

Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Opinion
on an Annex XV dossier proposing restrictions on
Polycyclic-aromatic hydrocarbons (PAH)

ECHA/RAC/RES-O-0000001412-86-279/F
ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Adopted

7 June 2019

7 June 2019

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

14 June 2019

[SEAC opinion number[reference code to be added after the adoption of the SEAC opinion]]

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 of 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 (PAH)**EC No.:** -**CAS No.:** -

This document presents the opinion adopted by RAC 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/termo> 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 **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**].

[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.] [No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and] 71(1)].

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

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[To be added by the ECHA Secretariat when compiling RAC's and SEAC's opinion]

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Polycyclic-aromatic hydrocarbons (PAH) (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.
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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 (PAH)** 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 (PAH) (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) Chrysene (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) Dibenz[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 <ul style="list-style-type: none"> 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.
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THE OPINION OF SEAC

See SEAC 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 2.9×10^{-5} for workers and 2.8×10^{-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 granules³ 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/m ³ -years ⁴ is 0.00014 for workers (1.4×10^{-4}). The excess lung cancer risk per µg/m ³ -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 ($n= 48/\text{group}$) 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 ($n=48/\text{group}$) 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/m³ -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/m³ -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 ($\mu\text{g}/\text{kg bw/day}$)	Inhalation exposure estimate ($\mu\text{g}/\text{m}^3\text{-year BaP}$)
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 ($\mu\text{g}/\text{kg bw/d}$)	Dermal exposure estimate ($\mu\text{g}/\text{kg bw/d}$)	Inhalation exposure estimate ($\mu\text{g}/\text{m}^3\text{-year BaP}$)
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 ($\mu\text{g}/\text{kg bw/d}$)	Dermal exposure estimate ($\mu\text{g}/\text{kg bw/d}$)	Inhalation exposure estimate ($\mu\text{g BaP}/\text{m}^3\text{-year}$)
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 following 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 uncertainty 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 buffings⁵ 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/m². 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.

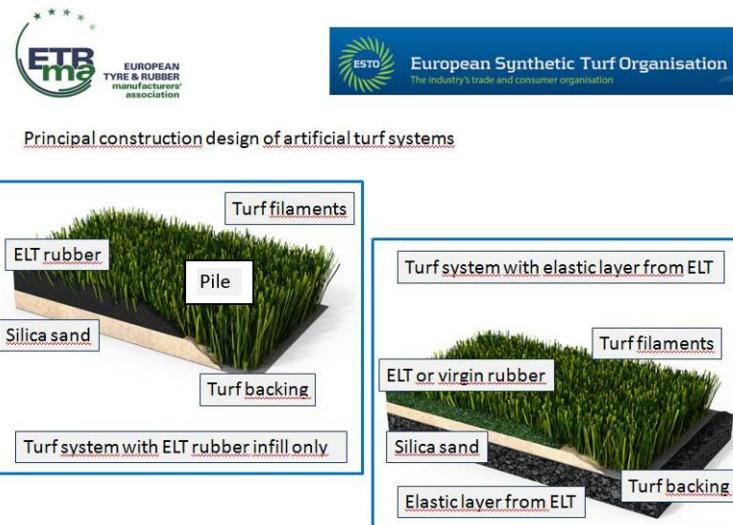
- *Concentration of PAHs in infill*

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 study⁶ (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/m². 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 synthetic 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/cm² of the four dermal pads was used to calculate dermal exposure.

The selected dermal exposure area of 5 150 cm² 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/cm² 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 maintenence 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/m³. 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/m³-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 installation and maintenance.

The consumer exposure assessment 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 scenarios

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 behaviour⁷. 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 cm² 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 assessment 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 cm² 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 negligible, found exposures of 12 µg/m³ 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 inhalation 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 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				
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 permitted (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 additivity 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 uncertainties identified in the proposal that are outlined in Table B43 of the Background Document. RAC agrees the main uncertainties in terms of the exposure assessment that contribute to an overestimation of the excess cancer risks are:

- That installation workers undertake infilling for 120 days per year
- The assumption 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 through to adulthood
- It is less likely that tiles or flakes/mulch are used in playgrounds rather than granules so exposure is expected to be lower from these forms

There is also uncertainties 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 manufacturers 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 uncertainties identified in the proposal that are outlined in Table B43 of the Background Document. RAC agrees the main uncertainties in terms of the exposure assessment 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 through 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 uncertainties 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 ELT⁸-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-wide⁹.

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 pitches¹¹, 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 material¹² 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 RAC¹³. 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) Chrysene (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) Dibenz[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 State 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 at 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

See SEAC opinion.

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 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

See SEAC opinion.

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 sumconcentration 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 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.

Product waste interface

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 11: 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 permitting 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-criteria¹⁴ 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 50¹⁵. 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 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 level¹⁶. 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.

¹⁴ Article 6 §4 of the WFD

¹⁵ 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.

¹⁶ For both ELT and non-ELT granules.

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 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 underlined¹⁷. 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 material¹⁸ sampling and extraction are of critical importance to get reliable and representative test results¹⁹ 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 private²⁰ and public) in the public consultation²¹. A compounding factor is that the term "granules" can encompass a wide

¹⁷ Comment number 1939 (ETRMA) and other actors who have submitted the ETRMA position paper.

¹⁸ 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).

¹⁹ This is less of an issue with virgin infill material because of the production processes involved.

²⁰ Comment number 1939 (ETRMA) and other actors who have submitted the ETRMA position paper.

²¹ Based on the choice of extraction solvent, discrepancies between results exist.

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 undergo 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 occurs 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 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 elsewhere²², 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.

²² 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, EAN²³ 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.

²³ 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 BMDL₁₀ 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

See SEAC opinion.