dry and dispose of it?).  • Reporting per polymer identity is inconsistent with this restriction proposal being a restriction of polymers without identity. Reporting the identity would not have any benefit.  • Reporting the quantity of microplastics released to the environment, either estimated or measured in the previous year is impossible for certain products. For instance, it is impossible to know precisely the actual volume of microplastics released via the cleaning of paintbrushes and rollers. If the consumer would always clean the used brush or roller (best-case scenario) and decide not to throw the dried out brush or roller away, the estimates of microplastics release from waterborne paints would be between 150 and 1500 t.p.a.      On implementation and enforcement :  Compliance deadlines should be rethought to avoid waste.    Today, compliance deadlines in many pieces of legislation (e.g. ATPs) are sell through dates, meaning that 18 months after the entry into force, it is no longer possible to make the product available to customers. No doubt, this approach will be used in the microplastics restriction proposal. However, this approach is raising a great deal of problems (see full list below) particularly the waste it generates (both substances and mixtures). Indeed, 18 months is often too short to use up all stocks of a particular item. DIY items have a very slow turn over of products.    For this reason, EDRA supports shifting away from sell through dates and move instead to ‘manufacturing of finished product deadline dates’ or importation dates as deadlines in the microplastics restriction in order to avoid waste.    Our view is that once something has been manufactured in full compliance and complete good faith, that that product should be allowed to be sold through (with the exception of extraordinary safety emergencies) to exhaustion, regardless of regulatory updates.    Other reasons supporting this approach aside from preventing generation of waste:    • Less stress for all – it is a huge and almost impossible administrative burden to ensure sell through especially in a field (i.e. chemicals) that is subject to so many changes.  • Manufacturer is the most important actor in the Chemical Product supply chain; it feels right therefore that they should bear the responsibility of managing these types of changes  • Avoids the absurdity and environmental impact of making changes to products which were perfectly compliant at the time of manufacture  • Save economic operators money and reduces commercial risk – retailers do not control market forces – volatility in the economy can profoundly delay sell through timeframes.  • If sell through forecasts are incorrect or slow down in sales are experienced, then the retailer is in big trouble – why should retailers shoulder this burden?      On timeline:  • Finding alternatives to (releasable) microplastics takes a lot of time. The timeline proposed is too tight for R&D teams to be able to achieve that for certain products (e.g. detergents/maintenance products and fertilisers/plant protection products). Longer transition periods are needed.  • the 24 month transition period for the labelling obligation applying to the paint and construction sectors is way too short as:  - the ‘instruction for use/disposal’ are not clear enough. We need more precision on what they are if they are to be labelled on the product  - Identifying with our suppliers the use of microplastics is huge and requires more time  36 months will provide a more realistic timeframe for economic operators. |
| **Specific information 1:**  a) If economic operators want to benefit from the exemption for biodegradable polymers, they have to prove that their polymers are indeed biodegradable by submitting their test results to ECHA. However, we should keep in mind that there are many conflicting methods to assess biodegradability of polymers. So the test results should be interpreted with caution.  d) Concerning the lower size limit, EDRA argues that a lower size limit below 100nm would cause serious problems from analytics and technical possibilities. Indeed, the testing methods under 100nm are not reliable today. For this reason, EDRA supports the SEAC’s recommendation to have a lower size limit of 100nm. However, this limit should be a recommendation and not a specification. |
| **Specific information 5:**  On timeline  • Finding alternatives to (releasable) microplastics takes a lot of time. The timeline proposed is too tight for R&amp;D teams to be able to achieve that for certain products (e.g. detergents/maintenance products and fertilisers/plant protection products). Longer transition periods are needed.  • the 24 month transition period for the labelling obligation applying to the paint and construction sectors is way too short as&#58;  - the ‘instruction for use/disposal’ are not clear enough. We need more precision on what they are if they are to be labelled on the product  - Identifying with our suppliers the use of microplastics is huge and requires more time  36 months will provide a more realistic timeframe for economic operators. |
| **Specific information 6:**  On reporting:  • EDRA wishes to challenge the reporting obligation as it will only create massive administrative burdens and cost while not providing any evidence for the effectiveness of the ’Use and Disposal’ information :  • Indeed, if for instance over a period of time as a result of the obligation to inform on use and disposal’ the number of consumers /professionals complying with the guidance on paint and roller cleaning would have increased by 20 % and so did reduce the release of microplastics this will not be visible with the reporting figures. As these figures nly indicates the amount of microplastics used (by industrials) or sold (to consumers).  In addition, the reporting obligation will be uneasy to comply with as retailers are facing difficulties to collect information from the upstream actors on their product composition for confidentiality reasons  As a result, this way of reporting does not allow for solid conclusions on the release of microplastics; it only shows the volumes of microplastics used or sold.  • While the core objective of this restriction is to avoid the further accumulation of microplastics in the environment, a regular survey on the behavior of consumers concerning ‘use and disposal’ would give an outcome that would give more insight on the effect of the objective (e.g. does the consumer clean the brush or let it dry and dispose of it?).  • Reporting per polymer identity is inconsistent with this restriction proposal being a restriction of polymers without identity. Reporting the identity would not have any benefit.  • Reporting the quantity of microplastics released to the environment, either estimated or measured in the previous year is impossible for certain products. For instance, it is impossible to know precisely the actual volume of microplastics released via the cleaning of paintbrushes and rollers. If the consumer would always clean the used brush or roller (best-case scenario) and decide not to throw the dried out brush or roller away, the estimates of microplastics release from waterborne paints would be between 150 and 1500 t.p.a. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  The background and the objectives of the restriction are clearly stated in the SEAC opinion and in the Background Document.  SEAC agrees that extensive guidance will be key to the implementation and enforcement of the proposed restriction.  When it comes to the “effectiveness of reporting” the SEAC opinion already clearly states that “*The Committees consider that the proposed reporting requirement is not a measure to monitor the effectiveness of the proposed restriction. Reporting only gives information on (the evolution of) emissions to the environment from uses not covered by the ban, not overall emissions of microplastics. However, it is considered to be relevant in order to assess if additional measures are needed in the future to reduce microplastics emissions that are not addressed with the current proposal*”.  Based on the limited information in your submission the requested changes to the opinion do not seem warranted. |
| **802** | **Date/Time:** 2020/09/01 19:22  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  MedTech Europe  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  MedTech Europe would like to suggest the following text adaptations in regards to entry 4.e - definition of IVDs in Table 4 (Proposed derogations by the Dossier Submitter), as follows:  In vitro diagnostic devices could also be defined as “reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, e.g. body fluids and tissue donations, derived from organisms”.  In vitro diagnostics devices are used by healthcare professionals in hospitals, and laboratories in order to treat patients or improve their health condition. They also provide reliable diagnostic test results. In addition to human health applications (i.e. in vitro diagnostics medical devices covered by Regulation (EU) 2017/746 (IVDR)), IVDs are also used for veterinary health applications (e.g. pet, poultry, livestock, etc.), as well as for preventing and controlling Transboundary Animal Diseases (TADs) at borders, and in the frame of EU and national animal health programmes. IVDs are also used for research and development activities. |
| **Specific information 5:**  In vitro diagnostic medical devices  IVD companies are considering the following instruction for IVD reagents containing microplastics&#58; “This product contains microplastics and as such release to the environment should be minimised where technically and practically feasible.” The word ‘minimise’ would allow customers to adopt the most appropriate and technically feasible solution for waste treatment, adapted to the specific IVD product under consideration.  The Safety Data Sheet is considered the most appropriate place for such a sentence (e.g. Section 13), and the presence of microplastics could also be indicated in Section 3. Changes of the SDS could be easier to implement and require less time than device label changes or changes to the Instructions for Use, which are strictly regulated for IVDs. |
| **Specific information 6:**  In vitro diagnostic medical devices  MedTech Europe does not believe that a general reporting requirement without a threshold limit (e.g. 0,1 t/a) is a proportionate solution, considering the many implications and resources needed, either if the reporting requirement for IVD’s intended to report on:  a) Releases to market (as per wording in Section 4.e, Table 19 of Background Document); or  b) Releases to the environment (as per wording in Paragraph 8, Table 17 of Background Document)  If a) then the reporting will show an increase year on year as demand continues to rise for diagnostic testing in the EU, however will not give any sense of reduction in releases which may have been achieved through voluntary measures. As indicated in the opinions, a recorded increase could lead to regulatory action, however this would not necessarily be based on any increase in emissions.  IVD supply chains are often multi-tiered, and within the current wording each supplier would be required to report releases to market. If a threshold limit were introduced, only the significant contributors would be required to report rather than hundreds, possibly thousands, of suppliers globally.  If b) then accurate reporting will not be technically feasible for suppliers as there are potentially tens of thousands of downstream users (DUs) in the EU, and this would require each one providing annual release data to each supplier based on their own waste treatment processes. This is not feasible for the following reasons:   Many IVD DUs have multiple instruments by multiple suppliers and would need to calculate which releases were related to which supplier, which at best could be only an estimate.   To estimate releases DU’s would need the volume of microplastics supplied to them per annum and determine what portion was captured via solid waste vs wastewater, the only way this could be measured accurately would be through continuous wastewater monitoring. The extremely low volume and size of particles are not even detectable in some cases and monitoring systems on this scale would introduce very high costs across the healthcare systems in the EU.  The above approach would be extremely high maintenance and costly process, which would not be proportionate to the extremely low estimated annual releases from the IVD sector (0.27t/annum). Again, a threshold limit here would reduce the burden but help ensure the significant portion of releases were targeted for estimation.  In case reporting is required even for very small volumes, MedTech Europe would like the restriction to clarify the following questions:   Depending on which scenario applies above, who will be responsible for reporting i.e.  a) Releases to market (as per wording in Section 4.e, Table 19 of Background Document) – would this be the supplier first placing on the market in the EU?  b) Releases to the environment (as per wording in Paragraph 8, Table 17 of Background Document) – we understand, in this case, it is the supplier first placing on the market in the EU?   Who will be responsible for reporting in the case of contract manufacturing? Would it be only the facility that is doing the physical manufacturing and not the company owning the final product?   Increase in sales could also affect the amount of microplastics release. Will the annual reports have a place to explain a change in trend for why emissions are increasing where companies can explain these types of scenarios, and describe what they are doing internally to limit the amount of microplastic release? COVID-19 is a pertinent example, where a new disease causes a surge in demand for products which IVD companies will be striving to support. |
| **SEAC Rapporteurs response:**  Thank you for your comments and the information.  We refer to the revised SEAC opinion as a response.  For clarification: The reporting requirement includes the reporting of releases to the environment, NOT to the market. The supplier, who places the product containing microplastics on the market for the first time, would be responsible for the reporting, NOT the professional user (e.g. hospitals). |
| **803** | **Date/Time:** 2020/09/01 19:24  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Union Française des Semenciers  **Org. country:**  France  **Attachment:** | **Comments on the SEAC draft opinion:**  Des microplastiques sont utilisés dans certains traitements de semences afin de lier les actifs, les additifs et les éléments nutritifs à la graine. Ces polymères peuvent être directement intégrés aux traitements de semences utilisés par les semenciers, mais ils peuvent aussi être ajoutés par les semenciers aux recettes du traitement de semences, c’est que l’on appelle des Agents Technologiques d’Application des Semences (ATAS).  Ils permettent la maitrise des risques d’émission de poussières porteuses de la matière active pendant le traitement, le stockage et le semis des graines. Ils ne sont pas présents dans toutes les solutions, mais régulièrement utilisés. La solution est de les remplacer par des polymères biodégradables. La mise au point d’alternatives est déjà étudiée par de nombreux fournisseurs en lien avec les semenciers. Comme toute transformation, elle demande un temps de recherche et développement. L’Union Française des Semenciers (UFS) souhaite qu’un délai suffisant soit accordé pour que les entreprises aient le temps de développer des solutions innovantes répondant aux objectifs fixés par la Commission Européenne. |
| **SEAC Rapporteurs response:**  Merci pour vos commentaires.  Please also refer to our response to Euroseeds (#527). |
| **804** | **Date/Time:** 2020/09/01 20:06  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Toy Industries of Europe  **Org. country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:**  Disclosure would undermine the protection of commercial interests including intellectual property. | **Comments on the SEAC draft opinion:**  The definitions of “microplastic” and “particles containing solid polymer” appear to possibly include in the scope of the proposed restriction specific mixtures used in toys which may not have been intentionally targeted.  “Kinetic Sand” (further referred to as KNS) sold mainly sold as a toy and is merely a physical mixture of a liquid polymeric binder and sand and each particle has a dimension of less than 5 mm.  We had back and forth exchanges with ECHA on the microplastics proposed restriction, since we are of the opinion that KNS would not be in scope. We were however recommended by ECHA to consider a conservative approach for KNS and to provide input to the consultation on the SEAC draft opinion.    If KNS was finally considered as a “microplastic”, this would, through the proposed restriction, impose a strict ban on its placing on the EU market as soon as the restriction applies.  This would have enormous economic consequences for the EU based manufacturing companies as well as further downstream users such as wholesalers and retailers selling the toy KNS on the EU market. This would also have a deep impact on upstream suppliers of raw materials. It is therefore requested to assess whether KNS should really be regarded as a “microplastic” and if a specific derogation to the proposed restriction shall be considered. |
| **Specific information 2:**  The definitions of “microplastic” and “particles containing solid polymer” appear to possibly include in the scope of the proposed restriction specific mixtures used in toys which may not have been intentionally targeted.  ‘microplastic’ means particles containing solid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 0.1μm ≤ x ≤ 5mm, or (ii), for fibres, a length of 0.3μm ≤ x ≤ 15mm and length to diameter ratio of >3.  ‘particles containing solid polymer’ means either (i) a particle of any composition with a continuous solid polymer surface coating of any thickness or (ii) particles of any composition with a solid polymer content of ≥ 1% w/w.  “Kinetic Sand” (further referred to as KNS) mainly sold as a toy and is merely a physical mixture of a liquid polymeric binder and sand. Each particle has a dimension of less than 5 mm. The EU based manufacturer of the sand with liquid binder, used for the Kinetic Sand branded products indicates that current formulations are protected by multiple patents and has indicated that the polymeric binder is indeed liquid also in the mixture placed on the market and there is no formation/transformation/phase transition/reaction to a solid polymer film/layer during or post production. The polymeric binder in contact with the sand grains is inert and unreactive and remains liquid.  We had back and forth exchanges with ECHA on the microplastics proposed restriction, since we are of the opinion that KNS would not be in scope. We were however recommended by ECHA to consider a conservative approach for KNS and to provide input to the consultation on the SEAC draft opinion.  If KNS was finally considered as a “microplastic”, this would, through the proposed restriction, impose a strict ban on its placing on the EU market as soon as the restriction applies.  This would have enormous economic consequences for the EU based manufacturing companies as well as further downstream users such as wholesalers and retailers selling the toy KNS on the EU market. This would also have a deep impact on upstream suppliers of raw materials. It is therefore requested to assess whether KNS should really be regarded as a “microplastic” and if a specific derogation to the proposed restriction shall be considered. |
| **SEAC Rapporteurs response:**  Thank you for your comment.  Your submission does not contain enough information to assess the possible risk to the environment and also the possible impacts on this application (if it indeed is covered by the scope). |
| **805** | **Date/Time:** 2020/09/01 20:46  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  International Pharmaceutical Excipients Council of the Americas (IPEC-Americas)  **Org. country:**  United States  **Attachment:** | **Comments on the SEAC draft opinion:**  The International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) represents excipient manufacturers, distributors and pharmaceutical/biopharma companies to support the safe production and use of excipients. IPEC-Americas is dedicated to working closely with regulatory authorities, industry organizations and scientific bodies (globally) to advance public health on matters relating to the quality, safety, manufacture, distribution, use and functionality of excipients. IPEC is the sole association representing excipients.  IPEC-Americas supports the comments provided by Cefic, the European Industry Chemical Council - attached below. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We refer to our responses to CEFIC’s submission (#735). |
| **806** | **Date/Time:** 2020/09/01 20:57  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Cosmetics Europe  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  Where relevant, our response to specific information requests is incorporated into our overall response. |
| **Specific information 4:**  see attachment |
| **Specific information 5:**  see attachment |
| **SEAC Rapporteurs response:**  Thank you for your comments.  The issues you raised already have been extensively discussed in the SEAC opinion (B 3.3.1) and in the Background Document (D. 5., please consider section D.5.6 in particular).  In addition, please find our specific responses to the factors you stressed in your contribution below:   1. Number of reformulations: The number of formulations affected by the restriction you provide lies within the range assessed by the Dossier Submitter. In the high cost scenario it is assumed that a much higher number of products will be reformulated than given in your assessment. Therefore, we do not see an underestimation here. With regard to the complexity of reformulation, we consider that it is adequately addressed by the Dossier Submitters approach (please find further details on this issue further below). 2. Availability of suitable alternatives: There is significant evidence that alternatives are available for the majority of functions of microplastics used in cosmetics. In addition to published sources, there were several comments in both consultations confirming this conclusion. SEAC acknowledges in the opinion that there could be a loss in performance when switching to alternatives. A potential loss in performance was also addressed in the high cost scenario of the cost assessment by estimating profit losses. However, we are aware that it is difficult to fully quantify the impact of performance loss. In this regard, available evidence (King & Hunt, 2020) of the WTP of consumers is reflected in the opinion: “*Although the two values cannot easily be aggregated and scaled, the comparison of the two shows that respondents value product performance highly, as expected, although the WTP for reductions in the environmental impacts of personal care products is also substantial*.” 3. Reformulation capacity: We highlight that a possible lack in reformulation capacity was explicitly addressed in the cost assessment in terms of profit losses. As there are uncertainties about the reformulation efforts triggered by the restriction and the resulting socio-economic impact of the transition period proposed for leave-on products, SEAC supports a review of the restriction after entry into force. 4. Impact on SMEs: We consider the net impact on SMEs uncertain. It is likely that there will be significant costs to SMEs, but it is also likely that for competitors who already produce microplastic-free cosmetics there will be significant benefits as well. This issue is also explicitly discussed in the opinion. 5. Competitiveness: Potential impacts on competitiveness are addressed in the Background document already. We consider that the overall impact on the cosmetics sector is too uncertain to draw a robust conclusion to what extent the competitiveness of the cosmetic sector as a whole would be affected by the restriction.   With regard to the average cost per reformulation estimated by the Dossier Submitter (550,000) in the cost assessment, we consider that your argument that the costs estimated by Cosmetics Europe (820,000 €) would be more representative does not hold. As far as we understand, this estimate is based on the upper range of possible reformulation costs derived in the AMEC report, which is based on the RTI study from 2002. As such it was not verified by a survey among your members. For the reasons clearly stated in the opinion we consider this figure to overestimate the average cost per reformulation. The information you provide does not disprove these arguments, therefore there is no basis for SEAC to change its conclusion. |
| **807** | **Date/Time:** 2020/09/01 21:26  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ETRMA - European Tyre & Rubber Manufacturers Association  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  This document is an overview of ETRMA’s responses to paragraphs: 4a, 4h, 5b, 5c, 7, 8 on page 6 of the RAC/SEAC Opinion, Annex XV proposing restrictions on intentionally added microplastics .  Rubber granules and rubber powders are made from the recycling of end-of-life tyres (ELT) and various other rubber goods. They are produced in a range of particle sizes from fine rubber powders and granulates to larger chips and shreds. These materials have different specifications and standards which are often critical to its use.  Only when produced in the size range of microplastics are rubber powders and granulates classified as free particles: as defined in Annex XV. The proposed restriction, as explained in this document, impede the recycling of rubber and interfere with the industry ´s ability to move towards a circular economy. |
| **Specific information 1:**  See document attached |
| **Specific information 2:**  See document attached |
| **Specific information 5:**  See document attached |
| **Specific information 6:**  See document attached |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Several changes have been made to the opinion regarding infill material, to which we therefore refer as a response to your comments. |
| **808** | **Date/Time:** 2020/09/01 21:44  **Type:**  BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  Fauna & Flora International  **Org. country:**  United Kingdom  **Attachment:** | **Comments on the SEAC draft opinion:**  Established in 1903, Fauna & Flora International (FFI) is the world’s oldest international wildlife conservation organisation. Our focus is on protecting biodiversity.  Since 2009 we have worked at the forefront of efforts to halt the avoidable release of microplastics into the marine environment. We worked with industry, government, and partner NGOs as a driving force behind the UK Microbeads Ban; are collaborating on the development of a publicly available standard for the handling of plastic pellets, and working to identify opportunities to limit microplastic fibre loss from the fashion and textile industry supply chain.  We welcome RAC and SEAC’s support for Annex XV dossier proposing European-wide restrictions on intentionally-added microplastics made of any plastic polymer.  However, we have serious concerns on some aspects of the proposal, which will significantly affect its success in addressing the harm caused by microplastic pollution. We highlight some key areas here, as well as in our answers to specific questions.  1. Biodegradability derogation  The exemption of so-called biodegradable plastic is a huge loophole that could undermine the impact of the proposed ECHA restriction. There is no standard to demonstrate biodegradability in the marine environment, under low or no light conditions and cold temperatures, and there are no plastics that have been demonstrated to fully biodegrade under realistic marine conditions. It therefore cannot be assumed that so-called biodegradable microplastics will not persist in the marine environment. Biodegradable microplastics are just as likely to transfer up the food chain and have adverse effects if ingested. We therefore strongly oppose the exemption for the use of so-called biodegradable polymers. We also urge ECHA to explicitly include compostable, bio-based and biodegradable plastic within its definitions of “microplastics” and “microbeads”, as all of these plastics present an environmental hazard.  2. Lower limit to definition of microplastic  FFI recommends removal of 0.1µm and 0.3µm as lower limits in the definition of microplastic, to avoid incentivising innovation towards nanoplastics.  3. Plastic pellets  Plastic pellets, powders and flakes (collectively referred to as “pellets”) have been independently estimated to be the largest source of intentionally added microplastic pollution in the ocean [1]. Pellet pollution has been recorded since the 1970s [2] and is present on all European beaches surveyed by volunteers [3].  We believe it is crucial to ensure that ECHA’s labelling and reporting requirements complement other measures currently being developed to address pellet pollution. Pellet loss in Europe is estimated at up to 167,431 tonnes per year [4]. This is significantly higher than the 41,000 tonnes cited in the Background Document. We would expect to see ECHA, RAC and SEAC at least cite the range of estimates for pellet loss, as they have done for other microplastics. We are unclear why pellets are not included at all in Table 2 of the SEAC opinion.  We recommend ECHA takes a clear position on the need for further action to address pellet pollution, including standalone legislation requiring supply chain accreditation.  4. Rinse-off products that do not contain microbeads  A four year delay from entry into force for rinse-off products that do not contain microbeads is considerably longer than has been needed elsewhere. In these four years, according to estimates in Table 2 (p. 7) there would be 12,400-19,600 tonnes of avoidable microplastic pollution from these products. The successful implementation of the UK Microbead Ban (The Environmental Protection (Microbeads) (England) Regulations 2017) [5] provides evidence that this delay is unnecessary. The UK Microbead Ban was announced in 2016 and implemented in 2018 giving the industry two years to reformulate all rinse-off products. The definition of “microbead” in the UK ban is “any water-insoluble solid plastic particle of less than or equal to 5mm in any dimension”, which meets ECHA’s definition of a “microplastic”. As such, the UK legislation prohibits the use of all microplastics in rinse-off personal care and cosmetics products, not only microbeads (contrary to the implication on p. 21 of the ECHA Background Document). Raw material mixtures without microplastics are therefore already available for virtually all rinse-off personal care and cosmetics products that would be impacted by the ECHA restriction, and have been available since the UK ban was implemented in 2018. Furthermore, as stated by the Dossier Submitter, some Member States (in addition to the UK) have already enacted national measures on microplastics in rinse-off cosmetic products.  The cost of reformulation for these products may also have been overestimated. As acknowledged by SEAC, many brands use the same formulations and add their own colours or fragrances. As noted above, many of these reformulations are already available, and we would welcome clarity about why the cost of reformulation is estimated to be EUR 36-2,000 million.  Additionally, we are concerned that “microbeads” and other microplastic ingredients are being subject to separate levels of restriction purely based on their function in a product. This is an arbitrary distinction as microbeads and other microplastics cause the same level of harm in the marine environment. We therefore recommend that ECHA remove this categorization, which is based on microplastics’ function in products rather than on the risk that they post to the environment.  5. Leave on cosmetics  SEAC concludes that “(i) releases from these uses are comparatively low (and might also be effectively managed by a requirement to include instructions for use and disposal)”. We strongly disagree, particularly in light of the UK Hazardous Substances Advisory Committee’s (HSAC) 2019 report [6], which made the following conclusion: “There is no scientific reason to treat microplastics from leave-on separately from rinse-off products. The release of microbeads from either source into the environment should be restricted on the basis of their persistence and potential to cause toxicological harm.”  Furthermore, a UK poll of 2,141 adults found that 42% of those who use face make-up (e.g. foundation, concealer) would wash it off down the drain [7]. This is a very different result to the Kantar TNS and Cosmetics Europe poll of 8,000 consumers, which showed that 75% of make-up users surveyed remove their make-up with cotton or wipes [8], and highlights significant potential variation in different geographies or demographics.  We therefore strongly support the inclusion of all leave-on products in the ban, and do not believe that Instructions for Use and Disposal would be adequate to address microplastic pollution from these products.  We also cannot support the Dossier Submitter’s proposal for a six-year transition period for these products. We note the industry estimate of five years to find alternative formulations. Microplastic-free formulations for some of these products are already available; for example, toothpaste and sunscreen. Both toothpaste and sunscreen enter the environment directly: sunscreen through swimming or when washed off in the shower, and toothpaste through discard down the drain directly after use. Restrictions on microplastic use in these products should therefore be introduced as soon as possible.  [1] Eunomia, 2016. Plastics in the Marine Environment Report.  [2] Karlsson et al, 2018. The unaccountability case of plastic pellet pollution. Marine Pollution Bulletin Vol. 129 pp. 52-60.  [3] https://www.nurdlehunt.org.uk/nurdle-finds.html  [4] Eunomia, 2018. Investigating Options for Reducing Releases in the Aquatic Environment of Microplastics Emitted by Products.  [5] UK Government, 2017. The Environmental Protection (Microbeads) (England) Regulations 2017. https://www.legislation.gov.uk/ukdsi/2017/9780111162118  [6] Hazardous Substances Advisory Committee, 2019. View on the risk to the marine environment of microplastic in leave-on cosmetic and domestic cleaning products. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/834893/hsac-advice-microbeads-2019.pdf  [7] Marine Conservation Society, 2017. Big loopholes for tiny microbeads in government’s proposed ban. https://www.mcsuk.org/press/big-loopholes-in-microplastics-ban  [8] European Chemicals Agency, 2018. Workshop: Intentionally added microplastics to products, Breakout session: Cosmetics. https://echa.europa.eu/documents/10162/23964241/02-cosmetic-europe-john-chave\_en.pdf/28a1a408-4e26-1bb8-4603-9c020a63d31a |
| **Specific information 1:**  1.  a. RAC’s recommendation for appropriate test methods and pass criteria used to identify biodegradable polymers (derogated under paragraph 3b), including any impacts on the availability of alternatives within the transitional periods proposed in paragraph 6. Please provide supporting evidence.  We strongly oppose the exemption for the use of so-called ‘biodegradable’ polymers [9] . The derogation in paragraph 3b states that “(bio)degradable polymers are exempt from the restriction on the basis that they do not contribute to the microplastic concern, even though they could remain in the environment for some time after use/release.” In upholding this derogation, ECHA, RAC and SEAC would be saying that plastic pollution is acceptable, instead of focusing on ways to prevent all forms of avoidable plastic pollution.  1. Marine biodegradable plastic does not exist  No internationally-recognised test or standard has demonstrated that such alternative materials are capable of breaking down in real-world environments, outside of carefully engineered, simulated conditions [10] . Policymakers and manufacturers of products and packaging made of ‘biodegradable’ polymers have a duty to take into account all environments where these polymers may end up, including places where temperatures, light, and oxygen exposure may not be conducive to degradation. This is particularly likely in freshwater and marine environments: for example, biofouling on ‘biodegradable’ plastics can quickly cause them to sink from surface waters to cooler waters, drastically reducing exposure to the ultraviolet light that is often required for degradation to occur [11] . Page 70 of the Background Document references McDonough et al.’s 2017 paper as an example of “fast degradation of down [the] drain biodegradable plastics,” but the document fails to note that this study uses water temperature of 22°C – a condition that would very rarely be met in the marine environment, much less at greater depths than sea surface.  The only internationally recognised standard (ASTM D7081-05) for marine biodegradability of plastic was withdrawn in 2014 [12] , and there are no plastics that have been demonstrated to fully biodegrade under realistic marine conditions. Degradation rates vary depending on numerous factors even within the same type of ‘biodegradable’ polymer [13] , and incomplete breakdown of ‘biodegradable’ plastic could lead to an accumulation of plastic fragments and particulates in soils and other environments, where such particulates have been shown to be toxic to wildlife [14] . None of the commercial plastics currently claiming biodegradable status on their labelling have passed test criteria to demonstrate that they are biodegradable in real-life marine conditions [15] , resulting in misleading marketing to consumers. If users believe these materials to be harmless to the environment, there is an increased risk that they will not be disposed of properly, perversely increasing the amount of plastic pollution [16, 17].  2. Precedents for not exempting biodegradable materials exists in legislation elsewhere  It is worth noting that no exemption was made for intentionally added “biodegradable” microplastics in the UK government’s 2018 microbeads ban (which applies to all microplastic ingredients in personal care and cosmetics products), lauded for its robust definition of microplastics [18] . Similarly, the equivalent Microbeads (Prohibition) Act 2019 in Ireland made no exceptions for “biodegradable” microplastics. Creating a situation in which biodegradable microplastic ingredients are permissible under ECHA regulations but banned in some states under their national regulations would cause confusion and difficulty for industry, and would miss an opportunity to introduce world-leading regulation in the EU.  The Dossier Submitter summary justifications for the significant transitional periods for agricultural and horticultural uses are on the grounds that “time is required for the development of biodegradable polymers,” and the SEAC opinion “notes the uncertainty regarding the ability to actually develop alternatives in the proposed transitional period.” This acknowledges that at present, no ‘biodegradable’ polymer proven to satisfactorily break down without harm or contribution to the microplastic concern exists. We do not believe, therefore, that so-called ‘biodegradable’ polymers should be exempted, given that they are yet to be developed, tested and conclusively proven not to contribute to the microplastic concern.    3. Biodegradable polymers pose an equally severe threat to the marine environment  Even if truly biodegradable polymers were developed, these would still constitute plastic pollution in the time it takes between release into the environment and full biodegradation.  The RAC’s recommendation acknowledges that these polymers could remain in the environment for some time after use/release. There is no acceptable length of time in which it is appropriate for plastic to be present in the environment, particularly as microplastics can cause harm within only a few hours if eaten by an animal, contributing to clogging and inflammation of the gastrointestinal tract, and potential starvation [19, 20].  So-called ”biodegradable” plastic is known to present risks to marine life. For example, in one study, high density polyethylene, oxo-degradable plastic and biodegradable PBAT/starch blend (Mater-BiTM) were all exposed to gastrointestinal fluids of sea turtles for over a month. Polyethylene and oxo-degradable plastic degraded negligibly and biodegradable PBAT/starch blend degraded by 4.5 – 8.5%, much slower than the 100% degradation that the manufacturers reported would occur at an industrial composting site [21] . All of these plastics would still be able to present a serious gastrointestinal tract blockage risk to the sea turtle.  Furthermore, it is an incorrect assumption that microplastics cannot entangle – microplastic fibres are able to entangle small organisms at the base of the food chain, which are vital to ocean ecosystem health [22] .  The current criteria for ‘biodegradability’ do not require polymers to fully disappear in all environmental conditions. The ingredients used in the applications specified in the opinion are designed to enter directly into aquatic, soil, and marine environments - for example fertilisers, paints and coatings, detergents (which will permit microplastic release into drains), cosmetic products (both rinse-off and leave-on, which are often later removed by washing in showers or sinks [23] ) and infill material for sports pitches, easily blown, washed, or carried off the pitch on shoes. Many more will inevitably enter further environmental compartments when disposed of incorrectly. We fully agree with RAC that this means biodegradability should be stringently tested in all environments, but we feel current criteria are still insufficiently rigorous to ensure that these materials do not add to the microplastic concern. While specific types of biodegradable polymers, such as compostable plastics, may one day form part of waste management solutions, research emphasises their limited effectiveness in reducing hazards associated with plastic pollution [24] .  Furthermore, a definition of what is meant by “biodegradable” is needed, as well as clarification of whether “biodegradable alternatives” refers to so-called biodegradable plastics or other non-plastic materials that are biodegradable.  On the basis of all of the above, we strongly oppose the derogation for biodegradables.  b. RAC’s preference for a ban on the placing on the market of infill material (meeting the definition of a microplastic) for synthetic turf sports pitches after a transitional period of six years. Specifically, will alternative synthetic turf systems that meet relevant performance standards be available in sufficient quantities for all types of pitches by the end of the six-year transitional period proposed? How many pitches would need to be replaced before the end of their expected lifetime and what would the impacts of such a replacement? Furthermore, is there evidence to suggest that indoor artificial pitches should be treated differently from outdoor pitches? Please provide supporting evidence.  We agree with the RAC opinion that a ban will be the best course of action to stop microplastic loss from pitches, and with the SEAC opinion that the restrictions are proportionate from a cost perspective. We would stress that a full derogation is clearly not justified in this case – there is clear evidence of ongoing loss of the material, and currently pitches do not provide sufficient technical containment to prevent pollution. We also agree with the SEAC observation that indoor pitches also present a potential for emissions to the environment, and as such should be covered by the restriction.  We believe the six-year transition period for infill materials is too long. Page 14 of the SEAC opinion states that contribution of emissions to the environment was a factor in determining transition periods, yet infill material is listed in Table 2 as releasing the greatest quantity of microplastic to the environment out of all the product groups under consideration. Furthermore, alternative materials for artificial pitch infill are widely available and have been used successfully on pitches for some time [25] , suggesting that a transition away from microplastic use will not impact societal access to pitches. Many of these alternatives are themselves waste products, for example coconut husks, 85% of which are currently burned or sent to landfill [26] , olive stones [27] , and walnut shells.  However, we do not support the use of end-of-life tyres, and are concerned by the description of the re-use of end-of-life tyres (ELT) in turf as an “environmental benefit”. Lifecycle benefits of tyre recycling assume that ELTs are replacing virgin plastic - but in the case of a broader microplastics restriction, and as mentioned above, the organic materials replacing ELTs are often also a waste product from a different process [28] , and grinding ELT up to be strewn onto a field exposed to wind and rainwater run-off is likely to increase the environmental hazard that it poses [29] .  The SEAC opinion itself notes that a benefit of banning ELT infill relates to “the chemical constituents in this type of infill, some of which are known to be hazardous to the environment. Especially the very high concentration of zinc oxide contained in the rubber particles is a source of 60 concern (RIVM 2018).” Stakeholders in the recycled tyre industry have suggested that a ban on ELT infill would lead to more tyres being dumped in the environment [30] , but we would argue that the threat of criminal disposal of waste products is not a reasonable basis on which to decide against adopting measures to reduce microplastic pollution. The reuse of tyres on pitches has shifted responsibility from tyre producers to the artificial turf industry to deal with this difficult waste product, delaying disposal and removing incentives from tyre producers to design and create more innovative products that are effectively incorporated into a future circular economy.  Regarding Option A in paragraph 4.h., Table 1 of the SEAC opinion, which would allow an exemption for sports pitches where risk management measures limited annual releases of microplastic to a maximum of 7g/m2, we consider that this sets a dangerous precedent for allowing permissible levels of microplastic pollution in the environment, undermining the overarching objective of this ECHA proposal. We strongly oppose this option.  c. The RAC opinion refers to a “hybrid restriction option” that would allow existing pitches using artificial turf with infill material meeting the definition of a microplastic to continue to be used beyond the introduction of the ban until the end of their useful life (as long as risk management measures were introduced). What would be the impacts of such a ‘hybrid’ restriction option? Please provide supporting evidence.  In principle, we support any initiative to ensure pitches can be used to the end of their useful life as this will reduce impact to communities and industry costs, and minimise the lifecycle footprint of the product. This can also reduce any unintended consequences, for example increasing the volume of pitch waste or increasing the production of new pitches in any given year.  However, this can and should be done in such a way to limit loss as much as possible during any transition period, rather than to maximise the quantity of pitches built with microplastic before the restriction comes into force.  We agree that existing pitches that continue to use microplastics should be required to implement baseline mitigation measures to minimise loss. Simple retrofitting measures could be used to keep down costs, such as netting around pitch edges, mobile boot brushing stations, filters in drains and providing information for users/maintenance staff. If effectively implemented, mitigation measures will also reduce the quantity of infill needed to top up the pitch for the remaining years of its life. Such measures would continue to be useful once infill has been replaced, as non-plastic infills are also best kept on the pitch.  We recommend that exemptions to a restriction should only apply to existing pitches from entry into force (i.e. a hybrid scheme should not be an excuse to build further SBR pitches during the transitional period).    d. RAC’s recommendation that a lower size limit for a microplastic is not strictly necessary as part of the conditions of a restriction as compliance/enforcement can be achieved by non-analytical means (such as via supply chain certification). Please tell us about the practical implications of this recommendation, including the costs and compliance as well as current analytical barriers for microplastics <100 nm. Please tell us whether setting a lower size limit would be justified for compliance/enforcement reasons. Please provide supporting evidence.  While we understand the technical difficulties with detecting particles smaller than 0.1µm, we agree with SEAC’s opinion that the difficulty of detecting a particular size should not have a bearing on the proposed definition of microplastic. FFI recommends removal of 0.1µm and 0.3µm as lower limits in the definition of microplastic.  Setting a lower size limit would likely incentivise innovation towards use of nanoplastics, permitting continued release of these polymers into the environment. This would be counter-productive to the purpose of this restriction and is rightly identified as a concern by RAC, particularly considering the remaining uncertainty around the full breadth of hazards posed by nanoplastics, given their potential increased capacity for environmental harm relative to larger particles [31] . We similarly agree with both RAC and SEAC that no lower size length cut-off for fibres is justified. Nanoplastics are already available for purchase and found within personal care products containing microplastics [32] . Removing lower size limits will ensure that developing nanoplastics for consumer products does not become a commercial enterprise, which would be highly concerning considering the current uncertainty regarding their extensive potential hazards [33] .  It should also be clear that companies should start reformulating their products to remove any microplastic ingredients smaller than 0.1µm from the restriction’s entry into force, even if the technical ability to detect and therefore police such nanoplastics is not yet available. The fact that their presence will not be monitored yet should not be used as a reason to delay their removal from products.  Regarding the statement that “SEAC finds it justified to set an upper size limit of 5mm as part of the definition, since it seems to represent the size at which the relevant exposure of organisms in the environment changes from ingestion (microplastics) to physical effects such as entanglement (larger plastics items)” (p. 20), while we agree that microplastics be defined with a 5mm upper limit for consistency with research and other national legislation, the claim that the impacts of small plastics change based on whether the plastic is over or under 5mm is completely unfounded. For example, some pellets are over 5mm but can still be ingested and are no less harmful if they are, particularly as they have the same ability to cause blockage, inflammation and starvation [34] . The physical effects caused by plastics of any size are also dependent on the size of the animal in question.  [9] UNEP, 2015. Biodegradable Plastics and Marine Litter. 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Vol. 14, p. 299 https://www.nature.com/articles/s41565-019-0437-7  [34] Cornish Plastic Pollution Coalition, 2018. Bio-bead pollution on our beaches Report, Second Edition. http://www.ramepbc.org/CPPC\_Biobead\_Pollution\_on\_our\_Beaches\_2nd\_Edition\_July\_2018.pdf |
| **Specific information 3:**  We would argue that the environmental impacts of the proposed ban on microplastic ingredients in these products would be highly positive, and the socio-economic impacts limited by comparison. This is particularly important due to the fact that some products in this category are designed or used in a manner that results in microplastic release directly into the marine environment – whether in home hygiene products like toothpaste, rinsed down drains, or others like sunscreen, frequently worn in swimming pools and in the sea.  We consider a transitional period of six years for toothpaste and sunscreen to be excessive, particularly given that examples of these products without microplastic ingredients are already on the market, proving the addition of microplastics to be unnecessary. For example, toothpastes in the UK have been banned from using any type of microplastic since January 2018 [35] , and various brands of sunscreen are already microplastic-free [36] . Exemptions should be strictly limited to substance-based medical devices that currently have no microplastic-free alternative, and reviewed regularly to establish whether innovations have facilitated microplastic-free formulations of those products without affecting their performance.  [35] UK Government press release, 2018. World leading microbeads ban comes into force. https://www.gov.uk/government/news/world-leading-microbeads-ban-comes-into-force  [36] Danae Kleida, 2019. Plastic-free sunscreens. Beat the Microbead website. https://www.beatthemicrobead.org/plastic-free-sunscreens/ |
| **Specific information 4:**  The potential proposed eight-year time period is longer than the six-year time-period proposed for medical devices. This is illogical, particularly given the undeniably much higher relative necessity of medical devices in comparison with fragrance encapsulation. Fragrance encapsulates are a relatively novel and non-essential addition to a range of products. Alternative products already exist that do not use fragrance encapsulates and have performed their function to date without the need for encapsulation (which is used in only a small percentage of such products) [37] . SEAC states on p. 65 of the opinion document that one of the key elements underpinning its conclusions is the concept of ‘essential use’. We suggest that essential use be taken into account regarding fragrance encapsulation, which cannot claim to be necessary for health and safety or the functioning of society, particularly as there is a technically and economically feasible alternative, as outlined above. Transitional periods of such length are not justified for these ingredients and would serve to permit continued release of these unnecessary microplastics into the environment.  [37] Laroche &amp; Gonzalez, 2018. Fragrance encapsulation in consumer products. ECHA Stakeholder workshop on intentional use of microplastic particles. https&#58;//echa.europa.eu/documents/10162/23964241/02\_ifra-laroche\_and\_gonzales\_en.pdf/2f1585db-13d3-4756-4911-7422a4d7381c |
| **Specific information 5:**  We support the inclusion of requirements for Instructions for Use and Disposal for derogated products, and where microplastics are still used, we would seek an additional requirement to inform users that a product contains microplastics. This could be achieved through clear outward labelling to enable informed consumer choice. This is particularly important where consumers have an influence on final disposal of the product, and where microplastic use is not necessary, for example in fragrance encapsulation in detergents.  On page 14 of the SEAC opinion it is stated that “Factors that were taken into account in the determination of the transitional periods were sector (product group) emissions to the environment and their overall contribution of emissions of intentionally added microplastics”. Given this, it is concerning that such a long transition period is proposed for Instructions for Use and Disposal (24 months) and reporting (36 months) for pellets, as they are the largest source of intentionally added microplastic pollution to the ocean (up to 167,431 tonnes lost to the environment in Europe per year [38] ).  For pellets, a delay of 24 months in order to implement Instructions for Use and Disposal is excessive, particularly given the fact that the plastic industry already has a detailed toolkit of best practice in their voluntary initiative Operation Clean Sweep [39] , to which they could easily refer. The first publicly available standard for pellet handling and management is also currently being developed by the British Standards Institution (BSI) and a steering group of companies from across the plastic supply chain, trade associations, academics, environmental NGOs and policymakers [40] . This standard will be available for use in mid-2021, and will also set out good practice as agreed between steering group members, so could form the basis of ECHA requirements. Similarly, French legislation already bans certain means of transporting pellets, which ECHA instructions for transporters could draw upon. As a result, we would suggest that Instructions for Use and Disposal should be required from entry into force, particularly given that the industry will be aware of these plans well in advance.  We urge any Instructions for Use and Disposal to take into account the different measures required for pellets, powders and flakes, all of which are different dimensions, but present the same level of environmental hazard.  We also urge ECHA to consider the attached policy briefing on addressing microplastic pollution from pellet loss, prepared by Environmental Investigation Agency with support from FFI and Fidra, in order to ensure complementarity between ECHA’s proposed Instructions for Use and Disposal requirements and any supply chain accreditation system. Supply chain accreditation for pellets is currently in development with the creation of the aforementioned BSI standard [41] and supply chain certification schemes, and could drastically reduce pellet pollution, particularly if reinforced by European-wide legislation.  [38] Eunomia, 2018. Investigating Options for Reducing Releases in the Aquatic Environment of Microplastics Emitted by Products. https&#58;//www.eunomia.co.uk/reports-tools/investigating-options-for-reducing-releases-in-the-aquatic-environment-of-microplastics-emitted-by-products/  [39] Operation Clean Sweep website. https&#58;//www.opcleansweep.org/  [40] BSI press release, 2020. Project launch&#58; First specification to prevent plastic pellet pollution. https&#58;//www.bsigroup.com/en-GB/about-bsi/media-centre/press-releases/2020/june/project-launch-first-specification-to-prevent-plastic-pellet-pollution/  [41] BSI press release, 2020. Project launch&#58; First specification to prevent plastic pellet pollution. https&#58;//www.bsigroup.com/en-GB/about-bsi/media-centre/press-releases/2020/june/project-launch-first-specification-to-prevent-plastic-pellet-pollution/ |
| **Specific information 6:**  For plastic pellets, 36 months is an excessive amount of time to wait before reporting requirements come into force, especially as there are already examples of large petrochemical companies voluntarily reporting on pellet handling measures and losses [42] . Furthermore, an internationally applicable standard on pellet handling is currently under development that will include requirements for monitoring and reporting, agreed by a diverse steering group with industry representatives from all stages of the plastic supply chain. This standard will be published in mid-2021. A framework for reporting will therefore be available around which ECHA can build its requirements, and there is no reason for the proposed 36-month delay to the start of ECHA reporting. We would propose that reporting be required from entry into force, particularly given that the industry will be aware of these plans well in advance.  FFI is supportive of ECHA’s intention to publish the summary of these reports each year, and we do not consider SEAC’s suggestion on p. 64 to change this to every two years justified, particularly given that continual improvement based on these annual reports will be crucial in tackling pellet pollution effectively.  Reports and summaries must be site- or vehicle-specific in order to be useful and complementary to other initiatives currently underway to tackle pellet pollution, as mentioned above. Joint sectorial submissions would not be appropriate, as pellet pollution is highly variable depending on different site or transport company practices. We also urge ECHA to ensure that reporting requirements apply to all elements of the supply chain including the transport sector, and that no exemptions are made for any plastic supply chain actor based on company size or volume of pellets handled. In that context, the term “industrial sites” in connection with reporting is inappropriate, as this would not cover haulage companies that transfer pellets between sites.  At a minimum, the reporting required by all companies handling or managing pellets should include the following elements:  • The quantity of pellets produced, handled or managed in each calendar year at site/vehicle level. Previous claims of confidentiality breaches are unfounded as company names could be redacted when this information is published in the public domain.  • The prevention measures that they have in place to prevent pellet loss at site/vehicle level  • The estimated volume of pellet loss in each calendar year at site/vehicle level  • All reporting should be at site/vehicle level, in order to effectively identify processes that lead to pellet loss and address these through corrective action  • Enforcement authorities should undertake site/vehicle visits to confirm self-reporting is accurate  • All sizes of spill and loss should be included. Pellet pollution is a pervasive problem because of the constant trickle of loss occurring at thousands of sites and from thousands of vehicles. As such, it is not appropriate to only report, record or implement corrective action for large-scale spills, which form a comparatively small proportion of annual pellet loss.  • There must be no exemptions for any company, site or vehicle in the supply chain – it is imperative that reporting applies to everyone, as pellet loss occurs at all stages of the supply chain and a supply chain’s amount of pellet pollution is a cumulative total of each stage’s individual loss. This includes recyclers, who turn waste plastic back into plastic flakes as raw material for plastic production.  In this reporting, we would include the following definitions, with which we are confident the industry would be familiar:  • Spill = loss from primary containment, but not loss to the environment;  • Loss = escape to the environment.  We would expect these requirements to be met by any other industrial company handling microplastics as well, such as the textile supply chain, which leads to microplastic fibre loss to the ocean before clothing is even sold to and washed by consumers. We would like to see greater clarity on how the reported information will be used, and how it will support other concurrent measures to tackle pellet pollution. We would encourage ECHA to use the reported information to enable companies to track year on year improvement towards zero pellet loss and to help measure the effectiveness of other complementary measures to address pellet loss (e.g. supply chain accreditation against robust standards).  More generally, SEAC’s opinion states that the reporting requirement for microplastics such as pellets “is proposed to, among others, monitor the effectiveness of the restriction and to ensure that significant emissions are not occurring from derogated uses” (p. 15). The SEAC opinion further notes that the reporting requirement on pellets will provide better data on uses and releases, and that further action may be justified (p. 26). Significant pellet emissions are well-documented and are known to be an ongoing problem, despite the existence of industry scheme Operation Clean Sweep (OCS), which was designed to minimise pollution and has existed since 1991. For example, ongoing pellet loss at the Port of Antwerp (an OCS member) was acknowledged in PlasticEurope’s 2019 Operation Clean Sweep Port of Antwerp Activity Report [43] . Therefore, action on pellet pollution at the European level should not be dependent on whether reporting under ECHA demonstrates a need for further action, particularly as this will be company self-reporting. We recommend ECHA takes a clear position on the need for further action to address pellet pollution, including standalone legislation requiring supply chain accreditation. Supply chain accreditation was identified in an independent report for the European Commission to be the most effective and affordable way of addressing pellet pollution [44] and is further referenced in the Commission’s A European Strategy for Plastics in a Circular Economy.  [42] As You Sow press release, 2020. Fourth largest plastics manufacturer agrees to report on plastic pollution pellet spills. https://www.asyousow.org/press-releases/westlake-chemical-plastic-pellet-pollution  [43] Plastics Europe, 2019. Operation Clean Sweep® Port of Antwerp Activity Report 2019. https://www.plasticseurope.org/en/resources/publications/1872-operation-clean-sweepr-port-antwerp-activity-report-2019  [44] Eunomia, 2018. Investigating Options for Reducing Releases in the Aquatic Environment of Microplastics Emitted by Products. https://www.eunomia.co.uk/reports-tools/investigating-options-for-reducing-releases-in-the-aquatic-environment-of-microplastics-emitted-by-products/ |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We cannot comment on issues within the remit of RAC. Please note that SEAC states in its final opinion that the effectiveness of the restriction will directly be linked to which one of RAC’s biodegradation scenarios is chosen.  Several changes have been made to the opinion regarding infill material, to which we therefore refer as a response to your comments.  We also refer to the opinion for a discussion on the lower size limit. Several changes were made to the final opinion.  With regard to the time needed to substitute microplastics in cosmetic products, the transition periods proposed (4 years for rinse-off and 6 years for leave-on products) are considered to strike a balance between timely reduction of releases and the economic impact of the restriction including those product categories where suitable are currently scarce. Please note that the scope of the UK ban of microplastics, which not limited to function, is narrower compared to the proposed restriction as it only covers plastics (defined as synthetic polymeric substance that can be moulded, extruded or physically manipulated into various solid forms and that retains its final manufactured shape during use in its intended applications). In this respect the definition is similar to the ISO definition of plastics that the Dosser Submitter rejected as the basis for the proposed restriction as it does not address all of the materials associated with the microplastic concern (e.g. particles produced by emulsion polymerisation, fragrance encapsulation, etc).  With regard to your comments on fragrance encapsulates, SEAC rapporteurs underline that the issue of essential use is of a political nature and as a scientific committee SEAC cannot base its conclusion on proportionality on it. As of yet SEAC does not have a set of guidelines on what is considered an essential use. On the length of the transition period for fragrance encapsulates, please also refer to our response to IFRA (#663).  With regard to instructions for use and disposal and reporting, it is likely that there are differences in the abilities of the companies covered to meet the obligations required. The transition periods as well as the flexibility in the means to fulfil the requirements account for all actors in the supply chain and try to balance the benefits for effective risk management and the costs to companies. Please note that the focus of the proposed restriction is on consumer and professional use, not on industrial uses (which includes pellets). |
| **809** | **Date/Time:** 2020/09/01 21:57  **Type:**  BehalfOfAnOrganisation  **Org. type:**  National NGO  **Org. name:**  Deutscher Olympischer Sportbund / German Olympic Sports Confederation  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  The German Olympic Sports Confederation (DOSB) is the non-governmental umbrella organisation of organised sport in Germany. Its 100 member organisations count more than 27.5 million member-ships in about 90.000 sports clubs. Under the umbrella of the DOSB, sport is the largest citizens` movement in Germany.  The community-based sport in Germany, represented by the DOSB, assumes social responsibility for the conservation and the sustainable use of natural resources. The DOSB is committed to the devel-opment of sports facilities that are environment- and climate-friendly and conserve resources. Therefore, the DOSB in principle supports the objectives of the ECHA restriction proposal. To ensure that all citizens have access to sports, adequate sports facilities in sufficient numbers are a basic requirement - without sports facilities, there is no sport!  The DOSB has dealt intensively with the restriction options for infill material (meeting the definition of a microplastic) on synthetic turf pitches proposed or preferred by the dossier submitter and the ECHA committees SEAC and RAC. Especially the DOSB expert working group “Microplastics in the Environment through Sport " analysed ECHA`s proceeding in detail. After extensive consultations, the DOSB expert group by majority came to the following conclusion:  OPTION B is the most balanced and sustainable option from a holistic perspective, taking into account economic, social and ecological aspects.  The reasoning for this is as follows:  - OPTION B reduces the high complexity and uncertainty for sports clubs, sports federations as well as municipalities. Therefore, it is the most sports organisation-friendly option.  - It comes with a transitional period that is at minimum necessary to enable all those affected (sports facility operators and users, synthetic turf industry) to adapt to the upcoming new regulations.  - OPTION B reduces the number of synthetic turf pitches in Germany, which will have to deal with the new regulations once the transition period expires, to a small number.  - Already today, synthetic turf pitches are built and operated in Germany in accordance with the conditions that will only arise in the future as a result of OPTION B (exclusive use of non-synthetic infill materials).  - OPTION B does not require any unplanned investment in existing synthetic turf pitches during the transition period.  - It avoids the need to establish costly risk management measures (RMMs).  - It reduces the release of microplastics in the long term (observation period 20 years) more effectively than the mandatory installation of risk management measures.  - It is the option with the lowest environmental impact, including the lowest greenhouse gas effect.  Moreover, the DOSB kindly asks for the following to be considered:  The municipalities support sport in Germany as a "voluntary service". The current COVID-19 pandemic limits the financial possibilities of the municipalities in the member states and endangers the ability to finance such "voluntary services" in Germany. At an appropriate time, it should therefore be reviewed whether the transitional period foreseen in OPTION B is affordable for (municipal) sports facility operators.  The European Commission is called upon to focus on the eco-friendly renovation of sports facilities and the construction of new sustainable sports facilities as part of the European Green Deal. In this way, the Commission would significantly support the achievement of one of the "Key Actions" defined in its Circular Economy Action Plan ("Restriction of intentionally added microplastics [...]").  Summary:  Regarding the implementation of ECHA's proposal for restrictions under Annex XV of the REACH Regulation on the placing on the market of consumer or professional use products of any kind to which microplastic particles are intentionally added, the DOSB advocates for the option B recommended by the RAC and thus for a transitional period of at least six years for infill material (meeting the definition of a microplastic) for synthetic turf pitches. |
| **Specific information 1:**  Regarding b.  After consultation with, among others, representatives of the synthetic turf industry, the DOSB concludes that, at the end of a transitional period of at least six years, a sufficient number of alternative synthetic turf systems without infill (meeting the definition of a microplastic) will be available in Germany that meet relevant performance standards.  The DOSB expects that in Germany no synthetic turf pitches would need to be replaced before the end of their regular product life. According to ECHA, after the ban on the placing on the market has come into force and the transitional period has expired, existing synthetic turf pitches can still be refilled until the end of their product life with stocks of the existing infill material (meeting the definition of a microplastic) and with alternative infill material as a substitute. This would guarantee the use of synthetic turf pitches with infill material (meeting the definition of a microplastic) until the end of their regular product life.  Regarding c.  OPTION C would cause short-term unbudgeted costs (for simple risk management measures) and medium-term high, likewise unbudgeted costs (for strict risk management measures) for sports facility operators. The DOSB therefore expects a decision for OPTION C to affect the limited municipal capacities for action and financing. Furthermore, the option does de facto not provide for transitional periods.  Conclusion: OPTION C does not represent a sports organisation-friendly alternative to OPTION A and especially to OPTION B. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Several changes have been made to the opinion regarding infill material, to which we therefore refer as a response to your comments. |
| **810** | **Date/Time:** 2020/09/01 22:25  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  <redacted>  **Org. country:**  Belgium  **Company name confidential: Yes**  **Attachment:** | **Comments on the SEAC draft opinion:**  <redacted> is supportive of the comments developed by Cefic relating to the restriction proposal for microplastics which align with our own position.    <redacted> is an association with a focus on pharmaceutical excipients, an important component of medicinal products which we note are derogated from the proposal. However, most excipients are not manufactured exclusively for the pharmaceutical sector and are used extensively in other industries impacted by the proposal. <redacted> fears that if such materials become restricted, they may no longer be available for use in medicinal products as their supply for pharmaceutical use only may not be economically viable. This could have further bearing on the supply of medicines as alternatives may not be readily available, and the required product development costs would be significant and not economically sustainable.  Also, the unclear labeling and reporting requirements result in considerable confusion especially in small and medium size enterprises that still count for many drug product manufacturers in Europe.  In conclusion, <redacted> concurs with Cefic that the proposal would benefit from a narrower, more focused scope targeting specific uses identified as high risk, grouping polymers to evaluate hazard and risk, adapting as science evolves and alternatives are developed. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We refer to our responses to CEFIC’s submission (#735). |
| **811** | **Date/Time:** 2020/09/01 23:26  **Type:**  BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  UEFA  **Org. country:**  Switzerland  **Attachment:**    <redacted> | **Comments on the SEAC draft opinion:**  UEFA prepared on behalf of its member associations the position paper attached in section V as a response to this public consultation. In addition, a document relating to alternatives to microplastics as an infill for synthetic football pitches, which was already shared informally with ECHA on the occasion of UEFA's participation in ECHA's committees, is also attached. |
| **Specific information 1:**  Please see the position paper attached in section V. |
| **Specific information 2:**  Please see the position paper attached. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Several changes have been made to the opinion regarding infill material, to which we therefore refer as a response to your comments. |
| **812** | **Date/Time:** 2020/09/01 23:59  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ETRMA, European Tyre and Rubber Manufactures Organisation  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  General comments are provided in the ETRMA overview response submitted earlier today, detailed annex attached hereunder. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Several changes have been made to the opinion regarding infill material, to which we therefore refer as a response to your comments. |
| **x** | **Date/Time:** 2020/09/01 21:45  **Type:**  BehalfOfAnOrganisation  **Org. type:**  National NGO  **Org. name:**  Svenska Fotbollförbundet  **Org. country:**  Sweden | **Comments on the SEAC draft opinion:**  Following the public consultation on microplastics from the Committee for Socio-Economic Analysis (SEAC), ECHA, the Nordic football associations is providing the following joint response regarding the possible ban of rubber granulate as performance infill on artificial football turf.  For several hundreds of thousands of young and old Nordic football players, artificial pitches have become a vital everyday necessity to be able to play football all year. With several thousand active pitches spread across the Nordic countries, the health and social impact is tremendous. This vital infrastructure is a concern for all the Nordic football associations representing a total of 1 200 000 registered football players.  We have previously made national comments and positions available via UEFA and stand by the arguments made by UEFA to ECHA but feel a sense of urgency to further emphasize the climatic conditions and the effect of a possible ban on everyday football in the Nordic countries.  The Nordic weather conditions require a large number of artificial turf pitches, primarily to be able to play football during the winter months, and rubber granules are currently the only performance infill that can endure the rough Nordic climate. Alternative infills like cork, bark and sand do not live up to the required football functionality. These infills can absorb water that can result in non-functional pitches.  We see a widespread market push towards a replacement of the well proven granulate pitch toward non-performance infill pitches. This is a stepping-stone but is not sufficiently relevant for football clubs. These non-infill pitches have been proven to be too hard and slippery for players and can cause additional injuries. Furthermore, non-performance infill football pitches are short-lived due to the carpet surface, which cracks more easily and needs to be changed more often.  The Nordic football associations work intensively and strategically with the operation and maintenance of artificial turfs and train operating personnel, football players and managers and invest in minimizing migration of granules to surrounding surfaces for example, focus on granules on snow covered football field, as well as panels around the sides of the pitch, shoe brushing stations, granular traps and water filters.  A ban on microplastics would mean that fewer people would be able to play football in the Nordic countries. As an example – up to ten natural grass pitches would have to be established for the termination of one artificial turf pitch to cope with the needed for playing hours. We can already see that this is impossible especially in our major cities and urban areas. It is also a fact that present alternatives without infill is significant more expensive.  Our preferred legal option is to limit the migration of granules from the football pitch. There are already several sustainable and innovative market-based solutions, which already have been proven relevant and that can be applicable for all pitches in Europe. We offer our support and assistance to develop and implement environmental solutions that guarantees the possibility for all Nordic and European football players to be able to play football all year long in all kinds of weather. At the same time, we work actively to get more environmentally friendly artificial turf solutions developed and are constantly testing new products  that are launched. Unfortunately, it seems that for developing good enough solutions there is still some way to go.  Thus, the Nordic football associations strongly urge ECHA not to recommend a total ban on the use of granulate infill and propose to further improve the physical barriers and behavioural design to prevent migration of granulate to the natural environment.  Håkan Sjöstrand, General Secretary, Swedish Football Association  Jakob Jensen, General Secretary, Football Association of Denmark  Marco Casagrande, General Secretary, Football Association of Finland  Pål Bjerketvedt, General Secretary, Football Association of Norway  Virgar Hvidbro, General Secretary, Faroe Islands Football Association  Klara Bjartmarz, General Secretary, Football Association of Iceland |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Several changes have been made to the opinion regarding infill material, to which we therefore refer as a response to your comments. |