Plastic Soup Foundation response to ECHA's specific information requests

1a.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.

UNEP (2015) has stated that "the adoption of plastic products labelled as 'biodegradable' will not bring about a significant decrease either in the quantity of plastics entering the ocean or the risk of physical and chemical impacts on the marine environment, on the balance of current scientific evidence". They also mention that "the process [complete biodegradation] is temperature dependent and some plastics labelled as 'biodegradable' require the conditions that typically occur in industrial compositing units, with prolonged temperatures of above 50°C, to be completely broken down. Such conditions are rarely if ever met in the marine environment."

We argue that the criteria for biodegradability of polymers must be stated very clearly, meaning that any substitute for conventional microplastics currently in use, must fully mineralize in any environmental compartment within a limited time frame. Defining this time frame is of great importance as it helps define the word 'biodegradability'. A microparticle may take 100 years to fully mineralize, and would therefore perhaps fit the definition of biodegradable. However, over those many years it has the potential to do harm to the environment and human health, while preventing this harm has been ECHA's motivation for proposing a restriction on microplastics. We therefore argue that a maximum time frame must be established within which a microparticle must be fully mineralized. We suggest that this mineralization should occur in a matter of days, rather than weeks or months. If a synthetic polymer does not comply with this criterium, it should not be a substitute for conventional microplastics. Particularly as we know that many of these intentionally added microplastics are released directly into the environment, rather than being released into the environment due to accidental or improper waste disposal. If polymers do not meet this requirement yet are used as alternatives to conventional microplastics, this would be a very regrettable substitution, and ECHA's aim to protect the environment and human health from persistent, bioaccumulative and toxic substances (both monomers and polymers) will have failed.

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.

Plastic Soup Foundation fully supports the briefing 'Microplastic loss from artificial (3G) pitches in context of the ECHA proposed restriction of microplastics intentionally added to products' submitted by Fidra.

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.

Plastic Soup Foundation fully supports the briefing 'Microplastic loss from artificial (3G) pitches in context of the ECHA proposed restriction of microplastics intentionally added to products' submitted by Fidra.

1d. 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 nonanalytical 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.

SEAC argues that the lack of methods to detect plastic particles < 100 nm implies that these particles should be exempted in this proposed restriction, as no detection would prevent the enforcement of these particles. We argue that the lack of methods to detect these particles should imply the contrary. It is of crucial importance that specifically these particles are also included in the restriction, as the lack of methods to detect these particles implies that the contamination of the environment by these particles cannot be monitored. Moreover, this exemption will most likely drive industry to use nanoplastics < 100 nm rather than searching for environmentally friendly alternatives. This will result in much higher concentrations of these particles in the environment. This is very problematic as there is a large body of scientific literature stating that the bioavailability and toxicity increases with decreasing particle size. This has been demonstrated for example for gold (Au) and titanium dioxide (TiO_2) nanoparticles, where particles in the nano-range have been found to cross the blood-brain-barrier in fish and rats and cause oxidative stress and neuroinflammation, among others (Prüst, Meijer, & Westerink, 2020). Gold and titanium dioxide particles of a larger size are however considered chemically inert. As plastics are also considered chemically inert, this is an important characteristic for comparison with plastic nanoparticles. Some interesting findings concerning the bioavailability and toxicity of plastic particles < 100 nm are:

- Uptake by placental tissue in mice was significantly higher for 40 nm particles compared to 100, 200 and 500 nm particles. Moreover, 20 nm and 40 nm particles induced cell apoptosis and reduced cell proliferation. (Huang et al, 2015).

- A stress response induced by 25 nm plastic particles was shown by a disruption in glucose homeostasis and increase in cortisol secretion, coinciding with behavioural changes in zebrafish larvae (Brun et al., 2019).
- Translocation of polystyrene nanoparticles in an *in vitro* human intestinal cell model showed strong size-dependent translocation, ranging up to 7.8 % for 50 nm particles and 0.8 % for 100 nm particles. (Walczak et al., 2015).
- Absorption across the GIT in rats was 34% for 50nm polystyrene particles compared to 26% for 100 nm particles, of which total, about 7% (50 nm) and 4% (100 nm), was in the liver, spleen, blood and bone marrow. Particles larger than 100 nm did not reach the bone marrow, and those larger than 300 nm were absent from blood. (Jani et al 1990).
- Parameters of lung inflammation in rats was significantly greater for 64 nm in size compared with 202 and 535 nm particles, which was caused by a significant increase in cytosolic calcium ion concentration (important in leading to pro-inflammatory gene expression such as chemokines). These findings suggest that ultrafine particles composed of low-toxicity material such as polystyrene have proinflammatory activity as a consequence of their large surface area (Brown et al., 2001).

More studies on the bioavailability and toxicity for particles < 100 nm, both *in vivo* and *in vitro*, can be found in Table 1.

Contamination of the environment by these particles will result in the bioaccumulation of these particles in organisms, as well as biomagnification, resulting in contamination of organisms higher up the food chain (Cedervall et al., 2012; Chae et a.l, 2018; Mattsson et al., 2017). Humans will be exposed via the consumption of among others seafood. In the past it was believed this exposure route to micro- and nanoplastics in humans was limited as the particles were expected to remain in the GIT. Since this is removed in most seafood before consumption, exposure was expected to be low. However, new insights have demonstrated that nanoplastics can enter the muscle tissue of marine organisms used for human consumption (Al-Sid-Cheikh et al., 2018; Karami et al., 2017), and substantial exposure to nanoplastics via the consumption of seafood is therefore expected. Moreover, recent scientific studies reported on the uptake and presence of micro- and nanoplastics in fruits and vegetables. The work by Li et al (Li et al., 2019; Li et al., 2020) show how micro- and nanoplastics can be taken up by the roots of plants and subsequently find their way to the edible, above-ground parts of the plants. Oliveri Conti et al (2020) reported the presence of microplastics in various fruits and vegetables, with apples being the most contaminated fruit having over 200,000 particles present per gram. As contamination of the terrestrial environment continues, partly due to the use of intentionally added micro- and nanoplastics in agriculture, but also as a result of other sources such as sludge, atmospheric deposition and degradation of agricultural plastics, exposure to micro- and nanoplastics in humans via crops will only increase.

Assessing the risk of this exposure to humans is still in its infancy, yet studies on various species, from invertebrates like scallops to mammals such as rats and mice, demonstrate the bioavailability and toxicity of these particles (Table 1). Moreover, *in vitro* studies using human cell models have demonstrated the translocation across important barriers in the human body, e.g. the GIT and the placental barrier (Table 1). Currently the capacity of micro- and nanoplastics to pass the blood-brain-barrier in a human cell model is being investigated, yet has already been demonstrated in different fish species (Table 1).

In conclusion, smaller particles are more bioavailable and have a higher toxic potential than larger particles, both from an environmental and human health perspective. Currently, detection methods

do not exist for particles < 100 nm. Perhaps industry will use this current lack of methods as a loophole to continue using nanoplastics in their products. However, if these particles are exempted, this is a lot more likely to happen. Moreover, many research groups around the world are currently working on the development of new detection methods (e.g. Abdolahpur Monikh et al., 2019; Materić et al., 2020). By the time this restriction is in place, also methods to detect smaller nanoparticles in environmental and human matrices will likely be in place. Therefore, the argument for not being able to enforce this restriction is no longer valid.

Table 1. Bioavailability, translocation and toxicity of plastic particles < 100 nm.

Model System	Particle size	Effects (translocation, toxicity)	Reference
Crustaceans & bivalves			
Brine shrimp	PS-NH2 50 nm	Reduced growth and development, impaired survival, oxidative stress	Varó et al., 2019
Scallop	PS-NPs 24 nm, 250 nm	Uptake was rapid and was greater for 24 nm than for 250 nm particles. After 6 h, autoradiography showed accumulation of 250 nm nanoplastics in the intestine, while 24 nm particles were dispersed throughout the whole-body, possibly indicating some translocation across epithelial membranes.	Al-Sid-Cheikh et al., 2018
Fish			
Zebrafish larvae (*Danio rerio*)	PS-NPs 25 nm	A stress response induced by 25 nm plastic particles was shown by a disruption in glucose homeostasis and increase in cortisol secretion, coinciding with behavioural changes in zebrafish larvae	Brun et al., 2019
Crucian carp (*Carassius carassius)*	PS-NPs 53 nm, 180 nm	Particle presence in brain (53 nm and 180 nm). Brain weight loss (53 nm and 180 nm). Behavioural changes and enlarged cerebral gyri (53 nm)	Mattsson et al., 2017
Japanese rice fish (*Oryzias latipes)*	PS-NPs of 40 nm	Particle presence in gills, intestine, testis, liver, blood and brain, suggesting penetration of BBB.	Kashiwada, 2006
Zebrafish, larvae (*Danio rerio*)	PS-NPs of 47 nm, PS-MPs of 41 µm	Particle presence in body. Inhibition of AChE by 9% (MPs), 40% (NPs) 21% (MP and NP co-exposed with EE2); locomotor hypoactivity 22% (NPs) and 18–36% (co- exposed with EE2)	Chen et al., 2017
Zebrafish, larvae (*Danio rerio*)	PS-NPs of 50 nm	Particle presence in head, gills and muscle. Decreased AChE activity 46% (NPs alone) and increased DA levels (only for mixture of PS-NP with BPA).	Chen et al., 2017
Japanese rice fish (*Oryzias latipes)*, Japanese dark chub (*Zacco temminckii)*	PS-NPs < 100 nm	Polystyrene particles < 100 nm in size were transferred from primary producer (algae) to higher trophic level species. Nanoplastics also negatively affected fish activity, and induced histopathological changes in the livers of fish. Additionally, nanoplastics penetrated the embryo walls and were present in the yolk sac of hatched juveniles.	Chae et al., 2017
Crucian carp (*Carassius carassius*), Bleak (*Alburnus alburnus*), Rudd (*Scardinius erythrophthalmus*), Tench (*Tinca tinca*), Pike (*Esox esox*), and Atlantic salmon (*Salmo salar*)	PS-NPs 24 nm	Particles transported through an aquatic food chain from algae, through zooplankton to fish, affected lipid metabolism and behaviour of the top consumer.	Cedervall et al., 2012

Mammals			
Sprague Dawley rats	PS-NPs 50 nm, 100 nm	Absorption across the GIT in rats was 34% for 50nm particles compared to 26% for 100 nm particles, of which total, about 7% (50 nm) and 4% (100 nm), was in the liver, spleen, blood and bone marrow. Particles larger than 100 nm did not reach the bone marrow, and those larger than 300 nm were absent from blood	Jani et al,. 1990
Mice		Uptake by placental tissue in mice was significantly higher for 40 nm particles compared to 100, 200 and 500 nm particles. Moreover, 20 nm and 40 nm particles induced cell apoptosis and reduced cell proliferation.	Huang et al., 2015
Sprague Dawley rats		Parameters of lung inflammation in rats was significantly greater for 64 nm particles compared with 202 and 535 nm particles. These findings suggest that ultrafine particles composed of low-toxicity material such as polystyrene have proinflammatory activity as a consequence of their large surface area.	Brown et al., 2001
Fischer rats	PS-NPs 50 nm	A negatively charged NP was taken up more than other NPs, with the highest amounts in kidney (37.4 lg/g tissue), heart (52.8 lg/g tissue), stomach wall (98.3 lg/g tissue) and small intestinal wall (94.4 lg/g tissue).	Walczak et al., 2015
Cell cultures			
BeWo b30 cells (human *in vitro* placental model)	PS-NP 50 nm	PS particles translocated across the placental cell layer	Kloet et al., 2015
Primary mouse astrocytes, neurons, microglia and brain vascular endothelial cells	PS-PEG and PS- COOH NPs of 55 nm	Decreased mitochondrial activity and cell viability (≥ 250 mg/L). Internalization of NPs (2 × 1014 NPs/L).	Murali et al., 2015
Human-derived embryonic stem cell (3D model)	PE-NPs of 33 nm	Penetration of NPs into 3D structure, internalization of NPs (≥360 mg/L). Increased cytotoxicity and oxidative stress (dose-dependent). 18-day exposure: PE-NP accumulation (≥ 22.6 mg/L). Altered gene expression (22.5 mg/L) and increased cytotoxicity (≥ 180 µg/mL).	Hoelting et al., 2013
Mono-culture (Caco-2 cells), a co-culture with mucus secreting HT29-MTX cells and a tri-culture with M-cells	PS-NPs 50 nm	Translocation of polystyrene nanoparticles in an *in vitro* human intestinal cell model showed strong size-dependent translocation, ranging up to 7.8 % for 50 nm particles and 0.8 % for 100 nm particles.	Walckzak et al., 2015

Bibliography

Abdolahpur Monikh, F., Grundschober, N., Romeijn, S., Arenas-Lago, D., Vijver, M. G., Jiskoot, W., & Peijnenburg, W. J. G. M. (2019). Development of methods for extraction and analytical characterization of carbon-based nanomaterials (nanoplastics and carbon nanotubes) in biological and environmental matrices by asymmetrical flow field-flow fractionation. *Environmental Pollution*, *255*(2019), 113304. https://doi.org/10.1016/j.envpol.2019.113304

Al-Sid-Cheikh, M., Rowland, S. J., Stevenson, K., Rouleau, C., Henry, T. B., & Thompson, R. C. (2018). Uptake, whole-body distribution & depuration of nanoplastics by the scallop Pecten maximus, at environmentally realistic concentrations. *Environmental Science & Technology*. https://doi.org/10.1021/acs.est.8b05266

Brown, D. M., Wilson, M. R., MacNee, W., Stone, V., & Donaldson, K. (2001). Size-dependent proinflammatory effects of ultrafine polystyrene particles: A role for surface area and oxidative stress in the enhanced activity of ultrafines. *Toxicology and Applied Pharmacology*, *175*(3), 191–199. https://doi.org/10.1006/taap.2001.9240

Brun, N. R., van Hage, P., Hunting, E. R., Haramis, A.-P. G., Vink, S. C., Vijver, M. G., … Tudorache, C. (2019). Polystyrene nanoplastics disrupt glucose metabolism and cortisol levels with a possible link to behavioural changes in larval zebrafish. *Communications Biology*, *2*(382). https://doi.org/10.1038/s42003-019-0629-6

Cedervall, T., Hansson, L. A., Lard, M., Frohm, B., & Linse, S. (2012). Food chain transport of nanoparticles affects behaviour and fat metabolism in fish. *PLoS ONE*, *7*(2), 1–6. https://doi.org/10.1371/journal.pone.0032254

Chae, Y., Kim, D., Kim, S. W., & An, Y. J. (2018). Trophic transfer and individual impact of nano-sized polystyrene in a four-species freshwater food chain. *Scientific Reports*, *8*(1), 1–11. https://doi.org/10.1038/s41598-017-18849-y

Chen, Q., Gundlach, M., Yang, S., Jiang, J., Velki, M., Yin, D., & Hollert, H. (2017). Quantitative investigation of the mechanisms of microplastics and nanoplastics toward zebrafish larvae locomotor activity. *Science of the Total Environment*, *584–585*(October), 1022–1031. https://doi.org/10.1016/j.scitotenv.2017.01.156

Chen, Q., Yin, D., Jia, Y., Schiwy, S., Legradi, J., Yang, S., & Hollert, H. (2017). Enhanced uptake of BPA in the presence of nanoplastics can lead to neurotoxic effects in adult zebrafish. *Science of the Total Environment*, *609*(October), 1312–1321. https://doi.org/10.1016/j.scitotenv.2017.07.144

Duncan, E. M., Broderick, A. C., Fuller, W. J., Galloway, T. S., Godfrey, M. H., Hamann, M., … Godley, B. J. (2019). Microplastic ingestion ubiquitous in marine turtles. *Global Change Biology*, *25*(2), 744–752. https://doi.org/10.1111/gcb.14519

Hennecke, D., Bauer, A., Herrchen, M., Wischerhoff, E., & Gores, F. (2018). Cationic polyacrylamide copolymers (PAMs): environmental half life determination in sludge-treated soil. *Environmental Sciences Europe*, *30*(1). https://doi.org/10.1186/s12302-018-0143-3

Hoelting, L., Scheinhardt, B., Bondarenko, O., Schildknecht, S., Kapitza, M., Tanavde, V., … Kadereit, S. (2013). A 3-dimensional human embryonic stem cell (hESC)-derived model to detect developmental neurotoxicity of nanoparticles. *Archives of Toxicology*, *87*(4), 721–733. https://doi.org/10.1007/s00204-012-0984-2

Karami, A., Golieskardi, A., Ho, Y. Bin, Larat, V., & Salamatinia, B. (2017). Microplastics in eviscerated flesh and excised organs of dried fish. *Scientific Reports*, *7*(1), 1–9. https://doi.org/10.1038/s41598-017-05828-6

Kashiwada, S. (2006). Distribution of nanoparticles in the see-through medaka (Oryzias latipes). *Environmental Health Perspectives*, *114*(11), 1697–1702. https://doi.org/10.1289/ehp.9209

Kloet, S. K., Walczak, A. P., Louisse, J., van den Berg, H. H. J., Bouwmeester, H., Tromp, P., … Rietjens, I. M. C. M. (2015). Translocation of positively and negatively charged polystyrene nanoparticles in an in vitro placental model. *Toxicology in Vitro*, *29*(7), 1701–1710. https://doi.org/10.1016/j.tiv.2015.07.003

Li, L., Luo, Y., Peijnenburg, W. J. G. M., Li, R., Yang, J., & Zhou, Q. (2019). Confocal measurement of microplastics uptake by plants. *MethodsX*, *7*, 100750. https://doi.org/10.1016/j.mex.2019.11.023

Lianzhen Li, Yongming Luo, Ruijie Li, Qian Zhou, Willie J. G. M. Peijnenburg, Na Yin, Jie Yang, C. T. & Y.

Z. (2020). *Effective uptake of submicrometer-plastics by crop plants via a crack-entry mode*. 1–17.

Materić, D., Kasper-Giebl, A., Kau, D., Anten, M., Greilinger, M., Ludewig, E., … Holzinger, R. (2020). Micro-and Nanoplastics in Alpine Snow: A New Method for Chemical Identification and (Semi)Quantification in the Nanogram Range. *Environmental Science and Technology*, *54*(4), 2353–2359. https://doi.org/10.1021/acs.est.9b07540

Mattsson, K., Johnson, E. V., Malmendal, A., Linse, S., Hansson, L. A., & Cedervall, T. (2017). Brain damage and behavioural disorders in fish induced by plastic nanoparticles delivered through the food chain. *Scientific Reports*, *7*(1), 1–7. https://doi.org/10.1038/s41598-017-10813-0

Murali, K., Kenesei, K., Li, Y., Demeter, K., Környei, Z., & Madarász, E. (2015). Uptake and bio-reactivity of polystyrene nanoparticles is affected by surface modifications, ageing and LPS adsorption: In vitro studies on neural tissue cells. *Nanoscale*, *7*(9), 4199–4210. https://doi.org/10.1039/c4nr06849a

Oliveri Conti, G., Ferrante, M., Banni, M., Favara, C., Nicolosi, I., Cristaldi, A., … Zuccarello, P. (2020). Micro- and nano-plastics in edible fruit and vegetables. The first diet risks assessment for the general population. *Environmental Research*, *187*(May), 109677. https://doi.org/10.1016/j.envres.2020.109677

Prüst, M., Meijer, J., & Westerink, R. H. S. (2020). The plastic brain: Neurotoxicity of micro- And nanoplastics. *Particle and Fibre Toxicology*, *17*(1), 1–16. https://doi.org/10.1186/s12989-020-00358-y

UNEP. (2015). *Biodegradable plastics & marine litter : misconceptions, concerns and impacts on marine environments*.

Varó, I., Perini, A., Torreblanca, A., Garcia, Y., Bergami, E., Vannuccini, M. L., & Corsi, I. (2019). Time-dependent effects of polystyrene nanoparticles in brine shrimp Artemia franciscana at physiological, biochemical and molecular levels. *Science of the Total Environment*, *675*(April), 570–580. https://doi.org/10.1016/j.scitotenv.2019.04.157

Walczak, A. P., Hendriksen, P. J. M., Woutersen, R. A., van der Zande, M., Undas, A. K., Helsdingen, R., … Bouwmeester, H. (2015). Bioavailability and biodistribution of differently charged polystyrene nanoparticles upon oral exposure in rats. *Journal of Nanoparticle Research*, *17*(5), 1–13. https://doi.org/10.1007/s11051-015-3029-y

Walczak, A. P., Kramer, E., Hendriksen, P. J. M., Tromp, P., Helsper, J. P. F. G., Van Der Zande, M., … Bouwmeester, H. (2015). Translocation of differently sized and charged polystyrene nanoparticles in in vitro intestinal cell models of increasing complexity. *Nanotoxicology*, *9*(4), 453–461. https://doi.org/10.3109/17435390.2014.944599

Xiong, B., Loss, R. D., Shields, D., Pawlik, T., Hochreiter, R., Zydney, A. L., & Kumar, M. (2018). Polyacrylamide degradation and its implications in environmental systems. *Npj Clean Water*, *1*(1). https://doi.org/10.1038/s41545-018-0016-8

1e. RAC agreed with several other revisions to the conditions of the restriction proposed by the Dossier Submitter (as reflected in the Background Document); including a clarification of the conditions to define natural polymers, a derogation for soluble polymers,…. What are the impacts of such changes? Please provide supporting evidence.

ECHA's aim to restrict the intentional use of microplastics in products is due to the risk these particles pose to environmental and human health. The concerns that exist for insoluble synthetic polymers are also true for their soluble counterparts. Water-soluble polymers like polyacrylamides (PAM) have high production volumes, and many of these are directly emitted into the environment, for example when used as a soil conditioner in agriculture. Hennecke et al (2018) conducted a degradation study of PAM in soils and concluded that this polymer is a persistent material which degrades very slowly in the environment, with a very conservative half-life time estimation of 5.4 years. Moreover, the monomers of PAM are a potent neurotoxin, and Xiong et al (2018) described how these acrylamides are released under anaerobic conditions. Buczek et al (2017) reported acute toxicity to early life stages of freshwater mussels by degraded PAM at environmental relevant concentrations. Finally, there is the potential for soluble polymers to become insoluble in the environment through for example flocculation. PAM has for example been detected as solid microplastics in beach sand and marine turtles (de Jesus Piñon-Colin et al 2018, Duncan et al., 2019).

Exempting soluble polymers from the restriction will allow the continued contamination of the environment by these persistent polymers. Moreover, when exempted, the market-demand for these polymers will increase and hence their concentrations in the environment will inevitably increase too. In conclusion, soluble polymers are as persistent as insoluble polymers and its degradation products can be toxic to organisms at environmentally realistic concentrations. As these polymers fit the persistent, bioaccumulative and toxic criteria, soluble polymers should not be derogated from the restriction proposed by ECHA.

2: Any uses of microplastics that are not specifically identified in paragraph 6 of the proposal would be subject to the conditions of the restriction without any transitional period. Please tell us about the impacts of the proposed restriction on any uses not specifically identified and assessed by the
Dossier Submitter, including appropriate transitional periods (please refer to the background document). For example, the consultation highlighted that the supply of (bulk) ion exchange resins to consumers/professionals could be affected, as could various uses in fashion, arts, crafts or as toys (e.g. play sand). Information on any relevant uses of inorganic polymers should also be provided.

3. The Dossier Submitter has proposed a transitional period of six years for substance-based medical
devices on the basis that the potential and timeline for substitution in these products is comparable to cosmetic products. Substance-based medical devices includes certain toothpastes, denture adhesives and products used for sun protection regulated under the Medical Devices Regulation (EU) 2017/745 rather than the Cosmetics Products Regulation (EU) 1223/2009. Please tell us about the impacts of the proposed ban, as well as of the six-year transitional period. Please indicate whether there are significant differences (function of microplastics, level of performance required for the product,…) between such substance-based medical devices and cosmetic products. Please tell us if you believe that a different transitional period would be justified, with supporting evidence.

4. The Dossier Submitter has proposed transitional periods of either five or eight years for the encapsulation of fragrances in detergents, cosmetic products or other mixtures. We welcome additional information (i.e. which has not already been provided in the previous consultation or call for evidence) on the suitability of these proposed transitional periods, including the timeline

for developing alternatives, reformulating products and any other relevant issues affecting the time needed to comply with the proposed restriction.

5. Paragraph 7 of the proposal describes a requirement (24 months after entry into force of the restriction) to provide relevant 'instructions for use and disposal' for certain uses derogated from the ban on placing on the market. The proposal was revised by the Dossier Submitter during opinionmaking in response to information submitted in the consultation (see background document). Please tell us about the practical implications of this revised requirement as well as the resources (including costs if possible) needed to comply with it? For example, please provide information about the supply chains, processes and number of actors that could be affected by this requirement as well as expected costs and other relevant impacts.

6. Paragraph 8 of the proposal describes a requirement (36 months after entry into force of the restriction) to report information on uses and releases of microplastics for certain uses derogated from the ban on placing on the market. The proposal was revised by the Dossier Submitter during opinion-making in response to information submitted in the consultation (see background document). Please tell us about the practical implications of the revised requirement as well as the resources needed (including the costs) to comply with it, including the potential for joint sectorial submissions? Please provide information about the supply chains, processes and number of actors that could be affected by this requirement as well as expected costs and other relevant impacts.