Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing a restriction on

Polycyclic-aromatic hydrocarbons (PAHs)

ECHA/RAC/RES-O-0000001412-86-279/F
ECHA/SEAC/RES-O-0000001412-86-292/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 7 June 2019) and SEAC's opinion (adopted 20 September 2019)

7 June 2019

ECHA/RAC/RES-O-0000001412-86-279/F

20 September 2019

ECHA/SEAC/RES-O-0000001412-86-292/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Polycyclic-aromatic hydrocarbons (PAHs)**
EC No.:	**-**
CAS No.:	**-**

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the public consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

The Netherlands has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/20503/term on **19/09/2018**. Interested parties were invited to submit comments and contributions by **19/03/2019**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: Yvonne Mullooly

Co-rapporteur, appointed by RAC: Ralf Stahlmann

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **7 June 2019**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Simon Cogen

Co-rapporteur, appointed by SEAC: Andreas Luedeke

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on ***14 June 2019.***

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at https://echa.europa.eu/fi/restrictions-under-consideration/-/substance-rev/20503/term on ***19 June 2019***. Interested parties were invited to submit comments on the draft opinion by ***19 August 2019***.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **20 September 2019**.

The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and] 71(1) of the REACH Regulation.

The opinion of SEAC was adopted **by a simple majority** of all members having the right to vote. The minority position, including its grounds, is made available in a separate document which has been published at the same time as the opinion.

TABLE OF CONTENTS

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Polycyclic-aromatic hydrocarbons (PAHs) (a) Benzo[a]pyrene (BaP) CAS No 50-32-8 (b) Benzo[e]pyrene (BeP) CAS No 192-97-2 (c) Benzo[a]anthracene (BaA) CAS No 56-55-3 (d) Chrysen (CHR) CAS No 218-01-9 (e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2 (f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3 (g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9 (h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3	1. Granules or mulches shall not be placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications if these materials contain more than 17 mg/kg (0.0017 % by weight of this component) of the sum of the listed PAHs. 2. The restriction shall apply 12 months after its entry into force. 3. Definitions for the purpose of this restriction entry: a) Granules are particles, typically in the 1-4 mm size range manufactured from rubber or other vulcanised or polymeric material of recycled or virgin origin or obtained from a natural source. b) Mulches are flake-shaped particles ranging in size from 4 mm up to 130 mm length (typically 10-40 mm) and 10-15 mm width, manufactured from rubber or other vulcanised or polymeric material of recycled or virgin origin or obtained from a natural source. c) Infill material in synthetic turf pitches are granules applied to synthetic turf pitches improving the sport technical performance characteristics of the turf system. d) Use in loose form is any application of granules or mulches in loose form for play or sport purposes other than infill in synthetic turf pitches. This covers the use in children playgrounds and in sport applications such as golf courses, athletic arena's, horse arena footing, nature trails and, shooting ranges.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that because the majority of rubber infill on the market comes from end of life tyres the proposed restriction on **Polycyclic-aromatic hydrocarbons (PAHs)** may have limited effectiveness as it will only be applicable in Member States where End of Waste status has been agreed. This impediment to the application of the restriction will need to be addressed for the restriction to be effective. However, if End of Waste status is agreed across all Member States then RAC agrees that a restriction is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

Polycyclic-aromatic hydrocarbons (PAHs) (a) Benzo[a]pyrene (BaP) CAS No 50-32-8 (b) Benzo[e]pyrene (BeP) CAS No 192-97-2 (c) Benzo[a]anthracene (BaA) CAS No 56-55-3 (d) Chrysen (CHR) CAS No 218-01-9 (e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2 (f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3 (g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9 (h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3	1. Granules or mulches shall not be placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications if they contain more than 20 mg/kg (0.002% by weight of this component) of the sum of the listed PAHs[1]. 2. Granules or mulches shall not be used as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications if they contain more than 20 mg/kg (0.002% by weight of this component) of the sum of the listed PAHs. 3. The restriction shall apply 12 months after its entry into force. 4. Granules or mulches placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications shall be batch labelled. 5. Definitions for the purpose of this restriction entry a) Granules are particles, typically in the 1-4 mm size range manufactured from rubber or other vulcanised or polymeric material of recycled or virgin origin or obtained from a natural source. b) Mulches are flake-shaped particles ranging in size from 4 mm up to 130 mm length (typically 10-40 mm) and 10-15 mm width, manufactured from rubber or other vulcanised or polymeric material of recycled or virgin origin or obtained from a natural source. c) Infill material in synthetic turf pitches are granules applied to synthetic turf pitches improving the sport technical performance characteristics of the turf system. d) Use in loose form is any application of granules or mulches in loose form for play or sport purposes other than infill in synthetic turf pitches. This covers the use in children playgrounds and in sport applications such as golf courses, athletic arena's, horse arena footing, nature trails and, shooting ranges.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on **Polycyclic-aromatic hydrocarbons (PAHs)** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified as stated in the RAC opinion as demonstrated in the justification supporting this opinion.

[1] 20 mg/kg is not a risk based limit since a dose without a theoretical cancer risk cannot be derived for these substances. As a general principle exposure should be lowered. A value of 20 mg/kg is a practical-based limit equating to an approximate reduction of 95% in what is permitted to give a theoretical risk of 2.9 x 10^{-5} for workers and 2.8 x 10^{-6} for the consumers (see Table 7).

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

Summary of proposal:

The use of End of Life Tyres (ELT) as performance infill in synthetic turf has increased in the last 10-15 years due to, for example, the prohibition on landfilling scrap tyres. One of the concerns over the use of ELT granules are the polycyclic aromatic hydrocarbons (PAHs) that are found in the rubber matrix. PAHs are carcinogenic and are known constituents of both extender oils and carbon black used in the manufacture of rubber tyres. Other substances such as ethylene propylene diene monomer (EPDM) and thermoplastic polymer (TPE), and organic material (e.g. cork and coconut matting) are also used as granules in infill materials. The proposed restriction covers eight PAHs in all types of granules and "mulches" used as infill material in synthetic turf pitches or in loose forms on playgrounds and in sports applications.

Granules and mulches are regarded as mixtures. Currently, the supply to the general public of mixtures containing REACH-8 PAHs is restricted above CLP-based specific concentration limits in Annex XVII entry 28. However, these CLP concentration limits are too high to ensure adequate control of the human health risks. Therefore the Dossier Submitter proposed to set a lower sum concentration limit for REACH-8 PAHs that is also closer to the lower concentration limits applicable to articles and toys made from rubber and plastic material in REACH Annex XVII, entry 50.5 and 50.6.

The Dossier Submitter considered that in principle all individuals in the EU may come into contact with granules and mulches. However, sub-populations of individuals in the EU that are most likely to come into contact with granules are workers for installation and maintenance, professional athletes, amateur athletes and children playing at playgrounds. Exposure estimates were combined in a range of lifelong exposure scenarios.

RAC conclusion(s):

RAC agrees that rubber infill containing PAHs up to their maximum concentration limit for the 8 PAHs listed in entry 28 of Annex XVII of REACH, would not provide an adequate level of protection to workers and the general population.

Key elements underpinning the RAC conclusion:

The basis for this restriction proposal is to protect humans against exposure to PAHs in mixtures of rubber infill which is primarily derived from ELT used in synthetic turf pitches. As the landfilling of ELT within the EU is prohibited, most of the rubber granules derived from ELT produced in the EU are consumed in the European Union in applications like sport pitches.

Currently rubber infill material does not fall within the scope of the existing REACH restriction entry 50 since this entry is only applicable to articles. While the general restriction in entry 28 applies to rubber granules meeting End-of-Waste status it permits higher concentrations of PAHs than currently permitted in articles made from the same material. While PAH concentrations, in the permitted range (circa 387 mg/kg)[2], are not found in rubber crumb

[2] The derivation of the 387 mg/kg is explained in Annex B.10.2.1 of the Background Document.

infill currently in use, it is important that this regulatory irregularity between PAH concentrations in articles and in mixtures is rectified and a limit value established.

Article 2 of REACH excludes waste from its scope. Therefore while the potential for exposure to PAHs exists for all ELT rubber granules used as infill material in synthetic turf pitches or in loose form on playgrounds or sport applications the restriction proposal will only apply in those individual Member States where ELT granules and mulches have formally achieved End-of-Waste (EoW) status.

This opinion is targeted only at carcinogenic risk, as cancer is generally known to be the most critical long-term human health effect associated with PAHs exposure. It is acknowledged that some PAHs may be associated with other human health effects such as mutagenicity, skin sensitisation and reproduction toxicity, however, these effects are not addressed in the scope of this opinion.

The concentration limit proposed by the Dossier Submitter is derived based on a variety of exposure scenarios for individuals involved in the installation or maintenance of synthetic pitches, individuals playing sports on them, i.e. professionals as well as the general population. The Dossier Submitter included in their exposure assessments exposure following the use of infill mixtures on playgrounds or other sporting applications where children may be exposed.

In order to avoid any regrettable substitution, the proposal also covers granules[3] made of other materials (recycled or virgin, synthetic or natural). No information has currently been provided in the Annex XV restriction report to support that these materials have the potential to contain PAHs. However, if they were to contain PAHs the same derived limit would be relevant to these materials.

[3] Granules used as infill in synthetic turf pitches generally have the size of approximately 3 mm or less. Mulches are larger in size (approximately 4-40 mm) and are e.g. used in loose applications in playgrounds.

Description of the risk(s) addressed by the proposed restriction

Information on hazard(s)

Summary of proposal:

The hazards and risks of PAHs and PAH-containing materials were reviewed by various international committees (ATSDR (1995); EFSA (2008); IARC (2010, 2012); WHO (1998, 2003), Health Council of the Netherlands (2006), EU (2008)). Furthermore, Germany prepared in 2010 an Annex XV restriction report for 8 PAHs in consumer products (BAuA 2010). These reports have assessed the animal and human toxicological data on PAHs in detail and it was not the goal of the dossier to redo those assessments.

The PAHs covered by the restriction proposal are all classified for carcinogenicity (category 1B) according to Regulation (EC) No 1272/2008. Carcinogenicity studies were assessed by the Dossier Submitter with the main purpose of identifying the most suitable starting point(s) for the quantitative risk characterisation. The following excess cancer risks were established:

Table 1: Oral, dermal und inhalative exposure to PAH and excess cancer risks

	PoD	**Excess cancer risks (1×10^{-6})**	**Excess cancer risks**	**Reference**
Oral	$BDML_{10}$ of REACH 8 PAHs of 0.49 mg/kg bw/day.	0.0007 µg/kg bw/day	1.43×10^{-3} per 1µg/kg bw/day	Culp et al. (1998)
Dermal	Route to route extrapolation from oral route leading to dermal $BDML_{10}$ of 0.74 mg/kg bw/day.	-	9.46×10^{-4} per 1µg/kg bw/day	-
Inhalation	-		The excess lung cancer risk per µg/m³ -years[4] is 0.00014 for workers (1.4×10^{-4}). The excess lung cancer risk per µg/m³ -year is 0.00042 for the general population (4.2×10^{-4}).	Armstrong et al. (2003, 2004)

In addition, of the eight PAHs evaluated in the dossier, BaP and chrysene are classified for germ cell mutagenicity in category 1B and 2, respectively, according to Regulation (EC) No 1272/2008. In addition, several international committees (WHO/IPCS 1998; EC 2002; FAO/WHO 2006) discussed the mutagenicity of these PAHs. Given the ability to induce genotoxic effects there is no threshold value below which no health risk exists for mutagenic PAHs.

[4] The unit µg/m³ – year describes the cumulative exposure of the year average inhalation exposure, which is summed up for the number of years exposed. This exposure metric was selected because the unit risk is also expressed in excess cancer risk per µg/m³ – year. By way of example if the year average exposure to BaP is 1 µg/m³ and exposure continues for 10 years then the result is 10 µg/m³ – year. The same value is obtained if the year average exposure is 10 µg/m³ lasting for one year.

Toxicokinetics (absorption, metabolism, distribution and elimination) was summarised by the Dossier Submitter based on the available key reviews, e.g. ATSDR (1995), EFSA (2008), EU (2008) and WHO (1998, 2003).

RAC conclusion(s):

Animal studies showed carcinogenic effects after oral, dermal and inhalation exposure to the eight PAHs. These findings are supported by human epidemiological studies, which showed an association of increased lung cancer and occupational airborne PAH exposure. Therefore, to protect playing children and sports persons of every age against health risks, RAC is of the opinion that material for synthetic turf pitches in loose form on playgrounds and sport applications should contain the eight PAHs in concentrations as low as reasonably achievable.

Key elements underpinning the RAC conclusion(s):

The eight PAHs covered by this restriction proposal are all identified as carcinogenic substances (table below) according Regulation (EC) No 1272/2008 as well as by the International Agency for Research on Cancer (IARC 2010, 2012).

Table 2: Overview of regulatory evaluations of the 8 PAHs

Chemical	CAS-No.	Carcinogenicity	
		EC 1272/2008	IARC
Benzo[a]pyrene	50-32-8	Carc. 1B (H350)	Group 1
Benzo[e]pyrene	192-97-2	Carc. 1B (H350)	Group 3
Benzo[a]anthracene	56-55-3	Carc. 1B (H350)	Group 2B
Dibenzo[a,h]anthracene	53-70-3	Carc. 1B (H350)	Group 2A
Benzo[b]fluoranthene	205-99-2	Carc. 1B (H350)	Group 2B
Benzo[j]fluoranthene	205-82-3	Carc. 1B (H350)	Group 2B
Benzo[k]fluoranthene	207-08-9	Carc. 1B (H350)	Group 2B
Chrysene	218-01-9	Carc. 1B (H350)	Group 2B

The carcinogenic effects of the PAHs as single compounds and in mixtures containing various PAHs are well described in numerous animal studies. Different routes of exposure have been examined. Benzo[a]pyrene (BaP) is the best-studied PAH and showed a carcinogenic potential in different species and routes of exposure. Following an oral exposure with pure BaP or PAH mixtures the tumour incidences increased in the gastrointestinal tract, liver and respiratory tract of mice and rats. Long term inhalation of PAH mixtures in rats and mice induced tumours in the lung. Dermal exposure to BaP and other PAHs induced malignant tumours in different strains of mice. Most of the eight PAHs have been tested in PAH mixtures in various studies, but no experimental data on the combined carcinogenicity of these eight PAHs are available.

No human data on the carcinogenic effects of single PAHs are available. Most of the available human studies investigated the carcinogenicity of PAH mixtures with BaP as marker compound. Several epidemiological studies described a carcinogenic effect in humans after occupational exposure to soot, coal tar and other PAH-containing mixtures. Due to differences in the study design (case control vs. cohort, differences in exposure measurements, not considering lifestyle factors, unawareness of co-exposure and incomplete data presentation),

the interpretation and comparison of these data is hampered. Overall, the majority of the epidemiological data described an association between airborne PAH exposure and increased lung cancer risk (Armstrong et al., 2003, 2004).

Although no epidemiological study focuses primarily on the relationship between synthetic turf pitches with rubber infill and human health effects, initial explorations have been carried out in the USA. One study from Washington State Department of Health (Wiesman & Lofy, 2017) examined a database of a football coach and found no increased number of players with cancer diagnosis (compared to cancer rates of Washington residents of the same age). The authors recommended further investigations due to limited exposure data. Bleyer and Keegan (2018) examined data from California and found no association between annual lymphoma county incidence and county-level synthetic turf field density. They also recommended to conduct further studies.

Both studies, conducted in the US, did not find a positive association between lymphoma/leukemia and playing sports on synthetic turf pitches.

The Dossier Submitter highlighted that the human health endpoint of utmost concern for these eight PAHs in the scope of this restriction proposal is carcinogenicity and the ability to induce genotoxic effects. A non-threshold approach is therefore applied and the derivation of a DNEL/DMEL is not considered reasonable in this case.

The Dossier Submitter selected the key studies for every route of exposure and calculated the excess lifetime cancer risks for all routes. The dose-response relationships have been used for the risk characterisation.

A lifetime feeding study in mice by Culp and co-workers (Culp et al., 1998) was selected as key study for oral and dermal exposure. In a 2-year carcinogenicity study, female B6C3F1 mice (n= 48/group) were fed pure BaP or two different coal tar mixtures containing high amounts of several PAHs. Two additional groups of 48 mice each served as controls, one group was fed the standard diet, while the other was fed the standard diet treated with acetone in a manner identical to the BaP diets. The BaP-treated animals (n=48/group) received BaP via the diet in concentrations of 0, 5, 25 or 100 ppm (equivalent to doses of 0, 0.7, 3.6 or 14 mg/kg bw/d; assuming 1 mg/kg bw/d corresponds to 7 ppm for mice, cf. EFSA (2008)) for 2 years. In the same experiment, groups of 48 female B6C3F1 mice were fed diets containing 0, 0.01, 0.03, 0.1, 0.3, 0.6 or 1.0% coal tar mixture 1, which contained benzo[a]pyrene at a concentration of 2240 mg/kg (equivalent to BaP doses 0.032, 0.096, 0.32, 0.96, 1.92 or 3.2 mg/kg bw/d), or 0, 0.03, 0.1 or 0.3% of coal tar mixture 2, which contained benzo[a]pyrene at a concentration of 3669 mg/kg (equivalent to BaP doses of 0.16, 0.52 or 1.6 mg/kg bw/d). Significantly increased incidences of papillomas and carcinomas were observed in the BaP-treated group in the forestomach, oesophagus, and tongue. The increase in incidence of neoplasms was related to dose, with statistical significance in the 25 and 100 ppm groups. Both coal tar mixtures induced a dose-dependent increase in tumours at various locations, *i.e.* in the liver: hepatocellular adenomas and carcinomas, in the lung: alveolar/bronchiolar adenomas and carcinomas, in the forestomach: squamous epithelial papillomas and carcinomas, in the small intestine: adenocarcinomas, histiocytic sarcomas, and, furthermore, haemangiosarcomas in multiple organs, and sarcomas. The lowest concentrations resulting in a statistically significantly increased tumour incidence were 0.3% for mixture 1 and 0.1% for mixture 2. This study indicated that BaP alone induced only tumours of the alimentary tract, whereas the coal tar mixtures also induced liver and lung tumours. EFSA (2008) concluded that BaP alone is not a suitable indicator for PAH exposure via the oral route. Relative concentrations of PAHs in food are variable and BaP was not detected in all samples. The marker method was expanded to two PAHs, four PAHs and eight PAHs. EFSA found the PAH 4 and PAH 8 markers to be more suitable indicators for PAHs in food. The PAH concentration in rubber granules varies and BaP is not detectable in all samples. The Dossier Submitter concluded that BaP alone is also not a suitable indicator for exposure to PAHs via rubber granules. Most of the eight PAHs under current evaluation are included in

the PAH mixture used by Culp et al. (1998).

The meta-analysis of Armstrong et al. (2003, 2004) was selected as a key study for assessment of human inhalation exposure. This meta-analysis combined studies conducted in the industries that share (almost exclusive) exposure to PAHs. The meta-analyses included 39 occupational cohorts (35 cohorts, one case-cohort and three nested case-control samples from within a cohort) exposed to PAHs for which risk estimates for lung cancer could be estimated and 27 cohorts for which risk estimates were published for bladder cancer. The underlying studies showed a substantial variation in exposure definition, ranging from no explicit definition to quantitative assessment of exposure to BaP. Exposures were measured as BaP, as a proxy (benzene-soluble matter, total PAHs, carbon black) that could be converted to BaP, or no measure of exposure. For the studies lacking information on exposure, the authors defined supplementary estimates for exposure to BaP for each industry/workgroup combination, based on available published exposure estimates in the same industries. There were 39 cohorts for which risk estimates were published for lung cancer. An overall relative risk estimate (URR) of 1.20 (95% confidence interval (CI): 1.11-1.29) per unit of 100 µg/m^3 -year cumulative BaP exposure was calculated for lung cancer. There were 27 cohorts for which risk estimates were published for bladder cancer. An overall relative risk estimate (URR) of 1.33 (95% confidence interval: 1.16-1.52) per unit of 100 µg/m^3 -year cumulative BaP exposure was calculated for bladder cancer.

Information on emissions and exposures

Summary of proposal:

The use of rubber granules as infill on artificial turf can result in the exposure of people to substances present in these granules. Exposure can occur when installing or maintaining the synthetic turf pitches, and when sporting or playing on these pitches. The Dossier Submitter identified four exposure scenarios covering:

- Installation of synthetic pitches with rubber infill
- Maintenance of synthetic pitches with rubber infill
- Playing sports on synthetic pitches with rubber infill
- Play and playing sports on synthetic parks/pitches with rubber infill

The first three scenarios refer to workers (including professional athletes) while the last one refers to consumers, with a special attention to children since it was foreseen that during childhood children may simultaneously play at playgrounds and participate in sports.

The 'lifelong' exposure for the installation and maintenance workers was set at a 40 years working life. A different approach was taken for the professional players since it is unlikely to be a professional player for 40 years. In a regulatory sense the professional players were considered as 'workers', but from a risk assessment point of view they were regarded as consumers. Therefore, the lifelong exposure for professional players was assessed in the same way as for the consumers.

Information on exposure to PAHs from rubber granules during installation and maintenance of pitches and for playing and sports is limited. Exposure assessments for installation workers were based on information from studies IndusTox (2009) and Waste and Chemicals (2016). For sports and playing exposure was based on studies performed by RIVM (2016, 2017) and ECHA (2017a).

Exposure assessments were performed for a theoretical case where the concentration of the mixture of REACH-8 PAHs is at a high concentration applicable to the PAHs according to

current restriction and for the 95th percentile of the PAH content in samples of ELT granules taken by RIVM.

The exposure estimates for the workers related to scenarios 1 and 2 are given in Table 3:

Table 3: Exposure estimates for the dermal and inhalation route for workers in ES1 and ES2, based on REACH-8 PAH content of 17 mg/kg; P95)

Worker scenario	Dermal exposure estimate (µg/kg bw/day)	Inhalation exposure estimate (µg/m³-year BaP)
Installation	0.00013	0.21
Large maintenance	7.3×10^{-6}	0.012
Small maintenance	2.4×10^{-5}	0.039

To describe the PAH exposure to consumers, several contributing scenarios were investigated in order to estimate a lifelong exposure to PAHs taking into account both playing on rubber infill materials at playgrounds and sporting on synthetic pitches. Specific contributing scenarios were considered valid for a specified period in a lifetime and added up to obtain the lifelong exposure. The scenarios were elaborated in such a way that they calculate a *reasonable worst case exposure* to PAHs from rubber granules for those exposed.

The exposure estimates for the professional and non-professional sports players are given in Table 4 and Table 5:

Table 4: Exposure estimates per route for the playground scenarios and the outfield player (based on REACH-8 PAH content of 17 mg/kg; P95)

Contributing scenario	Oral exposure estimate (µg/kg bw/d)	Dermal exposure estimate (µg/kg bw/d)	Inhalation exposure estimate (µg/m³-year BaP)
Lifelong prof. player	0.0012	0.00018	1.1×10^{-4}
Lifelong consumer	0.0011	0.00017	6.7×10^{-5}

*Oral exposure covered by playground scenario
W= worker

Table 5: Exposure estimates per route for the playground scenarios and the goalkeeper (based on REACH-8 PAH content of 17 mg/kg; P95)

Contributing scenario	Oral exposure estimate (µg/kg bw/d)	Dermal exposure estimate (µg/kg bw/d)	Inhalation exposure estimate (µg BaP /m³-year)
Lifelong prof. player	0.0015	0.00036	1.1×10^{-4}
Lifelong consumer	0.0014	0.00034	6.8×10^{-5}

* Oral exposure covered by playground scenario
GK = goal keeper
W = worker

RAC conclusion(s):

RAC agrees the source of PAHs in ELT granules/mulches originates from impurities in carbon black and extender oils used in the manufacture of tyres. While none of the eight polycyclic aromatic hydrocarbons (REACH-8 PAHs) within the scope of this restriction is registered, they may still be present in end of life tyres as impurities or by-products. However, RAC acknowledges the major source of PAH exposure to the general population (non-smokers) comes from food and inhaled air.

RAC agrees that while no supporting information on the content of PAHs in cork, TPE and EPDM has been provided, the proposed PAH limit should apply to any other type of synthetic pitch infill material with a probability of containing PAH or PAH impurities, in order to avoid similar or greater risk through regrettable substitution.

RAC notes that only reasonable worst case exposure scenarios have been presented and that it is unlikely that any individual would be exposed to the reasonable worst case in each contributing scenario throughout their entire life. However, RAC agrees with the Dossier Submitter that the six exposure scenarios selected provide a suitable range of activities where exposure is foreseen to occur. RAC agrees that the exposure scenario for professional players will also address amateur player exposure and that the exposure scenarios presented for children at play are appropriate.

The highest potential for exposure from synthetic pitch use exists on long-pile sports pitches.

As pitch construction is generally the same for all types of long pile sport pitches, RAC accepts the Dossier Submitter's exposure assessment for installation and maintenance of long pile sport pitches (including the assumption that no PPE is used) as a suitable exposure assessment for pitch installation.

RAC agrees that insufficient information is available to ascertain the effect, if any, of coating granules and mulches. The impact of coating is not taken into consideration for the purpose of exposure assessment as coated granules and mulches can undergo surface deterioration during their use resulting in the removal of such surface coatings layers.

RAC agrees the approach used to calculate lifelong exposure is appropriate.

Key elements underpinning the RAC conclusion(s):

- *Sources of PAH exposure within the general population*

The main exposure to PAHs within the general population (for non-smokers) comes from inhaled air and food. PAHs are emitted to air from a number of sources, such as processing of coal, crude oil, petroleum, and natural gas, production of aluminium, iron and steel, heating systems in power plants buildings and residences (oil, gas, charcoal fired stoves, wood stoves), combustion of refuse, fires (including wood fires), motor vehicle exhaust and used motor lubricating oil.

Within food, PAHs may be formed during processing and domestic food preparation such as barbecuing, smoking, drying, roasting, baking, frying or grilling and in the production of some oils, in particular olive and pomace oil. In 2008, EFSA calculated human dietary exposure to PAHs. Exposure varied between 235 ng/day and 389 ng/day for average and high consumers, respectively, for benzo[a]pyrene alone, rising to 1,729 ng/day and 3,078 ng/day, respectively, for the sum of eight of the most critical PAHs. Maximum levels have been set for PAHs in key foodstuffs, e.g. smoked meat and smoked meat products, smoked fish and smoked fish products, oils and fats, via Commission Regulation (EC) No 1881/2006 to reduce adverse effects on the health of consumers.

- *PAH exposure from ELT Rubber infill and mulches*

While infill material can be produced from a variety of virgin and recycled materials the majority of granules in the EU are produced from ELT. RAC notes that none of the 8 PAHs are intentionally added during the production of tyres. The main source of PAHs in tyres comes from PAH impurities in extender oils and carbon black used in tyre production. The International Carbon Black Association stated that in laboratory analyses most carbon black products have extractable PAH levels (REACH-8 PAHs) not exceeding 0.1%.

Exposure to PAH from rubber granules occurs when PAHs are released from the rubber granules following contact with the skin or sweat, or followng ingestion/inhalation into gastro-intestinal fluids, or lung fluids.

- *PAHs in extender oils*

While car tyres contain a greater percentage of extender oils (7%) than truck tyres (1.6%), truck tyres may be retreaded up to five times before they are eventually recycled. This may result in higher PAH concentrations in recycled ELT. Since 2010 the PAHs content in extender oil (and in imported tyres) has decreased due to the existing REACH restriction entry 50. The extender oil restriction in Entry 50 limits the REACH-8 PAH levels at 10 mg/kg and BaP at 1 mg/kg in the oils. However, it is acknowledged that while major tyre producers have applied the restriction it is not known if smaller producers outside the EU follow the restriction. RAC notes that Depaolini et al., 2017 indicated tyres from outside the EU have a somewhat higher PAH content compared to EU produced tyres. However, it is not known if this difference is due to the presence of extender oils or the type of carbon black used. Since there has been an increase in tyre imports from outside the EU between 2013-2016 there is still uncertainity as to whether these tyres also contain PAH concentrations <0.1%.

- *PAHs in carbon black*

Information in Table A1 of the dossier shows car tyres contain 28% carbon black and truck tyres contain approximately 24% carbon black. Carbon black is used as a filler for reinforcement and reacts during vulcanisation. Industrially manufactured carbon black is produced by pyrolysis of hydrocarbons at high temperatures under controlled process conditions. This results in the formation of unavoidable trace levels of organic impurities, such as PAHs.

RAC notes the recent changes in car design to lower rolling resistance, which has resulted in the tread of EU tyres being reinforced with silica (which has replacing part of the carbon black) thus reducing the carbon black content. However, since silica-reinforced tyres contain approx. 1.5 times more extender oils than carbon black-reinforced tyres so it is not clear what affect this new design development has on the overall PAH content in tyres.

- *ELT mulch v ELT infill*

ELT granules come, primarily from car and truck tyres, in a variety of different sizes depending on market requirements. The size of infill used in synthetic turf is typically 0.25-0.30 mm with the shape varying from rectangular to round.

Mulch is primarily derived from truck tyres and known to be used primarily (60%) in playgrounds. The size of ELT mulch made from tyre buffings[5] from retreading is 10-40 mm long and from ELT is 4-10 mm long but typical pieces of mulch are 10-40 mm. Some mulch is used loose while other mulch is bound in a resin to create a solid surface. Its most prevalent use is in the UK and some observed use in other Member States: FR, DE, AT, NL, BE and BU.

Exposure to PAHs from mulches may be lower due to a lower surface area, therefore exposure estimate for rubber infill granules in the dossier may overestimate exposure for mulch. However, as a consequence any limit derived for rubber infill granules will provide suitable protection for rubber mulch also.

RAC notes ETRMA (PC Ref 1939) have indicated that rubber mulch is always PU coated and mixed with a binder and applied at 10 kg/m^2. Limited information is available to determine how the lower surface area or coating of mulches or granules influences exposure to PAH so

[5] Rubber buffings are reportedly derived from grinding the outer layer of tyres in preparation for receiving a new tread.

RAC have not factored it into the exposure assessments as its use in infill is limited. However, it is anticipated that it could potentially reduce exposure.

- *PAHs from other infill sources*

Alternatives made of Thermoplastic elastomer (TPE) and Ethylene Propylene Diene Rubber (EPDM), i.e. synthetic rubber are imported. No information is available on the carbon black content of TPE and EPDM material before they are recycled into infill. The choice of infill in Germany is virgin EPDM.

Cork has also been included within the scope of the restriction, however, no evidence is provided to suggest how cork material could contain PAH or PAH impurities to support its inclusion within the scope of the restriction.

- *Synthetic pitch installation*

Two types of synthetic turf pitches exist (1) short pile 12-15 mm (2) long pile 20-25 mm & 50-70 mm. Short pile is used for sports such as hockey, cricket and lawn bowls and no infill material is used. Long pile is used primarily for football (soccer); other sport uses include rugby, gaelic sports, baseball, lacrosse and American football. Long pile pitches of 20-25 mm use sand material whereas 50-70 mm pile pitches use ELT derived infill material. The quantity of infill used depends on the height of pile. The most commonly used long pile height is 60 mm which uses 110-120 tonnes per pitch.

While some sport pitches are larger than soccer pitches RAC agrees it is appropriate to use the dimension for a FIFA international match soccer pitch for the exposure assessment, as soccer is the most common sport played on long pile synthetic turf pitches infilled with ELT granules.

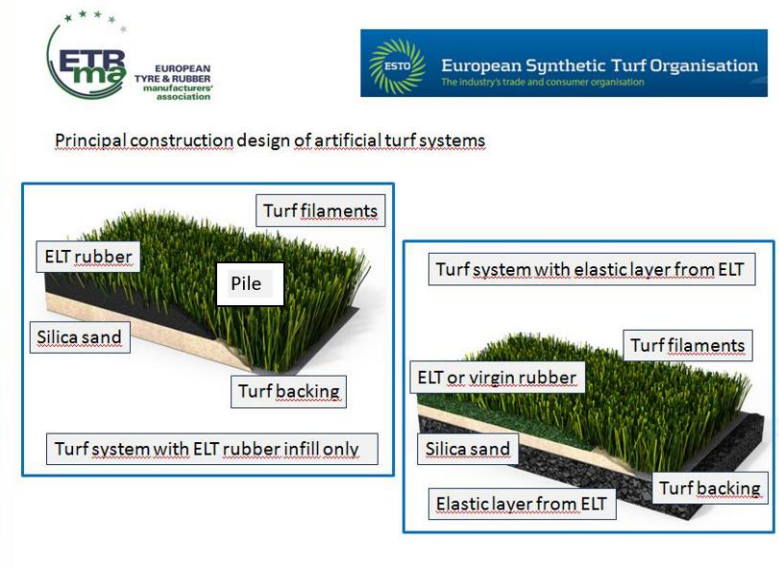
- *Concentration of PAHs in infill*

Results of sampling and analysis by RIVM (2017) of PAHs in ELT granules showed that the REACH-8 PAH concentration in ELT infill samples available varied from **2.9-21 mg/kg** with a **geometric mean of 11 mg/kg** and a **P95 of 17 mg/kg**. The data was provided by industry, authorities, other stakeholders and obtained from public literature in the EU in the year 2010 or later.

During the ECHA public consultation (PC Ref 1939) on the restriction proposal, further test information on PAH content was provided. For uncoated ELT, with the exception of one sample (registering at 53.41 mg/kg) the PAH concentrations for the 8 PAHs were consistent with the analysis data presented in the dossier (less than 20 mg/kg with a median of 8.47 mg/kg for the batch of 67 samples tested). Data provided for coated material showed the PAH levels for the 8 PAHs in coated ELT to be slightly lower with a median of 6.08 mg/kg. No significant differences were noted in the data provided for the concentration of PAHs in non coated ELT indoors or outdoors. A comparison of the concentration of the 8 PAH concentrations in the RIVM study and ELT samples from granules and sport fields from the European Risk Assessment Study on Synthetic Turf Rubber Infill was also provided during the ECHA public consultation (PC Ref 1939) which showed similar concentrations of the 8 PAHs in the studies (note the single sample of 53.41 mg/kg was removed during the comparison) ranging from 6.6 mg/kg to 11.7 mg/kg with a median of 7.1 mg/kg.

- *Pitch Installation - Exposure assessment*

Figure 1: Design of artificial turf systems



Pitch installation is undertaken during a maximum 6 month window every year (window is shorter in northern Member States than southern. Therefore, southern workers have the greatest duration of exposure. It takes on average 6 workers 30-35 working days to install a new pitch. The infilling process takes 12-18 hours per pitch. Infilling by larger operators is normally automated whereas smaller operators use workers to load the machines and drive the machinery. Where infilling is automated the exposure of workers to granules will be lower. RAC notes that the Dossier Submitter's exposure assessment does not provide for reduced exposure through the use of automated infilling systems.

Figure 2: Larger operators with automated infilling system

Figure 3: Smaller operations of infilling

To estimate reasonable worst case installation exposure period, the Dossier Submitter assumes that installation workers go from pitch to pitch after infilling so installation is based on three days per week for six hours per day continuously over a six month period. Sometimes these workers do other tasks e.g. pre-installation work.

Maintenance by brushing or raking of the infill can be undertaken by machine or manually. It varies from once per week to once every three months. Manual brushing occurs when smaller areas need to be fixed. Deep brushing and refilling of infill usually occur once per year however it may occur more often in front of the goal area. It is estimated one ton per pitch per year is used for maintenance refill.

Soccer is the sport mostly played on long-pile synthetic turf in the European Union therefore exposure scenarios are focussed on outfield football players and goalkeepers. Other sports also use long-pile synthetic turf pitches and these sports are included in the assessment through analogy with the soccer exposure scenarios. Sports that take place on short pile synthetic turf are not infilled with ELT rubber infill and therefore are not considered within the exposure scenario.

Exposure assessment parameters

RIVM (2017) performed migration studies to assess the availability for exposure through dermal and oral contact.

Oral migration studies showed that approximately 9% of the PAHs contained in the rubber granules are released from the granules into the gastrointestinal tract.

A dermal migration study indicated approximately 0.02% of the PAHs in rubber granules are released into sweat. Since PAHs are lipophilic compounds, migration in a more lipophilic medium than aqueous artificial sweat will result in higher migration meaning the dermal migration fraction of 0.02% may underestimate exposure. A study by Fraunhofer ITEM (2016) using a powder with more lipophilic properties than artificial sweat gave a dermal migration fraction of 0.05%. This was used by the Dossier Submitter in the reasonable worst case exposure assessment. RAC agrees that it was appropriate to base the migration fraction on Fraunhofers' study.

Dermal load: Data from the Ecopneus study[6] (2016) only provided information on the sum of dermal load from all four dermal pads, in the absence of other more suitable information RAC agrees with the use of the data to estimate reasonable worst case dermal exposure.

The exposure assessment assumes that all PAH inhaled via dust is available.

Worker exposure installation & maintenance

Inhalation and dermal exposure is the important routes of exposure for workers during installation and maintenance. Lifelong cumulative exposure estimates for the workers is derived from both dermal exposure and inhalation exposure. The greatest risk of exposure during installation and maintenance results from direct dermal contact and from the inhalable of dusts formed when big-bags containing granules are emptied. Lifelong exposure for installation and maintenance workers is based on 40 years.

The following worker exposure scenarios were presented by the dossier

Four exposure scenarios (ES) have been identified:

ES1: Installation of synthetic pitches with rubber infill – worker

ES2: Maintenance of synthetic pitches with rubber infill – worker

ES3: Playing sports on synthetic pitches with rubber infill – worker (professionals)

ES4: playing and playing sports on synthetic pitches with rubber infill – consumer

Exposure duration

The most commonly used pile height is 60 mm and this typically needs approximately 15 kg/m^2. Approximately 110-120 tonnes of infill is used on a full size football field (120 big bags). For shorter pile height, the infill quantity can be as low as 40 tonnes for the same area.

Refilling is done once per year with similar machines to those used during installation. For maintenance, on average 0.5-1 tonne of refill per year has to be supplemented for each field and for after-winter service (rubber infill can be unintentionally removed when pitches are cleared from snow) then 3-5 tonnes is used. Some areas of the field which are mostly used, like the front of the goal and centre of the field, are refilled more often during the year, which is considered small maintenance. The frequency of brushing varies from once per week to once every 2-3 months. New field installation takes a total of 30-35 working days. Base preparation takes approximately 20 days, laying of turf 8 days and 2-3 days spreading sand before infill is placed. The infill procedure takes about 2 to 3 days for about six hours per day. The maximum period of the year installation occurs is 6 months as pitches are normally only built during a six months window (summer period) since dry conditions are needed. The Dossier Submitter has used 18 hours per week for 26 weeks to calculate the length of exposure for installation workers and six hours per week for four weeks for large maintenance activities and two hours per week for 44 weeks for small scale maintenance work. Large scale contractors use automated machinery to infill and small scale operators use workers to load and drive infill machinery. The Dossier Submitter's exposure assessment assumes all infilling is undertaken manually leading to a worse case exposure. However, while noting the conservative nature of the Dossiers Submitters exposure assessment, RAC accepts the Dossier Submitters proposed duration of exposure in the reasonable worst case exposure assessments.

[6] Ecopneus (2016 unpublished), Characterisation of rubber recycled from ELTs and assessment of the risks associated with dermal and inhalation exposure.

Exposure studies for installation of synthethic pitches

There are four exposure studies regarding the installation of synthetic pitches with rubber granules (IndusTox 2009, Ecopneus 2016, Waste and Chemicals 2016 prepared by Ecopneus) that considered exposure to PAHs (both studies) or BaP (Waste in Chemicals 2016). The IndusTox study had nine workers and the Ecopneus and Waste and Chemicals studies combined had approximatley eight workers.

The biomonitoring data from the IndusTox study (2009) showed higher values than the Ecopneus (2016) study (max 0.53 µmol 1-OHP/mol in creatinine vs. 0.4 µmol/mol), which could be explained by a larger football pitch that was installed during the IndusTox study and thus higher exposure to PAHs. Both studies indicate, also based on their biomonitoring findings, that the contribution of installing rubber granules on artificial turf to the total PAH exposure is rather limited compared to background levels. However, the biomonitoring data cannot be used to derive a direct link between PAH content in rubber granules, worker activities and a risk estimate, since other sources cannot be excluded. Therefore, the biomonitoring data is not used in the exposure assessment.

The Waste and Chemicals (2016) study provided data for both the inhalation and dermal route of exposure. In addition to biomonitoring the Waste in Chemicals monitoring study included information on respirable dusts, (BaP content) in the breathing zone of workers, and BaP concentrations on pads used to assess dermal exposure, which were taken from four pads from four different body locations.

During the public consultation a draft confidential study ERASSTRI (2019) was made available which shows the PAH air concentrations are at background levels and the skin wipe samples did not detect PAHs i.e. lower exposure estimates.

Dermal exposure

Direct dermal contact is likely to occur when emptying the big bags containing rubber granules and the manual distribution of the rubber granules over the synthetic pitches. The Ecopneus study provides measurement data.

RAC notes that the Ecopneus study only provides information on the total sum of the dermal load from all four pads used rather than the total of each individual pads. In the absence of further information the highest sum 0.19 ng BaP/cm^2 of the four dermal pads was used to calculate dermal exposure.

The selected dermal exposure area of 5 150 cm^2 is considered by RAC to be appropriate as it is based on a dermal exposure to hands, half arms and half legs (PPE use is not taken into account for reasonable worst case exposure assessment). The 0.19 ng/cm^2 BaP measured in the Ecopneus study can be extrapolated to approx. 3.6 grams of rubber granules in contact with the skin during the installation. Dermal exposure for installation workers has been estimated at **0.00013 ug/kgbw/d** & **7.3 x 10^{-6}** for large scale and **2.4 x 10^{-5}** for small scale maintenenace workers.

Inhalation

The low vapour pressures of PAHs means they are less likely to contribute to inhalation exposure via volatilisation. Exposure to PAHs can occur in inhalable dusts formed when big bags of granules are emptied during installation and maintenance activities. The Ecopneus and Waste in Chemicals studies measured BaP concentrations in dust in the breathing zone during installation activities, giving a 90th percentile of 23.24 ng BaP/m^3. RAC accepts the use of this value for worker exposure (both installation & maintenance) noting that the sample size in the study was limited and that the concentrations measured could have included other sources of environmental exposure to PAHs.

No data was available to confirm the percentage of the PAHs released from the granules into lungs nor on the amount of particles/dust cleared by the lungs. Therefore, the inhalation exposure assessment assumed any PAH concentrations present in this dust were 100% available. While RAC agrees with the assumption, it may lead to an overestimation of PAH exposure in the lung when considering in the context of the oral study only 9% of the PAHs contained in the rubber granules were released from the granules. Inhalation exposure over 40 years is estimated at 0.21, 0.012 and 0.039 µg/m^3-yr BaP for installation, large scale maintenance and small scale maintenance respectively.

Oral

Oral exposure was not considered relevant by the Dossier Submitter for workers during installation and maintenance activities. RAC notes that due to the small size of the granules there may be accidental oral exposure during installation and maintenance workers, however, it is likely to be minimal. In any event exposure to PAHs from this route of exposure will be minimal since only 9% of the PAHs contained in the rubber granules were released in the oral study.

Worker Lifetime exposure

When considering the lifetime exposure of installation and maintenance workers, these cohorts of the population are also likely to be exposed during childhood and as recreational players during their lives. This was not taken into consideration by the Dossier Submitter which may lead to an underestimation of the exposure.

Sporting Professional Workers (incl. amateur) playing on synthetic pitches with rubber infill

Two exposure scenarios were provided.

1. **Contributing scenario W1: professional outfield player**

Outfield player 18-35 years of age four hours per day six days a week

2. **Contributing Scenario W2: professional goalkeeper**

Goalkeeper 18-35 years of age four hours per day six days a week.

RAC considers that the frequency of amateur players is similar to professional players and that these scenarios are appropriate to cover both groups in terms of exposure. Lifetime exposure for professional players is less than 40 years. However, after leaving performance-oriented sport, football players and goalkeepers often join veterans teams in later life, so RAC agrees that it is appropriate for the exposure scenario to consider lifelong exposure to this group in the same way as consumers are assessed.

Consumer Exposure

Consumer exposure to PAHs from the rubber granules can occur via the dermal route and/or the oral route via ingestion. Oral exposure is taken into account to cater for the accidental ingestion of rubber granules by young children.

Inhalation exposure is less likely since the 8 PAHs have a very low volatility and consumers are unlikely to be exposed to dusts formed during the emptying of big-bags which takes place during installationad and maintenance.

The consumer exposure assesment assumes that during their entire life both children and adults always play/train on long pile synthetic turf infilled with rubber granules. As it is unlikely

that this will ever be the case this will lead to an over estimation of the lifetime exposure risks.

ES4-10: Exposure playing and playing sports on synthetic pitches with rubber infill – consumers (children-adulthood)

Lifetime reasonable worst case exposure for consumers is based on the cumulative individual exposure from a number of sub scenarions

1. 2-3 years playing in a playground
2. 3-6 years playing in a playground
3. 6-11 years playing in a playground
4. 11-13 years playing in a playground
5. Plus additional exposure between the years of 4-11 playing sports +
6. Plus additional exposure for goal keeper starting at 7 age to 10 +
7. 11-18 years playing sport (performance related)
8. Additional exposure as an adult 18-35 years (performance related)
9. Plus exposure as a veteran 36-50 years of age

The consumer population is covered as a whole. The lifetime exposure for all consumers is based on the highest exposed individuals playing at playgrounds and sport pitches that use rubber infill. It is likely that the majority of consumers will be less exposed than the reasonable worst case scenario, as not all consumers are exercising and playing with such a heavy frequency on synthetic turf pitches as the highest exposed individuals.

Exposure during childhood occurs during day care, at school and on public sports pitches. As children grow older, the frequency and duration of exposure is increased (see Tables B32 and B33 in the Background Document). While RAC notes that the exposure scenario presented has not provided for the additional exposures of adults > 50 years of age it is not likely to have any significant impact on lifetime exposure risks since lifetime consumer exposure is based on playing soccer in a performance orientated level rather than recreational use to cover the highest exposure frequency.

No PAH exposure information is available for rubber granules in playgrounds, exposure is based on PAH exposure from rubber tiles as they are more or less expected to yield similar exposure profiles.

The body weight of a four-year-old child is estimated as 15.7 kg, based on the 25 percentile of the body weight distributions among children aged between 3 and 6 (RIVM, 2014).

Table 6: Anthropometric data for scenarios 1 to 4 based on RIVM 2014 and 2016

	Age (year)	Body weight (kg)	Contact area of relevant parts of the body (m^2)		
			Hands	legs	Feet
Scenario 1	2	12.4	0.014	0.072	0.018
Scenario 2	3 to 6	15.7	0.017	0.088	0.022
Scenario 3	6 to 11	24.3	0.023	0.128	0.031
Scenario 4	11 to 13	44.8	0.032	0.211	0.048

Oral exposure

All the exposure scenarios assume that children always play on synthetic turf with rubber granules. The input parameters selected by the Dossier Submitter are primarily based on RIVM (2016) study. Oral exposure to granules compared to tiles is expected to occur in children. Mouthing behaviour differences between tiles and granules has been taken into account where possible.

No data is available on hand-mouth contact of rubber granules. Data for oral exposure uptake is taken from the new US EPA (2017a) soil study which calculated a soil uptake of 0.09 g in 2-10 year olds. In the absence of other information this is considered an appropriate parameter in terms of the size of soil material compared to granules. This value does not include pica behaviour[7]. It is likely that oral exposure is not as relevant for mulch due to the larger size of the mixture. The frequency of ingestions is assumed to be 261 days per year but the exposure assessment for oral ingestion is based on exposure event rather than per day. The amount per day is regarded as an average. The orally ingested amounts used are 90 mg/event for children (<11 years) and 50 mg/event for children (11 years and up) and for adults when assuming playing on playgrounds and playing sports as an outfield player. Goalkeepers are expected to ingest higher amounts as they are more often closer to the ground. RAC accepts the oral amount ingested, for all age categories, of 90 mg/ exposure event as a reasonable worst case input but notes that it is likely that granules will likely be spit out. In addition exposure to PAHs in rubber granules from the oral route of exposure will be minimal as only 9% of the PAHs contained in the rubber granules were released in the oral study.

Dermal exposure

Contact via the skin depends on the frequency of contact with the rubber surface, the area of uncovered skin exposed and the dermal load. Dermal exposure should include exposure from any granules which end up in the clothing. A Norwegian study that specifically refers to rubber granules gave a dermal load of 0.21, 0.27, 0.56 and 0.87 g rubber granules on the skin for the various age ranges; these values also fall within the range of the US EPA study on soil adherence to skin. 1 g of rubber granules represents 12 cm^2 of skin contact. For children under four years of age 1 g is used, and 3.3 and 6 grams is used for children aged 11 to 19 years and for adults.

[7] Eating inedible objects (including soil).

The frequency of contact with material is likely to be greater for hands (261/365 days) than feet and legs (66/363 days). The variation between hands feet & legs is also based on reduced exposure in the winter period when those playing are likely to have fully covered arms and legs. However, RAC recognised this may not be true for all parts of the EU.

Goalkeepers are expected to have a higher dermal exposure contact than outfield players for football however in other sports outfield players may have a similar exposure to goalkeepers e.g rugby players. While the exposure assesment for goal keepers assumed a higher dermal contact through arms and legs it assumed hands were not exposed so this may lead to an underestimation for some players like rugby players. As no other information is available the value of 10 g of rubber granules per period of sport activity is considered an acceptable input parameter (10 g covers 120 cm^2 skin).

Inhalation exposure

The low vapour pressures of PAHs means they are less likely to contribute to inhalation exposure via volatilisation. While inhalation exposure is negligible there may be potential for the inhalation exposure of consumers from rubber dust. Data from a PM10 exposure study of PAH exposure in the NILU (2006) study which was conducted indoors where other environmental contributions are considered negliable, found exposures of 12 $\mu g/m^3$ which is an appropriate input concentration parameter to use to assess the exposure of consumers.

In the exposure scenario it is assumed that a child visits a playground with rubber granules containing PAHs for a few hours per day, on a number of days per year, from the age of two up to and including 12. While RAC notes it is more likely that children playgrounds are made from rubber mats or rubber bound in a resin rather than loose rubber granules where dust are less likely to be generated. RAC agrees inhaltion exposure from dusts (PM10's) cannot be excluded.

The input parameters chosen for reasonable worst case scenario (Table B32 of the Background Document) taken from RIVM, Baua and US EPA studies are therefore considered by RAC as appropriate.

Lifelong exposure

Lifelong exposure should be based on yearly average exposure over a lifespan of 70 years adding up the various exposure periods e.g. first ten years based on exposure for fraction of 0.1 of lifetime exposure. RAC agrees that goal keepers lifelong exposure should be calculated in a similar way but starting at age 7 with a higher dermal and oral exposure.

RAC considers simultaneous exposure can take place during play at playgrounds and during sport activities but notes that the exposure scenarios have used event-based input parameters rather than a daily exposure for dermal and inhalation exposure. For oral exposure RAC notes the exposure was based per event, however, this has been corrected for an amount ingested to the default 90 mg/day.

Estimates of lifelong exposures for a range of percentiles based on the results of the sampling by RIVM (2017) are outlined below.

Indirect Exposure

Indirect exposure of humans via the environment was not considered for this dossier but RAC notes that environmental airborne rubber dust particles may contribute to additional exposure via air.

Table 7: Lifelong worse case exposure

	6.7 mg/kg	17 mg/kg	20 mg/kg	21 mg/kg	387 mg/kg
Livelong exposure scenarios	Total risk	Total risk	Total risk	Total risk	Total risk
Professional player	7.5 E-07	1.9 E-06	2.2 E-06	2.4 E-06	4.3 E-05
Professional goalkeeper	10.0 E-07	2.5 E-06	3.0 E-06	3.1 E-06	5.8 E-05
Amateur player	7.2 E-07	1.8 E-06	2.2 E-06	2.3 E-06	4.2 E-05
Amateur goalkeeper	9.5 E-07	2.4 E-06	2.8 E-06	3.0 E-06	5.5 E-05
Installation workers	2.9 E-05	2.9 E-05	2.9 E-05	2.9 E-05	3.0 E-05
Maintenance workers (L)	1.6 E-06	1.6 E-06	1.6 E-06	1.6 E-06	1.7 E-06
Maintenance workers (S)	5.4 E-06	5.4 E-06	5.4 E-06	5.4 E-06	5.6 E-06

RAC notes it is unlikely than any individual would be exposed to reasonable worst case exposure scenarios in each contributing scenario throughout their entire life. RAC also recognises that the greatest exposure to the general population (non-smokers) is not from granules and mulches but comes from food sources and inhaled air. However airborne rubber dust particles may contribute to exposure via inhaled air. While recognising that the evidence provided in the dossier and during the public consultation supports that the concentration of the main 8 PAHs in ELT are below the proposed limit of 17 mg/kg RAC notes some test results have shown higher levels e.g. 53 mg/kg.

RAC notes the extensive work of the Dossier Submitter compiling data on PAH concentrations in granules and mulches, however, there is still a lack of data on the PAH concentrations in rubber infill across all Member States.

This information along with the fact that currently higher concentrations of PAHs in granules and mulches permitted in entry 28 of Annex VII (circa 400 mg/kg), supports the need to reduce the level of PAHs permitted in granules and mulches used as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications.

The 8 PAH substances are non-threshold carcinogens and as a general principle the exposure should be lowered. Since a dose without theoretical cancer risk cannot be derived a concentration limit lower than what is currently permitted (circa 387 mg/kg) should be set.

RAC recognises that food and inhaled air is the major source of PAH exposure to the general population but RAC still agrees that a limit for PAHs in infill material should be set. While acknowledging that based on the reasonable worse case exposure assumptions in the dossier, a concentration of 6.7 mg/kg (0.00067%) would give a lifetime excess cancer risk of below 1×10^{-6} to individuals exposed, RAC agrees further consideration is warranted in setting a limit, such as, taking into account the uncertainties in the risk in particular the uncertainties in the animal studies and that it is unlikely that any individual would only ever be exposed to infill pitches throughout their entire life. **RAC therefore agrees a practical risk reduction approach, similar to the Dossier Submitter RO1, but instead recommends a 95% reduction to the currently permited (387 mg/kg) limit in entry 28 of Annex XVII of REACH i.e. 20 mg/kg. This would equate to a theoretical risk of 2.9×10^{-5} for workers and 2.8×10^{-6} for consumers. RAC reiterates that 20 mg/kg is not a risk-based limit but a measure aimed solely at avoiding very high PAH concentrations.**

Characterisation of risk(s)

Summary of proposal:

The PAHs under analysis in the restriction proposal are genotoxic carcinogens. Given the ability to induce genotoxic effects there is no safe value below which no health risk exists for these PAHs.

The risk characterisation performed by the Dossier submitter shows that at the 95th percentile of the distribution of actual PAH levels measured in rubber granules used in the EU and sampled after 2009 (17 mg/kg), the excess lifetime cancer risks for workers are close to the 10^{-5} risk level for 40 years of work life exposure.

Professional players showed similar exposures throughout their life compared to the amateur players. Therefore, it was considered more appropriate to compare their lifelong exposure to the risk level for the general population considered acceptable by the Dossier Submitter.

For professional football players, excess lifetime cancer risks resulted slightly above the 10^{-6} risk level that is considered acceptable by the Dossier Submitter for the general population for lifelong exposure. The excess cancer risk for lifelong exposure of the amateur football player was slightly above the risk level considered acceptable for lifelong consumer exposure.

Table 8: Results of the risk assessment for workers, professional players and consumers according to the linear extrapolation; based on current REACH-8 PAH content in ELT-derived granules in the EU (P95; 17 mg/kg for the sum of REACH-8 PAHs)

Workers		**Excess cancer risk**
ES1: Installation		
	Total	2.9×10^{-5}
ES2: Maintenance – large		
	Total	1.6×10^{-6}
ES2: Maintenance – small		
	Total	5.4×10^{-6}
Professional player		**Excess cancer risk**
ES3: Outfield player		
	Total	1.9×10^{-6}
ES3: Goalkeeper		
	Total	2.5×10^{-6}
Consumer		**Excess cancer risk**
ES4: Outfield player		
	Total	1.8×10^{-6}
ES4: Goalkeeper		
	Total	2.4×10^{-6}

RAC conclusion(s):

RAC agrees that a PAH content in rubber granules corresponding to the current concentration limit for mixtures in entry 28 Annex XVII of REACH (i.e. 387 mg/kg) is unacceptable. However, due to limited data on inhalation exposure for installation and maintenance workers no reliable calculation of the total excess cancer risks can be done. In addition as the current concentrations of PAHs in ELT rubber infill are significantly below 387 mg/kg RAC considers it is unacceptable to permit such levels for non-threshold substances. To protect playing children and sportsmen of every age against health risks, RAC is of the opinion that material for synthetic turf pitches in loose form on playgrounds and sport applications should not contain the eight PAHs listed. However, RAC notes that the reasonable worst case exposure assessment is likely to overestimate exposure and excess lifetime cancer risk.

RAC agrees a limit should be set to protect playing children and sportsmen of every age against the health risks posed by PAHs. Unlike for threshold substances a dose without theoretical cancer risk cannot be derived, however, the potential for exposure should be lowered. In order to avoid very high PAH concentrations RAC agrees the current permissible limit should be lowered to at least 5% (i.e. 20 mg/kg) of the current permissible limit (circa 387 mg/kg) as a preventative measure.

Key elements underpinning the RAC conclusion(s):

In comparison to previous exposure assessments of PAH exposure from rubber granules by RIVM (2016, 2017) and ECHA (2017a) for consumers, the exposure scenarios in the Annex XV dossier were adapted as follows.

The main changes giving the higher excess risks came from

- a lower oral ingestion rate based on the updated chapter 5 of the US EPA factors handbook (US EPA, 2017a),
- a higher dermal migration fraction based on Fraunhofer ITEM (2016),
- the addition of inhalation exposure to the total risk estimate per scenario
- the addition of exposure scenarios to the lifelong exposure, i.e. playing at playgrounds from 2 instead of 4 years of age and exposure between ages of 4-13 years playing and playing sports.
- A new maximum conc. limit from 19.4 (20) mg/kg in the Dutch data set to a P95 of 17 mg/kg of the total EU dataset.

The calculated excess cancer risks for the amateur goalkeeper are slightly lower than previously calculated based on the updated chapter 5 of the US EPA factors handbook (US EPA, 2017a) which gave a lower oral ingestion rate for goalkeepers.

The Dossier Submitter's proposal has included three types of risk characterisation, one is based on the P95 of the infill material on the market, one based on a limit of 387 mg/kg from the mixture addititivity method and one based on back calculating to achieve a nominal 1×10^{-6} and 1×10^{-5} excess cancer risk. For non-threshold mutagens and carcinogens a dose without a theoretical cancer risk cannot be derived. While no EU legislation sets a reference risk level for the DMEL, i.e. 'tolerable' risk level for carcinogens, cancer risk levels have been set and used in different ways within and outside the EU. A limit of 20 mg/kg equates to a theoretical risk of 2.9×10^{-5} for workers and 2.8×10^{-6} for consumers.

Risk characterisation where rubber granules contain the REACH-8 PAH at 95%ile of the ELT rubber infill on the market

The results of the analysis of ELT rubber infill shows that the REACH-8 PAH concentration in ELT infill samples available varied from 2.9 to 21 mg/kg with a median of 11 mg/kg and a P95 of 17 mg/kg. The excess cancer risk for lifelong exposure (i.e. 40 years) based on exposure to 17 mg/kg is 2.9×10^{-5} for installation of synthetic turf pitches, 1.6×10^{-6} for large maintenance, and 5.4×10^{-6} for small maintenance. These risks range from just below to very slightly above the risk level of 1×10^{-5} in the REACH guidance. Dermal exposure for installation and maintenance is lower compared to the inhalation exposure.

It is not possible to link the PAH content in rubber granules to the inhalation exposure of workers during installation and maintenance. However, as the results of the Ecopneus study are within the range of results from PAH on the market it is appropriate to use the study to estimate inhalation exposure.

For professional players the reasonable worst case excess cancer risks based on 17 mg/kg is 1.9×10^{-6} and 2.5×10^{-6} for the outfield player and goalkeeper, respectively. These excess risks are also slightly above what the Dossier Submitter considered acceptable for the general population for lifelong exposure (i.e. 10^{-6}). The contribution to the total risk is highest for the oral route (during child years), followed by the dermal and inhalation route. However, RAC notes loose granular infill that is not bound in a matrix is not generally used in playgrounds.

The excess cancer risk for lifelong exposure is 1.8×10^{-6} for consumer outfield players and 2.4×10^{-6} for consumer goalkeepers. These risks are also slightly above the guidance (i.e. 10^{-6}).

Reasonable worst case risk characterisation where rubber granules contain the REACH-8 PAH up to their maximum concentration limit for mixtures in Annex XVII of REACH.

The maximum concentration limit calculated using the additivity method for the sum of the REACH-8 PAH is 387 mg/kg.

As it was not possible to link the PAH content in rubber granules to the inhalation exposure of workers during installation and maintenance. The inhalation exposure of workers during installation and maintenance was based on the Ecopneus study where the concentration was 8-13 mg REACH-8 PAH /kg. This study cannot be used to calculate inhalation exposure at a concentration limit of 387 mg/kg however it can be concluded it would be higher due to the higher PAH content.

For dermal exposure the excess cancer risk would be 1.1×10^{-6}, 5.9×10^{-8} and 2.0×10^{-7} for installation, large maintenance and small maintenance, respectively. While this is below guidance of 1×10^{-5} for 40 year worker exposure exposure via the inhalation route cannot be discounted since inhalation exposure contributes the most to the total risk for installation and maintenance workers the exposure is expected to exceed the guidance level.

The reasonable worst case excess cancer risk for professional outfield players or goalkeepers is 4.3×10^{-5} and 5.8×10^{-5}, respectively. This is above the guidance of 1×10^{-6} for the general population.

The excess consumer cancer risk for lifelong exposure to PAHs via playing and sporting on synthetic pitches with infill with rubber granules is 4.2×10^{-5} and 5.5×10^{-5} for outfield player and goalkeeper, respectively. Both of these estimates are above the guidance (i.e. 10^{-6}), and considered not acceptable by the Dossier Submitter.

Risk characterisation by calculating backwards, to establish a concentration of PAH that would result in a risk level of 1×10^{-6} for the general population and 1×10^{-5} for workers.

The REACH Guidance outlines 10^{-6} could be seen as indicative tolerable risk level when setting DMELs for general population and 10^{-5} could be seen as indicative tolerable risk level when setting DMELs for workers for a working life of 40 years (ECHA, 2012).

As for installation and maintenance workers inhalation exposure cannot be linked to the PAH content it was not possible to calculate a inhalation PAH content. The maximum permissible content level for PAHs in rubber granules for reasonable worst case professional football players and goalkeepers is 8.9 mg/kg and 6.7 mg/kg respectively. Since professional players and consumers have higher exposure estimates compared to the installation and maintenance workers any PAH content derived for professional and consumer players will also cover for the installation and maintenance workers. The maximum PAH content in rubber granules is 9.3 mg/kg for the reasonable worst case consumer amateur outfield player and 7.1 mg/kg for the reasonable worst case consumer amateur goalkeeper.

For installation and maintenance workers inhalation exposure cannot be linked to the PAH content therefore exposure via inhalation is low in the lifelong exposure calculations. The low exposure is based only on the low dermal exposure, however, at the higher PAH content of 387 mg/kg the dermal exposure is higher so it contributes more to the total risk even though still the inhalation exposure cannot be linked to the PAH content.

In the exposure scenarios for worker's childhood exposure was not included or playing sport as an adult. However, if childhood exposure and amateur outfield exposure was added to the exposure of installation worker at 387 mg/kg it would give an additional exposure of 4.6E-07 or 4.8E-07 for an amateur goalkeeper to the exposures in Table 7.

Uncertainties in the risk characterisation

There are a number of uncertainities identified in the proposal that are outlined in Table B43 of the Background Document. RAC agrees the main uncertainities in terms of the exposure assesment that contribute to an overestimation of the excess cancer risks are:

- That installation workers undertake infilling for 120 days per year
- The asumption that PPE (e.g. gloves) never worn
- The assumption that consumers and professionals only ever play on long pile ELT infilled synthetic pitches from childhood throught to adulthood
- It is less more likely that tiles or flakes/mulch are used in playgrounds rather than granules so exposure is expsected to be lower from these forms

There is also uncertainites which may lead to an underestimation of exposure for example it is noted that additional exposure to installation and maintenance workers during their childhood or as adults playing sport was not accounted for.

The exposure assessment is based only rubber infill however there may be other environmental sources of exposure that contribute to the lifelong exposure to PAHs which were not considered. However, compared to food which is the most important source of PAHs for the general population the estimated exposure from rubber granules is marginal.

Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

Manufacture of rubber granules is outside of the scope of the restriction dossier. Regarding installation and maintenance activities, the operational conditions can differ as to how the infill material is installed and handled.

For example, the pitch size and its location (indoor or outdoor) has influence as to how the granules are put on the artificial turfs. Especially for the smaller pitches manual labour is more commonly used for installing the rubber granules and as a consequence contact with rubber granules becomes more relevant.

The Dossier Submitter concluded based on the available information that there were no set standards for operational conditions and risk management measures at the EU level.

RAC conclusion(s):

RAC agrees with the uncertainities identified in the proposal that are outlined in Table B43 of the Background Document. RAC agrees the main uncertainities in terms of the exposure assesment that contribute to an overestimation of the excess cancer risks are:

- The assumption that consumers and professionals only ever play on long pile ELT infilled synthetic pitches from childhood throught to adulthood
- The assumption that PPE (e.g. gloves) is never worn
- It is more likely that tiles or flakes/mulch are used in playgrounds than granules. Exposure to PAHs is expected to be lower from these forms of product.

RAC agrees there are also uncertainites which may lead to an underestimation of exposure. For example, it is noted that additional exposure to installation and maintenance workers during their childhood or as adults playing sport was not accounted for.

The exposure assessment is based only on rubber granule infill however there may be other environmental sources of exposure that contribute to the lifelong exposure to PAHs which were not considered. However, compared to food which is the most important source of PAHs for the general population the estimated exposure from rubber granules is marginal.

It is unlikely than any individual would be exposed to reasonable worst case exposure in each contributing scenario throughout their entire life.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

Granules and mulches used in synthetic sports pitches and playgrounds are regarded as mixtures in the scope of REACH Regulation. The supply to the general public is only restricted above CLP-based specific concentration limits in Annex XVII entry 28 for REACH-8 PAHs which are however too high to ensure an appropriate control of the human health risks. No other risk management instrument currently in place in the EU was identified to adequately deal with the risk to humans from the use of granules and mulches in synthetic sports pitches and playgrounds.

In principle, all individuals in the EU may come into contact with granules and mulches. However, sub-populations of individuals that are most likely to come into contact with this material are workers for installation and maintenance, professional athletes, amateur athletes and children playing at playgrounds. The Dossier Submitter concluded that the current risk of using rubber granules as infill material on synthetic turf pitches and granules and mulches in loose form on playgrounds and in sport applications are unacceptable.

RAC conclusion:

RAC agrees the use of automated infilling machines by installation operators is an appropriate risk management measure. However, it is not something that is used by all installation and maintenance operators.

A reliance on PPE only as a risk management measure is not sufficient as it is the last element in the hierarchy of control.

RAC notes there are no recommended risk management measures in place for professional players, children or the general population using synthetic pitches.

Key elements underpinning the RAC conclusion(s):

The substances are not registered so there are no recommended RMM for the substances in any REACH dossier.

RAC agrees the use of automated infilling machines by installation or maintenance operators is appropriate as it removes/limits the exposure to installation/maintenance workers. However, the use of worker operated machinery and manual maintenance is not prohibited.

The only additional risk management measure for works mentioned is PPE. This is the last control measure under the hierarchy of control. While the use of PPE is recommended and will likely reduce exposure (if the granules don't make their way inside the PPE e.g. gloves) the main route of exposure is inhalation. RAC considers that the use of negative pressure face masks or dust masks for a 6 hour period is not an appropriate risk management measure to protect workers from exposure when considering the hierarchy of control measure that should be first considered.

There are no risk management measures in place for consumers, professional or amateur players.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter has analysed the risks for football players using synthetic turf pitches on which ELT[8]-derived granules containing PAHs are used. Furthermore, the risks were assessed for workers involved in installation and maintenance of these pitches, for children playing on playgrounds and for the general public using sports facilities other than pitches, where loose granules or mulches can also be found. The Dossier Submitter concluded that the existing concentration limits for eight polycyclic aromatic hydrocarbons (designated as REACH-8 PAHs by the Dossier Submitter) in mixtures do not allow the risks associated with these uses to be controlled. In addition, the Dossier Submitter concluded that a scientific basis is lacking for the large difference between the concentration limit for PAHs in mixtures (such as performance infill) supplied to the general public (REACH Annex XVII entry 28) and the limit values applicable for articles, toys and childcare articles falling under the scope of REACH Annex XVII entry 50, paragraph 5 and 6.

ELT-derived recycled rubber granules are the main source of infill material used on artificial football pitches and these granules are used on EU-wide scale, also for other sports such as rugby, baseball, Gaelic sports and lacrosse (sports which sometimes make use of the same pitches, but not always).

Because ELT-derived granules and mulches and alternative materials such as EPDM, TPE and cork are marketed and used throughout the EU, legal measures taken by individual Member States are not considered effective in addressing the risks of humans exposed to PAHs. An Union-wide restriction is therefore needed to ensure that the concentration of REACH-8 PAHs in granules or mulches used as infill on synthetic turf pitches or in loose form on playgrounds is sufficiently low. This will ensure safety for workers, safe sporting activities on synthetic turf pitches and other sporting facilities using loose granules or mulches and safe playing on playgrounds throughout the EU.

SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with the REACH-8 PAHs in granules and mulches used as infill material should be implemented in all Member States. As infill material (in the form of granules or mulches) are produced, marketed and used throughout the EU, if required, action should be taken on a Union wide basis.

Key elements underpinning the RAC and SEAC conclusion(s):

Based on ample evidence provided by the Dossier Submitter, SEAC recognises that the placing on the market and use of the REACH-8 PAHs in granules and mulches used as infill material in synthetic turf pitches and in loose form on playgrounds and in sport applications takes place Union-wide[9].

The Dossier Submitter presents information, sourced from ETRMA (2016), that the following countries harbour granulation plants: Belgium (1), the Netherlands (2), Denmark (2), Germany (10), Poland (10), Hungary (unknown), Italy (18), Spain (12), Portugal (3), France

[8] End-of-Life Tyres

[9] This is not only true for ELT-derived rubber granules, but also granules made from alternative materials such as EPDM and TPE.

(4) and the United Kingdom (5)[10]. During the public consultation, ETRMA has indicated that the following countries also harbour facilities: Austria, Greece, Romania and Sweden.

The Dossier Submitter then goes on to state that this does not even provide the full picture and that there are actually more than 110 formulators of rubber granules derived from ELT material located in the EU, a large majority of whom formulate infill material. While the majority of the granulation sites are located in Southern Europe, other EU regions also house large players. The Committee therefore finds it clear that production and formulation for use as infill material takes place Union-wide.

To show that the use of infill material takes place Union-wide, the Dossier Submitter presents information, sourced from FIFA (2017), on the number of certified synthetic turf pitches. It becomes clear that in 2017 in most European countries between 10 and 100 synthetic turf pitches had been FIFA certified. This is an underestimation of the total number of synthetic turf pitches[11], but this data does make clear to SEAC that synthetic turf pitches using ELT-derived granules as infill material are used on EU-wide scale.

Furthermore, the Dossier Submitter identified an unacceptable risk as a consequence of this EU-wide use. Hence, any measure aiming to effectively reduce/address this unacceptable risk for workers and the general public needs to be taken in all Member States of the European Union (as well as the 3 EEA members: Norway, Iceland and Liechtenstein).

Currently, the placing on the market and use of infill material[12] containing classified carcinogens, among which the REACH-8 PAHs targeted by this restriction proposal, is regulated through REACH Annex XVII entry 28. Entry 28 allows for higher concentrations of PAHs than is currently permitted for articles made from the same material (REACH Annex XVII entry 50). If rubber granules contain the REACH-8 PAHs up to their maximum concentration limit for mixtures in entry 28 of Annex XVII of REACH, this would not provide an adequate level of protection. This has been confirmed by RAC[13]. In order to be consistent it is therefore necessary according to SEAC that if more specific measures are taken to regulate this mixture, these should also apply across the whole territory. In addition to this, SEAC notes that the Dossier Submitter states that there is no scientific basis for the large difference between the concentration limit for PAHs in mixtures supplied to the general public (REACH Annex XVII entry 28) and the limit values applicable for articles, toys and childcare articles falling under the scope of REACH Annex XVII entry 50, paragraph 5 and 6. SEAC also notes that RAC agrees with the Dossier Submitter that this regulatory irregularity should be rectified.

[10] Figure A 3 in section A.1.3.2 of the Annex XV restriction report.
[11] See the discussion on the baseline in the section on costs of this restriction proposal.
[12] Rubber granules and mulches (or flakes) are regarded as mixtures according to the Guidance on substances in articles.
[13] See the discussion in the section on identified hazard, exposure/emissions and risk.

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

The proposal suggests restricting the placing on the market of granules and "mulches" for use as infill material in synthetic turf pitches or in loose form on playgrounds and in sports applications if these materials contain more than 17 mg/kg of the sum of the eight PAHs in the scope of Annex XVII entry 50:

a) Benzo[a]pyrene (BaP) CAS No 50-32-8

b) Benzo[e]pyrene (BeP) CAS No 192-97-2

c) Benzo[a]anthracene (BaA) CAS No 56-55-3

d) Chrysen (CHR) CAS No 218-01-9

e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2

f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3

g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9

h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3

The proposal is not limited to ELT-derived infill material, but targets all granules and "mulches" that are used in the same way.

No derogations are proposed.

RAC conclusion(s):

RAC notes that ELT infill generated from waste, falls outside the scope of REACH except where a Member States has established national EoW status criteria for ELT rubber infill. While setting of a PAH concentration with EoW criteria could be effective measure to control exposure it would only be effective if it was harmonised across all EU Member States.

RAC agrees a REACH restriction will only be an effective measure in those Member States where EoW status for ELT infill is set without a PAH limit. Therefore, based on the current information available, on the waste status of ELT material across the EU, RAC agree a REACH restriction will not be an effective EU wide measure to prevent the risk of exposure to PAHs from ELT infill across the EU as infill from ELT is confirmed to be still classed as a waste within a least two Member States.

RAC agrees a REACH Restriction would be the most effective risk management measure to reduce exposure to PAHs from virgin infill material containing PAHs.

Key elements underpinning the RAC conclusion(s):

Tyres placed on the EU market fall within the scope of articles under REACH. End of life tyres are a waste until they are declared non-waste and reach Member State EoW status. RAC notes in accordance with Article of the REACH Regulation waste is outside the scope of REACH. Therefore, a REACH restriction would not apply to ELT rubber infill in Member States where no End-of-Waste criteria is established.

RAC asked the Forum to confirm the EoW status of ELT infill in their Member State. Four Forum members responded, one (CY) confirmed EoW status, one (SE) confirmed no EoW status. It was not evident from the other two responses if EoW status is set in their respective Member States. As part of the public consultation three Member States responded to the EoW question. Two Member States confirmed no EoW status for ELT in their Member States (IE, SE). Therefore it is still not clear to RAC how many on the Member States the restriction will apply in.

As all Member States have not established EoW criteria the REACH restriction is not the most appropriate risk management measure. Only when ELT waste has reached End-of-Waste status in a Member State or if EoW criteria is harmonised in the EU for ELT will it fall within the scope of REACH.

RAC has assumed where a Member State's sets a higher PAH limit in their EoW criteria, then the applicable limit would still be the PAH limit set out in the REACH restriction. In those Member States where a lower limits is set the restriction would apply without prejudice to those limits. This justification is based on the presumption that in order for the waste to achieve EoW status, it would first and foremost need to comply with the EoW PAH criteria.

In terms of the EU strategy on the circular economy and chemicals in waste products it would appear to be appropriate that safe concentration limits should be set for waste when the EoW status is reached and ELT is placed back on the EU market.

For virgin infill material containing PAHs, the REACH restriction is an appropriate risk management measure as it will apply to all virgin material placed on the EU market. However, no information has been provided by the Dossier Submitter to confirm whether virgin infill material contains PAHs.

Justification for the opinion of SEAC

Introduction

In recent evaluations, RIVM (2017) and ECHA (2017a) concluded that the mixture concentration limits for polycyclic aromatic hydrocarbons (PAHs) in End-of-Life Tyre (ELT) derived rubber infill granules are too high to guarantee safe supply and use of these granules on synthetic turf pitches. ECHA (2017a) recommended a restriction under REACH to impose concentration limits that are closer to the much lower limit values for individual PAHs in articles supplied to the general public (1 mg/kg) and in toys (0.5 mg/kg) as laid down in REACH Annex XVII entry 50, paragraph 5 and 6.

PAH levels found in granules on synthetic turf pitches currently in use are assessed to result in an excess cancer risk[14] of 3.2 x 10^{-6} in highly exposed individuals (professional football players)[15]. To ensure even lower risk levels for use of infill granules and mulches, the Dossier Submitter conducted an analysis of risk management options (RMOs), including different restriction options under REACH, other existing EU legislation, and other possible Union-wide RMOs. Two of the RMOs were selected as possible restriction options and further evaluated in the impact assessment:

- R(M)O1: Sum content limit value of 17 mg/kg for REACH-8 PAHs
- R(M)O2: Sum content limit value of 6.5 mg/kg[16] for REACH-8 PAHs

Based on the impact assessment, the Dossier Submitter proposes RO1 to control human health risks due to the use of granules as infill material in synthetic turf pitches and use of granules or mulches in loose form on playgrounds and in sport applications.

[14] At a sum content limit value of 21 mg/kg (99th percentile).
[15] In some rare cases much higher risk levels due to PAH concentrations were seen. In these cases the risk reduction would be even greater.
[16] The value of 6.5 mg/kg was changed to 6.7 mg/kg in the Background Document as a result of recalculations of the exposure and risk following comments received in the public consultation. The remainder of the opinion still uses the value of 6.5 mg/kg.

Substance and risk coverage

The scope of this Annex XV dossier underpinning the restriction proposal is limited to the eight PAHs (REACH-8) that are in the scope of REACH Annex XVII entry 50 and that have a EU-harmonised classification in Annex VI of the CLP Regulation as a carcinogen (Carc. Cat. 1B). The justification to confine the Annex XV dossier and restriction proposal to the REACH-8 PAHs is as follows:

- Targeting only the REACH-8 PAHs that currently have an **EU-harmonised classification** as a carcinogen provides **a clear legal basis** for companies and enforcement authorities that is also consistent with entry 50 of REACH Annex XVII;
- **PAHs are generally present in aromatic extender oils and carbon black in the form of mixtures (combination of a range of PAHs)**, and hence these combinations of PAHs may also be found in rubber materials in which these products are used to perform a function. Limiting the permissible content of the REACH-8 PAHs will, in practice, limit the presence of all PAHs as these are contained in aromatic oils or carbon black as complex mixtures. Hence, **the REACH-8 PAHs are used as marker PAHs** limiting the content of a larger group of potentially carcinogenic PAHs that may be contained in recycled rubber granules.
- **Extending the marker group of REACH-8 PAHs will increase the administrative burden for companies and enforcement agencies** as they will have to broaden their PAHs analyses scope. Additional costs may be relatively limited though;

Use

To ensure safe use of any granules and mulches and avoid any regrettable substitution, **this restriction covers PAH concentrations in both granules made of recycled rubber and granules made of other materials** (recycled or virgin, synthetic or natural).

The restriction targets the placing on the market of granules and mulches for use as **performance[17] infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications**. The uses covered in the scope of the restriction proposal are as follows:

- Use of granules as performance infill in synthetic turf sport pitches;
- Use of granules or mulches in loose form on playgrounds and in other sport applications.

[17] The "performance" of a synthetic turf pitch is always compared to that of a natural grass sports pitch. To assess the "performance" of artificial turf pitches, the following broad characteristics are taken into account (not exhaustive): interaction between player and the surface (e.g. risk of injury), interaction between the ball and the surface and durability.

SEAC conclusion(s):

A. Scope of proposed restriction

SEAC in general agrees with the scope of the restriction as proposed by the Dossier Submitter including the adaptations made during the opinion development. SEAC notes that ECHA, on request of the European Commission, is currently performing a broader study looking at the potential risks of other substances in granular infill that may be of concern to human health or the environment. SEAC considers it prudent to wait for the results of this study and at this moment in time advises not to broaden the scope of this restriction to other hazardous substances besides PAHs[18]. This is in order to avoid possibly restricting substances for which the concern to human health and environment has not yet been fully assessed. SEAC notes that it would have been more efficient if all concerns linked to performance infill were assessed before proposing actions.

Initially, SEAC was uncertain on why the specific limit value of 17 mg/kg was chosen. It is important to note that RAC has indicated that based on risk reduction alone there is no significant difference in choosing 17 mg/kg over 20 kg/mg, the latter being RAC's pragmatic proposal[19] for the limit value. Further socio-economic information provided by the Dossier Submitter suggests that a limit of 17 mg/kg would also be feasible for actors needing to comply with the proposed restriction and would address the need for minimisation of exposure to non-threshold substances.

SEAC supports a one-year transitional period as a reasonable timeframe for implementation.

B. RMO analysis

The majority of the possible risk management options (RMOs) discussed by the Dossier Submitter are variations on the same RMO: proposing different limit values, whether they be content or migration limits, and changing the applicability of these limit values (e.g. lowering the extender oil limit value, imposing a limit value of PAHs in carbon black). These were rejected for different reasons by the Dossier Submitter. Some would not have provided any added value in comparison with the proposed restriction, others would not have been very effective in terms of risk reduction (while also taking a long time to afford those small benefits), were less practical, not technically feasible or there simply wasn't a scientific basis to consider the RMO any further.

The Dossier Submitter notes that the considered risk management options focus on the risks from PAHs in relation to carcinogenicity. Other potential risks (e.g. to the environment) of the use of ELT granules and mulches in sport and play applications have not been addressed.

The Dossier Submitter did however consider two RMOs where a different approach is taken. One proposes to lower the existing specific concentration limit for the REACH-8 PAHs via an amendment of the harmonized classification. This option was disregarded since this seems not to be possible for category 1B genotoxic carcinogens. The second option to minimise the exposure to the REACH-8 PAHs in granules or mulches is to communicate about the risks to athletes and users of pitches or sports facilities where granules are employed as infill material. This option was disregarded as well because it is seen as not being effective.

[18] This advice in no way precludes discussions on possible future restrictions linked to the presence of hazardous substances in granules.

[19] RAC considers the restriction proposal to be a preventative measure.

Overall, the analysis conducted has provided sufficient justification for SEAC to agree that the proposed restriction is the most appropriate EU-wide measure to address the risk from the REACH-8 PAHs in granules and mulches used as infill material. SEAC agrees with the Dossier Submitter's conclusion that the other risk management options assessed are not as appropriate as a restriction under REACH due to limitations in scope, effectiveness and overall added value.

Key elements underpinning the SEAC conclusion(s):

A. Scope of proposed restriction

Prior to submitting this restriction proposal, both ECHA and RIVM (the Dossier Submitter) published several reports[20] in which it was assessed if the presence of potentially hazardous substances in infill material could pose a health risk to the general population[21] and safe supply and use cannot be guaranteed.

Safe supply and use was defined by the Dossier Submitter as follows: "*What is defined to be safe supply and use in case of non-threshold substances like the REACH 8-PAHs depends on the risk level that you accept as society. What risk level is accepted is a policy-based rather than a scientific choice. There is no EU agreed acceptable risk level for non-threshold substances. Member States may differ in the risk level that is considered acceptable. For this dossier, an acceptable risk level of 10^{-6} for consumers and 10^{-5} for workers is applied. Risk levels that fall within or below this order of magnitude are seen as acceptable and will result in safe supply and use.*"

For this restriction proposal the Dossier Submitter decided to include not only ELT-derived granules in the scope, but also include other types of performance infill in granule or mulch form[22]. The justification to include possible alternatives was stated to be "*the principle that all granules and mulch materials used in the same sport and play applications should be safe. […] and in addition [to] avoid regrettable substitution and create a level playing field for all granules/mulches that are placed on the market for the uses under consideration*". SEAC takes note that available measurements for alternatives are limited, but according to the Dossier Submitter these show that alternatives indeed may contain PAHs. Paucity of information notwithstanding, the Committee can agree with the Dossier Submitter's proposal to add alternatives to the scope of the proposed restriction based on the provided justification. The Dossier Submitter did however indicate that cork and other natural materials could be derogated since no evidence is available that these contain PAHs. SEAC does however not advise this since it could require a proper definition of "natural materials" and would complicate enforcement. Furthermore, if they do not contain PAHs then the restriction does not apply to these materials anyway. SEAC notes that it would not entail fewer costs to exclude cork and other natural materials from the scope – as it is not expected that these will be tested for the presence of PAHs.

[20] These reports focused on ELT-derived rubber granules and mulches specifically.
[21] Including children, professional players and workers installing or maintaining the pitches.
[22] Synthetic material such as EPDM, TPE and PE; natural materials such as cork and natural fibres.

SEAC mostly agrees with the Dossier Submitter that the way the restriction proposal is worded, seems to provide a clear legal basis for companies and enforcement authorities, which is also consistent with REACH Annex XVII entry 50[23]. However, SEAC notes that the scope uses specific **terminology** (e.g. pitches, playgrounds, sport applications, infill material, loose form, granules, mulch). The Forum requested that these terms should be properly defined for ease of enforcement. Companies needing to comply with the restriction would also benefit from this added clarity. SEAC therefore supported this request and the Dossier Submitter has subsequently provided definitions for several of the specific terms used in the restriction wording.

The proposed limit value of 17 mg/kg corresponds to the 95th percentile of the distribution of REACH-8 PAH concentrations currently found in ELT-derived performance infill in the EU, i.e. the concentration for which 95 % of the ELT-derived infill material is envisaged to comply. Since the Dossier Submitter concluded that concentrations in the range of 15-20 mg/kg are expected to be achievable for almost all of the actors producing ELT infill, the decision to go for 17 mg/kg was seen as somewhat arbitrary. It is important to note that RAC has indicated that based on risk reduction alone there is no significant difference in choosing 17 mg/kg over 20 mg/kg, the latter being RAC's pragmatic proposal[24] for the limit value.

At the request of the Committee, the Dossier Submitter provided detailed clarifications regarding the choice of the limit value. In the illustration below (Figure 4) the Dossier Submitter tried to visualize the feasibility for ELT recyclers to comply with various levels of the limit value. This illustration was prepared on the basis of information received from various actors in the ELT recycling market.

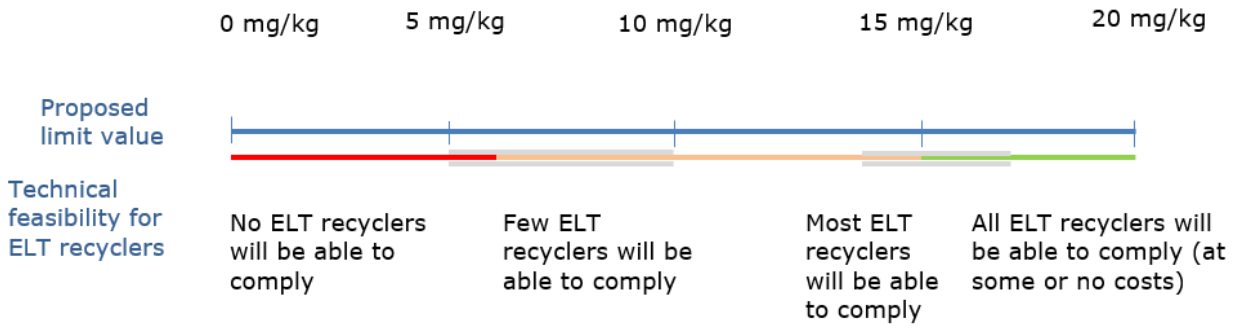
- In the red area (0-6 mg/kg) no ELT recycler is expected to be able to meet the limit value.
- In the orange area (6-15 mg/kg) some ELT recyclers are expected to be able to meet the limit value. The number of ELT recyclers able to meet the limit will increase with the limit value, with few recyclers expected to be able to meet the limit value towards the lower end of this range and most recyclers towards the higher end.
- In the green zone, all ELT recyclers are expected to be able to comply. At 15 mg/kg this will imply some costs, at 20 mg/kg costs are expected to be reduced to zero.
- At the transition from red to orange and from orange to green a grey zone is indicated as there is some uncertainty where exactly the shift points are.

SEAC found this information to be very helpful since it clearly shows the Dossier Submitter's reasoning behind choosing 17 mg/kg as a limit value. It corresponds to the lowest possible concentration all recyclers are expected to be able to meet with a reasonable degree of certainty (technical feasibility criterion) incurring some costs[25]. Even if RAC sees no significant difference from a risk reduction viewpoint between 17 and 20 mg/kg, minimisation of exposure for non-threshold substances as a principle might be wanted.

[23] It is outside of the remit of SEAC to provide legal judgements, but the proposed restriction wording seems consistent with analogous restrictions in the past.
[24] RAC considers this restriction proposal to be a preventative measure.
[25] For a discussion on the costs see the corresponding section.

Therefore, a case could be made for choosing 17 mg/kg as the limit value for the proposed restriction based on this socio-economic information. However, a number of comments in the public consultation note the lack of a harmonised analytical method and variations of up to 30 % between test data using different analysis methods[26]. This should also be taken into account when determining the limit value. Because of the imprecise nature of the different analysis methods, a trade-off exists between ensuring any limit value and unjustifiably rejecting some material.

Figure 4: Illustration of the expected consequences of various REACH-8 PAH limit values for the ELT recycling sector



Since PAH concentrations in scrap tyres and manufactured granules and mulches on the EU market are expected to be relatively stable, the Dossier Submitter did not take the PAH concentration into account when determining the **transitional period**. SEAC agrees with this assessment. Measures other than pre-production selection techniques to lower the PAH content of the input material (ELT)[27], which take a long time to take effect and would therefore warrant a longer transitional period, are not deemed efficient to be able to comply with the proposed restriction[28]. Because of the choice of limit value, the restriction will immediately render 5 % of the currently manufactured granules incompliant. The proposed transitional period should therefore allow a limited but reasonable period to eliminate stock produced prior to entry into force (e.g. using or selling off). ELT-derived granule manufacturers should also be allowed time to implement measures in order to guarantee compliance (e.g. pre-production selection techniques).

Based on this, SEAC can agree that a transitional period of one year, as proposed by the Dossier Submitter, will allow sufficient time for actors in the supply chain to meet the proposed requirements. The Committee has no information to advise a longer transition period. On the contrary, an unintended consequence could be that manufacturers may try to sell off their non-compliant stock quickly by producing higher concentration mixes of the material in order to get rid of it before the 1-year transition is over. Furthermore, based on statements made by several stakeholders during a workshop organised by the Dossier Submitter, a case might have been made for a shorter transition period. These stakeholders state that due the societal attention in some European countries to the use of ELT-derived granules on synthetic turf, any restriction imposed would have an immediate effect on the market for infill material and any transition period would be ineffective. SEAC does not find these stakeholders' statements justified based on the information provided by the Dossier Submitter, i.e. the need for some actors to have time to comply with the proposed limit value (17 mg/kg).

[26] This has also been noted in the Forum advice.
[27] Upstream from tyre recyclers, i.e. tyre manufacturers.
[28] See also the discussion on RMOs 6 and 7.

It is important to note however that the Dossier Submitter's assessment of the transitional period might not hold true for the limit value of 20 mg/kg proposed by RAC. Since an even smaller fraction of the ELT-derived granules currently on the market would not be in compliance, one could question the need for a transitional period at all. However, SEAC notes that there would still be time needed to set up a system for securing that the limit value is respected and to identify those rare batches of non-compliant infill material.

B. RMO analysis

SEAC agrees with the scope of the Dossier Submitter's analysis in which many possibly relevant other EU-wide measures have been assessed.

Limit values for PAHs in granules

- R(M)O1: Sum content limit value of 17 mg/kg for REACH-8 PAHs

  This restriction option prohibits the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 17 mg/kg (0.0017 % by weight of this component) of the sum of the listed PAHs. The specific limit value reflects the 95th percentile of the REACH-8 PAH concentration in measurements taken from synthetic turf pitches, i.e. at the moment 5 % of the ELT volume sold is expected to be above this concentration limit.

  This is the proposed restriction option by the Dossier Submitter and the corresponding socio-economic impacts are discussed more in detail further on in this opinion.

- R(M)O2: Sum content limit value of 6.5 mg/kg for REACH-8 PAHs

  This restriction option prohibits the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 6.5 mg/kg (0.00065 % by weight of this component) of the sum of the listed PAHs. The specific limit value reflects the REACH-8 PAH concentration below which the excess lifetime cancer risk of all individuals exposed stays below 1 x 10^{-6}.

  This is an alternate restriction option and the corresponding socio-economic impacts are discussed more in detail further on in this opinion.

- RMO3: Content limit for all carcinogenic PAHs

  This restriction option is comparable to RMO1 and RMO2, but more PAHs would be covered.

  SEAC notes that RAC agrees with the Dossier Submitter's view that limited added value could be expected from adding more PAHs to the restriction proposal. The REACH-8 PAHs serve as marker substances which means that regulating only these will also reduce the risks linked to other PAHs. SEAC also recognises the fact that adding PAHs to the restriction proposal would mean that it would not be in line with the current REACH Annex XVII entry 50. The Dossier Submitter also expects that there would be additional compliance costs, but no further evidence was provided for this.

- RMO4: Migration limit

  This restriction option is comparable to RMO1 and RMO2, but sets a migration limit instead of a concentration limit.

RAC states that migration is known to relate better to the actual risk for human health than content. The Dossier Submitter however makes the argument that migration is taken into consideration in the risk assessment through the inclusion of oral, dermal and inhalation absorption factors. Therefore it was considered that there would be no added value in proposing a restriction based on migration limits. RAC acknowledges that migration is taken into account in the risk assessment.

SEAC agrees with the Dossier Submitter that there are practical[29] as well as methodological problems with this restriction option, including that it would be more costly[30] to monitor enforcement and compliance than an alternative option based on the content of PAHs in infill material. Indeed, a content limit value for PAHs is a generally well understood and straightforward way of defining a restriction, more practical and better enforceable compared to a migration based restriction.

Overall, SEAC finds it justified that the Dossier Submitter did not deem it relevant to further analyse this option.

- RMO5: Limit value consistent with the PAH limit values applicable to articles and toys

  This restriction option has similarities with RMO2 and similar impacts are expected in practice.

  RAC states that there is no scientific basis for this restriction option as exposure to PAHs from articles and toys may be very different compared to the use of granules and mulches in sport and play applications.

Limit values for PAHs in tyre manufacture

- RMO6: Limiting the PAH concentration in carbon black

  In the current tyre production process, carbon black is used as a filler for the reinforcement of the vulcanised material and it also has a function to colour the tyres. Carbon black content percentages in car and truck tyres will typically vary between 24 and 28 %.

  Based on the information available to and assumptions made by the Dossier Submitter, it was estimated that the maximum REACH-8 PAHs levels in ELT as a consequence of PAH impurities in carbon black would be between 20 and 280 mg/kg[31]. The absence of clear minimum and typical PAH concentrations in tyres prevented the Dossier Submitter from estimating a reliable PAH concentration range in ELT. Because of this and other uncertainties[32] no robust conclusions could be drawn by the Dossier Submitter on the feasibility and impacts this restriction option would have. Due to this lack of information, it is difficult for SEAC to ascertain the appropriateness of this measure.

[29] Forum indicates that there are much more parameters to consider in migration testing, so that the complexity of the analysis is significantly increased.
[30] Migration testing is also more expensive.
[31] Assumptions made by the Dossier Submitter: between 2 % (minimum level in the tread) and 28 % (maximum reported level in whole car tyre) of the tyre weight is carbon black with a maximum content of 1000 mg/kg REACH-8 PAHs.
[32] E.g. variety in carbon black grades and their price differences, difference in PAH concentration of carbon black-reinforced tyres and silica reinforced ones, technical feasibility of reducing carbon black percentages.

However, the Committee can acknowledge that this restriction option would be slower to show results since the average life-time of tyres needs to be taken into account as a delaying factor. In contrast, setting a concentration limit for the placing on the market of granules and mulches as infill material would start having an effect immediately even though the full risk reduction potential of the proposed restriction option (RMO1) will only be visible after ten years (lifetime of artificial pitches).

SEAC wishes to note that acting at the source would also be beneficial in terms of a reduction of PAH atmospheric and water emissions. Since environmental effects were not addressed by the Dossier Submitter, SEAC cannot assess to which extent these effects would render this restriction option appropriate.

Considering the amount of uncertainties associated with the evaluation of this RMO, SEAC cannot arrive at a conclusion on the appropriateness of this restriction option. RAC supports future consideration of this as an additional risk management option to reduce the PAH content at source if such information become available.

- RMO7: Further reduction of PAH limit value in extender oils used in tyre manufacture

  Extender oils are used in the manufacture of tyres as a plasticiser. According to the Dossier Submitter the typical concentration of extender oils in car tyres is 7 % and in truck tyres 1.6 %. The restriction on PAHs in extender oils used in the manufacture of tyres that entered into force in January 2010 restricts BaP at a level below 1 mg/kg and the other REACH-8 PAHs at a level of 10 mg/kg in the oils.

  Based on the available evidence, the Dossier Submitter states that a further reduction of the PAH limit value in extender oils would probably have limited effect on the PAH concentrations in future ELT-derived infill material. The maximum contribution of extender oils to the total PAH concentration that is currently found in scrap tyres and ELT-derived granules lies between 0.08 % and 24 %[33]. According to the Dossier Submitter other additives, such as carbon black (see above), could provide higher contributions to the overall REACH-8 PAH content in tyres.

  The Committee also acknowledges that this restriction option would be slower to show results since the average life-time of tyres needs to be taken into account as a delaying factor. In contrast, setting a concentration limit for the placing on the market of granules and mulches as infill material would start having an effect immediately even though the full risk reduction potential of the proposed restriction option (RMO1) will only be visible after ten years (lifetime of artificial pitches).

  As such, SEAC finds it justified that the Dossier Submitter did not deem it relevant to further analyse this option.

[33] Maximum contribution of extender oils to the REACH-8 PAHs content would be 0.7 mg/kg and 0.016 mg/kg for car and truck tyres respectively. The REACH-8 PAHs concentration in ELT infill samples available to the Dossier Submitter ranged between 2.9 mg/kg (1st percentile) and 21 mg/kg (99th percentile) with a geometric mean of 10 mg/kg.

Other

- RMO8: Amendment of harmonised classification in Annex VI of CLP

  Labelling provisions already apply to granules and mulches at their placing on the market as these products are considered mixtures. The Dossier Submitter states that the concentrations of the PAHs in general would however be too low to result in human health hazard classification of these products based on the existing specific concentration limits applicable for classification of mixtures. As a risk management measure for PAHs therefore classification, labelling and packaging rules under CLP are considered not to be effective.

  The Dossier Submitter considered the option of lowering the existing specific concentration limits for the REACH-8 PAHs by amending the harmonised classification in Annex VI of the CLP Regulation. This option was however discarded as the current CLP guidance on classification of Category 1B genotoxic carcinogens does not allow for setting specific concentration limits that are lower than 0.01 %.

  As such, SEAC agrees with the Dossier Submitter that there is no potential for risk reduction via this restriction option.

- RMO9: Risk communication

  At the beginning of 2017 ECHA published an Annex XV report (ECHA, 2017a) presenting an evaluation of the possible health risks of recycled rubber granules used as infill in synthetic turf sports fields. In that report it was recommended that "*players using the synthetic pitches should take basic hygiene measures after playing on artificial turf containing recycled rubber granules. For example, they should always wash their hands after playing on the field and before eating, quickly clean any cuts or scrapes, take off their shoes/cleats, sports equipment and soiled uniforms outside to prevent tracking crumb rubber into the house, and any players who accidentally get crumb rubber in their mouths should not swallow it*". SEAC acknowledges that the dissemination of these recommendations was too recent in order for the Dossier Submitter to investigate the effectiveness of this type of risk communication. SEAC therefore concludes that the effectiveness of voluntary behavioural adaptations in this specific area is unknown at this time.

  SEAC does wish to note that the level of risk should be taken into account in determining the appropriate risk management measure. It could be possible that, in this case, voluntary measures espousing good hygiene are a useful and low-cost approach.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

Based on the analysis provided by the Dossier Submitter the proposed restriction can effectively reduce the maximum allowed concentration of REACH-8 PAHs in the mixtures under consideration and hence reduce exposure and risk of athletes using synthetic turf pitches, workers involved in installation and maintenance and children playing on synthetic turf pitches and playgrounds to an acceptable level.

The dossier evaluated nine risk management options two of which were brought forward for further impact analysis.

Table 9: Overview of RMOs

Risk management option	Description	Considerations with respect to risk reduction capacity, proportionality to the risk and practicability
R(M)O1: Sum content limit value of 17 mg/kg for REACH-8 PAHs	In this RO, a concentration limit for the sum of the REACH-8 PAHs is set at 17 mg/kg for granules and mulches in sport and play applications. The limit value here is set on the 95 percentile of the PAH content currently found in ELT derived infill in the EU as this value is expected to be the lowest value that is technically feasible and achievable for tyre recycling sector in the EU and will result in acceptable risk levels.	This option is assessed further in the impact assessment, defined as RO1. This is the proposed restriction option.
R(M)O2: SUM content limit value of 6.5 mg/kg for REACH-8 PAHs	In this restriction option (RO) a concentration limit for the sum of the REACH-8 PAHs is set at 6.5 mg/kg for granules and mulches in sport and play applications. In this RO, the limit value is derived from the selected acceptable excess lifelong cancer risk level of 1 in a million under the reasonable worst case scenario conditions for the highest exposed population (i.e. professional goalkeepers).	This option is assessed further in the impact assessment, defined as RO2
RMO3: Content limit for all carcinogenic PAHs	Comparable to the proposed RO, however, it covers 2-3 more PAHs	Limited expected added value in terms of risk reduction as the REACH-8 PAHs serve as marker substances, furthermore this option is not in line with current entry 50 restriction in REACH and expected additional compliance costs. This RMO is disregarded by the Dossier Submitter.
RMO4: Migration limit	Comparable to the proposed RO, however, migration limit instead of concentration limit	Migration better relates to the actual risk and a migration limit may because of that be preferred. However, the proposed restriction accounts for migration in the risk assessment and therefore is deemed sufficient. Migration limit is expected to be

Risk management option	Description	Considerations with respect to risk reduction capacity, proportionality to the risk and practicability
		less practical and enforceable. This RMO is disregarded by the Dossier Submitter.
RMO5: Limit value consistent with the PAH limit values applicable to articles and toys	In this restriction option, the limit value is set consistent with the limit value that applies to articles or toys in paragraphs 5 and 6 of entry 50 in Annex XVII of REACH and applies to individual PAHs (instead of a sum limit of REACH-8 PAHs)	There is no scientific basis for this restriction option as exposure to PAHs from articles and toys may be very different compared to the use of granules and mulches in sport and play applications. In practice, the impacts of this option may be comparable to RO2. This RMO is disregarded by the Dossier Submitter.
RMO6: Limiting the PAH concentration in carbon black	In analogy with the existing extender oil restriction limiting PAHs in tyres in the oils used in tyre production, also the PAH concentration in the carbon black feedstock of tyres can be reduced with a legal limit	Effectiveness of this RMO in terms of risk reduction of the use of granules and mulches in sport and play applications is expected to take years or decade(s) as tyre manufacturers would need time to adapt and it takes a tyre life time before any effect would be seen in ELT granules and mulches. Furthermore, the Dossier Submitter has no information on the technical and economic feasibility of this RMO. This RMO is disregarded by the Dossier Submitter.
RMO7: Further reduction of PAH limit value in extender oils used in tyre manufacture	This RMO would sharpen the limit value of the existing extender oil restriction, entry 50 1-4 REACH Annex XVII	Based on the current limit value and the current PAH concentrations in ELT it is estimated that only a minor part of PAHs in ELT come from extender oils. Further reduction of the current limit value thus is expected to have limited risk reduction capacity. This option would also require a lot of time to have an effect on ELT material. This RMO is disregarded by the Dossier Submitter.
RMO8: Amendment of harmonized classification in Annex VI of CLP	PAH concentrations in ELT derived granules do normally not exceed current CLP concentration limits applicable for classification of mixtures and restricting supply to the general public. Lowering the existing specific concentration limit for REACH-8 PAHs via amendment of the harmonized classification could in theory render Annex XVII entry 28 more restrictive and as a consequence control risks to consumers	This RMO has been disregarded as the current CLP guidance on classification Category 1B genotoxic carcinogens does not provide the possibility to lower the specific concentration limits.
RMO9: Risk Communication	Via campaigns advice could be given to athletes and other users of these facilities to adapt behaviour in order to minimise their exposure to the granules	This RMO has been disregarded as the effectiveness is expected to be limited.

The effectiveness of the two restriction options selected compared to the baseline is given qualitatively in Table 10.

Table 10: Comparison of impacts of RO1 and RO2 compared to the baseline. Plusses and minuses indicate whether impacts are expected to be positive or negative for society and how they compare for RO1 and RO2. Plusses and minuses and qualitative estimates are the Dossier Submitter's estimates based on the impact assessment

Impact category	Explanation	RO1	RO2
Effectiveness (risk reduction)	*Human health (PAHs)*	+	++
	Human health (other effects/substances)	No change	+
	Environment (substances)	No change	++
	Environment (GHG)	No change	-
	Environment (microplastics)	No change	+

RAC conclusion(s):

The main benefit of this restriction is that it ensures that the very high PAH concentrations currently permissible (up to 387 mg/kg) are avoided.

A REACH restriction may have limited effectiveness since it will only be applicable in Member States where End-of-Waste (EoW) status has been agreed or to virgin material placed on the market. RAC cannot confirm in how many Member States ELT rubber infill is considered to have reached EoW status.

RAC notes that no information on the technical and economic feasibility of restricting the carbon black content in tyres is available but supports future consideration of this as an additional risk management option to reduce the PAH content at source if such information become available.

RAC agrees a dose without a theoretical cancer risk cannot be derived for these substances. In the case of RO1, with the proposed limit of 17 mg/kg, RAC agrees that such a limit would equate to a theoretical cancer risk of 2.4×10^{-6} for the general population and 2.9×10^{-5} for workers.

Key elements underpinning the RAC conclusion(s):

End of life tyres that rubber infill is formulated from waste and in accordance with Article 2(2) of the REACH Regulation waste is outside the scope of REACH. The REACH Restriction will only apply in those Member States where End-of-Waste status have been established (RAC is only aware on EoW status in two Member States NL & CY). The absence of EoW criteria in some Member States means the restriction will lower the effectiveness as the restriction will not be applicable. In those Member States where End-of-Waste status has been achieved the restriction will be effective as it will ensure unacceptable concentrations of PAHs are not permitted.

The restriction will be effective in controlling PAH exposure from any virgin infill material potentially containing PAHs placed on the EU market.

It is recognised that recyclers cannot control the PAH content of the tyres. While RMO6 restricting the carbon black content in tyres was considered by the Dossier Submitter, it was disregarded as the Dossier Submitter has no information on the technical and economic feasibility of this RMO. In addition tyre manufacturers would need time to adapt and as a result it would take at least a tyre life time (approx. 7 years) before any effect would be seen. While it is appropriate to explore in future how to reduce the PAH content at source it is known that retreaded tyres tend to have a higher PAH content due to the higher carbon black content. These tyres could be deselected/removed by recyclers for other uses where worker or consumer exposure is not foreseen or for use in energy recovery. This could help reduce the

content of PAHs in rubber infill.

The Dossier Submitter brought two risk management options forward for analysis, RO1 and RO2. RAC recognises that the greatest exposure to the general population (non-smokers) is not from granules and mulches but comes from food sources and inhaled air. However, RAC agrees that airborne rubber dust particles may contribute to PAH exposure via inhaled air, ingestion and dermal contact.

In RAC's opinion while it is unlikely than any individual would be exposed to reasonable worst case exposure in every contributing scenario throughout their entire life the exposure to any of these non threshold carcinogens should be reduced. While no EU legislation sets a reference risk level for the DMEL, i.e. 'tolerable' risk level for carcinogens, cancer risk levels have been set and used in different ways within and outside the EU based on theoretical cancer risk. RAC notes that RO2 provides a theoretical cancer risk of 9.5×10^{-7} for the general population and 2.9×10^{-5} for workers.

RAC notes no harmonised method for the sampling, sample preparation and analysis of ELT infill and mulches exists.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

The Dossier Submitter calculated the cost impacts for two restriction options: RO1 and RO2. The costs of these options were derived by comparing the costs under the baseline scenario with the costs under both restriction options and include economic impacts, wider economic impacts and environmental impacts.

The **baseline**, the "business as usual" scenario, is defined by the Dossier Submitter as the current and predicted future use of performance infill granules in synthetic turf pitches without the proposed restriction options. To describe the baseline for this restriction proposal the Dossier Submitter describes the following elements:

1. The number of artificial turf pitches and sport/play areas with loose infill/mulch installed across the EU that make use of performance infill and the expected trends in the number of pitches installed over the next decade (the Dossier Submitter has also performed a sensitivity analysis for this element, as discussed in the Key elements underpinning the SEAC conclusion of this section);

2. The share of various types of infill used on artificial turf pitches, the quantities infill used and the expected trends related to the application of the different types of infill over the next decade (the Dossier Submitter has also performed a sensitivity analysis for this element, as discussed in the Key elements underpinning the SEAC conclusion of this section);

3. The current PAHs concentration levels in ELT-derived infill material and other infill materials and the expected trends therein;

4. The number of people potentially at risk due to PAH concentrations above the proposed

limit value.

For **RO1** the proposed concentration limit is set at the 95th percentile of the distribution of PAH concentrations currently found in ELT-derived performance infill in the EU. This suggests that 5 % of the infill produced in the EU does currently not comply with the proposed limit value. It is however expected/assumed that in RO1 ELT-derived granules and mulches will still be used in sport and play applications and that all companies providing these materials will be able to remain in business (implying no major effects on the various actors concerned/involved). It is furthermore expected that EU tyre recycling companies will take measures to comply with the limit value which might increase the price of ELT infill. This might make alternative infill somewhat more competitive (implying a slightly higher use of these materials), but it has to be borne in mind that these alternative remain significantly more expensive. **The overall societal costs of RO1 are estimated to be around €30-55 million over a 10-year period (with a mid-range scenario of €40 million)**. These costs consist of revenue losses since 5 % of the ELT is no longer used as ELT infill and sold for a lower price on an alternative market. In addition, to identify non-compliant ELT infill, test costs arise for the ELT recylers as well as enforcement costs for national authorities.

For **RO2** the proposed concentration limit is set at the 14th percentile of the distribution of PAH concentrations currently found in ELT-derived performance infill in the EU. This suggests that 86 % of the infill produced in the EU does currently not comply with the 6.5 mg/kg limit value. The Dossier Submitter expects that it is not possible for recycling companies to assure stable PAH concentrations over time at or below this limit value. Consequently, the Dossier Submitter assumes that this implies the end of market for rubber granules used as infill material in artificial turf pitches and in loose form on playgrounds and in sport applications. In RO2 it is assumed that for infill in newly installed (only non-ELT) pitches and refills, 43 % EPDM, 43 % TPE, 14 % cork will be used in the first year after the introduction of the restriction. Furthermore, a gradual introduction of up to 5 % of no infill installation is assumed over the 10 years following entry into force (and 40 % EPDM, 40 % TPE, 15 % cork). **The overall societal costs of RO2 are estimated to be around €3 000-3 500 million (with a mid-range scenario of €3 100 million) due to market impacts and €80 million for additional greenhouse gas emissions over a 10-year period.**

SEAC conclusion(s):

SEAC agrees in general with the methods used and assumptions made by the Dossier Submitter in deriving cost estimates for the different actors in the supply chain (ELT recyclers, installation and maintenance companies, test companies, national authorities).

However, due to lack of information, several assumptions regarding key parameters were made by the Dossier Submitter. Consequently, several uncertainties in the cost assessment of restriction options RO1 and RO2 have to be recognized. These can be grouped into uncertainties relating to the future trend in the number of artificial turf pitches and the tonnage of performance infill used in the baseline, the reaction of performance infill producers (recyclers) to market changes in RO1 and RO2, and uncertainties due to the cost estimates per pitch. These uncertainties are discussed in the section "Uncertainties in the evaluation of RAC and SEAC".

Recycling companies will have to take measures to comply with the limit value (e.g. by improved selection of source material, i.e. ELT). Hence, societal costs arise related to resource

use for activities which would not have taken place if the material were intended to be used as infill material (in relation to the cost of preparing the material for alternative uses). In case these measures are not implementable or insufficient the recyclers will sell non-compliant ELT-granules at a lower price on alternative markets (e.g. for material re-use or energy recovery). This implies that infill material compliant with the limit value is used for the infill market while non-compliant infill is used for other purposes.

Therefore, recyclers will face an income loss, since non-compliant ELT infill is sold on alternative markets on which only lower revenues can be realized. The Dossier Submitter has used the sale to alternative markets as a means to quantify the restriction costs (10-year window of analysis). In the stakeholder consultation, it was stated that revenue loss represents an overestimate of the societal costs. Furthermore, over a time horizon of 10 years the recylers may be are able to reduce the fraction of non-compliant ELT granules by developing other markets for alternative uses to reduce revenue losses, or other measures to reduce non-compliant ELT infill.

Key elements underpinning the SEAC conclusion(s):

SEAC agrees that the choice of geographical boundary (the EEA-31) and the temporal scope of the analysis (10 years, i.e. the lifetime of an artificial pitch) for the calculations is appropriate.

A. Baseline

i. Number of artificial sport pitches in Europe

The ESTO[34] Market Report Vision 2020 describes the evolution of the number of artificial pitches between 2012 and 2020. The Dossier Submitter used this report to estimate the number of full size synthetic turf pitches as well as the number of mini-pitches over the next decade (2018-2028). According to that report, in 2012 there were 13 000 synthetic turf football pitches and over 45 000 mini-pitches in the EU. ESTO estimates the number of full size and mini-pitches by 2020 to reach 21 000 and around 70 000 respectively. This translates into annual growth rates of 6.2 % and 5.6 % for football pitches and mini-pitches with performance infill, respectively.

Using these growth rates the Dossier Submitter estimates the number of full size synthetic turf pitches to be around 34 000 in 2028, and the number of mini-pitches around 110 000. These estimates take into account newly installed pitches only. To get to an estimate of re-installed (mini-)pitches, the Dossier Submitter assumes that 10 % of the existing pitches are reinstalled yearly.

Taking all this into account the Dossier Submitter concludes that the total number of full pitch (re-)installations between 2018 and 2028 will be on average 4 300 and the total number of mini-pitch (re-)installations will be on average around 6 600 annually.[35]

In order to perform a sensitivity analysis when assessing the societal costs of RO1 and RO2 the Dossier Submitter also used two other growth rates: 0% (lower range scenario) and 12%

[34] European Synthetic Turf Organisation
[35] For the figures and calculations see Excel sheet "Figure D1, Table D1, E31" which is provided as part of the Background Document.

(upper range scenario).

Examples of other types of sports that are using synthetic turf pitches are rugby, American football, lacrosse and Gaelic sports. The number of pitches exclusively dedicated to other sports is considerably smaller. Therefore, the Dossier Submitter focusses only on football pitches and mini-pitches for the baseline situation. SEAC supports this decision since it will have no significant impact on the calculation of the costs for both ROs assessed.

The number of artificial turf systems forms the basis for the calculation of the restriction costs. The trend in the installation of new pitches and replacement of old pitches over the next decade (2018-2028) was also confirmed by ETRMA in its reply to ECHA queries regarding this issue (2016). Therefore, SEAC considers the basis for the extrapolation performed by the Dossier Submitter as well-founded. The expected growth rates of the number of pitches will be driven by the expected number of athletes and children playing on these pitches. The Dossier Submitter considers the growth rates of the number of user to remain stable in the near future (see below). SEAC recognizes that depending on the scenario for growth rates of population, the growth rates of athletes and children will also vary. However, SEAC cannot conclude on the possible impact variations in population growth rates will have since also other factors will have an influence on the demand for pitches.

ii. Types and amounts of performance infill used on artificial turf pitches in the Europe

The Dossier Submitter indicates that, overall, infill manufactured from recycled ELT is by far the most common form of performance infill used in the EU (current estimate based on ESTO (2018): 90 %). Other infill materials used are manufactured from ethylene propylene diene rubbers (EPDM) (approximately 4 %), thermoplastic elastomers/thermoplastic rubbers (TPE) (approximately 4 %), poly ethylene (PE), and organic material (cork) (approximately 2 %)[36]. The estimates provided by FIFA (2017) slightly diverge, but since the estimates of ESTO were confirmed in the stakeholder workshop (24 November 2018) the Dossier Submitter used these market shares for cost estimation. SEAC considers them as plausible starting points for analysis.

According to information received by the Dossier Submitter the majority of these alternative infills are expected to be virgin material; however, some of it may be from recycled materials as well. These alternatives vary greatly in terms of infill price, properties, maintenance and recycling costs, and other key attributes.

The Dossier Submitter assumes that for the newly installed pitches (new installations and re-installations) the market share of ELT infill used will be gradually reduced from 90 % in 2018 to 70 % in 2028 in the baseline situation. The market share of the respective alternative infills are inversely assumed to increase gradually from 10 % to 30 % in 2028 (TPE and EPDM: 4 % to 12 % each; cork and other organic material: 2 % to 6 %). These estimates are based on personal communication with three manufacturers and on information received from stakeholders during a workshop held by the Dossier Submitter in 2017. SEAC finds these estimates to be of an uncertain nature since views differ on the extent to which this shift will be pursued. Because of this uncertainty, SEAC asked the Dossier Submitter to carry out a sensitivity analysis in order for the Committee to assess the influence of the future ELT market share on the costs. The following 2028 ELT market shares were chosen: 50 % ELT (lower

[36] ESTO (2018)

range), 70 % ELT (medium range), 90 % ELT (upper range).

According to the Dossier Submitter there are about 140 formulators of rubber granules operating in the EU, most of which formulate and supply infill material throughout the EU. Import of ELT-derived rubber granules or rubber mulch as end-products from outside of the EU is minimal, if non-existent. However, the import of alternative infill materials – primarily EPDM and TPE granules – into the EU is observed.

Rubber mulch is predominantly produced from recycled tyre buffings or nuggets and has a wide range of uses in the EU. It has been estimated that about 60 % of rubber mulch ends up being used in playgrounds. Compared to rubber granules, the volume of rubber mulch formulated in the EU is quite low. No exact figure is currently available. The Dossier Submitter indicates that the volume is expected to be minimal compared to the use of infill in synthetic turf pitches and mini-pitches. SEAC therefore considers the absence of a quantitative estimate on the use of mulch in the EU for the baseline to be justified and causing no significant uncertainties for the overall impact assessment.

Based on the above considerations and the figures available to the Dossier Submitter, the total annual use tonnage of ELT-derived infill material is estimated to grow from 350 000 tonnes in 2016, 390 000 tonnes in 2018 to 550 000 tonnes in 2028 in the baseline situation.

The tonnages are calculated based on the estimated number of newly installed and reinstalled pitches (full size and mini-pitches), the average surface area of pitches and the amounts of infill per square meter. The surface area of football pitches varies somewhat, but the Dossier Submitter assumes the average surface area to be 7 600 m^2. This average was confirmed by the synthetic turf sector as the standard-size football pitch. Based on stakeholder information, per square meter 15 kg ELT infill is used. This calculates to 114 tonnes of ELT infill used per full-size pitch which was corroborated by figures presented by ESTO (2017). Therefore, SEAC considers this estimate to be plausible.

The variability in the surface area of mini-pitches, however, is larger compared to football pitches, ranging from one-tenth to half of the size of a football pitch. In the stakeholder workshop the average surface of a mini-pitch was by some stakeholders estimated to be one-tenth of a football pitch, and 10 to 14 tonnes of ELT infill were used per mini-pitch. The Dossier Submitter has assumed an average tonnage of 14 tonnes per mini-pitch (about 10 kg per square meter), and furthermore assumed, based on ESTO (2017), that for about 50 % of the mini-pitches sand infill is used. Since the variability in the technical design of mini-pitches is larger compared to regular football pitches, some degree of uncertainty about the amount of ELT infill used for mini-pitches is recognized by SEAC.

For annual maintenance, 1 tonne per full size and 0.1 tonne per mini-pitch is assumed to replace the ELT infill lost during the year (based on information of suppliers of turf-pitches). The variability of these estimates is considered to be large since it depends on use intensity and quality of the maintenance. However, ETRMA (2016) has estimated that in 2016 a share of about 10 % of ELT infill is used for maintenance, thus roughly confirming the Dossier Submitter´s assumptions. SEAC recognizes remaining uncertainties concerning ELT infill applied for maintenance, but considers them as moderate.[37]

[37] The Dossier Submitter's assumption for the amounts of infill in the baseline scenario are summarised in Tab. D1 (Annex XV restriction report).

Furthermore, the amount of ELT infill used for new installations and maintenance provided by ETRMA (2016) can be considered roughly in line with the amount calculated by the Dossier Submitter for 2016[38]. The total amount including re-installations after end-of-service life is estimated by the Dossier Submitter to be 346 000 tonnes in 2016. This figure is comparable with the number provided by an EU association (association and number confidential). Thus, the available evidence supports the Dossier Submitter's estimates. SEAC considers the assumptions used for extrapolation as well-founded but recognizes the uncertainties.

iii. PAH concentrations in performance infill

The eight polycyclic aromatic hydrocarbons (PAHs) – all carcinogens – that are the main target of this restriction proposal, are present in ELT-derived infill material. Following REACH Annex XVII entry 50, the content of PAHs in extender oil, and therefore in tyres, has been reduced, but not eliminated from 2010 onwards.

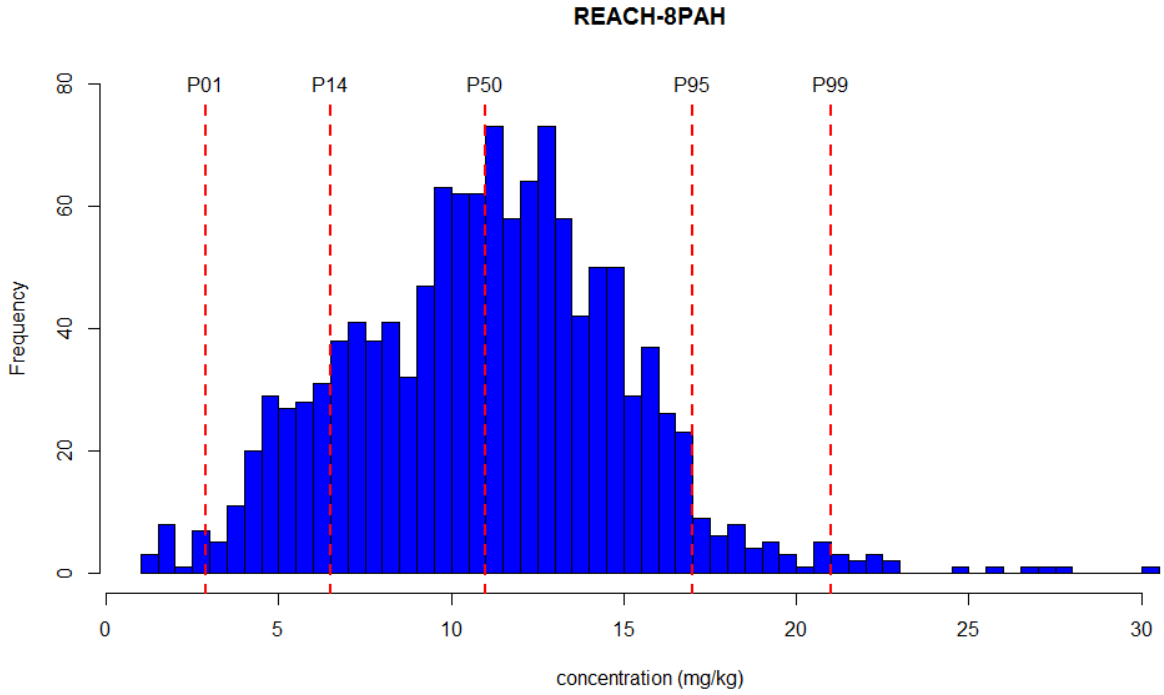
For this dossier, the data of 1 373 samples were collected of which 1 234 contained information on all REACH-8 carcinogenic PAHs. Most samples were taken in the Netherlands (1 035), other samples were taken in various European countries: Belgium, Denmark, Germany, Italy, Portugal, Spain, Sweden, and the UK. Concentration data was provided by industry, authorities, other stakeholders and obtained from public literature.

The information collected covers samples taken from sports turf pitches or from big bags at the site of the ELT infill manufacturer. In case samples were taken from turf pitches, each sample represents one pitch. Samples from sports turf pitches were, in most cases, pooled samples from multiple locations on one field. Samples from manufacturers were taken from one big bag or pooled from multiple big bags. As the data are sourced from various studies and industry information, there may be differences in the sampling strategy across samples. The overview provided is limited to uncoated granules produced from ELT rubber. It should be noted that rubber granules in most cases originate from ELT, but may be mixed with other rubber waste streams. Concentrations are only included when sampled in the EU in the year 2010 or later. In 2010 a REACH restriction on extender oils used for the production of tyres or parts of tyres became effective.

The Dossier Submitter deems this sample size/set to be representative for ELT turfs in the EU since the tyre market is an EU market and the extender oil restriction applies in all EU countries. Due to the variability in the sampling strategies of the samples included, SEAC cannot fully agree with this conclusion. For SEAC it is plausible that scrap tyres across the EU are expected to have similar PAH content. Differences in PAH concentrations in manufactured granules may however appear due to differences in scrap tyre selection and granule manufacturing processes. The REACH-8 PAHs concentration in ELT infill samples available varied from 2.9 (1st percentile) to 21 mg/kg (99th percentile) with a 50th percentile of 11 mg/kg (see Figure 5). Since the Dossier Submitter deemed the sample size/set is representative for the EU, it was also concluded that concentrations of 15-20 mg/kg are expected to be technically feasible for the vast majority of actors producing ELT infill.

[38] 80 000-130 000 tonnes (ETRMA) vs 141 000 tonnes (Dossier Submitter)

Figure 5: Histogram of all available measured REACH-8 PAH concentrations (n=1 234). Vertical red lines indicate the 1st percentile (2.9 mg/kg), 14th percentile (6.5 mg/kg), 50th percentile (11 mg/kg), 95th percentile (17 mg/kg) and 99th percentile (21 mg/kg)



In addition to ELT, also non-tyre rubber materials and waste articles may be used for the formulation of granules. Use of non-ELT crumb rubber from other sources has been indicated as a potential source of infill material that may contain higher PAHs content. However, no clear source could be found confirming this observation. Also no information is available that this use may be increasing in the EU.

Some ELT from before 2010 appears still to be placed on the EU recycling market. Gradual reduction in PAHs content from before 2010 to 2017 is observed in the PAH measurements available to the Dossier Submitter. The decrease seems to level off in the last four years.

Based on the available information, the Dossier Submitter assumes that no further reduction or increase of the PAH concentrations in ELT is expected in the baseline situation. The Dossier Submitter considers the situation described for ELT-derived granules to also be representative for the PAH concentrations in ELT-derived mulches as the feedstock material (scrap tyres) is the same.

In regards to non-ELT infill, the Dossier Submitter only has limited information available. Based on personal communications it is stated that the majority of the infill will be virgin material. These materials could in theory contain PAHs if for example carbon black or PAH containing oils[39] are used in the production. The Dossier Submitter only presented some information for EPDM. A large proportion of EPDM articles used on the market contain carbon black (e.g. roofing sheets, floor mats) and hence black carbon containing EPDM will be abundant in the waste stage. The analysis of alternatives shows that some low quantities in

[39] Unlikely according to the Dossier Submitter in case of EPDM as PAH containing oils are said not to match with the material.

PAHs have been found in EPDM. For other non-ELT infill no information was provided or is available.

iv. Number of people potentially exposed

- Athletes and children playing on synthetic turf

As many artificial pitches use infill material other than sand, the size of population that comes in direct contact with potentially PAH-containing infill material is considerable according to the Dossier Submitter. It has been estimated that the number of registered players for the four previously mentioned sports in the EU exceeds 20 million (inclusive 71 049 professional football players). However, when accounting for unregistered players and users of mini-pitches, the number may well be in excess of 46 million individuals.

The section on benefits will go into more detail on this.

- Installation and maintenance workers

In total, it is estimated that between 4 000 and 14 000 workers are involved in installation and maintenance of synthetic turf pitches. Since no numbers on workers in Europe is available the estimate was based on the number of installation and maintenance activities per year and an estimate of working days per installation and for maintenance per pitch per year. Depending on whether maintenance is done part-time or full-time a range of 4 000 to 14 000 workers are potentially exposed to ELT infill. Since currently about 90 % of the synthetic turf contains ELT infill it is plausible to assume that all workers will come into contact with ELT infill.

The assumptions for the calculation of the estimate are plausible to SEAC, although some uncertainties regarding the working time distributed over maintenance activities have to be recognized.

B. R(M)O1: Sum content limit value of 17 mg/kg for REACH-8 PAHs

This restriction option prohibits the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 17 mg/kg (0.0017 % by weight of this component) of the sum of the listed PAHs.

Under RO1 the Dossier Submitter does not expect a significant change in the number of artificial turf pitches, the share of the different types of artificial turf systems and in the tonnage of performance infill used for these pitches (ELT granules, EPDM, TPE, cork). This expectation is mainly based on discussions held during a 2017 stakeholders workshop organised by the Dossier Submitter. Since 5 % of the ELT infill would not comply with a concentration limit of 17 mg/kg, it seems plausible to SEAC that the comparatively low reduction of the ELT infill market will have an economic impact, but SEAC is not aware of any evidence that this will endanger the economic viability of activities linked to the use of ELT granules as infill material on artificial pitches and playgrounds.

The Dossier Submitter has reported that in the Netherlands some municipalities have already shifted to the use of alternative types of infill, and a drop in sold volumes of ELT-infill is therefore observed. This shift is attributed to the societal concern due to perceived health and

environmental risks of ELT-infill. In case the shift continues and also occurs in other EU Member States, this may reduce the compliance costs of the restriction. Moreover, the restriction in itself may intensify substitution efforts due to the public attention it is awarded. However, there is uncertainty about the (continued) impact of the effects linked to societal concern and its representativeness for the EU as a whole. The Dossier Submitter has therefore assumed that owners of artificial pitches (e.g. municipalities and sport clubs) will not respond to the restriction and concerns linked to cancer risks of ELT-infill by shifting to alternative infill. Some impact on the compliance costs is however recognised by SEAC. The Committee finds it plausible that in case some owners make a voluntary shift to alternative infill, the compliance costs are somewhat overestimated.

The economic impacts identified by the Dossier Submitter are summarised in Table 11 and discussed in more detail below the table.

Table 11: Summary of economic impacts under RO1 (based on the Annex to the restriction report)

Activities	**Economic impact to society**
Changes in resource use	
Formulation/Production of recycled rubber mixtures	Revenue loss: €25 million – €50 million (considered by SEAC to overestimate the loss to society) Extra test costs: €5 million
Tyre manufacturers	-
Production of non-ELT performance infill	-
Production of artificial turf	-
Installation and maintenance of artificial pitches	-
Enforcement	Enforcement costs: €0.5 million
Distributional effects	
Municipality/sport clubs/ schools/private-sector companies	Increased prices for newly installed pitches: Max: €30 million – €55 million (depending on share of compliance costs passed on)

Formulation of recycled rubber mixtures

i. Extra costs as a result of measures to guarantee compliance

According to the Dossier Submitter measures to guarantee compliance could include improved selection of tyres for production of ELT infill. However, these measures could be insuffient to fully comply with the limit value. Therefore, for quantification the costs of selling non-compliant ELT granules on alternative markets are used. By selling on

alternative markets, the revenue loss from not being able to place it on the market as performance infill are at least partly offset.

Three scenarios are presented: Selling the ELT granules on the energy market at a slightly positive price point (€5 per tonne); at a negative price point (€-30 per tonne); selling on an alternative market for material re-use (moulded objects; €100 per tonne)[40]. Since the amount of ELT granules shifted to the energy market can be considered as insignificant, the assumption of a constant selling price for granules sold on the energy market or on an alternative market is considered to be plausible by SEAC.

The energy market for tyre fuel granules is assumed to represent the lower end of what ELT recycling companies can get for their material, which is considered plausible by SEAC. The total loss of the ELT sector is estimated to be between €25 and €50 million. The Dossier Submitter has not formulated an expectation of the most plausible scenario, but as a central estimate a revenue loss of €41 million was calculated. For ELT granules used as performance infill a selling price of €220 per tonne is applied and €5 per tonne for ELT sold on the energy market.

This revenue loss can be considered to overestimate the societal loss of RO1 for the formulators of recycled rubber mixtures. The societal costs due to the restriction comprise activities undertaken by recyclers to comply with the limit value. These are activities such as the improved sorting of source material (i.e. ELT), all activities needed to prepare non-compliant infill for sale on alternative markets and the actual sale of ELT granules on these alternative markets. In case these activities for an improved sorting are not implementable or insufficient the recyclers will sell non-compliant ELT granules at a lower price on alternative markets (e.g. for material re-use or energy recovery). Therefore, recyclers will face a revenue loss.

The costs of sorting or preparation of infill in order to put them to alternative use could not be quantified by the Dossier Submitter. The Dossier Submitter has instead used the revenue losses of selling non-compliant infill on alternative markets at a lower price to quantify the societal loss. Based on responses received during the public consultation the revenue loss will represent an overestimate of the societal costs. Over a time horizon of 10 years the recyclers may be able to reduce the fraction of non-compliant ELT granules by developing other markets (thereby also reducing the revenue loss), or other measures to reduce non-compliant ELT infill (e.g. by blending non-compliant material with compliant material). Furthermore, these losses may be passed on to the owners of artificial turf pitches (municipalities, sport clubs, schools) through an increase in the price of ELT infill, or indirectly paid by EU citizens/car owners (e.g. because of the increased price of tyres).

However, recyclers might be able to identify more valuable uses for non-compliant ELT granules than waste incineration, which will reduce revenue losses. Therefore, the central estimate of €41 million may overestimate the revenue loss. SEAC considers this plausible and as such considers revenue losses to more realistically be between €25 and €50 million.

[40] Price point information was provided by stakeholders.

Although the price for ELT infill may slightly increase, the quantities of ELT infill sold, and thus the distribution of shares of the various infill types under RO1 are assumed to be equal to those under the baseline situation. SEAC considers this plausible due to the large difference in prices of ELT infill compared to alternative infill (ELT infill: €220 per tonne; EPDM: €1 750 per tonne; TPE: €1 600 per tonne), and due to the relatively small share of non-compliant ELT infill under RO1.

For the calculation of the revenue losses, a limit value of 17 mg/kg was assumed which means that about 5 % of the ELT infill on the market will not be compliant. Applying the limit value of 20 mg/kg proposed by RAC, the share of compliant ELT infill would increase from 95 % to about 99 % (based on the data presented in Figure 5 above). This will reduce the revenue losses by a factor of about 5 (i.e. from €25-50 million to about €5-10 million). Taking into account that revenue losses overestimate the societal loss of RO1, the losses will be even lower. Furthermore, responses received from stakeholders during the public consultation provide some indication that societal concern about the health hazards of ELT infill represent a business risk for the ELT infill market. According to the responses, this uncertainty would be partly removed under RO1. Some recyclers expect an increase in sales and revenues, which could offset potential costs of RO1 for the ELT recycling sector and these costs may even be reduced to close to zero especially with a limit value of 20 mg/kg. SEAC considers these considerations as plausible, but considers it uncertain whether societal costs of RO1 will be completely offset by increased revenues.

ii. Increase in costs to test for PAH content to guarantee compliance

The cost per test of one sample of ELT performance infill is estimated to be between €25 and €232[41]. As a central estimate €130 per test was used which leads to additional testing costs of about €5 million over 10 years.

For this it was assumed that 50 % of the recyclers are already testing the PAH-content of their infill due to societal concerns in some Member States. The remaining 50 % of the producers will increase their testing frequency. These assumptions were not justified any further by the Dossier Submitter and the calculation shall therefore only be considered as a rough estimate to illustrate these costs. Therefore, SEAC considers the uncertainty of these calculations to be high, but of lesser importance given the magnitude of costs for measures to guarantee compliance.

iii. Potential change in company structure and jobs

Since only a small fraction of the infill may not be compliant the Dossier Submitter assumes that the impact on the economic viability of companies is small and no effect on employment will arise. SEAC is not able to verify this, but has not been made aware of any evidence of the proposed restriction endangering economic viability for companies.

[41] Personal communication of a test laboratory to the Dossier Submitter.

Municipality/sport clubs/schools/private-sector companies

iv. (Slightly) increased price of artificial turf with ELT-derived infill

The Dossier Submitter assumes that in the EEA-31, local authorities will finance the extra costs for pitches and playgrounds that make use of infill/loose granules/mulch. This presupposes that formulators of recycled rubber mixtures would be able to completely pass on the additional cost for compliance to local authorities. SEAC finds it plausible that costs for the operators of artificial pitches and playgrounds will increase, but it is uncertain whether the costs can be completely passed on.

In the dossier it is assumed that the price increase for ELT infill will not impact the quantities of ELT infill sold, and thus will not lead to a reduction in the number of newly installed and re-installed turf pitches. SEAC considers this plausible since the price increase per tonne of ELT infill is likely to be small. Moreover, demand for pitches by municipalities and schools is driven by goals set by the responsible local administration. This demand may therefore be relatively inelastic to price changes.

Citizens/general EU population

v. Potential slight increase in costs for sport pitches and public playgrounds

The Dossier Submitter assumed a slight increase in the market price of ELT infill as a result of the additional measures recyclers would need to take in order to ensure compliance. This increase in market price and the corresponding potential increase in costs for sports pitches and public playgrounds has not been quantified. A financial burden for users of pitches or taxpayers is expected in case taxes or membership fees for use of artificial turf pitches are increased. This is considered plausible by SEAC, but this burden is likely to be small under RO1.

Enforcement

vi. Increased enforcement costs (compliance costs)

The estimation of enforcement costs is based on the ECHA study on the administrative burden of enforcement for new restriction proposals assuming enforcement costs of €55 000 for EU-28 per year. Based on SEAC scrutiny and on the ECHA study on enforcement costs, these costs were recalculated to be about €0.5 million over the assessed time horizon of 10 years. It has to be recognized that the ECHA study only covers the administrative costs of enforcement. Own tests done by the enforcement authorities are not included.

Based on already established routines for enforcing PAH limits under REACH Annex XVII entry 50 (articles, toys) the Dossier Submitter considers this cost estimate as merely illustrative for the order of magnitude of the costs. SEAC considers this cost estimation as uncertain since enforcement costs are mainly driven by costs per control and frequency of controls. The impact of the entry 50 restriction on the frequency of controls and the costs of the currently proposed PAH restriction has not been made clear in the restriction report.

With regard to testing, the Dossier Submitter states that in the baseline laboratory testing by the infill producers (recyclers) is already done to a significant extent. However, more testing would be required by the users due to public concern. Usually enforcement authorities will not undertake own tests and only check the documentation of tests that have been carried out. Based on information from Dutch national inspectorates, in some cases enforcement authorities are expected to do sampling and perform own tests if there is doubt as to the quality and/or reliability of the results of the analyses done by the recyclers. However, no information is available on the frequency of tests done by enforcement authorities.

Since no justification is provided by Dossier Submitter on the testing already taking place in the baseline, the Dossier Submitter's statement regarding the impact of additional testing on the enforcement costs cannot be evaluated by SEAC and is therefore considered uncertain. The effect of additional tests for enforcement costs is however considered to be small since producers have already done tests in the baseline and they are forced to demonstrate a low concentration level of REACH-8 PAHs due to public concern.

C. R(M)O2: Sum content limit value of 6.5 mg/kg for REACH-8 PAHs

This restriction option prohibits the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 6.5 mg/kg (0.00065 % by weight of this component) of the sum of the listed PAHs.

Table 12 gives an overview of the (wider) economic impacts as identified by the Dossier Submitter and the actors these impacts are attributable to (based on Table 14 in the restriction report, figures have been rounded off). A more detailed discussion follows below the table.

Table 12: Summary of economic impacts under RO2 (numbers rounded; based on the Annex to the restriction report)

Activities	Economic and wider economic impact to society
Changes in resource use	
Formulation/Production of recycled rubber mixtures Economic impact Wider economic impact	 Net revenue loss (end-of-market ELT infill): €820 million Alternative revenue (ELT sold on energy market): €-110 – €380 million Net revenue loss: €460 – €950 million (considered by SEAC to overestimate the loss to society) 400 temporary job losses: €40 million
Production of non-ELT performance infill	Extra societal costs related to other types of performance infill: €2 400 million
Production of alternative turf pitches	Extra costs related to other types of artificial systems (artificial carpet, shockpad): €1 000 million.
Installation and maintenance of artificial turf pitches	Total extra societal costs of installation: €210 million maintenance: €150 million
Waste management of artificial turf pitches	Extra societal benefits of TPE recycling: €35 million
Enforcement	Enforcement costs: €0.5 million
Distributional effects	
Tyre manufacture	Increased costs due to recycling costs passed over
Municipality/sport clubs/schools/ private-sector companies	Increased prices for newly installed pitches

Production of recycled rubber mixtures

i. <u>End of market for rubber granules in artificial turf and lose applications on sport pitches and playgrounds</u>

The Dossier Submitter assumes that under this restriction option ELT recyclate will no longer be used as infill material for artificial pitches and playgrounds (end-of-market scenario). This is based on the Dossier Submitter´s analysis of 1 234 samples which shows that more than 80% of the analysed samples contain more than 6.5 mg/kg (i.e. 14th percentile in Figure 5) of the sum of REACH-8 PAHs. The Dossier Submitter states

that the producers of recycled rubber mixtures (recyclers) will not be able to produce ELT infill with stable PAH concentrations below this limit value. The restriction dossier does not provide further explanations to justify this end-of-market scenario. SEAC does however find it plausible that due to increased costs for quality supervision of ELT material compared to the relatively low volume of performance infill produced[42], a sharp increase in unit cost of production would occur such that ELT recycling for infill is no longer economically viable for all recyclers. SEAC does however find the assumption that all production of ELT infill material would be halted, an extreme one and therefore considers this scenario unlikely. Some of the recyclers may find it economically feasible to produce compliant ELT infill also under this scenario.

ii. Increase in costs of tyre recycling (revenue loss)

For ELT granules used as performance infill a selling price of €220 per tonne is applied (see also discussion under RO1). The total selling price of ELT granules in the baseline is estimated to be around €840 million. Since RO2 implies end-of-market for ELT infill, a loss in revenues of €840 million is expected.

iii. Increase of other options of ELT/rubber recycling (new income)

To reduce the revenue loss, ELT granules previously used as performance infill are assumed to be completely shifted over to alternative uses (e.g. cement kilns, civil engineering, and energy market). The same three scenarios for selling prices on other markets as for RO1 are applied. Based on these scenarios, the order of magnitude of the alternative income is assumed to be between €-110 million and €380 million. In the middle scenario, it is assumed that granules are sold on the energy market at a slightly positive price of €5 per ton implying alternative revenue of €19 million. Based on the above a medium estimate of the net revenue loss of €819 million was calculated (selling price of €5 per tonne on the energy market compared to €220 in the baseline).

Due to the additional large quantity of ELT supplied to alternative markets price stability on these markets does not seem plausible, and a price decrease may arise. Since the full quantity of ELT granules previously used as infill is shifted to the energy market, SEAC finds a negative selling price to be plausible as well. Therefore, a selling price of zero or a negative price (scenario 2: €-30 per tonne) seems to reflect a worst-case for the possible economic impact for producers of recycled rubber mixtures (recyclers). Therefore some uncertainties remain for SEAC whether a net revenue loss of €819 million or €952 million is more appropriate for the quantification of the economic impact for recyclers.

SEAC considers the revenue loss to overestimate the societal loss of RO2 for the formulators of recycled rubber mixtures. The societal costs due to the restriction correspond to the activities undertaken by the recyclers to comply with the limit value. These activities arise due to improved sorting of source material (i.e. ELT) and all activities necessary to prepare the non-compliant infill for sale on alternative markets. In case these activities for an improved sorting are not implementable or insufficient the recyclers will sell non-compliant ELT granules at a lower price on alternative markets (e.g. for material re-use or energy recovery). Therefore, recyclers will face a

[42] 30 % of the ELT recycling market is geared towards producing infill material – ETRMA (2016) as reported in ECHA (2017).

revenue loss.

The costs of these activities could not be quantified by the Dossier Submitter. The Dossier Submitter has instead used the revenue losses of selling non-compliant infill on alternative markets at a lower price in order to quantify the societal loss. Based on responses received during the public consultation the revenue loss will represent an overestimation of the societal costs. Over a time horizon of 10 years the recyclers may be able to reduce the fraction of non-compliant ELT-granules by developing other markets (thereby also reducing the revenue loss), or other measures to reduce non-compliant ELT infill (e.g. by blending non-compliant material with compliant material). These losses may be passed on to the owners of artificial turf pitches (municipalities, sport clubs, schools) through an increase in the price of ELT infill, or indirectly paid by EU citizens/car owners (e.g. because of increased prices of tyres).

iv. Potential change in company structure and jobs

Since the end-of-market situation will cause significant revenue losses the viability of companies, especially smaller companies, will be endangered. Some of these companies may respond to these lost market opportunities by reducing their production capacities and employment. It does however seem plausible that job losses will be compensated by an increase in jobs in the artificial turf sector, especially in the production of alternative infill material. It is therefore assumed that only some temporary unemployment will arise. SEAC considers this plausible.

To calculate these temporary jobs losses, the Dossier Submitter assumes that 15 % of the total jobs in the ELT sector are related to ELT infill. This roughly reflects the share of ELT rubber used for production of ELT infill. Based on stakeholder information the total number of FTE in this sector is between 2 500 and 2 900 (ETRMA, 2018) such that 405 jobs would be temporarily lost. The societal costs of job losses, which were estimated by applying the SEAC approach for valuing job losses[43], are €39 million assuming a net present value of the social cost of a job loss in the EU-28 of €95 000 (Dubourg, 2016)[44]. Since no further justification is provided for the fraction of jobs lost in the ELT sector, SEAC considers this estimate as uncertain although SEAC finds it plausible that temporary unemployement will arise.

Tyre manufacture

v. Potential increase in price of new tyres

Due to the end-of-market for ELT infill, options for an alternative use for this material have to be identified. However, these alternative uses can be described as lower value uses. The loss in value was approximated by the revenue loss of the producers of recycled rubber mixtures.

In the EU, landfilling of ELT has been prohibited since 2006 following the European Directive 1999/31/EC. This Directive is based on the 'polluter pays' principle and calls for Member States to take measures against accepting used tyres in a landfill (certain

[43] Dubourg (2016), ECHA (2016)
[44] Dubourg (2016) calculated the net present value of the social costs of one lost job in the EU-28 in 2014 to be €86 827. The Dossier Submitter uses the OECD PPP deflator to make a more recent (2016) estimate.

exceptions apply). National law defines the legal framework and assigns the responsibility to the producers (tyre manufacturers and importers) to organise the management chain of ELT. Currently, 14 countries operate an ELT management company set up by tyre manufacturers (and in total 18 countries have a producer responsibility scheme). Thus, not all EU Member States have such a system in place, and without such a system no impact of the restriction is expected for tyre manufacturers. However, in the Member States with such systems in place some of the losses could be passed on to the tyre manufacturers. The tyre manufactures may then respond by an increase in tyres prices. Due to the variability in institutional settings in the Member States, SEAC can only speculate whether and to what degree these losses for recyclers are passed on to tyre manufacturers.

Municipality/sport clubs/schools/private-sector companies

vi. Increased costs for newly installed (mini-)pitches and for replacement of (mini-) pitches and potential change in maintenance costs

The Dossier Submitter assumes that in the EEA-31, local authorities will finance the extra costs for pitches and playgrounds that make use of infill/loose granules/mulch. Depending on the institutional system, this can lead to an increase in the local municipality tax and membership fees and these costs are thus expected to be (indirectly) paid by EU citizens.

The overall extra costs for artificial turf systems with EPDM, TPE and cork infill and no-infill systems compared to artificial turf with ELT-derived infill are estimated to be around € 3 000 million.

SEAC finds it plausible that costs for the operators of artificial pitches and playgrounds will increase, but there are some uncertainties about the magnitude of the additional costs and whether these can be completely passed on.

Citizens/general EU population

vii. Potential increase in costs for sport pitches and public playgrounds

The increased costs for pitches described in point vi may lead to a financial burden for EU citizens in case taxes or membership fees for use of artificial turf pitches are increased.

Production of non-ELT performance infill

viii. Increased market for non-ELT performance infill in newly installed pitches, re-fill and in potential early replacement of existing pitches and in refill of existing pitches

Since RO2 implies the end-of-market of ELT performance infill, municipalities and owners of artificial pitches will have to shift to systems using alternative infill. The Dossier Submitter´s assumptions on the change in the tonnage from ELT infill to EPDM, TPE, and cork infill are as follows[45]: 43 % EPDM, 43 % TPE, 14 % cork will be used in the first year after the introduction of the restriction[46]; a gradual introduction of up to

[45] Infill in newly installed (only non-ELT) pitches and maintenance.
[46] The Dossier Submitter however assumes that for maintenance of existing pitches only EPDM (50 %) and TPE (50 %) will be used.

5 % of no infill installation is assumed over the 10 years following entry into force (and 40 % EPDM, 40 % TPE, 15 % cork).

The costs of shifting to turf systems with alternative infill are to a great extent caused by the significantly higher costs of alternative infill per tonne (€1 750 for EPDM, €1 600 for TPE, €1 350 for cork) compared to ELT infill (€220). The Dossier Submitter assumes that the increase in demand for alternative infill will not affect price. The total extra societal costs related to other types of performance infill are therefore estimated to be around €2 400 million over 10 years.

Given the strong increase in consumption of alternative infill (EPDM, TPE, cork) SEAC considers the assumption of price stability for alternative infill to be highly uncertain. At least for the period during which production capacities or imports from non-EU countries need to be expanded, an increase in prices can be expected. An increase in price of the alternative infill material will further raise the extra societal costs of shifting to turf systems with alternative infill. However, over the long-term the increase in production capacities of alternative infill may reduce the prices of alternative infill and the price difference to ELT infill. Thus, there are some uncertainties concerning the estimation of societal costs of alternative infill. It is nonetheless plausible to SEAC that over the next 10 years these costs will be significantly higher compared to the costs of use of ELT infill.

Other costs related to the shift to alternative artificial turf systems, besides the use of alternative infill are discussed in the sections below.

Production of artificial turf pitches

The information on costs per artifical turf pitch system was collected through personal communication between the Dossier Submitter and the turf sector, and was also received during the call for evidence. The information was not scrutinized in detail by SEAC but seems plausible. Overall, the approach for cost assessment seems plausible.

ix. Increase in demand of specific types of artificial turf systems and elements within that system

Besides the increase in costs related to alternative performance infill (discussed above), other additional costs due to differences in the turf system need to be taken into account. Systems with alternative performance infill require a shockpad and an artificial carpet with short piles while systems with ELT infill do not require a shockpad and have a carpet with long piles. The total extra costs related to other types of artificial systems are estimated to be around € 1 000 million. Alternative pitches (non-ELT) also need more sand infill compared to the ELT system which increases the costs in RO2 compared to the baseline even further. The total extra societal costs of sand infill are estimated to be around €170 million.

The prices for shockpads, carpets and additional sand infill are based on information received during the call for evidence and personal communications with synthetic turf producers, and are considered plausible. SEAC however considers the assumption of price stability as not very plausible. The increase in demand for shockpads and artificial carpets may increase prices for additional components of artificial turf systems, which

may decrease over the long-term if production capacities are adapted accordingly. In conclusion, it is plausible that additional costs of alternative turf systems will arise, but there are some uncertainties around the estimated values.

x. Market opportunity for innovative artificial field turf structures, like turf without infill

The Dossier Submitter mentions business opportunities for innovative artificial turf producers (without using infill) which may arise due to the end-of-market for ELT infill as well as the relatively high costs of artificial turf systems with alternative infill. No further quantification was provided about the expected development in market shares of these types of turf systems.

Installation and maintenance of artificial pitches

xi. Increased market because of other installation requirements for artificial turf systems with alternative infill/no-infill

Different artificial turf systems have other installation costs. The total extra societal costs of installation are estimated to be around €210 million. The additional installation costs are estimated based on information received during the call for evidence and personal communications with synthetic turf companies, and are considered plausible.

xii. Increased market due to (slightly) more frequent maintenance in case of cork (and EPDM and TPE infill)

The total extra societal costs of maintenance are estimated to be around €150 million. The additional installation costs are estimated based on information received in the call for evidence and personal communications with synthetic turf companies, and are considered plausible.

Waste management of artificial turf pitches

xiii. Change in waste composition may influence the waste handling possibilities

The Dossier Submitter assumes that the costs of waste management are more or less equal for different systems, with TPE being an exception since better recycling options exist. The restriction does not affect the type of end of life treatment of artificial turf systems (landfilling, incineration or recycling). The total extra societal benefits of better waste management of TPE are estimated to be around €30 million. SEAC considers this estimate plausible.

Enforcement

xiv. Increased enforcement costs (compliance costs)

In case the market for ELT infill disappears, enforcement authorities only have to check the type of infill used on turf pitches by simple visual control in combination with administrative information containing laboratory test results. If alternative materials are used which may contain PAHs (e.g. EPDM) some chemical analysis may still be needed if the administrative information proves insufficient.

Based on the average administrative costs of enforcement, the net present value of compliance costs is estimated to be to be around €0.5 million. The Dossier Submitter originally calculated enforcements costs of €15 million which were recalculated based on SEAC scrutiny. It has to be recognized that the administrative costs of enforcement are based on an ECHA study that only covers the administrative costs of enforcement. Own tests done by the enforcement authorities are not included, and the estimated value may underestimate the enforcement costs.

Based on already established routines for enforcing PAH limits under REACH Annex XVII entry 50 (articles, toys) the Dossier Submitter considers this cost estimate as merely illustrative for the order of magnitude of the costs. SEAC considers this cost estimation as uncertain since enforcement costs are mainly driven by costs per control and frequency of controls. The impact of the entry 50 restriction on the frequency of controls and the costs of the currently proposed PAH restriction has not been made clear in the restriction report.

Benefits

Summary of proposal:

For **RO1** the Dossier Submitter identifies benefits from a reduction of health risks (**human health impacts**) for athletes (including professionals), playing children, and installation and maintenance workers because the limit value helps to avoid exposure to infill material with PAH concentrations above 17 mg/kg. The Dossier Submitter uses qualitative and (semi)quantitative arguments to describe the human health benefits. Since PAH-exposure values at the current limit value of 387 mg/kg are considered to be very rare, the number of avoided cancer cases is estimated assuming a risk reduction from 21 to 17 mg/kg at the level of the professional keeper (realistic worst-case scenario). The number of avoided cancer cases is expected to be limited in this scenario and is estimated at <2 avoided cases in a 10 year period. For illustrative purposes, this number of cancer cases was monetised by using a WTP-value for premature death of €5 550 000 (updated to 2016) resulting in health benefits of about **€11 million**.

The level of **societal concern** of the general public surrounding the (perceived) risk is used by the Dossier Submitter to qualitatively characterize the social impacts of the two restriction options compared to the baseline scenario. In this case the societal concern is mainly triggered by the potential health issues linked to sports activities on artificial pitches or use of playgrounds on which ELT performance infill or ELT mulch is applied. As high PAH concentrations are avoided, RO1 may also alleviate some of the societal concern (**social impacts**) surrounding the possible negative health impacts resulting from the use of infill material containing PAHs in artificial sports pitches.

The lower limit value of 6.5 mg/kg proposed under **RO2** is expected to mean end-of-market for ELT-derived infill. Hence the Dossier Submitter identifies a larger reduction of health risks (**human health impacts**) compared to RO1 resulting from less exposure to PAHs and also because it is expected that alternative infill materials contain less other hazardous chemicals. The number of avoided cancer cases for a risk reduction from 21 to 0 mg/kg, assuming the realistic worst-case scenario of the professional keeper, is estimated to be at <12 avoided cases in a 10 year period resulting in monetised health benefits of about **€67 million**.

Due to end-of-market of ELT infill further health benefits may arise connected to other health hazards of PAHs (skin sensitisation, mutagenicity). These potential benefits were only

mentioned, but not quantified. End-of-market of ELT-derived infill may also reduce environmental risks (**environmental impacts**) due to the reduction of PAHs and potentially other hazardous chemicals. The impacts of the shift to alternatives on levels of greenhouse gas (GHG) and microplastics emissions was analysed and quantified. The Dossier Submitter found that microplastics emissions may decrease as a result of replacing ELT infill by cork or replacement of the artificial pitch by a no infill system. GHG emissions may increase due to the shift from recycled rubber infill to alternative infill made from virgin material resulting in an additional societal cost of RO2 of about €80 million. Regarding societal concerns a reduction is expected which will be potentially larger in RO2 than in RO1 since it is expected that existing pitches using ELT-derived infill will be gradually replaced by alternative infill material (**social impacts**).

SEAC conclusion(s):

SEAC considers the number of cancer cases that could be avoided under RO1 and RO2 to represent an overestimation of the potential **health benefits**, which was also confirmed by the Dossier Submitter. The excess cancer risks used for this calculation are based on the exposure scenario of the professional keeper which is representative for only a small share of the potentially exposed population (realistic worst-case scenario). However, the population taken into account (46 million) for the calculation of the excess cancer cases covers all parts of the population coming into contact with artificial turf pitches (workers, registered and unregistered athletes, professional football players, children). This overestimates considerably the relevant population (e.g. professional and amateur football players frequently playing on turf pitches). SEAC finds it plausible that, as stated by the Dossier Submitter, large parts of the population will be faced with lower exposure levels, and therefore bear a lower excess cancer risk. Therefore, SEAC considers the calculated cancer cases and monetised health benefits to be merely illustrative of the potential health benefits of the restriction.

All REACH-8 PAHs are classified as Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410). In this respect it is plausible for SEAC that eliminating the use of ELT infill will cause an **environmental benefit** under RO2. However, it is also considered plausible that a shift to the alternatives EPDM and TPE (RO2) may engender an increase in GHG-emissions[47], but emissions of microplastics to the environment will likely decrease. Under RO1 this environmental benefit is lower since ELT infill use will continue, but PAH concentrations above 17 mg/kg are avoided. SEAC considers this a plausible assumption.

Benefits of a reduction in **societal concern** regarding turf pitches with ELT infill were qualitatively assessed based on the public debate taking place in the Netherlands and other European countries (e.g. France and Belgium). SEAC recognizes the societal concern linked to the health and environmental impacts of ELT infill, but cannot take it into account for the benefit assessment. It is not fully clear in which sense these concerns represent impacts in addition to the impacts already covered and taking them into account would cause double counting of impacts. Moreover, the representativeness of the Dutch concerns as applied to the EU population is unclear.

Key elements underpinning the SEAC conclusion(s):

SEAC agrees that the choice of geographical boundary (the EEA-31) and the temporal scope of the analysis (10 years, i.e. the lifetime of an artificial pitch) for the calculations is not fully

[47] Some uncertainties regarding the quantified amount have to be taken into account.

appropriate. Some underestimation of the restriction benefits will arise based on the chosen temporal scope.

Under RO1 the ELT-infill producers continuously have to sort out non-compliant ELT-infill. The lifetime of artificial pitches is, on average, 10 years and after that the ELT-infill has to be replaced. Consequently it will take about 10 years after entry into force of the restriction for the annual health and environmental benefits to reach maximum capacity. Benefits will remain at this maximum level for several years after that.

The same can be said for the development of the environmental and health benefits under RO2. For years 10 to 20 benefits are expected to be larger than for years 0 to 10. The Dossier Submitter considers that this will not have a significant impact on the benefit-cost ratio of RO1 and RO2, which SEAC considers plausible. SEAC however concludes that the temporal scope is not adequate for consistent comparison of restriction benefits and costs.

Types of health impacts included

The health impact assessment of the Dossier Submitter focuses on the carcinogenic effects of the REACH-8 PAHs. All REACH-8 PAHs are classified in Annex VI of CLP as carcinogen (Carc. Cat. 1B). BaP is also classified as a skin sensitizer (Skin Sens. 1 (H317)) and for its effects on reproduction (Repro. 1B). But, it was found uncertain whether BaP in ELT infill may cause effects for the skin. Since reprotoxic effects have a threshold, and genotoxic carcinogenic effects are considered non-threshold effects, carinogenicity is considered as the main health concern of the restriction proposal. This was considered plausible by RAC.

Estimated population at risk

Artificial turf with ELT infill[48] is used in sports such as football, rugby, Gaelic sports and lacrosse. The Dossier Submitter has estimated the number of players registered in EEA-31 for these sports to be about **20 million** (includes 71 049 professional football players). This number is based on personal communication received from the relevant sports organisations and federations and are considered plausible by SEAC. However, also unregistered sports players may come into contact with artificial turf pitches. Based on an estimate provided by UEFA about the share of the population playing football in the associated 55 UEFA countries (7.2%) it is estimated that there are about **38 million** registered and unregistered football players in EEA-31. Since the EEA-31 countries are also members of UEFA and cover a large share of the population of the associated UEFA countries this estimate seems plausible, but some uncertainties have to be recognized.

The Dossier Submitter considers the available information on the number of users of mini-pitches with ELT infill to be insufficient. As a best-informed guess it was assumed that half of the European synthetic turf mini-pitches use ELT infill which gives about **31 500** mini-pitches and that each mini-pitch has 252 frequent users between the ages of 0 and 14[49]. Assuming 252 frequent users per pitch and 31 500 mini-pitches, the population of frequent mini-pitch users in the EU was estimated to be **7.9 million children** which corresponds to almost 10 % of the EU population in this age cohort. It is considered uncertain by SEAC whether these user numbers are representative for the EU-28 as a whole and not just the Netherlands.

The Dossier Submitter makes clear that the number of sports players who come into frequent contact with artificial turf with ELT infill is smaller since a share of the players will always or

[48] In the restriction report a broader approach is chosen and contact of players to turf with all types of infill is discussed and not only ELT infill. It is however estimated that currently 90 % of the synthetic turf contains ELT infill (both for pitches and mini-pitches).
[49] Estimates based on the use of so-called Cruyff courts (size: 42x28 m = 1 176 m^2).

at least partly play on natural grass or on turf without infill. Thus the numbers put forth by the Dossier Submitter represent an overestimate of the exposed population. Given the paucity of information, the Dossier Submitter was not able to quantify the share of players not or seldom coming into contact with ELT infill. The Dossier Submitter does however consider these players as part of the EU-population who may therefore potentially derive health benefits from the restriction due to a decrease in PAH-exposure.

Estimated risk reduction potential

The Dossier Submitter considers the main benefit of restriction options RO1 and RO2 to be the avoidance of excessive exposure levels of PAHs in ELT granules and mulches. Given the concentration limits for the individual REACH-8 PAHs set in entry 28 of Annex XVII of REACH, a sum concentration limit of 387 mg/kg for mixtures is currently allowed for ELT-derived infill. In order to quantify the health benefits, the excess cancer risk of 21 mg/kg (P99) is used (reasonable worst-case) in the baseline and not the theoretical maximum of 387 mg/kg since this excessive level of PAHs was rarely observed in the analysed samples.

Inputting the P99 concentration level of 21 mg/kg as well as the limit values for RO1 (17 mg/kg) and RO2 (0 mg/kg since End-of-Market assumed) into the exposure scenarios specified by the Dossier Submitter, this may result in a risk reduction under RO1 ranging from 4.6×10^{-7} to 6.1×10^{-7} for the professional and amateur outfield football player and goalkeeper respectively, and from 2.5×10^{-6} to 3.1×10^{-6} under RO2. For the calculation of the risk reduction potential, it was assumed that all members of the population are exposed to the P99 concentration (21 mg/kg) or the P95 concentration (17 mg/kg). However, in the former case, 99 % of the population are actually exposed to concentrations below 21 mg/kg and in the latter case, 95 % are exposed to concentrations below 17 mg/kg.

SEAC recognizes the risk reduction under RO1 and RO2 for the highest-exposed population and that excessive exposure levels to PAHs (up to 387 mg/kg) are not taken into account for the quantification of the health benefits. The majority of the population will however be subjected to lower levels of excess cancer risks and the risk reduction will consequently be lower as well.

Estimated number of cancer cases avoided

Workers during installation and maintenance of pitches, professional and amateur athletes and children playing on playgrounds are considered as groups of the population which may frequently come into contact with ELT granules and mulches. However, since information on the share of these groups performing sports activities on pitches and playing on playgrounds with ELT infill and mulch is not available, the size of the population at risk was not quantified by the Dossier Submitter. Instead of estimating the population size at risk[50], the Dossier Submitter has utilised a so-called realistic worst-case approach to estimate the theoretical maximum health benefits of the proposed restriction. These health benefits are defined as follows:

Theoretical maximum reduction in health impact =

Population x Maximum risk reduction x

Share of pitches that still make use of ELT-containing infill

[50] Based on, for example, the ratio of artifical turf pitches to natural grass pitches.

It is clearly stated in the dossier that the derived numbers overestimate the health benefits of both RO1 and RO2 for the following reasons:

- Population: As a worst-case assumption for the population exposed, the estimated total number of registered and unregistered athletes, users of mini-pitches, and installation/maintenance workers was used (46 million). However, not all sport/play/work activities will take place on ELT infill containing pitches. In the exposure scenarios it is estimated that 100 % of the time spent on these activities, the different actors come into contact with artificial turf containing ELT-derived infill having a specific concentration of PAHs. For example, it is estimated that in Finland artifical football pitches have a share of about 75 % of all football pitches. This is considered as above average compared to other EU Member States. In addition, ELT infill is not applied on all artifical pitches.
- The Dossier Submitter has derived a dose-response relationship linking different exposure scenarios (parameters: body weight, frequency/duration of playing/doing sports, exposure routes, etc.) with excess cancer risk. Exposure scenarios were defined for maintenance and installation workers, football players (professional and amateur, outfield football players and goalkeepers) and children. In order to calculate the risk reduction for the professional goalkeeper, as well as the individual football player, the highest lifelong exposure (70 years) was assumed.
- Under RO1 the permissible PAH concentration in ELT infill is reduced from 387 mg/kg to 17 mg/kg, and under RO2 to 6.5 mg/kg (which effectively means a PAH concentration of zero since end-of-market for ELT infill is assumed under RO2). In reality only a small part of the population will be exposed to the highest permissible PAH concentration, and thus for the majority of the registered and unregistered football players the risk reduction is expected to be lower.
- The restriction addresses placing on the market of infill and mulch and thus affects only new installations, replacements and refill of pitches. The health effect will linearly increase over the years as more and more ELT pitches will be replaced over time, and will be at its maximum in year 10. Consequently, it will take about 10 years after entry into force of the restriction for the annual health benefits to reach maximum capacity. Health benefits will remain at this maximum level for several years after that. Therefore, for years 10 to 20 benefits are expected to be larger than for years 0 to 10, and thus some underestimation of the health benefits will arise due to this.

Monetised health benefits

The avoided cancer cases are monetised by the Dossier Submitter using the reference values for premature death due to cancer (SEAC/32/2016/05.2 Rev.1). SEAC considers the approach chosen as an overestimation since the higher reference value of the €5 550 000 (updated to 2016) is applied, and since it is assumed that all cancer cases will result in death. For illustrative purposes, the number of avoided cancer cases was monetised by using this WTP approach, resulting in health benefits of about €11 million under RO1 and €67 million under RO2.

Since latency between exposure and occurrence of cancer was not taken into account, some overestimation of the valuation has to be recognized. The most important factors of overestimation are the exposure scenario of the professional goalkeeper, the exposed population considered (46 million), the fact that a share of the athletes will always or at least partly do sports on natural grass or on turf without infill, and the assumption that all players

make use of ELT infill pitches having REACH-8 PAHs concentration of 21 mg/kg (17 mg/kg under RO1). If one assumes that a fraction of the registered football players (15 million) may face an exposure scenario which approaches the one of the professional goalkeeper, the monetised health benefits will be reduced by a factor of at least 3 resulting in (still overestimated) monetised health benefits of about €4 million. In addition, since only a small share of the registered players will play on pitches with REACH-8 PAHs concentration of 21 mg/kg, the fraction of highly exposed players will be even an order of magnitude lower.

Benefits for the environment

All REACH-8 PAHs are classified as Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410). Thus it is plausible for SEAC that eliminating the use of ELT infill will result in an environmental benefit under RO2 as well as RO1 (but to a smaller degree). It is also considered plausible that this benefit may be small under RO1 as ELT infill will continue to be used, since only a small share of ELT infill and mulches with PAH-concentrations above 17 mg/kg will be avoided.

The data provided by the Dossier Submitter shows that EPDM and TPE infill contain lower or no PAHs compared to ELT. Thus it is plausible that under RO2, which assumes end-of-market for ELT infill, environmental benefits due to the shift to alternatives (EPDM-/TPE-/cork-infill, natural grass) will arise. These additional environmental benefits were not quantified because of limited data. Also exposure to other chemicals hazardous to the environment, such as zinc and cobalt, will be reduced[51]. Since these chemicals are not in the scope of the restriction and the available data on exposure to the environment is limited, potential benefits due to a reduction of these chemicals are not further taken into account. Moreover, in case of a shift to artificial turf systems without ELT infill, the installed shockpad or elastic layer below the turf itself could be made of ELT granules. This may reduce or cancel out some of the environmental benefits.

In addition to the reduction of environmentally hazardous chemicals, under RO2 two further sources of environmental impacts of shifting to alternatives were analyzed by the Dossier Submitter:

- GHG emissions:

The shift to the alternative infill EPDM and TPE under RO2 will entail an increase in CO2-emissions (in tonne CO2 equivalents) compared to the baseline due to the use of virgin instead of recycled material. In the Dossier Submitter's assessment the additional tonnes of CO2-emissions are multiplied with the unit cost value per tonne[52], resulting in a **societal cost** of around **€80 million** in the first 10 years after the entry into force (discount rate: 4 %). The calculation is plausible according to SEAC, but the assessment mentions some uncertainties. Firstly, no information on CO2-emissions linked to the use of cork or other organic infill is available. The Dossier Submitter assumed that the GHG-emissions of cork and artifical turf systems without infill are equal to ELT infill. This assumption can result in an over- or underestimation of the change in CO2-emissions. The relative shares of pitches without infill and with cork infill are however relatively small compared to pitches with EPDM and TPE infill (EPDM and TPE sum up to about 25 % in year 10).

Additionally, the difference in terms of GHG emissions between different artifical turf systems (systems with ELT infill have carpets with longer pile length than systems with alternative infill, but systems with alternative infill have an additional shockpad installed below the

[51] Or at least comparable to ELT infill in case of zinc.
[52] Taken from the EU guide to cost-benefit analysis of investment projects (EC, 2014).

carpet) is not included in any study known to the Dossier Submitter. The dossier has assumed that the GHG impact of energy and material use for producing a shockpad is higher compared to the relative gain of producing shorter piles instead of higher piles. SEAC considers this to be plausible.

Under RO1 no change in the use of ELT infill and alternative infill (EPDM, TPE, cork) compared to the baseline is expected, and consequently no change in GHG emissions will arise. However, this can be considered uncertain. In the baseline some voluntary shift to alternative infill was already assumed e.g. due to public concerns linked to the health hazards of ELT-infill. Likewise, recyclers mentioned in the public consultation that the restriction may reduce the health and environmental hazards of ELT infill. Under RO1 negative views about the use of ELT infill in the public could therefore be partially removed. Due to this, savings in GHG emissions could arise which would represent an additional environmental benefit of RO1, but which cannot be quantified.

- Microplastics:

The use of synthetic infill material can result in environmental pollution by microplastics if the infill materials are lost from the pitches. It is plausible that this situation will improve compared to the baseline due to the use of cork infill or artificial turf systems without infill at all. The Dossier Submitter additionally notes that EPDM and TPE granules are used in lower quantities and are heavier and thus less infill should get lost from pitches and spread into the environment. It is estimated by the Dossier Submitter that over 10 years **30 000 tonnes less performance infill** is lost to the environment which SEAC considers as an additional environmental benefit of RO2.

Benefit due to reduction of societal concern

The level of **societal concern** of the general public regarding the (perceived) risk is used by the Dossier Submitter to qualitatively characterize the social impacts of the two restriction options compared to the baseline scenario. In this case the societal concern is mainly triggered by the potential health issues linked to sports activities on artificial pitches or the use of playgrounds on which ELT performance infill or ELT mulch is applied. In the Netherlands and other European countries (e.g. France and Belgium) these health concerns have triggered public debate and some municipalities have responded to these concerns by shifting to alternative artificial turf systems. These reactions and the observed drop in ELT infill in the Netherlands give some creedence to the relevance of the societal concern. However, a quantification of this concern could not be provided. Moreover, it is not fully clear in which sense these concerns represent impacts in addition to the impacts already covered. Thus, taking these into account would cause double counting of impacts. The representativeness of the Dutch concerns as applied to the EU population is also unclear. SEAC recognizes the societal concern linked to the health and environmental impacts of ELT-infill, but cannot take it into account for the benefit assessment.

Overall proportionality

Summary of proposal:

The Dossier Submitter concludes for a limit value of 17 mg/kg that **RO1 is proportional**. The costs of this restriction option are expected to be limited and affordable for the actors at stake. At the same time, (very) high PAH concentrations and consequent risk levels are avoided for the population that comes into contact with granules or mulches in sport and play applications. In addition, societal concern related to human health effects may be reduced due to avoidance of high PAH concentrations.

RO2 is expected to be more effective than RO1 in terms of risk reduction, as it is expected that ELT-derived infill will no longer be marketed at a 6.5 mg/kg limit value and the alternatives are assumed to contain no or very low levels of PAHs. Moreover, concerns raised in the media related to human health effects will be reduced over time as high PAH concentrations are avoided. The costs to society of RO2, on the other hand, are expected to be substantial. Hence, the Dossier Submitter concludes that **RO2 is not proportional**, however it may be affordable to some actors in society.

RAC and SEAC conclusion(s):

The main benefit of this restriction (RO1) is that it ensures that the very high PAH concentrations currently permissible (up to 387 mg/kg) are avoided. This effect will arise under the limit value proposed by the Dossier Submitter (17 mg/kg) and under the limit value of 20 mg/kg as proposed by RAC.

The Dossier Submitter quantified only the health benefits. Benefits for the environment will also arise, but could not be quantified. The Dossier Submitter has quantified the restriction costs for recyclers by using the revenue loss associated with selling ELT granules on alternative markets at a lower price. SEAC considered these costs to overestimate the societal costs. Responses received during the public consultation provided an indication that the restriction costs under the limit value of 20 mg/kg could be lower compared to the values provided in the restriction report since the fraction of non-compliant ELT-granules (about 5 %) would be lower as was assumed by the Dossier Submitter. Given the benefits as described before and the fact that SEAC finds it plausible that the restriction costs would approach zero for a limit value of 20 mg/kg, the restriction is considered proportional for a limit value of 20 mg/kg as proposed by RAC.

In addition, SEAC notes the preventive nature of this restriction since excessive values of REACH-8 PAHs concentrations will be avoided.

Regarding RO2, SEAC recognizes that significant restriction costs would arise, and concludes that this restriction option cannot be considered proportional, although the preventive nature of this restriction option also has to be taken into account.

The Dossier Submitter has provided information on the affordability of the restriction for the different actors to support considerations on proportionality.

In order to gain additional insights regarding the consequences of the restriction, SEAC considered the affordability of the restriction for relevant subpopulations of the EU-population and companies.

SEAC considers RO1 as affordable for the actors who may have to bear at least part of the restriction costs[53]: Over their lifetime subpopulations of individuals in the EU most likely come into contact with ELT infill (with ELT mulch on children's playgrounds, with ELT infill as a teenager and as an adult when doing sports on artificial turf pitches as an amateur or professional). Nearly every individual of these subgroups may benefit from the avoidance of excessive exposure to PAHs in ELT infill at some point in time. Moreover, SEAC considers plausible that the restriction is economically bearable for the producers of ELT infill.

RO2 is not considered affordable for most actors since, as an example, the cost per pitch may increase by about 30 %. Therefore, it can be expected that fewer artificial turf pitches will be installed and not all producers of ELT infill will be able to stay in business.

Key elements underpinning the RAC and SEAC conclusion(s):

Comparison of the monetised reduction in cancer cases (€11 million) with the total restriction cost (€30 to €55 million) under RO1 shows that costs exceed the monetised health benefits. The same holds true for RO2 (€3 100 million > €67 million). However, SEAC considers the restriction costs overestimated. Furthermore, responses received from stakeholders during the public consultation indicate that the avoidance of excessive REACH-8 PAHs concentrations will reduce business risk for the ELT infill market, as well as possibly increase sales and revenues of ELT infill. This could offset potential costs of RO1 for the ELT recycling sector even further.

It was already demonstrated that the calculation of the risk reduction, and the corresponding number of avoided cancer cases, under RO1 and RO2 may overestimate the health impacts. The Dossier Submitter therefore considers it a theoretical maximum in order to illustrate possible health impacts which may arise under some worst-case conditions like doing sports over the lifetime on artificial pitches with ELT-infill. Thus, the monetised health benefits are overestimated. However, some further health benefits may arise due to the avoidance of other hazardous substances in ELT granules and mulches (avoided skin sensitisation and reproduction toxicity effects), as well as benefits for the environment due to the avoidance of REACH-8 PAH exposure[54]. These benefits could not be quantified and monetised. Moreover, the restriction may reduce public concerns about the hazards linked to the use of ELT infill, and reduce the voluntary shift to alternative infill already taking place in the baseline. Thus, additional GHG emissions connected to the shift to virgin infill materials (EPDM, TPE) and alternative artificial turf systems, will be avoided.

Taking into account the overestimated restriction costs and monetised health benefits, as well as the non-quantified benefits, SEAC cannot conclude on the proportionality of this restriction for a limit value of 17 mg/kg by comparing the quantified restriction costs with the monetised benefits.

In light of the limit value of 20 mg/kg proposed by RAC, the avoided monetised cancer cases would slightly decrease, but excessive REACH-8 PAHs up to 387 mg/kg concentrations would still be avoided. Furthermore, the quantified restriction costs would consequently be reduced from €30-55 million to about €10-15 million[55]. Taking into account that revenue losses overestimate the societal loss of RO1, the actual societal costs are even lower. Therefore, since SEAC finds it plausible that the restriction costs would approach zero for a limit value of

[53] E.g. since the cost per pitch may increase by less than 1 %, and costs per registered and unregistered athletes about €0.90 – 1.45 over 10 years, this will likely not have significant impacts of affordability for these actors.
[54] Due to the Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) classification of the REACH-8 PAHs.
[55] Revenue losses would be reduced by a factor of 5 from €25-50 million to €5-10 million. Adding the testing costs of €5 million this sums up to €10-15 million.

20 mg/kg, the restriction is considered proportional for a limit value of 20 mg/kg as proposed by RAC.

The Dossier Submitter has based its conclusion on proportionality on the affordability of the restriction for the actors in society having to bear the costs. SEAC cannot conclude on proportionality based on affordability considerations. Furthermore, SEAC wishes to emphasize that affordability in and of itself is not a useful criterion for impact assessment of regulations.

SEAC agrees that in order to gain further insights into the consequences of the restriction, additional impact assessment criteria should be considered to support the policy-making process. SEAC considered the impacts of the restriction in terms of 'affordability' for the actors having to bear the costs. However, it should be underlined that an affordable measure is not necessarily economically feasible, and affordability does not imply a measure is (net) beneficial for society.

- RO1:

Seven indicators for the assessment of affordability were provided for RO1 and RO2 to characterize the ability of different actors to bear the costs. Since the distribution of the restriction costs between the different actors is uncertain, affordability was evaluated for different economic actors who will at least partly have to bear the restriction costs: owners of pitches and mini-pitches (municipalities, sports organisations), registered and unregistered athletes. See Table 13 for an overview of costs per input unit over 10 years:

Table 13: Cost indicators for RO1

	Societal costs over 10 years	**Unit of input**	**Societal costs per unit of input**
Costs per cancer case avoided	*€30-55 million*	*<2 cancer cases avoided (theoretical maximum)*	*>€15-25 million per cancer case avoided*
Costs per full size pitch (2028)	*€20-45 million*[56]	*34 000 pitches*	*€1 000-1 300 per full size pitch (football)*
Costs per registered football player	*€20-45 million*	*15 million football player*	*€2.30-3.60 per registered football player*
Costs per registered and unregistered football player	*€20-45 million*	*38 million football player*	*€0.90-1.50 per registered and unregistered football player*

The additional costs for pitches will increase by less than 1 % (€1 300 of €223 000). This cost increase will very likely not have a negative impact on the artificial turf pitch owner on whether to install a pitch using ELT infill material or not. The additional cost per registered football player ranges from €2.25 to €3.59 and per registered and unregistered football player from €0.90 to €1.50 over 10 years, which can be considered small and thus bearable. Of course, since the input units for athletes are overestimated as not all sport activities will take place on artificial turf pitches using ELT infill, the cost indicators are underestimated and thus affordability of the restriction for these actors is overestimated (without however changing the order of magnitude of the indicators). As such, SEAC considers that the restriction is unlikely to present serious affordability concerns for the relevant subpopulations of EU citizens (professional and amateur athletes) and owners of pitches.

[56] For calculation of this indicator only the restriction costs for the full size pitches were taken into account.

For the calculation of the revenue losses a limit value of 17 mg/kg was assumed which means that about 5 % of the ELT infill on the market will not be compliant. However, RAC has already agreed to propose a limit value of 20 mg/kg. Thus, the share of non-compliant ELT infill will be reduced from 5 % to about 1-2 %. This will reduce the revenue losses by a factor of about 5 (for a share of non-compliant infill of 1 %).

- RO2:

See Table 14 for an overview of costs per input unit over 10 years:

Table 14: Cost indicators for RO2

	Societal costs over 10 years	**Unit of input/ impact**	**Societal costs per unit**
Cost per cancer case avoided	*€3 100 million*	*<12 cancer cases avoided (theoretical maximum)*	*>€270 million per cancer case avoided (theoretical maximum)*
Costs per full size pitch (2028)	*€2 500 million*[57]	*34 000 pitches*	*€73 000 per full size pitch (football)*
Costs per registered football player	*€2 500 million*	*15 million football player*	*€160 per registered football player*
Costs per registered and unregistered football player	*€2 500 million*	*38 million football player*	*€70 per registered and unregistered football player*

Since the input units for athletes are overestimated and not all sport activities will take place on artificial turf pitches using ELT infill, the cost indicators are underestimated and thus affordability of the restriction for these actors is overestimated. In contrast to RO1, the overestimation of the number of athletes doing sports activities on artificial turf pitches with ELT infill may change the order of magnitude of the indicators.

The additional costs for pitches will increase by about 33 % (€73 000 of €223 000). This cost increase may make installation of turf pitches unaffordable for some municipalities and sports organisations due to limited financial investment budgets. Therefore, SEAC considers it likely that RO2 will present affordability concerns for the owners of pitches. In addition, it cannot be excluded that also relevant subpopulations of EU citizens (including athletes) may have affordability concerns.

Uncertainties in the proportionality section

The uncertainties identified for restriction costs and benefits described in the corresponding sections of the opinion also apply here. In addition, the histogram of REACH-8 PAHs concentrations (Figure 5) is mainly based on samples taken from the Netherlands. Due to differences in scrap tyre selection, granule manufacturing processes, and variability in the sampling strategies across the EU, uncertainties about the geographical representativeness of the samples arise. Moreover, the samples were taken from 2010 onwards, which causes uncertainties about the representativeness of the samples for the current situation. Consequently there are uncertainties on the conclusion regarding the concentration level that most producers will be able to comply with and thus also on the compliance costs. However, these uncertainties are considered moderate, and do not have a significant influence on SEAC's conclusions on proportionality of RO1 and RO2.

[57] For calculation of this indicator only the restriction costs for the full size pitches were taken into account.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The proposed restriction was considered by the Dossier Submitter to be practical because it is implementable, manageable and enforceable.

The restriction ascertains that with respect to risks associated to the use of granules and mulches in synthetic sports fields and playgrounds; PAH contamination is controlled.

A sum concentration limit for REACH-8 PAHs in mixtures placed on the market and used for the applications in the scope of the restriction was considered by the Dossier Submitter to be readily implemented and managed by stakeholders involved. PAHs controls are already common practice for ELT derived granules formulators.

The sum concentration limit for REACH-8 PAHs in principle is clear and therefore the proposed restriction is expected to be enforceable by national enforcement bodies across the EU. However, the Dossier Submitter noted that some factors may negatively impact EU-wide enforceability of the proposed measure:

- the possible differences between Member States in the interpretation of the product or waste status of ELT derived granules or mulches marketed for uses in the scope of the restriction
- a proper understanding across stakeholders in the EU of the terminology used (e.g. performance infill, mulches, loose form, sport applications etc.)
- current absence of EU harmonised methodology for PAH extraction and analyses from rubber and other matrices.

Currently limited information is available on the extent to which these factors may be of influence and how these will develop in the future.

RAC and SEAC conclusion(s):

Taking into account, among other elements, information in the Background Document, the public consultation and the advice given by Forum, SEAC is of the view that the proposed restriction options are practical and enforceable. RAC agrees that the proposed restriction is practical and enforceable if there is harmonisation of the status of ELT as a non-waste across the EU. However, in the absence of such confirmation RAC does not agree that the restriction is enforceable or effective.

Targeting the placing on the market and use of substances/mixtures by setting a concentration limit is a well-known approach for restrictions and is easily understandable for all parties affected.

We agree however with the Dossier Submitter that certain factors such as the waste-status, terminology and testing methodology may impact enforceability. SEAC notes that, even though limited information is available, the Dossier Submitter might underestimate the negative impacts these issues will have on the effectiveness of the proposed restriction, especially regarding the End-of-Waste status.

RAC agrees compliance checking at the point of sale will not always be possible if rubber granules are not marketed for use as infill for synthetic turf pitches, playgrounds or other sport applications. As rubber infill to be bound *in situ* is outside the scope of the proposal RAC

agrees there may be difficulties for enforcement authorities with respect to granules or mulch placed on the market for use as infill material to be bound *in situ*. Therefore, RAC recommends that the restriction conditions require a label for this use.

There will also be difficulties verifying test certificates. Infill material is generally sold in bulk form, in order for the analytical certificates to be verifiable, bulk infill material would need to be traceable to a the batch that was tested.

RAC supports the Forum's recommendation that harmonised methods should be developed for: (1) sampling, (2) sample preparation and (3) analysis of PAHs in rubber granules and mulches. However, until these are developed, the existing methods identified in the dossier can be used.

RAC recommends definitions are included in the legal text for terminology used to provide clarity to the scope of the restriction. Definitions should be included for granules, mulch, sport applications and loose form.

RAC agrees that a migration based limit would not be appropriate. Apart from the uncertainty surrounding the available of test methods for migratory exposure a migration based limit may not account for potential exposure from coated rubber material that may occur following the breakup or weathering of coated granules and mulches during use.

Key elements underpinning the RAC and SEAC conclusion(s):

Targeting the placing on the market and use of substances/mixtures by setting a concentration limit is a well-known approach for restrictions and is easily understandable for all parties affected. As such, SEAC agrees with the Dossier Submitter that the proposed restriction is implementable and manageable.

The Forum raised concerns about the enforceability of the restriction's scope and wording. The scope of the restriction is limited to placing on the market for use as infill for synthetic turf pitches, playgrounds or other sport applications. If rubber granules and mulch "is not marketed" i.e. placed on the market at the point of sale as a material for use as infill for synthetic turf pitches, playgrounds or other sport applications it will fall out of scope and the restriction will not apply. If this product is subsequently "used" as infill this will constitute a "misuse". Since use is not restricted (only the placing on the market for use) then misuse will not be covered by the restriction. The current scope does not cover granules or mulch when used bound *in situ*. The current restriction on placing on the market will not apply to rubber granules and mulch placed on the market for use in playgrounds or other sport applications if bound in a matrix *in situ*. The Forum considered that legal text should be revised to provide for placing on the market for use and any subsequent use of the material, along with provisions for the labelling of test batches for test certification verification.

The Dossier Submitter touches upon many issues that are of importance to the enforceability of the proposed restriction. These are analysed below.

<u>Product waste interface</u>

End-of-Waste criteria specify when certain waste ceases to be waste and obtains a status of a product (or a secondary raw material). In the context of this restriction this is an important issue since waste is not covered by REACH and granules remaining waste would not be affected by the proposal.

Since most non-ELT granules are said to be virgin materials the product waste interface will mostly, but not exclusively, be an issue for ELT-derived materials. Forum has also underlined the issues surrounding EoW-status. The Dossier Submitter indicates they do not have access to EU-wide information on the End-of-Waste status of ELT-derived granules and mulches.

Only the specific End-of-Waste status in the Netherlands is briefly discussed.

Whereas in the Netherlands a formal End-of-Waste decision is available for use of ELT-derived granules as infill in synthetic turf pitches, the situation is less clear in other EU countries. During the consultation seven Member States provided some information on the waste status of ELT and ELT-derived granules. If the material is considered waste then the restriction will not apply.

Table 15: Information on End of Waste Status in seven Member States

Country	**Status of ELT-derived granules**	**Remarks**
The Netherlands	National End-of-Waste decision	For use as infill, in place since 2005
Finland	No End-of-Waste criteria	ELT granules are waste but imported SBR is product. Case-by-case assessment through environmental permitting
United Kingdom	End-of-Waste criteria set for various ELT materials	Criteria notified to European Commission. PAH content is not (yet) part of the criteria.
Ireland	No End-of-Waste criteria	ELT granules are waste
France	No End-of-Waste criteria	Uncertainty in the implementation of End-of-Waste criteria flagged
Sweden	No End-of-Waste criteria	Some manufacturers classify as waste. Use on pitches is regarded a recovery operation (construction), no waste disposal. Environmental permiting scheme applied
Norway	No End-of-Waste criteria	ELT ceases to be waste when processed into granules. However, mechanical processing is no recovery operation

In response to queries by SEAC, the Dossier Submitter has informed SEAC that companies marketing ELT infill material consider it a product and not waste. Furthermore, the Dossier Submitter finds it prudent to assume implicitly the EoW status when ELT derived granules are placed on the EU market. Since the WFD provides discretionary freedom to Member States when there are no EU EoW-criteria[58] and considering the paucity of information regarding EoW status in other Member States (aside from the ones previously mentioned), SEAC does not believe this assumption to be entirely appropriate. When it is not clear how Member States will treat rubber granules derived from ELT (waste or not) then it is also unclear if these infill materials will fall under the scope of the proposed restriction. In other words, more concrete information from the Member States is needed to assess the validity of the Dossier Submitter's assumption of implicit EoW-status.

Based on the above discussion it seems clear to SEAC that uncertainty regarding the waste status will hamper enforcement and might even be one of the main problems affecting the effectiveness of the proposed restriction.

Terminology

SEAC mostly agrees with the Dossier Submitter that the way the restriction proposal is worded, seems to provide a clear legal basis for companies and enforcement authorities that is also consistent with REACH Annex XVII entry 50[59]. However, SEAC notes that the scope uses specific **terminology** (e.g. pitches, playgrounds, sport applications, infill material, loose form, granules, mulch). The Forum requested that these terms should be properly defined for ease of enforcement. Companies needing to comply with the restriction would of course also

[58] Article 6 §4 of the WFD

[59] It is outside of the remit of SEAC to provide legal judgements, but the proposed restriction wording seems consistent with analogous restrictions in the past.

benefit from this added clarity. The Dossier Submitter has subsequently provided definitions for several of the specific terms used in the restriction wording.

RAC supports the Forum advice to provide definitions for the type of products that come within the scope of the proposal i.e. granules, mulch, infill material, sport application as these will support ensure compliance. While REACH already has definitions for "placing on the market" and "use" it is recognised that the scope of "for use as infill" may cause difficulties for compliance checking at the point of sale if the granules or mulch is not marketed as infill material within the scope of the restriction. In such cases it may only be possible to undertake compliance activities at a site during its actual application.

Mixture definition

According to the Dossier Submitter this issue warranted some discussion since some granule formulators expressed the opinion that some granules should be regarded as articles instead of mixtures. SEAC notes that in 2016 the European Commission agreed with the majority of the Member States on the legal status of rubber granules. During the preparatory phase of the restriction proposal ECHA experts, at the request of the Dossier Submitter, also confirmed that mulches should be regarded as a mixture. The Forum has indicated that when defining "granules", "mulches" and "material" (see section terminology), this terminology needs to be defined as a mixture.

The Dossier Submitter used the above-mentioned EU legal interpretation as the starting point for the proposed restriction and therefore also considers non-ELT granules as mixtures, but recognises that diverging interpretations may play a role at the national enforcement level[60]. It is therefore possible that in some Member States performance infill suppliers will need to comply with REACH Annex XVII entry 50, paragraph 5. According to SEAC this does not change the enforceability of the proposed restriction, but does raise issues concerning a Union-wide level playing field.

Coloured and coated granules

The Dossier Submitter notes that in some cases colouring and coating of granules and mulches (both ELT and non-ELT) can introduce challenges for enforcement. Alternatives such as virgin EPDM and TPE may be coloured in the production phase and even ELT derived granules can in some cases be coated which makes them likely to be mistaken for alternative granules.

Although these challenges exist the Dossier Submitter does not expect them to hamper chemical confirmation of the composition and PAH content. Forum, however, does note that a specific approach may be needed for the different types of granules.

Analytical methods (sampling, extraction and analysis)

According to the Forum, the restriction is enforceable if further development of harmonised methods for sampling and chemical analysis is undertaken. The Forum has advised RAC that there is currently no EU standard available for the extraction and chemical analysis of PAHs contained in a rubber matrix, but that there are methods that can be used. The AfPS GS 2014:01 PAH (i.e. ZEK 01.4-8) method is presented as the most rigorous and suitable method for extracting and analysing PAHs contained in rubber material. The Forum on enforcement have confirmed that while sampling, sample preparation and analysis methods are available for PAHs these methods should be harmonised.

How to establish a representative sample will be an important consideration in developing a harmonised sampling procedure. The lack of harmonised sampling, sample preparation and analysis methods were also raised by numerous respondents in the public consultation as an

[60] For both ELT and non-ELT granules.

issue in determining compliance. By way of example, it is currently not clear how many samples are required to form a representative sample of a 1 tonne bag of infill noting that a 1 tonne bag of infill contains approximately 12 million granules and the test sample (0.5 g) equates to approximately six granules.

RAC and Forum recommend the relevant EU standardisation organisations include the sampling and sample preparation in the development of a standard protocol for the quantitative analysis of the 8 PAHs in the rubber materials under the restriction proposal, to facilitate a harmonised enforcement of such restriction.

During the public consultation the need for an EU harmonised standard for measuring PAH content was also underlined[61]. While SEAC/RAC also wishes to stress the importance of such harmonised methods, the Committee notes that in the past restrictions have been found to be enforceable even if no harmonised analytical methodology existed at the time of adoption.

The Dossier Submitter concluded that currently, the AfPS GS 2014:01 PAH method seems to be the most rigorous and suitable standardized method for extracting and analysing PAHs contained in rubber material. Most samples which were used to determine the REACH-8 PAH concentration were analysed using this method because of this judgement.

Due to the physicochemical nature of the recycled material[62] sampling and extraction are of critical importance to get reliable and representative test results[63] according to both the Committees and Forum. To date appropriate sampling strategies do not exist and the extraction procedure for the preferred analytical method for rubber granules (AfPS GS 2014:01 PAH) was challenged by stakeholders (both private[64] and public) in the public consultation[65]. A compounding factor is that the term "granules" can encompass a wide variety of materials (recycled or virgin, synthetic or natural) and different analytical methods may therefore be necessary.

According to the Dossier Submitter the European Commission is currently reviewing the need for standardising analytical methods for measuring PAHs in rubber and plastic articles. In light of Forum's concerns this might also be needed for rubber and plastic granules.

In the 2018 JRC report on PAH analysis of rubber and PVC materials, a method for total content and a method for migration of PAHs are mentioned. Basing the limit on migratory exposure is not considered appropriate as rubber infill will undergoes further breakup and weathering during its use. RAC notes the large variation in the PAH content between different forms of ELT's as well as variations between coated and uncoated ELT. The public consultation has provided additional information on the PAH content which ranged from 2.77 up to 53.4 mg/kg for non-coated. As exposure occur via all route it is important that the total content of PAH exposure is taken into account. The method for total content is not standardised but could be considered in the development of a standard method for measuring PAHs in rubber materials under this restriction.

Concentration limits

As was stated previously, the AfPS GS 2014:01 PAH method was preferred by the Dossier Submitter for the analysis of the rubber granule samples. Since the limit of quantification of this method is 0.2 mg/kg, SEAC as well as Forum agree with the Dossier Submitter that the

[61] Comment number 1939 (ETRMA) and other actors who have submitted the ETRMA position paper.
[62] Solid mixture that can be considered as heterogeneous since the raw materials (i.e. tyres) used to produce it are also inhomogeneous (different types of tyres having different compositions and components).
[63] This is less of an issue with virgin infill material because of the production processes involved.
[64] Comment number 1939 (ETRMA) and other actors who have submitted the ETRMA position paper.
[65] Based on the choice of extraction solvent, discrepancies between results exist.

concentration limits under RO1 (17 mg/kg) and RO2 (6.5mg/kg) are enforceable.

Transitional period

The choice of the transitional period has already been discussed elsewhere[66], but from an enforcement standpoint SEAC notes that the Dossier Submitter and Forum indicate that a one-year transitional period will not provide any specific challenges. The Dossier Submitter did however mention that the time needed to establish an EU harmonised analytical methodology might hamper enforcement.

[66] See the section "Justification whether the suggested restriction is the most appropriate EU wide measure – Scope including derogations".

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The restriction was considered by the Dossier Submitter monitorable through regular enforcement by national enforcement bodies. Reporting can be done on the level of compliance. Information on non-compliance may be made available through RAPEX notifications. Measurements carried out by independent test institutes, media, or green and consumer groups may supplement the monitoring information obtained at national level. Information on market trends as regards the use of ELT derived granules and mulches and alternative materials may provide valuable additional information on the effectiveness of the restriction.

RAC and SEAC conclusion(s):

Based on the information in the Background Document and the Forum advice on this aspect SEAC concludes that the proposed restriction option for PAHs in granules and mulches is monitorable.

While RAC notes it is possible to monitor the PAH content in infill it has concerns in respect to the monitorability of the restriction. It will be difficult to monitor the effectiveness of the restriction in respect of ELT granules and mulches marketed for uses outside the scope of the restriction which are subsequently used within the scope of the restriction.

RAC agrees for infill placed on the market for uses within the scope of the restriction (EoW), the results of any non–compliance can be shared and monitored by Member States and COM via RAPEX.

Key elements underpinning the RAC and SEAC conclusion(s):

Targeting the placing on the market and use of substances/mixtures by setting a concentration limit is a well-known approach for restrictions and is easily understandable for all parties affected. As such SEAC agrees with the Dossier Submitter that the proposed restriction is monitorable, for example through the usual enforcement approaches (i.e. determining the percentage of non-compliant granules and mulches).

The Forum on enforcement have confirmed to RAC that sampling, sample preparation and analysis methods are available for PAHs while acknowledging the importance of harmonising these methods.

It is recognised that different forms of ELT have variations in PAH content. As infill is generally sold in bulk form (1 tonne bags) without batch, EAN[67] numbers, barcodes etc. it will be difficult to make a clear connection with such bulk sales to analytical certificates. RAC notes information from Cyprus during a recent campaign where it the enforcement authority analysis conflicted with the company certification of analysis.

RAC notes it will not be possible to monitor the impact of the restriction in respect of granules and mulches not marketed as infill within the scope of the restriction but subsequently used as infill within the scope of the restriction. In such cases it may be only be possible to undertake compliance activities at the site of use/application if the current draft wording covers use.

[67] European Article Number

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

This risk characterisation includes a number of assumptions and uncertainties.

Hazard

The most important uncertainties on the hazard side of the risk assessment are the fact that PAH 'mixture' composition in toxicological or epidemiological studies that were used are different between studies and differ from typical PAH composition in ELT granules. However, this is an uncertainty common to most exposure investigations related to PAH. Therefore, due to the different PAH content and potency in the mixtures, the use of the derived $BMDL_{10}$ value based on a study with coal tar is inherently inaccurate to assess the risk of PAH mixtures in rubber granules for oral and dermal exposure. The same uncertainty also applies for the inhalative exposure. Additionally, the information on exposure to BaP from coal tar pitch may include exposure to BaP vapours due to elevated temperatures in the processes. The BaP exposure from rubber granules is most likely to BaP contained in rubber dust. Furthermore, other PAHs not included in the group of REACH-8 PAHs may be genotoxic carcinogens as well which could point towards possible underestimation of risks. Differences in route-specific absorption have been considered but differences in metabolism have not been taken into account. A standard linear extrapolation method was applied to assess the risks of PAHs in rubber granules and no additional factor for intraspecies differences as a consequence of 'early-life exposure' was applied.

Exposure

On the exposure side some crucial assumptions on contacted amounts, frequency, and duration were made, e.g. on the oral ingestion by players aiming for a reasonable worst-case lifelong exposure estimate.

Taken together, these uncertainties on hazard and exposure point to an overestimation of the risks, which is mainly driven by the conservatism in the assumption that people play 100% of their playing and playing sports time on artificial turf with ELT-derived infill for the majority of their life.

RAC conclusion(s):

RAC agree that overall the uncertainties surrounding the exposure assessment will likely lead to an overestimation of the risks. However, PAHs are genotoxic and carcinogenic compounds with a non-threshold mode of action and therefore a conservative approach is justified.

Key elements underpinning the RAC conclusion(s):

Hazard

PAH 'mixture' composition in studies that were used differ from typical PAH composition in ELT granules. This is an inherent problem that cannot be solved if complex mixtures of substances are evaluated. The approach used for this restriction is pragmatic and conservative with respect to the composition of the mixture.

Exposure

The exposure assumption that 100% of play and playing sports occurs on artificial turf containing ELT-derived infill for the majority of their life is considered to be very conservative.

Not all pitches and play areas are artificial.

Limited information on worker exposure is available so it is not clear what percentage of a person's overall exposure to PAHs comes from rubber infill/mulches. RAC agrees the major source of PAH exposure to the general population (non-smokers) comes from food and inhaled air rather than exposure to PAHs coming from rubber crumb. RAC also agrees that it is not plausible that a child or adult would only ever play during their entire life on rubber infill material.

The exposure assessments were based on the assumption that no RMMs were used. This is unlikely to be true in all scenarios.

The exposure for children on playgrounds is based on unbound rubber granules, whereas rubber mulch, flakes and granules bound in a resin are used which are less likely due to their shape and size to be ingested and dust formation is expected to be lower.

SEAC

Summary of proposal:

The Dossier Submitter identifies a number of uncertainties for both RO1 and RO2:

- **Costs of RO1** may be lower if early replacement of existing pitches by the owners of the pitches (municipalities, sport clubs) would occur before end of life cycle as a result of public concerns regarding ELT infill. As such, the number of turf pitches using ELT infill in the baseline is overestimated. In addition, SEAC considers the revenue loss not to be an adequate measurement of the societal costs of the restriction. Costs could be lower if less action needs to be taken to comply with the 17 mg/kg limit. Testing costs could be lower if testing for PAHs already happens in the baseline situation by the majority of tyre recyclers. Testing costs could also be higher if testing is more expensive than estimated.
- **Benefits of RO1** might be overstated due to the exposure assessment's reliance on worst-case assumptions. Benefits might also be understated if high PAH concentrations occur more often than suggested by the available measurement data. Benefits are also understated since environmental benefits of avoidance of high PAH concentrations could not be quantified, but may also be overestimated in case additional GHG-emission costs due to incineration of ELT-waste arise. The restriction may also increase the trust in the quality of ELT granules and thus increase the recycling rate.
- **Costs of RO2** may be substantially lower if quantities of ELT infill are overestimated or if existing pitches face early replacement as a result of public concern regarding ELT infill. Costs may also be lower than estimated if alternatives become cheaper at increased demand or if the price difference between synthetic turf with ELT infill and alternative synthetic turf systems decreases significantly if costs are to be made to clean up environmental pollution if ELT-derived infill is used. In addition, SEAC considers the revenue loss not to be an adequate measurement of the societal costs of the restriction.
- **Benefits of RO2** are mainly uncertain with respect to the potential health and environmental benefits associated with the assumed reduction in exposure to other (non-PAH) hazardous chemicals. The size of these other potential benefits is unknown, and could not be quantified. Environmental benefits may also be overestimated in case additional GHG-emission costs arise due to incineration of ELT-waste.

The Dossier Submitter concludes that these uncertainties may affect the estimated costs and benefits but that the overall conclusions on proportionality are not expected to change.

SEAC conclusion(s):

Please see relevant sections on costs, benefits and proportionality for justification.

Key elements underpinning the SEAC conclusion(s):

Please see relevant sections on costs, benefits and proportionality for justification.