ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): eight polycyclic aromatic hydrocarbons (PAHs)[1] in granules and mulches used as infill material in synthetic turf pitches and in loose form on playgrounds and in sport applications

IUPAC NAME(S): -

EC NUMBER(S): 200-028-5, 205-892-7, 200-280-6, 205-923-4, 205-911-9, 205-910-3, 205-916-6, 200-181-8

CAS NUMBER(S): 50-32-8 (63466-71-7), 192-97-2, 56-55-3 (1718-53-2), 218-01-9 (1719-03-5), 205-99-2, 205-82-3, 207-08-9, 53-70-3

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[1] Benzo[a]pyrene (BaP), Benzo[e]pyrene (BeP), Benzo[a]anthracene (BaA), Chrysene (CHR), Benzo[b]fluoranthene (BbFA), Benzo[j]fluoranthene (BjFA),Benzo[k]fluoranthene (BkFA), Dibenzo[a,h]anthracene (DBAhA)

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Annex A: Manufacture and use

The restriction dossier focusses on granules and mulches used as infill material in synthetic turf pitches and in loose form on playgrounds and in sport applications. Granules and mulches can be produced from a variation of virgin and recycled materials, however, majority of granules in the EU are produced from End-Of-Life Tyre (ELT). The use of recycled (ELT) material that contains polycyclic aromatic hydrocarbons (PAHs) as synthetic turf infill and in loose form in sport and play applications is the reason to start this restriction proposal. Two product life-cycles are important for this dossier: the tyre life-cycle and the life-cycle of synthetic turfs, granules and mulches used as infill and in other sport and play applications. Both are connected as ELT granules and mulches are mixtures formulated from ELT and placed on the EU market for such uses. Annex A on manufacture and use is structured into three sections:

1. Description of the life-cycle of tyres
2. Description on the lifecycle of artificial turf, infill and mulches
3. Description of existing regulation that is already in place that is relevant for the above two product life-cycles

Note that the eight polycyclic aromatic hydrocarbons (REACH-8 PAHs) within the scope of this Restriction Dossier have not been registered under the REACH Regulation but they may be present as impurities in other registered substances or in mixtures, as is the case for ELT granules and mulches. Since PAHs in general are impurities or by-products, they are not specifically placed on the market and used. Therefore, information from REACH registrations and from other sources on the 'use' of PAHs in granules and mulches was absent. For this reason, the Dossier Submitter focussed on obtaining information on marketing and use of tyres, ELT and ELT-derived and other granules and mulches and on the PAHs contained in these materials.

A.1. Tyres: production, import and export and end-of-life

A.1.1. Tyre production and PAHs

A.1.1.1. Tyre production

In the EU, tyre production in 2016 by European Tyre Rubber Manufacturers Association (ETRMA) members was estimated to account for over 25 % of the world tyre production, i.e. 4.94 million tonnes. Global tyre manufacturing output is estimated to be about 17 million tonnes in 2016 (Smithers Rapra Market Report, 2017[2]). ETRMA members manufacture all tyres that are produced within the EU. According to one producer of tyres, there may be more than 30 000 types of tyres placed on the market in their country of which 700 are produced by this company. This includes tyres for a variation in vehicles and a various of types of tyres per vehicle that e.g. differ in technical performance characteristics. Each of the producers has their own blend of chemicals to be used in the production of tyres. However, 75 % of the tyre consists of a substructure,

[2] http://www.scraptirenews.com/crumb.php

which is more or less the same in each tyre. The specifics come in the 25 % tread of the tyre that will touch the road.

A.1.1.2. Composition of tyres

The European Tyre and Rubber Manufacturers Association (ETRMA 2016, replies to questions posed by ECHA) provided information on the substances in tyres. Many of the substances used in the production of tyres react during the vulcanisation process, creating a three-dimensional network ('rubber matrix') in which those chemicals are bound.

Passenger car tyres and truck tyres represent the majority of tyres sold on the EU market. Table A 1 provides their respective average composition (pre-vulcanisation).

Table A 1: Main components of new passenger car and truck tyres (average composition)

Material	Car	Trucks	Reacting during vulcanisation?
Rubber/elastomers	43 %	42 %	YES
Carbon black (reinforcement, pigment and filler) and silica (reinforcement, filler)	28 %	24 %	YES
Metal (reinforcement)	13 %	25 %	NO
Textile (lining)	5 %	-	NO
Zinc oxide (vulcanisation enhancer)	2 %	2 %	YES
Sulphur (vulcanising agent)	1 %	1 %	YES
Accelerators/anti-degradants	2.5 %	2.2 %	YES/NO
Stearic acid	1 %	0.7 %	YES
Oils	7 %	1.6 %	NO

Source: ETRMA, 2016

According to one tyre producer in Austria, over 200 ingredients go into a tyre. Substances used in tyr0e manufacturing can generally be categorised in different groups:

- Reactive substances, which are involved in chemical reactions that transform these substances:
  - Substances that react during the manufacturing process, by the creation of links with polymers and/or fillers:
    - Peptisers (promote the reduction of polymer molecular weight, thus increasing the efficiency of rubber mastication).
    - Bonding agents;
    - Vulcanisation agents and accelerators;
    - Cobalt salts;
    - Some types of tackifiers (chemicals acting as an adhesive between two surfaces that are required to stick together)
  - Substances that react during the service life:
    - Antioxidants, which react with ozone or ambient oxygen during the service life of tyre and are present at the end-of-life in concentrations lower than the initial concentration.

- Non-reactive substances, like plasticisers (according to ETRMA, no phthalates are used in the manufacturer of tyres).

Some of the above listed chemicals are associated with transformation products:
- Vulcanisation agents (example: benzothiazole compounds, cyclohexylamine, di cyclohexylamine);
- Anti-aging agents and antidegradants (example: aniline, phenylenediamine compounds).

Styrene butadiene rubber (SBR) has partially replaced the natural rubber in the production of tyres in the EU and in the US, however natural rubber is widely used in Asian countries in the production of tyres. The change to SBR was due to the lack of natural rubber on the market. According to one producer of tyres in Finland, approximately half of the rubber used in the production of tyres is natural rubber. It is estimated that a typical new tyre may contain up to 30 kinds of synthetic rubber and eight kinds of natural rubber.

A.1.1.3. Extender oil and carbon black

Extender oil and carbon black used in tyre production PAHs generally contain PAHs as an impurity and these are the main sources of PAHs in tyres. PAHs however, may also come from degradation of other materials present in tyres. From 2010 the PAHs content in the extender oil (and in imported tyres) has been decreased due to restriction entry 50 of Annex XVII of REACH (see A.3.2.).

According to ETRMA (2016, replies to questions posed by ECHA) the major tyre producers have applied the restriction entry 50 of Annex XVII to REACH as regards PAHs in extender oils on a global level. However, there may be differences in the composition of tyres produced in the EU versus tyres produced outside the EU as it is not known if smaller producers outside the EU are following the restriction and whether there may be variations in other substances used in the production of tyres e.g. as different continents set different requirements to tyres. As far as imports are concerned, it may be difficult to check what types of oils have been used in the production of tyres, using the ISO 21461:2006 method[3]. Depaolini et al., 2017 indicate that tyres from outside the EU have somewhat higher PAH content compared to EU produced tyres.

The differences may be also due to type of carbon black used in the production of tyres. In the current tyre production process, carbon black used as filler for reinforcement of the vulcanised material and it also has a function to colour the tyres. Carbon black content percentages in the tyre typically will vary between 24 and 28 % in truck and car tyres respectively (See Table A 1). According to the International Carbon Black Association (2017, comments via the call for evidence in 2017) 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. The International Carbon Black Association stated that

[3] 1H-NMR bay-proton analysis is a relatively complex technique (both expensive and requiring high skills) and furthermore is a destructive test.

in laboratory analyses with heavy extraction conditions (strong organic solvent, elevated temperature for many hours), most carbon black products will typically have extractable PAH levels (REACH-8 PAHs) not exceeding 0.1 %.

Since early 1990s, a development started in the EU to design car tyres that have lower rolling resistance to reduce energy use of cars. To achieve this, the tread of EU tyres currently are reinforced with silica, replacing part of the carbon black used (personal communication Professor Noordermeer[4]). In the tread carbon black percentages therefore are typically reduced to between 2-5 % weight to weight (personal communication tyre sector). The silica-reinforced tyres contain about 1.5 times more oil than the carbon black-reinforced ones (personal communication Professor Noordermeer). As both extender oils and carbon black may contain PAHs, it is not clear whether this development affects the overall PAH content in tyres on the European market. Most non-EU producers have adopted this silica reinforcement technology, at least for the EU market.

Little information is available to the Dossier Submitter on PAH concentrations in extender oils currently used in tyre manufacture for the EU market. According to Professor Noordermeer (personal communication) the discussion in the EU on PAHs in extender oils started in the early 1990s. The PAH issue was flagged as a concern for the environment and resulted in proposals for EU-wide measures for tyre oils early 2000 and legislation by January 2010. According to an opinion by CSTEE (2003) on the abrasion of tyre treads and release of PAHs to the environment it was scientifically justified to conclude that PAHs are emitted to the environment as a result of the abrasion of tyre tread. CSTEE in its opinion refers to studies published by the Swedish KEMI, the German UBA and the European Association of the Rubber Industry (BLIC) reporting tyre treads to contain up to 28% extender oils and 17-357 mg/kg (average 137) total PAHs in the tyre material. B(a)P levels were reported between 1 and 16 mg/kg with an average of 5 mg/kg. BLIC reported total PAH concentrations in the range of 300-700 mg/kg and estimated total PAH concentrations between 13 and 112 mg/kg in ELT particles due to the oils. Other sources referred to in the CSTEE opinion show ranges of 1-230 mg/kg, 30-360 mg/kg and a single reported value of 226 mg/kg in tyre material. No information is provided in the report on the definition and chemical identification of the total PAHs concentration figures. The group may have been much larger than REACH-8 PAHs. CSTEE in its conclusions refers to both the 1998 IPCS evaluation of 33 PAHs and a 1998 RIVM evaluation of 17 PAHs of which only four were found not to be human carcinogens.These figures provide some indication of much higher PAH levels in oils and tyres on the EU market almost ten years prior to entry into force of the EU extender oil restriction in 2010. The extender oil restriction now limits the REACH-8 PAH levels at 10 mg/kg and BaP at 1 mg/kg in the oils.

[4] Jacques W.M. Noordermeer, em. Professor of Elastomer Technology and Engineering (University of Twente, the Netherlands).

A.1.2. Import of tyres and rubber

Regarding the imports of tyres, in the last decade imports from China are dominating the market, especially in the passenger and truck tyres segments (ETRMA Statistics Report 2017[5]). In fact, there has been a massive increase of imports in absolute terms and in terms of market share in the period between 2013 and 2016. The main driver for the increased import of tyres from China has been price. The low-priced imports have had a considerable detrimental effect on the European Union industry. The European Commission, in response to the alleged dumping of tyres from China and the ensuing price distortions, started implementing regulation (EU) 2018/163 [6], thereby making imports of new and retreated commercial vehicle tyres originating from China subject to registration. Imports of moto/scooter tyres and agricultural tyres into the EU, on the other hand, are dominated by the ASEAN countries and India respectively. More details on imports are available in ECHA's report (2017), Annex V.

Depaolini et al. (2017) analysed ELT and selected waste tyres (in Italy) based on origin and age. This study reported that 70 % of the ELT were manufactured by European factories, 20 % were of Far East origin (most from China, Japan and Korea), 4 % from Turkey and 4 % from other parts of the world (like the U.S. and Africa). Classification by age showed that less than 15 % were more than seven years old, with the oldest being 20-25 years.

Besides tyres, it is known that other rubber goods (besides tyres) are imported from outsite the EU. According to ETRMA (2016, as reported in ECHA 2017), imported tyre-related rubber goods (including those in the form of granules) are mainly declared under the HS code 4004.04 and under this code approximately 35 000 tonnes have been imported into the EU per year, over the last three years. The Dossier Submitter has no other sources of information underpinning or further elaborating import into the EU of rubber granules. Furthermore, no information is available on the quality of this material and whether quality may be related to the country of origin.

Parts of this rubber material, may also enter the EU having the status of waste[7]. No EU harmonised End-Of-Waste criteria are available for these waste streams. Imports of rubber waste material for HS codes 4003.00, 4004.00, 4012.20 in the EU 31 (including Norway, Liechtenstein and Iceland) are reported. The following categories are covered by these codes:

- 4003.00: reclaimed rubber, in primary forms or in plates, sheets or strips;
- 4004.00: waste, parings and scraps of rubber (other than hard rubber) and powders and granules obtained from them;
- 4012.20: used pneumatic tyres.

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[5] http://www.etrma.org/uploads/documents/20180329%20%20Statistics%20booklet%202017%20-%20alternative%20rubber%20section%20FINAL%20web.pdf

[6] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2018:030:FULL

[7] The correlation table (under Commission Implementing Regulation (EU) 2016/1245 setting out a preliminary correlation table between customs and waste codes) does not imply that the listed goods are waste. It only gives an indication that these may be waste.

The imports of rubber material for HS codes 4003.00, 4004.00, 4012.20, in the EU-28 and EEA (Norway, Liechtenstein and Iceland) from non-EU countries are shown in Table A 2 for a 10-year period (2006-2015).

Table A 2: Total imports of waste rubber material into the EU-28 and EEA in 2006-2015

Product HS code	Explanation	Total imports 2006-2015 (tonnes)
4003.00	Reclaimed rubber, in primary forms or in plates, sheets or strips	202 985
4004.00	Waste, parings and scraps of rubber (and powders and granules obtained from them)	509 923
4012.20	Used pneumatic tyres	383 703

Source: Eurostat public trade database

Additional specific information on the imports of used pneumatic tyres under TARIC 4012200090 is provided in the confidential Annex H. TARIC 40122000908 includes all types of imported used pneumatic tyres, other than those used on civil aircraft (i.e. TARIC 4012200010). Constraints in the dissemination of statistics on imports under TARIC codes is laid down by the EU legislation[9].

Used pneumatic tyres have also been documented to be imported in the EU. Given the lack of information on the origin of these used tyres, it is difficult to ascertain whether they meet the same quality standards as tyres placed on the market and used in the EU. Based on the information presented in this section the Dossier Submitter cannot conclude on annual volumes of imported (and exported) used tyres, rubber granules or mulches to and from the EU.

A.1.3. End-of-life of tyres

A.1.3.1. Recycling options including infill

The volume of both used tyre arisings[10] and ELT derived material used in the EU has been growing steadily over the past decades. Treatment routes for used tyres in the EU consist

[8] Under Commission Implementing Regulation (EU) 2016/1245, setting out a preliminary correlation table between customs and waste codes, the import of used tyres (TARIC 4012200090) alerts customs officials that this material may be waste.

[9] Statistics on trade in goods with non-EU countries are collected and compiled on the basis of Regulation (EC) No 471/2009 of the European Parliament and of the Council. According to Article 10 "Dissemination of external trade statistics", paragraph 2: *"Without prejudice to data dissemination at national level, detailed statistics by the TARIC subheading and preferences shall not be disseminated by the Commission (Eurostat) if their disclosure would undermine the protection of the public interest as regards the commercial and agricultural policies of the Community.*

[10] The quantity of Used Tyres arising in a specific geographic market available for collection and subsequent recovery.

of energy recovery, material recovery, retreating, reuse and export, and landfill disposal[11][12] (see Figure A 1). Figure A 2 further specifies the various uses of ELT material and shows that 14 % of ELT is used in synthetic turf.

In 2013, there were about 625 000 tonnes of rubber granules formulated in the 28 EU countries and Norway (ETRMA 2015, as reported in ECHA 2017). The yearly output capacity of the European rubber granule formulators is about 1 million tonnes. Granules may have various sizes and can be used for various of the uses presented in Figure A 2. Most of the formulated rubber granules derived from ELT are consumed in the European Union in a wide array of applications, including sport surfaces, children's playgrounds, moulded objects and road applications. 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. Note that besides mulches, ELT is also used on playgrounds e.g. as tiles or in-situ flooring. Various estimates are available on the quantity of granules used in the application of synthetic turf. According to the ETRMA, about 80 000 to 130 000 tonnes of rubber granules derived from ELT are used annually as infill for synthetic turf pitches in the EU. VACO – the Netherlands' Professional Association of Tyre and Wheel Manufacturers – estimates the volume to be as high as 200 000 tonnes (VACO, 2015, as reported in ECHA 2017). Another source reports an estimated EU annual tonnage for ELT derived materials used on all types of pitches that is substantially higher than 200 000 tonnes (EU association 2018, figures claimed confidential).

Based on the information from EU industry (i.e. 950 000 tonnes of rubber granules formulated in the EU of which up to 200 000 tonnes are used as infill material), the percentage share of infill material in the overall EU ELT market is about 21 %. Besides the use as infill, ELT may also be used as a shock absorbance system[13] below synthetic turf. It is said that in the EU around 30 % of ELT derived rubber is used on synthetic turf pitches in total (infill and shock absorbance systems to the synthetic turf pitches) (ETRMA 2016, as reported in ECHA 2017). Shock absorbance systems may thus use around 9% of the ELT derived rubber (i.e. 85 500 tonnes) in the EU. According to ETRMA (2018, replies to the questions by ECHA/RIVM), mulch in playground as low impact surface area is used in France, Germany and the UK. Partly this mulch is used in loose applications, partly mulch or granules are bound together (e.g. by using a resin binder) to create a solid surface. Mulch according to ETRMA is primarily derived from truck tyre treads that are recovered in the process of truck tyre re-treading. It is estimated that around 8 000 tonnes of mulch is used per year in the UK.

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[11] Under the European Landfill Directive (2006) tyres are prohibited from being placed into landfill.

[12] Note that pyrolysis of tyres to derive carbon black and fuel also occurs in the EU and there are developments to devulcanize tyre material for recycling purposes (personal communication recycling sector). It is not know to the Dossier Submitter on what scale these processes currently take place.

[13] This may be loose ELT in the substructure below the pitches or a so-called e-layer (solid layer). Note that also shockpads can be used below (specific types of synthetic turf). These are said to be made of a foam instead of ELT/rubber (personal communication synthetic turf sector).

Intra-EU trade of rubber granules usually occurs from Central and Southern European states, where the granulation sites are most present, towards the Northern and Western Europe (with some exceptions e.g. Germany and Netherlands applied), where demand for infill material is not always met by locally formulated products.

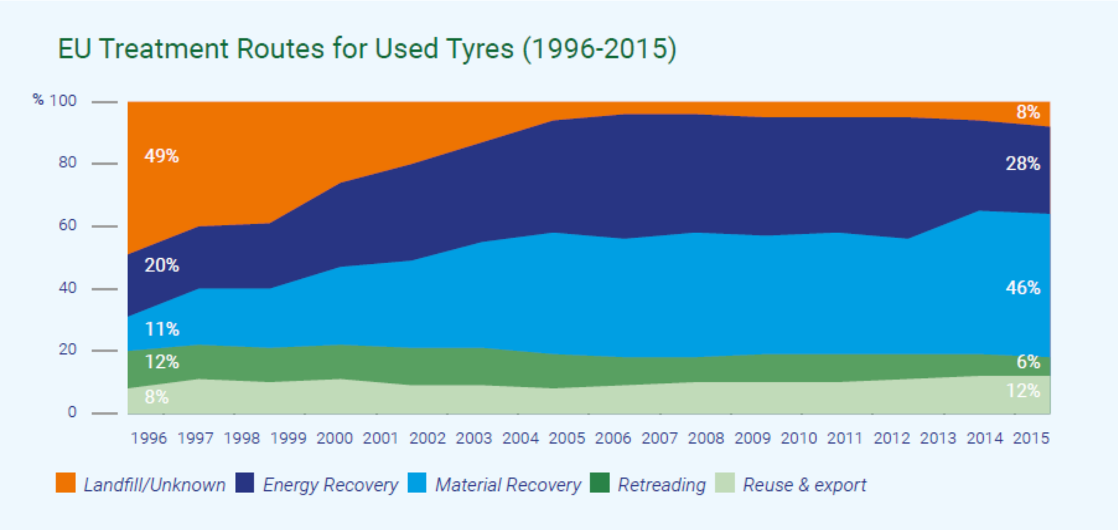

Figure A 1: EU treatment Routes for used tyres (1996 – 2015)

Source: ETRMA

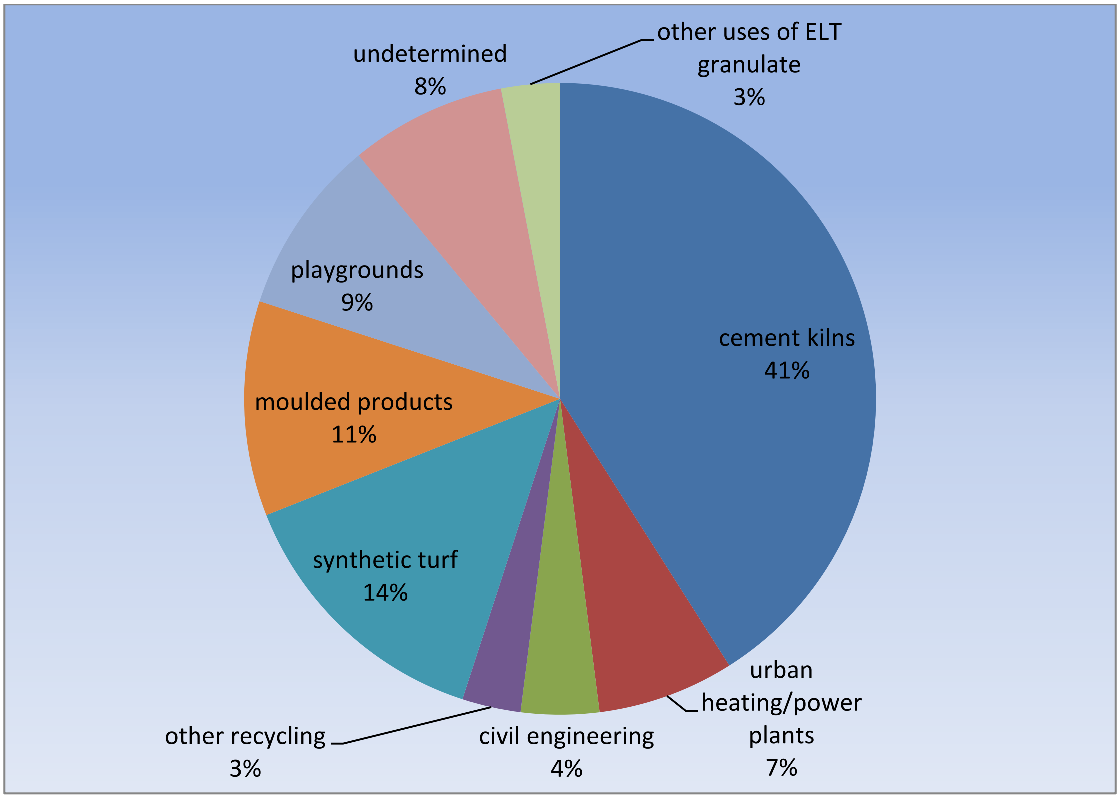

Figure A 2: ELT recovery routes

Source: ETRMA (2018)

A.1.3.2. EPR Schemes

In the EU, landfilling of end-of-life tyres (ELTs) has been prohibited since 2006 following the European Directive 1999/31/EC. The Directive stipulates the 'polluter pays' principle and calls for Member States to take measures against accepting used tyres, with certain exceptions[14], in a landfill. In 2016 there were 15 ELT management organizations set up at the initiative of tyre manufacturers working throughout Europe under the Producer Responsibility Principle and 21 countries with an extended producer responsibility (EPR) regulation for tyres representing about 66 % of European used tyres arisings (See also Figure A 5)[15]. In 2018, there are already 23 countries operating under an EPR system representing about 65 % of total EU arisings.

Under the EPR, ELTs have to be managed by their manufacturers and importers. According to ETRMA[16], where implemented, the EPR is followed through in various ways from a single ELT management company dealing with all ELT collection and treatment in a country (such as in Portugal, the Netherlands and Sweden), through multiple ELT management companies or consortia (such as in Italy, France and Spain) or through individual producer responsibility (in Hungary). Free market[17] systems operate in Austria, Switzerland, Germany and the UK. In Textbox A 1 below, the three different ELT management schemes are further explained.

Textbox A 1: ELT management schemes, 3 different systems within the EU: Extender Producer Responsibility, liberal system and Government responsibility through a tax.

1 Scheme - Extended Producer Responsibility

Used in Belgium, Bulgaria, Slovakia, Czech Republic, Estonia, Finland, France, Greece, Hungary, Italy, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, and Sweden.

Under this scheme the producer is held responsible for the waste generated by the consumer. These producers are required by law to collect and organise the treatment of an equivalent amount of the volumes of tyres sold in the same year or the year before. The process is financed through an environmental contribution charged upfront by ELT companies to their affiliated tyre manufacturers and importers on tyre sales. The fee is passed on by producers and distributors throughout the value chain to the end user. Usually, the fee is added to the purchase price of the new tyre which the consumer pays eventually.

Exact fees are determined nationally according to the tyre size and type and hence vary greatly. Some examples for passenger car types are given below:

- Finland ≈ 1.75 €/tyre
- Sweden ≈ 1.85 €/tyre

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[14] Excluding tyres used as engineering material, and shredded used tyres five years from the date laid down in Article 18(1) (excluding in both instances bicycle tyres and tyres with an outside diameter above 1 400 mm).

[15] Materials forming the secondary or waste product of industrial operations.

[16] End of Life Tyre Report 2015, ETRMA: http://www.etrma.org/uploads/Modules/Documentsmanager/elt-report-v9a---final.pdf

[17] Under the Extended Producer Responsibility, tyres manufacturers and importers have to organise the management of ELTs. Under the Free market system, the national legislation sets the objectives to be met but does not designate those responsible. In this way, all the operators in the recovery chain contract under free market conditions and act in compliance with the legislation.

- Norway ≈ 1.65 €/tyre + (24–25 % of VAT added)
- Portugal ≈ 1.20 €/tyre
- France ≈ 1.35 €/tyre
- The Netherlands ≈ 1.30 €/tyre[18]

On average the fee fluctuates from 1.2 to 2 € depending on the Member State.

2 Scheme - Liberal system (Free market)

Used in Austria, Croatia, Germany, Ireland, Switzerland.

Under this model, the legislation sets the objectives but does not designate those responsible for carrying out these objectives. Therefore, all the operators in the recovery chain contract under free market conditions and act in compliance with the legislation.

Fees are determined nationally according to the tyre size and type and general market conditions in the given Member State.

- Ireland: The standardised fee is €2.80 for a car tyre and €1.50 for motorcycle tyres (excluding VAT).
- Switzerland:
  - ≈ CHF 2.50 to CHF 3.50 (2.15 EUR to 3.2 EUR) for passenger car tyres
  - ≈ CHF 5.00 to CHF 7.50 (4.6 EUR to 6.9 EUR) for van and SUV tyres
- Germany: ≈ 2.60- 3.00 EUR/tyre

3 Scheme - Government responsibility through a tax

Used in Denmark and Slovak Republic.

Under the tax system, authorities are responsible for the management of ELTs. It is financed by a tax levied on tyre producers and subsequently passed on to the consumer.

System explained on the example of the Danish model:

Denmark 19- Tyre producers and importers pay a levy to the Danish Customs and Tax Administration (Skat). The levy varies between 10 – 225 DKK (~ 1.34 – 30.20 EUR) per tyre depending on the type/size. The levies are transferred from Skat to the Environmental Protection Agency (EPA). EPA-approved tyre collectors collect scrap tyres at car dealers, workshops, garages etc. Tyres suitable for retreating are delivered to retreating companies. Scrap tyres are delivered to EPA-approved recycling plants for granulation or pyrolysis. A subsidy is paid to the tyre collector by the Danish Tyretrade Environmental Foundation on behalf of EPA for tyres delivered to recycling plants.

- Subsidy per kg:
  - Max. 1.55 DKK (~ 0.21 EUR) for tyres with rim diameter < 24 inches.
  - Max. 2.10 DKK (~ 0.28 EUR) for tyres with rim diameter ≥ 24 inches.

Overall, what emerges from the available information is that the ELT management schemes can differ significantly in different European countries and each country may face quite unique situations varying from historical stockpiling to extra quantity of ELT stemming from irregular sales/imports, as described in ECHA's report (2017), Annex V.

[18] https://zoek.officielebekendmakingen.nl/stcrt-2015-18635.html
[19] http://www.daekbranchens-miljoefond.dk/english

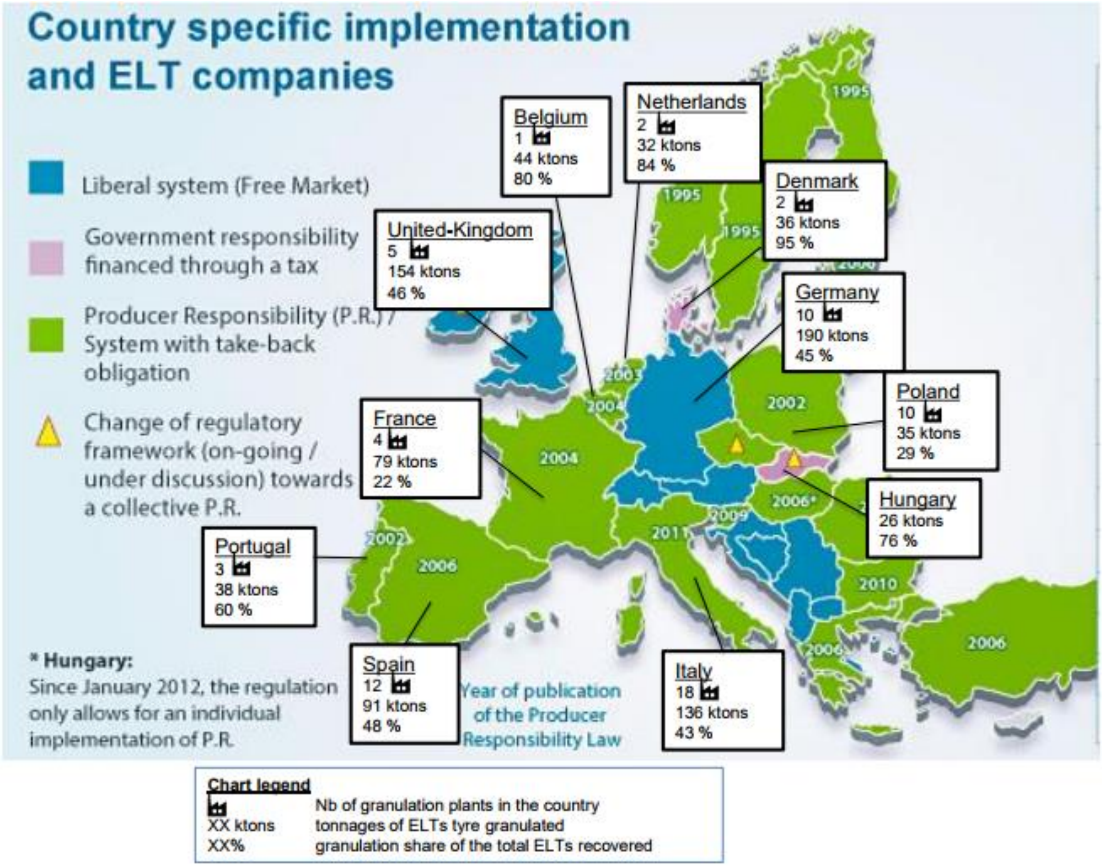

Figure A 3: Country specific implementation and ELT granulation companies

Source: ETRMA

A.2. Artificial turf, granules and mulch: formulation, import and export, use and end-of-life

A.2.1. Formulation of granules and mulches from ELT

Rubber crumb is the name generally used by the industry for any material derived by reducing scrap tyres or other rubber into uniform granules with the inherent reinforcing materials such as steel and fibre removed along with any other type of inert contaminants such as dust, glass, or rock[20]. Scrap tyre rubber comes from different types of tyres (ETRMA 2016, as reported in ECHA 2017):

- passenger car tyres (including e.g. trailers, caravans), which represent about 70 % of the total weight of EU-28 scrap tyres;
- truck and bus tyres, which constitute about 20% of the total weight of EU-28 scrap tyres;
- other tyres (e.g. used on off-the-road vehicles such as agricultural tyres (tractors etc.)), which account for less than 10 % of the total weight of EU-28 scrap tyres.

In this dossier more often the term ELT is used to refer to the recycled rubber material after service life of tyres.

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[20] http://www.scraptirenews.com/crumb.php

A.2.1.1. Formulating companies

It has been estimated that there are over 110 formulators of rubber granules derived from ELT material located in the European Union, a large majority of whom formulate infill material. Some key industrial players estimate the number to be closer to 140. Italy, Spain, France, Germany, and UK have the highest number of recycled rubber granule formulators and the largest annual output of rubber granules (see Figure A 3). The majority of granulation sites are located in the Southern Europe whereas the Western Europe, Central and Eastern Europe and Northern Europe smaller number of formulators (See Figure A 4). There are over 49 formulators of rubber granules located throughout Southern Europe, with grinding/granulation sites, concentrated around the areas of Spain, Portugal, and Italy. The largest scrap tyre recycler in Europe operates four large plants (one in Denmark, three in Germany). This company has by far the largest tyre recycling capacity in the European Union, with a production of up to 280 000 tonnes of rubber granules and powder annually. The company has about 30 % of market share on the EU infill material market. In addition, in Sweden, Germany, UK, Poland, Italy, the Netherlands, Greece and Portugal there are some of the largest ELT-derived infill material formulators in the EU. Their total market share exceeds 45 % of the total infill material market. The remaining market share, i.e. 25 % is held by over 100 formulators (ELT-derived infill material and other infill material), all of which are scattered throughout Europe. There are dozens of European ELT infill material formulators whose annual output is below 10 000 tonnes. Figure A 5 gives an impression of quantities of ELT produced in the largest ELT granule producing countries in the EU in the period 2010-2013.

A.2.1.2. Selection process

Before tyres are grinded into mulches, granules or powders, tyres may be selected. As an example, in the Netherlands, all tyres are said to be manually inspected on the basis of criterion whether they are collected in the Dutch market or not. First step is that reusable tyres are sorted out for shipment outside the EU (i.e. to African region) for second hand use of tyres. Second step is that the older tyres (before 2010) are deselected for manufacture of their consumer products because of the expected high(er) PAHs concentrations prior to the extender oil restriction. All deselected tyres may be used for industrial product range manufacture purposes. No Off-the-Road truck tyres and no other rubber materials are said to be used as feedstock for granules.

Another tyre recycling company reported to separate truck tyres from car tyres. Firstly because truck tyres unlike car tyres are nowadays still selected for retreating. A truck tyre may be retreated up to five times before the article reaches the end of its service life. Car tyres are not retreated anymore for economic reasons. Import of cheaper tyres manufactured outside the EU has reduced the profit margins on new tyres and because of the low prices of imported tyres, retreating has lost economic attractiveness.

A.2.1.3. Formulation processes

There are several processes for formulating ELT derived infill material[21] [22]. The most common process is ambient grinding, whereas cryogenic processing seems to be slowly gaining a foothold.

Ambient process
Ambient grinding can be accomplished in two ways: using granulators or cracker mills. In an ambient system, the rubber, tyres or other feedstock remain at room temperature as they enter the cracker mill or the granulator.

Ambient grinding is a multi-step processing technology that uses a series of machines to grind and separate the rubber, metal and fabric components of the tyre. In general, whether using granulation equipment or cracker mills, the original feedstock is first reduced into small chips. The chips are further ground to separate the rubber from the metal and fabric. Finally, a finishing mill will grind the material to the required product specification.

After each processing step, the material is classified by sifting screens that return oversize pieces to the granulator or mill for further processing. Magnets are used throughout the processing stages to remove wire and other ferrous metal contaminants. In the final stage, fabric is removed by air separators.

Cryogenic process
Cryogenic processing refers to the use of liquid nitrogen during the processing. Most rubber becomes embrittled or "glass-like" at temperatures below -80°C. The use of cryogenic temperatures can be applied at any stage of the size reduction of scrap tyres. Cryogenic grinding avoids heat degradation of the rubber and produces a high yield of product that is free of almost all fibre or steel, which is liberated during the process. The process results in granules with smoother surface compared to the granules from ambient process. For scrap tyre-derived rubber, the steel is separated out of the product by the use of magnets. The fibre is removed by aspiration and screening. According to one formulator the use of cryogenic method does not cause any friction or any degradation (of molecular weight, thermal, mechanical or devulcanisation) in the polymer chains.

Different rubber granule market segments have different rubber granule size requirements. Within a specific rubber granule market, each application has its own requirements in terms of particle size and purity (the accepted level of maximum moisture content is about 1 % by weight). The size of the infill material used in synthetic turfs is typically 0.25 – 3.00 mm[23]. The shape of the infill material varies from rectangular to round. According to ETRMA (2018, replies to questions posed by

[21] http://www.scraptirenews.com/crumb.php
[22] Tyre buffings, a byproduct of tyre retreading, is not used to produce infill materials, according to ETRA (2017).
[23] Recommendation by one company: http://www.synturf.org/images/GuidelineTencate_Infill_Systems_UV_dust.pdf

ECHA/RIVM), the size of mulch produced from tyre buffings from retreating is 10 - 40 mm long, whereas that from ELT is 4 – 10 mm long.

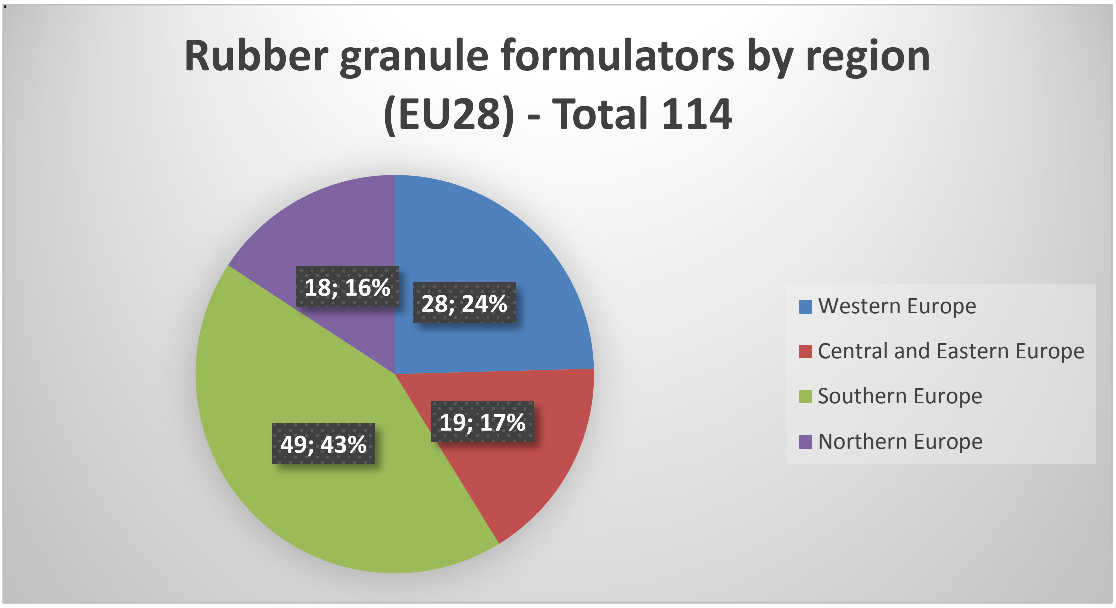

Figure A 4: ELT-derived rubber granule formulators by region (EU28)

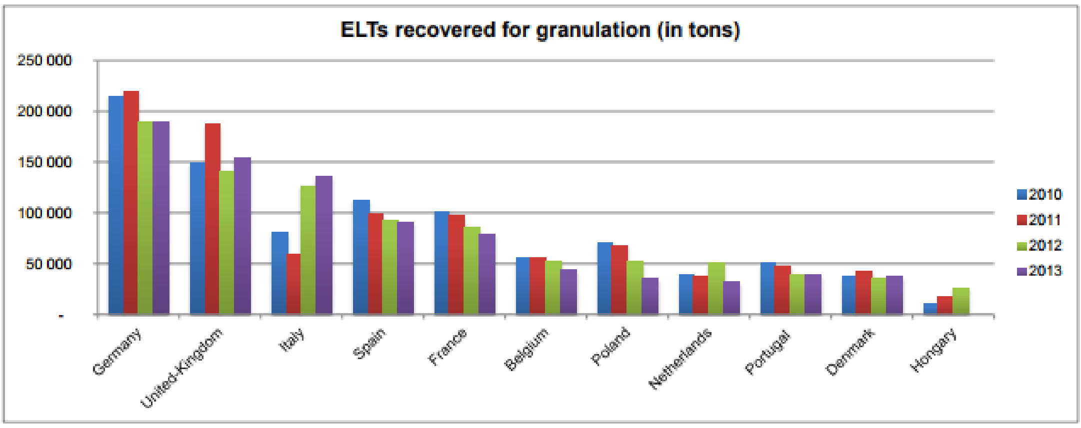

Figure A 5: ELTs recovered for granulation (in tonnes)

Source: ADEME report (2015)

A.2.2. Import and export of granules and mulches

The knowledge on import of rubber granules that are used as infill material or as loose granules and mulch is scarce. In the ECHA report (2017) it is mentioned that samples of rubber granules as infill material from the Asian market were analysed[24]. ESTO (2016,

[24] Just one example. Total concentrations of REACH-8 PAHs were around 3 000 mg/kg; chrysene and benzo(a)pyrene levels higher than the limit values in entry 28 of Annex XVII to REACH.

replies to questions posed by ECHA) also considers that some infill material derived from ELT may be imported from Turkey, Ukraine and Russia and that it may be used in some eastern EU Member States, especially those adjacent to the three non-EU countries.

However, imports of finished rubber granules as well as mulch from recycled tyres from outside of the European Union are assumed to be almost non-existent as verified by multiple industrial actors and further corroborated by the analysis of available trade information. This can be best explained with reference to the pricing of rubber granules within and outside the European Union market. Pricing of the various existing infill materials, including crumb rubber, is afforded special attention in Annex E.2. on alternatives. It is evident from the pricing analysis that it makes no financial sense to import rubber granules from outside the EU, provided that the local prices are very competitive for foreign exporters to compete against, especially, when factoring in transportation, customs and VAT costs. Though, it is generally economically unviable to import finished rubber granules into the EU from outside, the situation is cardinally different when it comes to alternative infills, most notably infills made of Thermoplastic elastomer (TPE) and Ethylene Propylene Diene Rubber (EDPM). The two infill materials are imported into the EU due to the price asymmetries existing between the EU and various non-EU markets.
It has been suggested, with reference to the data collected from four ELT recycling companies - (Portugal, France, Italy and Spain) – that export constituted about 16% of the total market outlets of the formulated ELT granules and powders in 2014. Some of the important export destinations were named Americas, Middle East and Africa. Some sources suggest that about 100,000 tonnes of rubber granules are sold outside of EU annually (VACO 2015, as reported in ECHA 2017). However, the exact annual volume of rubber granules exported from EU to those markets is hard to estimate.

A.2.3. Use of artificial turf systems

A.2.3.1. Generations of artificial turf and types of sports

Synthetic turf pitches have been used since 1960s in the USA. Synthetic turf pitches were introduced in the EU in 1970. These new pitches were initially only occasionally used for football, but after 1996 they were developed to better suit football[25]. Since then, in many countries part of the natural grass or sand pitches have been replaced by synthetic turf pitches for several reasons, e.g. increasing the playing time per field and saving water consumption. ESTO (2018, replies to questions posed by ECHA and RIVM) estimates that synthetic turf pitches represent less than 15 % of the entire sports market in EU, however the share varies across the Member States. Based on data from Finland 75 % of the sporting occasions (Football) take place on artificial turf, but this is likely an overestimation for most other countries across the EU (Finnish Football Association 2017, as reported in ECHA, 2017). The first generation of synthetic turf pitches makes use of a short pile (12-15 mm) without any infill material [26]. Nowadays short pile turfs without

[25] http://cn.tencate.com/amer/grass/Synthetic-turf-101/Request-a-Presentation/default.aspx
[26] ESTO website: http://www.theesto.com/synthetic-turf-faqs/

infill material are used for sports such as hockey, cricket and lawn bowls. The second generation of synthetic turf pitches were introduced in 1970s. The piles were longer (20-25 mm) and the pitches had sand infill to support the pile. The third generation of synthetic turf pitches were introduced in the late 1990s. The pile lengths were even higher (50 – 70 mm) and performance infill materials were used in addition to sand infill. These long pile synthetic turf pitches can be with or without an elastic layer underneath.

According to ESTO, football is by far the largest sports' user of long pile synthetic turf pitches[27]. Examples of other sports using this type of surface are:
- Rugby;
- Gaelic sports;
- Baseball;
- Lacrosse; and
- American football.

In addition multi-purpose synthetic turfs have been developed. According to ESTO (2018, replies to questions posed by ECHA and RIVM) the sports that use the multi-purpose sport pitches typically are tennis, mini tennis, netball, basketball, five-a-side football and hockey. Other sports that may use this type of pitches are uni-hockey, rugby union and rugby league, lawn bowls, cricket, tag rugby, rounders, athletics practice, tri-golf, roller hockey, volleyball and lacrosse. These pitches may be used with or without the infill material. Currently the estimate is that 50 % of these pitches use sand and 50 % performance infill, but the trend of using performance infill is growing (ESTO 2018, replies to questions posed by ECHA and RIVM). The type of performance infill used varies across the Member States, e.g. in Germany most mini-pitches use virgin EPDM, whereas in France and the UK, the performance infill is mainly derived from recycled tyres.

A.2.3.2. Description of the 3rd generation artificial turf system including infill

A.2.3.2.1. The artificial turf system

As said, several different types of synthetic turfs are available, but the construction principle is usually the same. The turf is composed of plastic material, e.g. polyethene, polypropylene or nylon, which is attached to a plastic web of polypropylene or polyester. According to one producer of synthetic turfs in the Netherlands, polyethene is the main material of which turf for sport pitches is produced nowadays, as it is softer and kinder to the skin compared to other materials. Polypropylene is typically used for the production of other types of artificial turfs (for gardening/landscaping). Sand and performance infill material are used to fill the spaces between the artificial grass piles. The sand provides weight and holds the plastic web in place, while the performance infill material provides elasticity. There may also be antioxidants added to the grass made of plastic to improve weather resistance, UV stabilisers to protect against light degradation and also colourants to make the artificial grass green. During maintenance of the pitches, detergents as cleaners, conditioners and de-icing chemicals may be used.

[27] See more information in Section 2.1.

The quantity of infill used in a long pile synthetic turf surface will depend on the height of the pile (turf filament), performance required and the type of infill used. The most commonly used pile height is 60 mm and this will typically have between 110 and 120 tonnes of infill on a full size football field[28]. If the system incorporates a shockpad (or an elastic layer), the pile height may be lower (40-50 mm) and the infill quantity could be as low as 40 tonnes. According to ETRMA, a smaller quantity of rubber per square metre is also used on smaller pitches such as mini-pitches (ca. 10 kg/m^2).

The shockpad underneath the turf may be produced from a foam, an elastic layer may be produced from ELT[29], polyethene or other elastic material. According to one producer of artificial turf systems, this alternative system is especially used when alternative infill (non-ELT infill material) is used to limit the cost increase of the overall turf system, as the alternative infill is much more expensive compared to the ELT infill. This is further explained in Annex E.2. on alternatives.

The ground layer (sub-base or substructure) under the synthetic turf system is constructed before the turf is installed. According to one infill material formulator in Italy (2017, comments via the call for evidence) the main function of the substructure is the creation of a durable, stable, flat surface on which the synthetic turf system is installed. The depth of the substructure depends on the turf system installed on it and the climate conditions at the location of installation. The same company states that an additional function of the substructure is to prevent leaching substances to reach the soil or groundwater below the installation. Figure A 6 illustrates these two types of artificial turf systems.

[28] FIFA (2015/2016): International matches: Length: minimum 100 m, maximum 110 m and width: minimum 64 m, maximum 75 m (https://www.fifa.com/mm/Document/FootballDevelopment/Refereeing/02/36/01/11/LawsofthegamewebEN_Neutral.pdf)

[29] Note that there may be environmental issues related to the use of ELT as shock absorbance system underneath artificial turf systems (RIVM 2018).

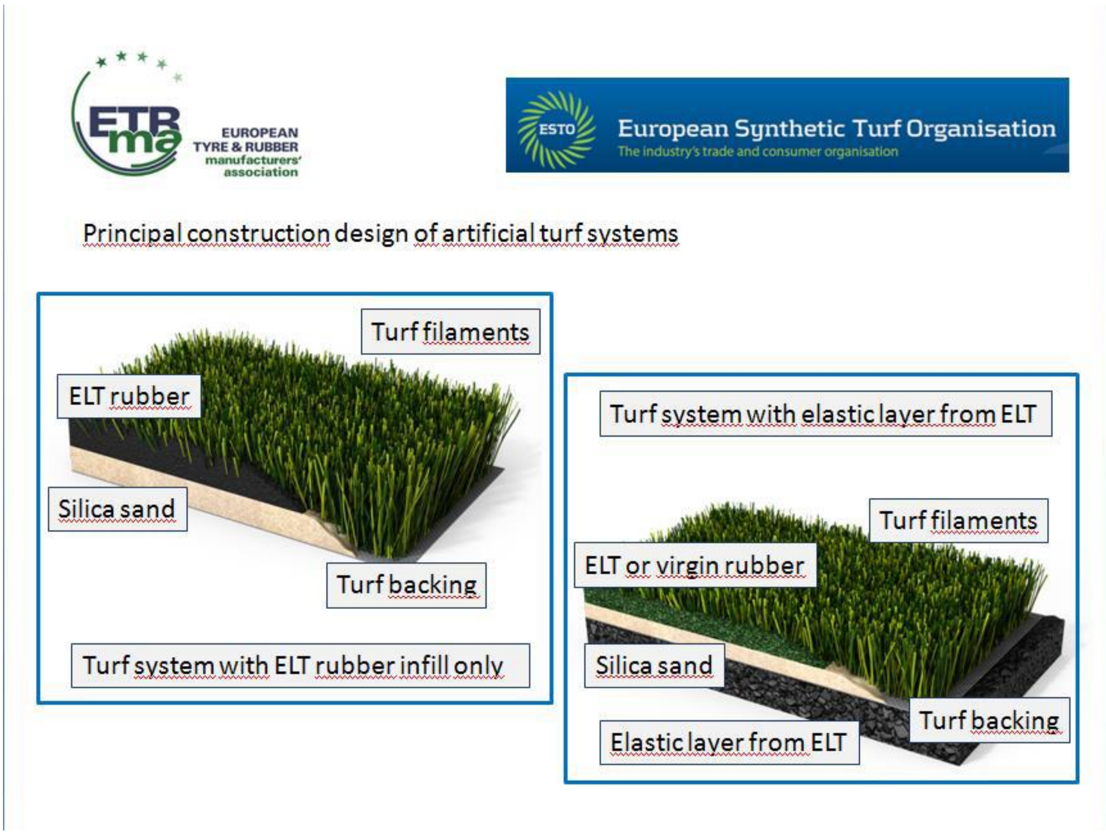

Figure A 6: Two types of synthetic turf systems

Source: ETRMA and ESTO (2016)

As rugby and Gaelic sports pitches are larger than football pitches, they use proportionally more infill per field.

Modern synthetic turf surfaces use pile heights ranging from 35 to 65 mm (many systems being based on 60 mm carpets) and a mixed ballast layer composed of sand and infill material. ESTO estimates that over 95 % of all synthetic turf installations are currently located outdoors.

A.2.3.2.2. Number of pitches in various EU Member States

Figure A 7 presents the number of annually installed synthetic turf football pitches in a number of EU countries. Further information on the number of pitches, the types, quantities and shares of infill used is provided in Annex D.

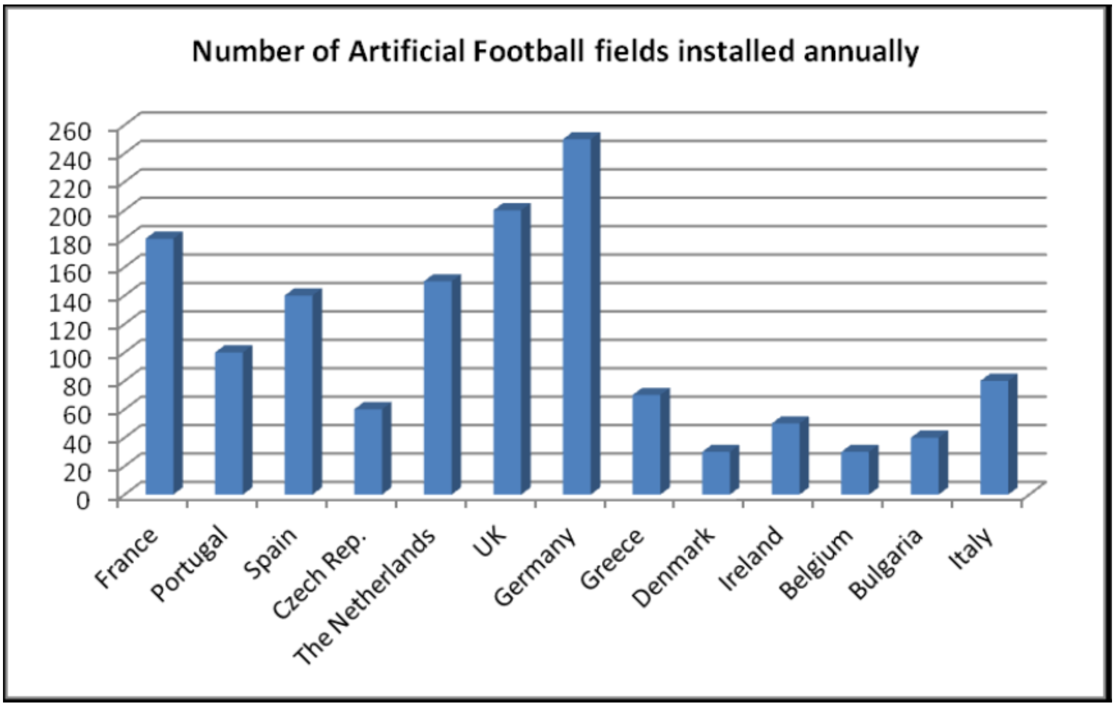

Figure A 7: Number of artificial football pitches installed annually
Source: ETRMA (2016)

A.2.3.2.3. Quality criteria for artificial turf

These systems have been approved by FIFA (the Fédération Internationale de Football Association), UEFA (the Union of European Football Associations) and World Rugby.
The criteria established by FIFA[30] in 2006 on the quality requirements for football turf include an Annex on 'general requiremtns' in which the manufacturer of the turf is given the task to asure the purchaser the turf is chemically safe. According to this FIFA quality guidance 'The manufacturer should be asked to supply to the purchaser an assurance that the sports surface together with its supporting layers, does not contain in its finished state any substance which is known to be toxic, mutagenic, teratogenic or carcinogenic when in contact with the skin. Furthermore it should be ascertained that no such substances will be released as a vapour or dust during normal use.' In addition, it is prescribed that parties that receive the licence for synthetic turf pitches have the responsibility to ensure that if any dangerous substances are identified their content does not exceed the limits in force. Reference is made to the former EU limitations Directive (EU Council Directive 76/769/EEC), which are restrictions currently captured by Annex XVII of REACH. The 2006 FIFA quality concept has in 2015 been amended into the 2015 FIFA Quality Programme for Football Turf (FIFA, 2015) which does not anymore contain quality criteria related to chemical safety of the synthetic turf. The current FIFA Quality

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30 FIFA QUALITY CONCEPT Handbook of Requirements for Football Turf, March 2006 Edition: https://www.fifa.com/mm/document/afdeveloping/pitchequip/fqc_requirements_manual_march_2006_326.pdf

Programme for Football Turf certifies final installations subjected to a testing procedure. On its website, FIFA lists providers that fulfil their quality programme. The number of pitches in the EU that fulfil the FIFA quality programme is not known. According to one producer of synthetic turfs, all pitches they produce are checked against FIFA criteria and they receive certificate for this. World Rugby has also published guidelines for quality of synthetic turfs[31] but the criteria do not cover chemical safety of the turf and the infill material. More information on the FIFA quality program is presented in Annex E.2.

A.2.3.2.4. Quality criteria for infill material

Some Member States have specific control systems in place for artificial turf. For example, the French Football Association (FFF, replies to questions posed by ECHA in 2017)[32] notes that the owners of the pitches are municipalities, who require laboratory reports to prove that the performance infills fulfil the national standard (NF P 90112). This standard sets up limits on heavy metals. Municipalities are also responsible for the maintenance of the pitches. FFF controls the quality of pitches every five years. According to FFF, the main driver for choosing the infill material is the price.

According to the DEFRA, UK[33] (2017, replies to questions posed by ECHA), the samples are typically collected as part of the field test verification of the artificial grass pitches. The process involves the collection of about 5 kg of infill once the pitch is built. The Department for Environment, Food and Rural Affairs (DEFRA) tests these samples for physical properties for compliance to a standard for sporting performance. DEFRA keeps reference samples for the quality system. According to Sport England (2017, replies to questions posed by ECHA)[34], the relevant sports standards which are used are FIFA Quality Program, World Rugby Regulation 22 [35] and more recently BS EN 15330-1. In the Netherlands RecyBEM has introduced a standard for REACH-8 PAHs content (20 mg/kg) in infill material[36]. Furthermore there is a Milieukeur – a Dutch environmental quality label - certificate available making statements on REACH-8 PAHs content (similarly 20 mg/kg of rubber)[37].

A.2.3.3. Installation and maintenance

A.2.3.3.1. Installation of artificial turf

According to ETRMA (2016, as reported in ECHA 2017) outdoor and indoor installation procedures are similar. The installation of a new field takes a total of 30-35 working days. Normally, there will be between two to four workers on the field during installation and on average six workers in total to install the field. Infilling a full-size football pitch normally takes two to three days. The duration of the rubber infill procedure is six hours

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[31] Rugby Turf Performance Specification, 2016 Edition: http://www.smartconnection.net.au/wp-content/uploads/2017/06/2016-Rugby-Turf-Performance-Specification.pdf
[32] Berly, Jean-Michel (FFF), personal communication
[33] Carmichael, Penny (DEFRA), personal communication
[34] Atherton Tony (Sport England), personal communication
[35] https://www.worldrugby.org/handbook/regulations/reg-22
[36] https://www.recybem.nl/nl/BEM-norm
[37] http://www.smk.nl/Public/Milieukeur_NonFood_schemas/2017/VHTSCHEMA_NL10.pdf

per day. If the same workers install the new field, it is assumed, given that installation typically occurs during warm periods (6 months and typically during the summer period when pitches are not used due to holiday season [38]) that as a worst-case workers do the infill procedure approximately 120 days per year. Workers use protective clothing and protective masks to prevent inhalation of dust. However, ESTO notes that this will happen when personal protective equipment (PPE) regulations are robustly enforced. According to ETRMA, workers sometimes don't use any type of PPEs during the rubber infill operations (except acoustic earmuffs because of the truck noise).
Other tasks during installation than infilling are the preparation of the base such as placing aggregates with the right gradation, compaction etc. (20 days), laying down the synthetic turf (and potentially a shockpad or elastic layer underneath and the turf) (eight days) and spreading the sand layer (2-3 days).
Pitches are normally built during the six warmer months of the year (depending of the geographical position of a Member State). The artificial turf carpet and infill need to be dry to allow the infill to flow into the carpet pile. According to ESTO (2016, as reported in ECHA 2017), the air temperature immediately above the synthetic turf field with infill material derived from ELT can reach in excess of 80 °C during very warm and sunny periods, and that it would be unusual for work to proceed in hot conditions.

According to the ESTO (2016, as reported in ECHA 2017), the procedures used to install the infill vary depending on the country and contractor. Larger companies will use machines to distribute the infill and brush into the synthetic turf carpet (see Figure A 8). For smaller areas and smaller companies, companies typically load one ton or 1.5 m^3 big-bags into a small tractor unit (open driving space), which distributes the infill across on the pitch (see Figure A 9). This is normally done by one or two units per field. Big-bags are unloaded directly in the cargo bed of the truck, however if problems arise, workers can break the sacks manually. The infill is then brushed into the carpet using another tractor. Manual raking might occur as well.

[38] In the Netherlands installation typically occurs outside the football season, during June-August.

Figure A 8: Mechanised application of infill (photo submitted by ESTO)

Source: ESTO

Figure A 9: Semi-mechanised application of infill

Source: ESTO

A.2.3.3.2. Maintenance of synthetic turfs

Different types of maintenance activities occur on the pitches. Maintenance work can include brushing or raking the rubber granules after the games. Brushing can be done with machines designed for this purpose, but manual brushing also occurs when a smaller area needs to be fixed. According to Salonen et al. (2015) the frequency of brushing varies being once per week to once every 2-3 months. This may vary depending on the countries/pitches. One producer of the artificial turf informed ECHA that the brushing is done on weekly basis, as it is important that the field does not have areas with too small amount of infill. If this would be the case it may lead to injuries for the players and it may damage the pitch, shortening the lifetime. Shoveling of the rubber granules from the containers occurs as well. Nilsson et al. (2008) refers to a maintenance guide which provides the following information: the regular maintenance consists of cleaning, marking, deep-cleaning, surface loosening (1-2 times per year, according to one synthetic turf producer), filling up and watering. Watering can be relevant during the summer months with respect to cooling down and reduced friction. Salting (de-icing) of synthetic turfs may occur during the winter and snowy periods[39]. Cleaning of machines is conducted regularly. Furthermore leaf blowers may be used to get rid of leaves in the fall.[40]

Deep brushing with refilling of infill material typically happens ones per year. This annual maintenance is done due to losses of infill and to overcome the effect of compacting. On average 0.5-1 ton of refill per year has to be added to each field and for pitches where winter service is needed (where an amount of rubber infill will be removed during snow clearance from the field) 3-5 ton is added. For the dossier we assume annually 1 ton of ELT –derived granules are added for maintenance on a full size pitch and 100 kg on a mini-pitch. Refilling is done annually with similar machines to those used during the installation of the pitches. For some areas of the field which are most used, such as in front of the goal and in the center of the field, infill material is added more often during the year.

According to FIFA (2015)[41] chemicals that can be used on synthetic turfs, after authorisation, include algaecides, mossicides, weed killers and de-icers. In this FIFA Quality Program instruction of regular maintenance is provided.

Another maintenance guidance[42] provides the frequencies for the maintenance:

- Raking: 4-6 weeks (indoors: as needed);
- Brushing: 4-6 weeks (indoors: 2-3 weeks);
- Aerating: maximum of 3 times per year, ideally after every sport season, and after snow clearing, if applicable (beginning in second year) (same for indoors); a
- Sweeping: as needed (same for indoors).

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[39] With salting the snow and ice melt quicker and when the slush is removed, it is possible to start using the field earlier than without using de-icing chemicals.

[40] Note that this activity may result in the spreading of infill to the surrounding environment and may result in environmental pollution, see RIVM 2018.

[41] https://football-technology.fifa.com/media/1026/fifa_quality_programme_for_football_turf.pdf

[42] http://www.fieldturf.com/media/W1siZiIsIjIwMTYvMDcvMjAvMTcvMTkvNTYvMzY1L0Jyb2NodXJlX01haW50ZW5hbmNlX0d1aWRlbGluZXNfRmllbGRUdXJmXzIwMTZfRW1haWwucGRmIl1d/Brochure%20-%20Maintenance%20Guidelines%20-%20FieldTurf%20-%202016%20-%20Email.pdf

A.2.3.4. Users of artificial turf

A.2.3.4.1. Players

Football, lacrosse, Gaelic games and rugby are the most popular and most frequently played sports on 3rd generation synthetic turf in Europe (See Table A 3). Football is by far the most popular sport in Europe, claiming 15.4 million registered players in the EU and EEA as of 2015-2016 (UEFA, 2016[43]). In terms of number of players in the EU and European Economic Area, football is followed by rugby, Gaelic sports and lacrosse respectively. The number of rugby players in Europe is estimated to be in excess of 3.6 million (World Rugby, 2016[44]). The number of players for Lacrosse and Gaelic games is far lower, totalling approximately 32 000 and 374 000 players respectively (European Lacrosse Federation, 2017 and GAA, 2017). With exception of Gaelic games, which are sports predominantly played only in the Republic of Ireland, the three other sports have a wider European coverage.

On the basis of the aforementioned information, one may conclude that there are about 20 million registered football, lacrosse, Gaelic games and rugby players in the EEA-31 (EU-28 plus Iceland, Norway and Liechtenstein). This does not include the number of players for other sports, which occasionally may take place on artificial turf pitches. If the number of registered players (i.e. 20 million), is combined with the number of unregistered players, one gets more realistic picture of the population that likely comes in direct contact with artificial turf pitches. For football alone, about 7.2 % of the population in the 55 UEFA associated countries was estimated by UEFA to be a football player (registered and unregistered) in 2016. Assuming that the number (i.e. 7.2 %) is applicable for of EEA-31 (EU-28 plus Iceland, Norway and Liechtenstein) as well, it can be estimated that there are over 38 million players (registered and unregistered) in EEA-31. This number of unregistered football players and registered football players, in other words, is around 1.9 times higher than that of registered players. The number of registered and unregistered football, lacrosse, Gaelic games and rugby players is assumed to be more or less equal to the estimate solely for football (1.9 x 20 million). These figures are further used in Annex D.4.

[43] UEFA football player statistics 2015/2016, personal communication.

[44] http://publications.worldrugby.org/yearinreview2016/en/44-1

Table A 3: Number of registered players in the EU and EEA.

Country	Football[45]	Gaelic games[46]	Lacrosse[47]	Rugby[48]
Austria	295 038	-	275	1 258
Belgium	311 972	-	575	34 261
Bulgaria	32 174	-	30	2 360
Croatia	145 117	-	50	2 882
Czech Republic	309 336	-	1120	14 989
Cyprus	15 293	-	-	-
Denmark	351 935	-	70	7 373
England	1 916 996	-	21 150	2 139 604
Estonia	13 567	-	20	-
Finland	127 145	-	590	5 734
France	1 802 500	-	95	634 028
Germany	3 908 892	-	3170	29 191
Greece	424 713	-	-	-
Hungary	177 561	-	45	5 630
Iceland	20 715	-	-	-
Republic of Ireland	274 260	374 281	260	190 422
Italy	1 111 853	-	185	88 232
Latvia	16 246	-	125	2 225
Lithuania	19 674	-	-	5 925
Liechtenstein	1914	-	-	-
Luxembourg	33 704	-	-	3 768
Malta	30 733	-	-	21 780
The Netherlands	917 770	-	915	64 440
Northern Ireland	44 056	-	-	-
Norway	321 477	-	500	1 853
Poland	843 888	-	400	75 254
Portugal	162 144	-	50	48 551
Romania	117 713	-	-	24 610
Scotland	140 073	-	730	164 191
Slovakia	65 535	-	240	-
Slovenia	44 048	-	20	472
Spain	842 055	-	190	82 220
Sweden	454 811	-	280	5 725
Switzerland	262 567	-	615	7 873
Wales	104 579	-	125	83 120
Total	15 662 054	374 281	31 825	3 665 751

[45] Source: personal communication, UEFA (data for 2015-2016)
[46] Source: personal communication, Gaelic Athletic Association (data for 2017)
[47] Source: personal communication, European Lacrosse Federation (data for 2016)
[48] Source: personal communication, World Rugby (data for 2016) * Total number of players given.

A.2.3.4.2. Other uses of synthetic turfs

Synthetic turf pitches may be used for different type of other sports and plays, e.g. working places, sport clubs may organise recreation days for multifunctional sports. Small children may also play beside the synthetic turfs, for example, while being with their parents who are following their older sisters or brothers playing. In addition, infill material may be carried to homes attached to socks or other clothes, in shoes and other equipment. Babies may place the granules into their mouths, before cleaning of the floors at homes occurs. Some school classes, day-care groups and children in general use the pitches for different types of play/sport activities. Children may especially play on mini-pitches. Synthetic turf pitches may also used for concerts and other type of events where a large number of people are standing and sitting on the field. The number of people, including small children who are using the synthetic turfs with performance infill material, may be considerable. In Annex D a rough estimate of the number of users of mini-pitches is derived to get an idea of the potential size of this group. Note that the users of mini-pitches may be both adults and children.

A.2.4. Use in loose applications

Similar to rubber granules, mulch (or flakes) are regarded as mixtures according to the Guidance on substances in articles[49]. According to ETRMA (2018, replies to questions posed by ECHA and RIVM), there is no harmonised definition of "rubber mulch". ETRMA made a survey in its network and the following is related to the rubber mulch from tyre origin. ELT rubber mulch are around 4-10 mm long. Different types of mulch produced from tyre buffings[50] are placed on the EU market: 10-20 mm long pieces, 30-70 mm long, up to 15 mm width (large) pieces and up to 130 mm long and 10-15 mm width (large) pieces. Typical ones are of 10 – 40 mm long.
Rubber mulch is predominantly produced from recycled tyre buffings or nuggets of synthetic rubber. Other materials such as EPDM are also used to produce rubber mulch, although, to a considerably less extent. It has been estimated that there are about 5 to 20 times more ELT-derived mulch used in the EU than the mulch derived from virgin material (Melos, personal communication). Rubber mulch is shredded up using the same ELT that rubber granules are made from. Hence they contain the same array of substances. Buffings are produced from recycled truck tyre tread and solid tyres when the remainder of the worn-down tread is removed from the tyre prior to retreating. ELT granules used in mulch are produced from an ambient granulation process.
Rubber mulch is usually used in the following applications:

- Playgrounds
- Landscaping
- Gardens
- Parks
- Golf courses
- Nature trails
- Horse arena footing
- Athletic arenas
- Residential

[49] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c
[50] https://spartonenterprises.com/news/what_are_rubber_buffings

Among the applications playgrounds occupy the lions share. It is estimated that about 60 % of rubber mulch ends up being used in playgrounds, whereas the remaining 40 % goes into other applications (Melos, personal communication). In addition to playgrounds, landscaping and gardens are two of the most popular applications in the European Union.
The increasing popularity of rubber mulch within the European Union can be explained with reference to the litany of benefits that they are believed to offer. Some of the key benefits that usually are associated with the use of rubber mulch can be summarized as follows:

- Provides effective shock absorption
- Reduces injury risk and impact attenuation
- Cost-effective
- Low maintenance needs
- Does not rot and decompose
- Wind resistance
- Inhibits weed growth
- Resists mould, mildew and fungi
- Lasts long
- Available in a wide range of colours
- Can cater to various aesthetic requirements

Rubber mulch is used in playgrounds as low impact surface area. The material may be used in loose form and also in situ bonded by a PU based resin. According to ETRMA rubber mulch is always PU coated and mixed with a binder.
The volume of mulch required to cover surfaces depends on the application. There are many mulch calculators available online enabling the calculation of the exact volume of mulch for the given application and specificities (area shape, width, length, and depth).[51] On average, it has been estimated by Melos Gmbh – one of Europe's largest producers of EPDM mulch, that 10 kg of mulch is required for every square meter.
According to ETRMA and other rubber mulch formulators and distributors, there has been some use of mulch observed in France, Germany, the UK, Austria, the Netherlands, Belgium, Bulgaria and Switzerland. It has been also gleaned from various relevant stakeholders that the use of rubber mulch is almost non-existent in Portugal, Spain, and Sweden. In the UK the demand has grown over the past 3 years and the application of mulch in play areas represents around 8 000 tonnes per year. It must be noted here that the use of mulch is most prevalent in the UK when compared with other EU Member States.

A.2.6. End-of-life of artificial turf, granules and mulches

According to ESTO (2018, reply to questions posed by ECHA/RIVM), the lifetime of synthetic turf is typically 10-12 years. ESTO (2017[52]) estimates that 98 % of all synthetic turf sports surfaces will be replaced with another synthetic turf surface. Third generation pitches were developed after 1996 and the use became increasingly popular after 2006 when the EU landfilling prohibitions on ELT material came into force. Some of the turfs have thus already

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[51] https://www.mulchman.co.nz/mulch-calculator (There are many other similar mulch calculators available online that could be obtained by entering the keyword 'mulch calculator' in any of the search engines.

[52] http://www.theesto.com/publications/end-life-statement-synthetic-turf-sports-surfaces/

been replaced and the replacement will continue as the use of the synthetic turfs has been growing. For the ease of analysis therefore, an average 10 year service life is applied in this Dossier, which means that it is assumed that all pitches installed in the year 2005 are assumed to be resurfaced in 2016 (See Annex D). This means that based on our estimations around 62 % of all full size synthetic turf pitch installations will be reinstallations.

A.2.6.1. Reuse and recycling

Synthetic turf will be a waste after its service life. Artificial turf and the infill material used to be landfilled in the EU. Following the 2006 regulatory measures against landfilling applied across the EU, artificial turf and infill material may now go through various recovery routes instead of being landfilled. Artificial turf and infill can be processed or cleaned in order to be suitable for reuse or recycling. Infill material, in particular ELT derived infill, can be re-used multiple times without its quality being compromised according to the sector.

Old synthetic turf can be reused in a myriad of ways. For example, in baseball it can be used in a batting cage, whereas in golf it could be put to use in driving ranges. Sports pitches often rely on the use of old synthetic turf, primarily as grass field side-lines or running track protectors. Furthermore, old synthetic turf is often reused in various landscaping and recreational activities, such as pet parks, dog running space, and play areas. However, if recycling of old synthetic turf, rather than its reusing is opted for, there is a number of ways in which recycling may take place. Used synthetic turf can be converted to energy by means of incineration (cement kilns, district heating), pyrolysis or gasification. ESTO does not recommend this, due to its high CO_2 emissions.

Occasionally there are other uses as well. However, material recycling of the synthetic turf is said to be difficult as the quality of the turf has decreased during the use and it will decrease further when lifting of the turf occurs. As regards infill material, ESTO informs that at least two of its members are currently investing in waste (infill) collection and infill cleaning and separation. Full recycling is also said to be difficult due to the range of materials used in the surface. Actors themselves however, claim to be able to recycle large part of the synthetic turf systems often in other sport applications (personal communication synthetic turf sector). A company formulating TPE infill material in Italy (2017, comments through the call for evidence) noted that TPE infill materials can be reused, or recycled and reused in other plastics applications.

Although material recycling of synthetic turf may be possible, ESTO notes that separation of various polymers into pure enough polymers is expensive, thus the carpets are recycled to produce lower price products such as flower pots. However, attempts are ongoing to convert synthetic turfs into higher value products.

ESTO notes that the infill from recycled tyres (or turf containing ELT infill) is prohibited for disposal in landfill, in the same way as tyres. ESTO also recommends that landfilling of synthetic turf should be avoided. One company specialised in recycling synthetic turf claims that it is much cheaper to recycle a pitch than to landfill it. Their process is patented and provides high purity materials recovered.

The procedure to recycle the synthetic turf is described by one company[53]:
De-sanding the artificial turf field, where sand and rubber are removed from the field. Sand and rubber are then separated and the clean sand can be reused. The rubber will be possibly placed on the market for further recycling. The infill material is reused after dry cleaning, in case the quality of the infill allows for it.
If possible, the artificial turf will be made ready for reuse. When re-use is not an option, further dismantling and recycling are the following steps. After complete unraveling of the artificial turf, synthetic components and latex will be separated, the latex will be used for generating energy and the synthetic materials will then be used for coverings for drainage tubes, infill production for artificial turf and re-granulating for the production of new artificial turf.
Liu Q. et al. (2017) have studied solid-state shear milling technology to produce ultrafine powder from the synthetic turfs. According to the writer the powder can be used to produce wood–plastics products with considerable economic benefits and social effects.[54]
Concerning the substructure of the synthetic turf system, there may be a need to clean the layer in case it is contaminated with the substances leached from infill material such as metals or organic compounds. According to a company formulating TPE infill material in Italy (2017, comments via the call for evidence), due to absence of heavy metals in TPE which can leach into the lower installation levels, no cost for cleaning a potentially contaminated substructure and renovation of this layer, and for possible soil remediation arises if this material is used.

According to various actors in the sector, re-use and recycling of synthetic turf is still limited in practice in Europe, although there may be differences among Member States. In the Netherlands for example it is said that large part of artificial turf is currently recycled. Because not much information is available to the Dossier Submitter on the actual re-use of infill materials for a second or third (etc.) life on synthetic turf pitches, for the ease of analysis in the Annex XV dossier, re-use of granules is assumed to be zero.

A.2.6.2. Waste prevention

ESTO has identified three items to prevent the generation of waste at the end of service life of a synthetic turf system:

1. Infill free systems: more than 90% of the weight of the turf system consists of infill material hence, infill free systems would reduce the waste volume, There are initiatives developing infill free systems and the first systems are currently tested in practice in the Netherlands;
2. Longer life turf: delays the need for early replacement. The Dossier Submitter does not have further information on this development to expand the life-time of synthetic turf;
3. Improved shockpads: providing the possibility to lay the new turf over the existing shockpad.

[53] https://www.tufrecycling.nl/en
[54] http://pubs.rsc.org/en/content/articlepdf/2017/ra/c7ra11206h

A.2.7. Uses advised against

Several formulators of infill material using recycled tyres as a raw material say to only use tyres that have been produced or imported after 2010, when the restriction on extender oils became effective. This is not a formal use advised against by actors, however, it may be interpreted like that. The Dossier Submitter does not know how formulators handle tyres from before 2010 in practice and whether it is common practice in the EU to separate these.

A.3. Relevant existing legislation

A.3.1. REACH: PAHs in mixtures

Recycled rubber granules and mulches are regarded as mixtures as agreed upon by the European Commission supported by a majority of Member States (see CA/30/05/2016 CARACAL paper). REACH restrictions that apply to these type of mixtures are entry 5 to Annex XVII of REACH on benzene and entries 28-30 on CMR substances.

- Entry 5 (benzene): Shall not be placed on the market or used in mixtures (concentration limit value; equal to or greater than 0.1 % by weight).
- Entries 28-30: CMR substances (categories 1A and 1B) shall not be placed on the market or used in mixtures for supply to the general public.

Harmonized CLP classifications and concentration limits for the eight PAHs specified in REACH Annex XVII entry 28-30 are shown in Table A 4. In its scope, this existing entry 28-30 restriction does affect granules and mulches placed on the market for use on synthetic turf pitches and in loose form on playgrounds as, according to the legal interpretation by the European Commission, these uses should be regarded as 'supply to the general public'. This is consistent with the interpretation given in ECHA's guidance on paragraph 5 and 6 of entry 50 of Annex XVII (ECHA guidance March 2018). In this guidance the term 'supply to the general public' is explained. Playgrounds located in public areas and football pitches in most cases are owned by local municipalities and are used by members of a sports club that are part of the general public as a whole. The PAH content limit values of this restriction for supply to the general public are too high to provide a strict control of risks according to the Dossier Submitter (see Annex B), which has formed the basis for the current restriction proposal.

Table A 4: CLP harmonized classification and concentration limit values for eight PAHs in Annex XVII entries 28-30.

Name	EC Number	CAS Number	CLP Annex VI harmonized classification	Limit value[55] (% w/w)	Limit value (mg/kg)
Benzo[a]pyrene (BaP)	200-028-5	50-32-8; 63466-71-7	Carc. 1B (H350) Muta. 1B (H340) Repro. 1B (H360FD)	0.01	100
Benzo[e]pyrene (BeP)	205-892-7	192-97-2	Carc. 1B (H350)	0.1	1000
Benzo[a]anthracene (BaA)	200-280-6	56-55-3; 1718-53-2	Carc. 1B (H350)	0.1	1000
Chrysene (CHR)	205-923-4	218-01-9; 1719-03-5	Carc. 1B (H350) Muta. 2 (H341)	0.1	1000
Benzo[b]fluoranthene (BbFA)	205-911-9	205-99-2	Carc. 1B (H350)	0.1	1000
Benzo[j]fluoranthene (BjFA)	205-910-3	205-82-3	Carc. 1B (H350)	0.1	1000
Benzo[k]fluoranthene (BkFA)	205-916-6	207-08-9	Carc. 1B (H350)	0.1	1000
Dibenzo[a,h]anthracene (DBAhA)	200-181-8	53-70-3	Carc. 1B (H350)	0.01	100

A.3.2. REACH: PAHs in extender oil and PAHs in articles

Paragraph 1 of entry 50 of Annex XVII of REACH describes that from 1 January 2010 onwards extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres, if they contain more than 1 mg/kg (0.0001 % by weight) BaP, or more than 10 mg/kg (0.001 % by weight) of the sum of the 8 listed PAHs. Paragraph 2 of this entry describes that tyres and treads for retreating manufactured after 1 January 2010 shall not be placed on the market if they contain extender oils exceeding the limits indicated above. Paragraphs 3 and 4 define a derogation related to retreading and further define the term 'tyre'. Based on information that is available to the Dossier Submitter this restriction on extender oils has reduced the PAH levels in tyres manufactured in the EU and imported into the EU to the level that is currently found in tyres. In the analysis of available samples from 2010 to 2017 a decrease in PAH content is observed, which levels of in the last three years (see Annex D and Appendix B1). The information suggests that any effect of the 2010 extender oil restriction has already become effective in the waste phase and that industry already before 2010 took measures to reduce PAH content in extender oil and tyres.

Paragraph 5 and 6 of entry 50 describe the restriction on the 8 listed PAHs in articles and toys. Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0.0001 % by weight of this component) of any of the listed PAHs (paragraph 5). Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0.5 mg/kg (0.00005 % by weight of this component) of any of the

[55] Limit value applicable based on harmonized classification as Carc. 1B (H350) (specific concentration limits applicable to Benzo[a]pyrene (BaP) and Dibenzo[a,h]anthracene (DBAhA))

listed PAHs (paragraph 6). On request of the European Commission, in March 2018 ECHA published a Guideline to further clarify the scope of this restriction[56].

Currently, there are several ways to determine the PAH content in rubber of plastic matrices. However, there is no set standard at this moment. The European Committee for Standardisation (CEN) and more precisely, a dedicated CEN Technical Committee has initiated the process to develop standards to determine the PAH content in materials obtained from ELT. The documents which are currently under preparation include:

"Materials obtained from End of Life Tyres – Derived rubber – State of the art concerning PAH determination" and

"Materials obtained from End of Life Tyres – Derived rubber – Determination of the PAH content".

In parallel, the European Commission has requested the Joint Research Centre (JRC) to develop a method to determine the migration of PAHs from plastic and rubber articles (Final Draft report is submitted to Commission). More information on available analytical methods is presented in Appendix E1.

A.3.3. Waste framework directive

Some Member States have stated that rubber granules from recycled tyres are waste. According to REACH Article 2(2), waste as defined in the waste framework directive is not a substance, mixture or article within the meaning of REACH and any current restrictions do not apply to waste. According to the Waste Framework Directive, waste ceases to be waste if criteria have been set at Community level or if Member States have decided on this and notified the Commission. In addition, case-by-case decisions can be made by Member States and these do not have to be notified to the Commission. If criteria would be developed, they should take into account that the use of the substance or object will not lead to overall adverse environmental or human health impact. Criteria have not been set at Community level. Only one Member State has notified the Commission on setting of criteria.

A.3.4. European Landfilling Directive

The European ban on landfilling of whole waste tyres from July 2003 and on shredded tyres from 2006 under the European Landfill Directive (1999/31/EC) had the effect of encouraging the recycling of waste tyres. Waste incineration possibilities of ELT are limited because of the high caloric value of the rubber material due to which waste tyres cannot be incinerated in regular waste incineration facilities. Part of the EU waste tyres are incinerated, mainly in cement kilns (see A.1.3.). Capacity for use of ELT-tyres is said to be limited in these systems. Between 1996 and 2015 the percentage of all EU waste tyres that were landfilled or with unknown reported destination decreased from 49% to about 8%, and remained at that level until 2016. The share of waste tyres used for energy recovery appeared to be stable between 20 % in 1996 and 28 % in 2015. The material recovery

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56 https://echa.europa.eu/documents/10162/106086/guideline_entry_50_pahs_en.pdf/f12ac8e7-51b3-5cd3-b3a4-57bfc2405d04

share in the same period increased from 11 % to 46 % (see Figure A 2). The EU-wide prohibitions on landfilling together with the specific material properties have thus provided a basis for the recycling sector to develop tyre recycling options in the area of material recovery. The manufacture and placing on the market of granules for use as infill in synthetic turf pitches and rubber mulch and granules for playgrounds is one of these recycling options.

A.3.5. Worker protection legislation

The Chemical Agents Directive (98/24/EC) and the Directive on Carcinogens and Mutagens at work (2004/37/EC) aim to protect workers from chemical risks at the workplace. The employer's obligation is to assess any risk to the safety and health arising from the hazardous substances present at the workplace. If a risk is identified, employers are required to eliminate or reduce the risk to a minimum. Under the Chemicals Agents Directive, several occupational exposure limit values (OELs), both indicative and binding, as well as biological limit values have been established. In addition, each Member State may have limit values for other substances or higher limit values compared to the EU OELs. PAHs in recycled rubber granules may be released to the air or in the airborne dust. The relevant OELs (or biological limit values) need to be followed.

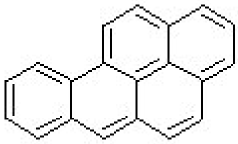
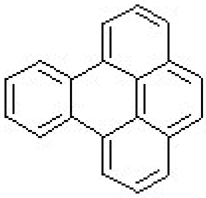
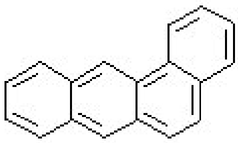
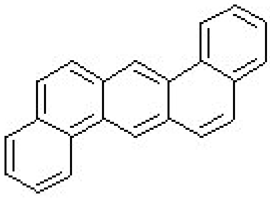
Annex B: Information on hazard and risk

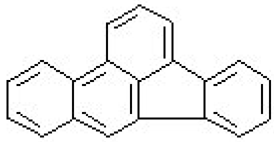
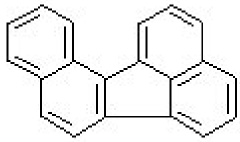
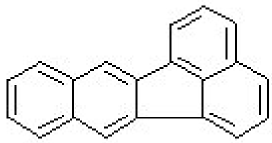
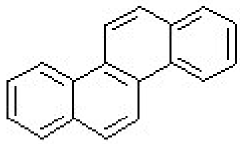
B.1. Identity of the substance(s) and physical and chemical properties

As explained in section 1.2 of this restriction dossier, the scope is limited to the eight PAHs included in entry 50 to Annex XVII of REACH: benzo[a]pyrene (BaP), benzo[e]pyrene (BeP), benzo[a]anthracene (BaA), dibenzo[a,h]anthracene (DBAhA), benzo[b]fluoranthene (BbFA), benzo[j]fluoranthene (BjFA), benzo[k]fluoranthene (BkFA) and chrysene (CHR).

B.1.1. Name and other identifiers of the substance(s)

Textbox B 1: Information on the composition of the REACH-8 PAHs

Chemical Name: **Benzo[a]pyrene** EC Number: 200-028-5 CAS Number: 50-32-8 IUPAC Name: Benzo[d,e,f]chrysene	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Benzo[e]pyrene** EC Number: 205-892-7 CAS Number: 192-97-2 IUPAC Name: 1,2-Benzopyrene	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Benzo[a]anthracene** EC Number: 200-280-6 CAS Number: 56-55-3 IUPAC Name: 1,2-Benzanthracene	Molecular weight: 228.3 g/mol Molecular formula: $C_{18}H_{12}$ Structural formula: 
Chemical Name: **Dibenzo[a,h]anthracene** EC Number: 200-181-8 CAS Number: 53-70-3 IUPAC Name: 1,2:5,6-Dibenzanthracene	Molecular weight: 278.3 g/mol Molecular formula: $C_{22}H_{14}$ Structural formula: 
Chemical Name: **Benzo[b]fluoranthene** EC Number: 205-911-9 CAS Number: 205-99-2 IUPAC Name: 2,3-Benzfluoranthene	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula:

	
Chemical Name: **Benzo[j]fluoranthene** EC Number: 205-910-3 CAS Number: 205-82-3 IUPAC Name: 10,11-Benzofluoranthene	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Benzo[k]fluoranthene** EC Number: 205-916-6 CAS Number: 207-08-9 IUPAC Name: 11,12-Benzofluoranthene	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Chrysene** EC Number: 205-923-4 CAS Number: 218-01-9 IUPAC Name: 1,2-Benzophenanthrene	Molecular weight: 228.3 g/mol Molecular formula: $C_{18}H_{12}$ Structural formula: 

B.1.2. Composition of the substance(s)

The textbox below presents some information on the composition of rubber granules with respect to the eight PAHs under current evaluation. The concentration data of PAHs in ELT granules are provided by industry, authorities, other stakeholders and obtained from public literature sampled (from a granules production site or a sports field) in the EU in the year 2010 or later. Values below LOD are set to LOD. See Annex B.1. for details.

Textbox B 2: information on the composition of the REACH-8 PAHs

Chemical Name: **Benzo[a]pyrene** EC Number: 200-028-5 CAS Number: 50-32-8 IUPAC Name: Benzo[d,e,f]chrysene Concentration range (P01-P99): 0.20 – 3.1 mg/kg
Chemical Name: **Benzo[e]pyrene** EC Number: 205-892-7 CAS Number: 192-97-2 IUPAC Name: 1,2-Benzopyrene Concentration range (P01-P99): 0.44 – 5.8 mg/kg
Chemical Name: **Benzo[a]anthracene** EC Number: 200-280-6 CAS Number: 56-55-3 IUPAC Name: 1,2-Benzanthracene Concentration range (P01-P99): 0.20 – 3.9 mg/kg
Chemical Name: **Dibenzo[a,h]anthracene** EC Number: 200-181-8 CAS Number: 53-70-3 IUPAC Name: 1,2:5,6-Dibenzanthracene Concentration range (P01-P99): 0.10 – 1.0 mg/kg
Chemical Name: **Benzo[b]fluoranthene** EC Number: 205-911-9 CAS Number: 205-99-2 IUPAC Name: 2,3-Benzfluoranthene Concentration range (P01-P99): 0.20 – 4.0 mg/kg
Chemical Name: **Benzo[j]fluoranthene** EC Number: 205-910-3 CAS Number: 205-82-3 IUPAC Name: 10,11-Benzofluoranthene Concentration range (P01-P99): 0.20 -1.7 mg/kg
Chemical Name: **Benzo[k]fluoranthene** EC Number: 205-916-6 CAS Number: 207-08-9 IUPAC Name: 11,12-Benzofluoranthene Concentration range (P01-P99): 0.15 – 1.9 mg/kg
Chemical Name: **Chrysene** EC Number: 205-923-4 CAS Number: 218-01-9 IUPAC Name: 1,2-Benzophenanthrene Concentration range (P01-P99): 0.20 – 4.4 mg/kg

B.1.3. Physicochemical properties

Textbox B 3: Pysiocochemical properties of the REACH-8 PAHs

Property	Substance	Value	Reference
Physical state	Benzo[a]pyrene	yellowish	WHO (1998)
	Benzo[e]pyrene	pale yellow	WHO (1998)
	Benzo[a]anthracene	colourless	WHO (1998)
	Dibenzo[a,h]anthracene	colourless	WHO (1998)
	Benzo[b]fluoranthene	colourless	WHO (1998)
	Benzo[j]fluoranthene	yellow	WHO (1998)
	Benzo[k]fluoranthene	pale yellow	WHO (1998)
	Chrysene	colourless	WHO (1998)
Melting point	Benzo[a]pyrene	178.1 °C	WHO (1998)
	Benzo[e]pyrene	178.7 °C	WHO (1998)
	Benzo[a]anthracene	160.7 °C	WHO (1998)
	Dibenzo[a,h]anthracene	266.6 °C	WHO (1998)
	Benzo[b]fluoranthene	168.3 °C	WHO (1998)
	Benzo[j]fluoranthene	165.4 °C	WHO (1998)
	Benzo[k]fluoranthene	215.7 °C	WHO (1998)
	Chrysene	253.8 °C	WHO (1998)
Boiling point	Benzo[a]pyrene	496 °C	WHO (1998)
	Benzo[e]pyrene	493 °C	WHO (1998)
	Benzo[a]anthracene	400 °C	WHO (1998)
	Dibenzo[a,h]anthracene	524 °C	WHO (1998)
	Benzo[b]fluoranthene	481 °C	WHO (1998)
	Benzo[j]fluoranthene	480 °C	WHO (1998)
	Benzo[k]fluoranthene	480 °C	WHO (1998)
	Chrysene	448 °C	WHO (1998)
Relative density	Benzo[a]pyrene	1.351	WHO (1998)
	Benzo[e]pyrene	Not available	
	Benzo[a]anthracene	1.226	WHO (1998)
	Dibenzo[a,h]anthracene	1.282	WHO (1998)
	Benzo[b]fluoranthene	Not available	
	Benzo[j]fluoranthene	Not available	
	Benzo[k]fluoranthene	Not available	
	Chrysene	1.274	WHO (1998)
Vapour pressure	Benzo[a]pyrene	7.3 E-7 Pa at 25 °C	WHO (1998)
	Benzo[e]pyrene	7.4 E-7 Pa at 25 °C	WHO (1998)
	Benzo[a]anthracene	2.8 E-5 Pa at 25 °C	WHO (1998)
	Dibenzo[a,h]anthracene	1.3 E-8 Pa at 20 °C	WHO (1998)
	Benzo[b]fluoranthene	6.7 E-5 Pa at 20 °C	WHO (1998)
	Benzo[j]fluoranthene	2.0 E-6 Pa at 25 °C	WHO (1998)
	Benzo[k]fluoranthene	1.3 E-8 Pa at 20 °C	WHO (1998)
	Chrysene	8.4 E-5 Pa at 20 °C	WHO (1998)
Partition coefficient n-octanol/water (log value)	Benzo[a]pyrene	6.50	WHO (1998)
	Benzo[e]pyrene	6.44	WHO (1998)
	Benzo[a]anthracene	5.61	WHO (1998)
	Dibenzo[a,h]anthracene	6.50	WHO (1998)
	Benzo[b]fluoranthene	6.12	WHO (1998)
	Benzo[j]fluoranthene	6.12	WHO (1998)
	Benzo[k]fluoranthene	6.84	WHO (1998)
	Chrysene	5.91	WHO (1998)
Water solubility	Benzo[a]pyrene	0.0038 mg/L at 25 °C	WHO (1998)
	Benzo[e]pyrene	0.0051 mg/L at 23 °C	WHO (1998)
	Benzo[a]anthracene	0.014 mg/L at 25 °C	WHO (1998)
	Dibenzo[a,h]anthracene	0.0005 mg/L at 27 °C	WHO (1998)
	Benzo[b]fluoranthene	0.0012 mg/L at 20 °C	WHO (1998)
	Benzo[j]fluoranthene	0.0025 mg/L at 25 °C	WHO (1998)
	Benzo[k]fluoranthene	0.00076 mg/L at 25 °C	WHO (1998)
	Chrysene	0.0020 mg/L at 25 °C	WHO (1998)

B.1.4. Justification for grouping

Numerous PAHs have been investigated for their carcinogenic potential and many PAHs share the same genotoxic mechanism of action, i.e. metabolic activation to electrophilic dihydrodiol epoxides and/or quinones which are capable of covalent binding to DNA (WHO, 1998). Consumers and workers exposed to PAH-containing rubber granules will not be exposed to a single PAH but will inevitably be exposed to complex mixtures of probably up to several hundred PAHs.

The eight PAHs addressed by this dossier currently have a harmonised classification for carcinogenicity under the CLP regulation (Annex VI to Reg. (EC) No. 1272/2008). Furthermore, BaP and CHR are classified for mutagenicity and BaP also for toxicity to reproduction and skin sensitisation under the CLP regulation. Consequently, from the perspective of consumer and worker protection, highest priority should be given to the regulation of these eight substances in one group. Moreover, these eight PAHs have previously been the subject of a previous restriction dossier, as prepared by Germany (BAuA, 2010), focussing on establishing a concentration limit for PAHs in consumer products. The REACH-8 PAHs are included in Annex XVII entry 50 of REACH.

In addition to those addressed in this dossier, clearly many more of the PAHs possibly contained in rubber granules may be genotoxic carcinogens (while others may not) and the reason for them not being listed in Annex VI to the CLP regulation may simply be that they have up to now not been evaluated for their carcinogenicity.

B.2. Manufacture and uses (summary)

Please refer to Annex A.

B.3. Classification and labelling

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Table B 1: CLH Classification of the REACH-8 PAHs

Name	CAS	CLH according 1272/2008 (including possible SCLs and M-factors)
Benzo[a]pyrene	50-32-8	Skin Sens. 1 (H317) Muta. 1B (H340) Carc. 1B (H350) (SCL: C ≥ 0.01 %) Repro. 1B (H360FD) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[e]pyrene	192-97-2	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[a]anthracene	56-55-3	Carc. 1B (H350) Aquatic Acute 1 (H400) (M=100) Aquatic Chronic 1 (H410)
Dibenzo[a,h]anthracene	53-70-3	Carc. 1B (H350) (SCL: C ≥ 0.01 %) Aquatic Acute 1 (H400) (M=100) Aquatic Chronic 1 (H410)
Benzo[b]fluoranthene	205-99-2	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[j]fluoranthene	205-82-3	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[k]fluoranthene	207-08-9	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Chrysene	218-01-9	Muta. 2 (H341) Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

B.3.2. Classification and labelling in classification and labelling inventory/ Industry's self classification(s) and labelling

The self-classifications written in *italic* in the table below are additional when compared to the harmonised classifications according to EC Regulation 1272/2008.

Table B 2: Self classification of the REACH-8 PAHs

Name	CAS	Self-classification
Benzo[a]pyrene	50-32-8	Skin Sens. 1 (H317) Muta. 1B (H340) Carc. 1B (H350) Repro. 1B (H360FD) *Repro. 2 (H360)** Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) *Aquatic Chronic 4 (H413)*
Benzo[e]pyrene	192-97-2	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[a]anthracene	56-55-3	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Dibenzo[a,h]anthracene	53-70-3	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[b]fluoranthene	205-99-2	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[j]fluoranthene	205-82-3	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[k]fluoranthene	207-08-9	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Chrysene	218-01-9	Muta. 2 (H341) *Carc. 1A (H350)* Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

* it is noted that a Repro. 2 classification should correspond with a H361 hazard statement

B.4. Environmental fate properties

Not quantified for this dossier.

B.5. Human health hazard assessment

Hazards and risks of PAHs and PAH-containing materials were reviewed within various risk assessment frameworks and 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). Recently, ECHAs Risk Assessment Committee (RAC) established a dose-response relationship for the carcinogenicity of coal tar pitch - high temperature (CTPHT) (ECHA 2017c).

These reports have assessed the animal and human toxicological data on PAHs in detail and it is not the goal of this dossier to redo those assessments.

Given the targeting, primarily mutagenicity (section B.5.7.) and carcinogenicity (section B.5.8.) will be addressed, as well as toxicokinetics (section B.5.1.).

B.5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

Extensive descriptions are available in the standard reviews, e.g. ATSDR (1995), EFSA (2008), EU (2008) and WHO (1998+2003).

B.5.1.1. Absorption

B.5.1.1.1 Oral

Recently, RIVM (2016) evaluated, as part of their assessment of the product limit of PAHs in rubber articles, the available data on oral absorption. Based on this, RIVM (2016, 2017) selected an oral absorption fraction of 0.3 which will be used for current evaluation as well. It is noted that this value will only be applied for route-to-route extrapolation (see section B.5.11.), and the risk assessment will be based on an external dose metric. Below, a justification for this value is described (based on RIVM 2016).

For experimental animals, the gastro-intestinal absorption of PAHs, especially BaP, is well documented. Absorption of (unbound) PAHs from the gastro-intestinal tract appears to vary per animal species. Table B 3 provides an overview of studies on oral bioavailability of PAH in different species. Oral absorption of BaP was reported to be 35-99 % in rats, 12 % in goats and 30.5 % in pigs. It is known that the use of rodent models for human exposure assessment is limited by the physiological differences between rodents and primates (Zhang et al., 2013). In fact, no single animal can mimic the gastro-intestinal tract characteristics of humans. However, pig and human colon morphology appears similar (Zhang et al., 2013, Kararli, 1995). Furthermore, in the pig study the PAHs were administered orally via milk, which is considered a relevant vehicle because it is likely that children playing outside and people playing sports are (semi-) fed rather than fasted. For these reasons, an oral absorption fraction of 0.3 (30 %) was assumed, based on the report by Cavret et al. (2003).

Table B 3: Overview of oral bioavailability studies (taken from: RIVM, 2016)

PAH	Animal	Route of administration	Bioavailability %	Reference
BaP	rat	Oral gavage	35-99 %	Ramesh et al., (2004); as cited by EFSA (2008)
Chrysene	Rat	Oral gavage	75-87 %	Ramesh et al. (2004)
BaP	Pig	Orally via milk	30.5 %	Cavret et al. (2003)
BaP	Goat	Oral gavage	12 %	Grova et al. (2002)
BaP	Rat	Intraduodenal infusion	30 %	Foth et al. (1988)
BaP	Rat	Oral gavage	10 %	Foth et al. (1988)
BaP	Rat	Oral gavage	40 %	Ramesh et al. (2001)

B.5.1.1.2 Dermal

Recently, RIVM (2016) evaluated, as part of their assessment of the product limit of PAHs in rubber articles, the available data on dermal absorption. Based on this, RIVM (2016, 2017) selected a dermal absorption fraction of 0.2 which will be used for current evaluation as well. It is noted that this value will only be applied for route-to-route extrapolation (see section B.5.11.), and the risk assessment will be based on an external dose metric. Below, a justification for this value is described (taken from RIVM 2016).

Studies investigating the dermal absorption fraction of PAHs in animals and humans have used soil or a solvent like acetone or ethanol as vehicle. Ruby et al. (2016) and Spalt et al. (2009) reviewed earlier investigations of dermal absorption of BaP from soil. Figure B 1 shows an overview of all available *in vitro* and *in vivo* dermal absorption data in both animals and humans with the vehicle soil or solvent (acetone or ethanol) (see Table B 5 for detailed information on the data). Dermal uptake of BaP/PAHs from soil appears to be lower compared to the situation when acetone or ethanol was used as a vehicle (Figure B 1). In general, animal studies report percentages between 7-100 % or 0-65 % in solvent and soil respectively. Human studies report percentages between 4-78 % or 0-27 % in solvent and soil respectively (Figure B 1). In the current assessment, it is assumed that after diffusion to the skin, the PAHs are present on the skin in an unbound state, *i.e.* not bound to soil, rubber or any other particles. Implicitly, it follows that absorption of unbound PAHs is more efficient compared to absorption of PAHs from soil, which first need to partition from the soil before they can be absorbed. Hence, the actual absorption fraction is probably larger than those empirically derived with soil as vehicle. On the other hand, it is assumed that applying PAHs in the presence of a solvent enhancing the absorption, overestimates the required absorption fraction. This is in agreement with BAuA (2010), who report that the use of these highly lipophilic solvents may result in an overestimation of PAH migration rates. For this reason, an estimate of 20 % for dermal absorption was used in the present report, which is smaller than most empirical findings in humans using a solvent but larger than most findings using soil as a vehicle (Figure B 1).

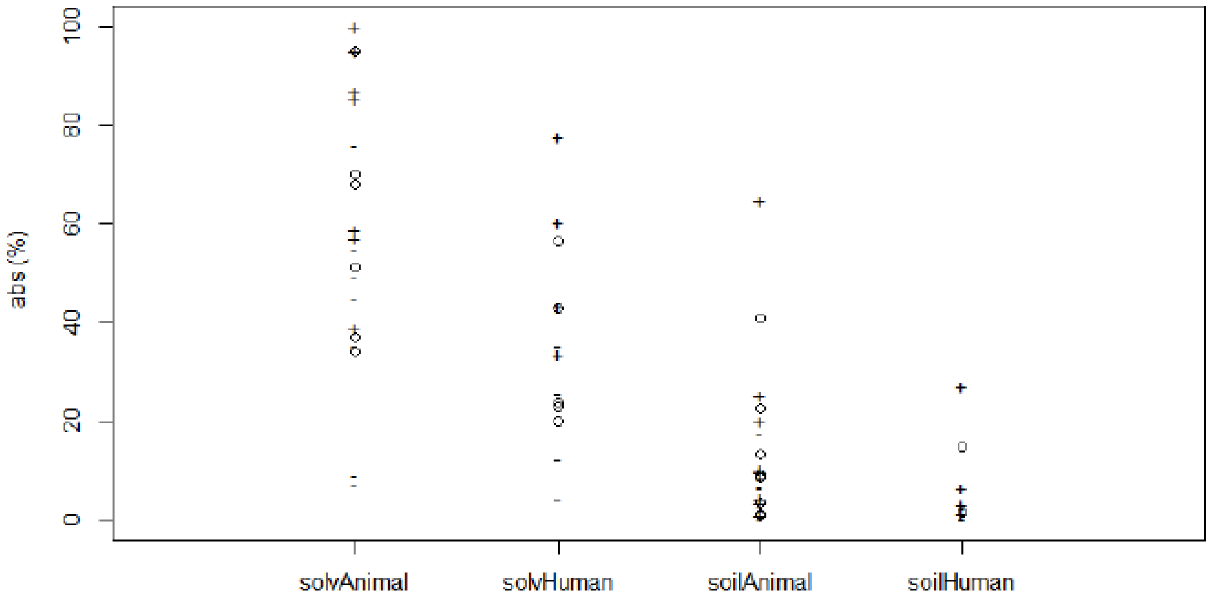


Figure B 1*:* Dermal absorption data based on literature in vitro and in vivo data in soil or solvent (acetone/ethanol). Circles indicate mean, -/+ indicate reported minimum and maximum values or are an approximation of the range obtained by taking mean -/+ 2SD (taken from: RIVM, 2016).

Table B 4: Detailed information on the dermal absorption data (this refers to BaP unless otherwise stated) as used for setting a dermal absorption fraction (taken from: RIVM, 2016).

	Vehicle	Value %	Reference
Human skin	Acetone	23.7 % ± 9.7 %	Wester et al. (1990)
Rhesus monkey	Acetone	51 %(± 22)	Wester et al. (1990)
Hairless guinea pig	Acetone	37 % (± 0.9)	Ng et al. (1992)
Human Skin	Acetone	56.4 %(±10.59)	Moody et al. (2007)
Human Skin	Ethanol	20 %	Bartsch et al. (2016)
In vitro (rat, hairless guinea pig,human; Testskin;human In vivo rat and guinea pig	Acetone, according to abstract of ref #10	Animal	Moody et al. (1995)
Human skin	Soil	1.4 % ± 0.9	Wester et al. (1990)
Rhesus monkey	Soil	13.2 % ± 3.4	Wester et al. (1990)
Human Skin	Soil	14.8 % ± 6.17	Moody et al. (2007)
In vitro human skin	Soil	Between ~0.3% and ~1.1 %	Roy and Singh (2001)
Pig skin	Sand or Clay, pure BaP	9.0 ± 0.4 – 22.7 ± 1.3	Abdel-Rahman et al. (2000)
In vitro human skin	Soil. aged	0.14 - 1.1 %	Stroo et al. (2005)
In vitro pig skin	Pure, soil and aged soil	Pure: 76±3.2 Soil:8.5±0.9 Soil : 3.5±0.5 Aged soil: 3.7±0.5 Aged soil:1.8±0.2	Turkall et al. (2010)
In vitro human skin	Soil	0.2-6.5 %	Roy et al. (1998)
In vitro and in vivo rat	1) BaP in crude petroleum 2) Soil fortified with BaP in crude petroleum	In Vitro, @24h 1) ~12 % 2) ~1 % In Vivo, @24h 1) 5.5 % (se=1.4) 2) 1.1 % (se=0.3)	Yang et al. (1989)
Vitro human (n=14) and guinea pig (n=5) skin	Sediment	Guinea pig: Naphthalene: 59±15.5 Phenanthrene:62±6.5 BaP: 41±11.9 Human: Phenanthrene:14±6.6	Moody et al. (1995)

The Dossier Submitter notes that the selected values for oral and dermal absorption differ from the ones used by ECHA (2017a, 2017c). In their evaluation of the possible health risks of recycled rubber granules, ECHA (2017a) applied an oral absorption fraction of 0.5. Recently, ECHAs RAC, in their evaluation of a dose-response for carcinogenicity for CTPHT, proposed an oral absorption fraction of 1 and a dermal absorption fraction of 0.3 (ECHA, 2017c). As noted, the absorption fractions will be applied for route-to-route extrapolation (see section B.5.11.). As, in case of route-to-route extrapolation, a limited absorption for the starting route and a high absorption for the route of interest would lead to a worst-case estimate, the Dossier Submitter considers, also taking into account the chemical-specific data on absorption, that an oral absorption fraction of 0.3 and a dermal absorption fraction of 0.2 would result in a realistic worst-case risk assessment.

B.5.1.1.3 Inhalation

Occupational studies provide evidence that inhaled PAHs are absorbed by humans. Animal studies also show that pulmonary absorption of BaP occurs and may be influenced by carrier particles and solubility of the vehicle; however, the extent of absorption is not known (ATSDR, 1995). It is noted that ECHAs RAC assumed the default absorption from inhalation exposure of 100 % for both experimental animals and humans since quantitative data on the absorption of PAHs from CTPHT and CTPHT volatiles after inhalation exposure for humans are lacking (ECHA, 2017c).

B.5.1.2. Distribution

Extensive summaries of the available data on distribution have been provided a.o. by ATSDR (1995), WHO (1998 or 2003), or EFSA 2008.

A summary is provided by WHO (2003):

"In laboratory animals, PAHs become widely distributed in the body following administration by any one of a variety of routes and are found in almost all internal organs, particularly those rich in lipid (WHO, 1997). Maximum concentrations of BaA in perfused tissues (e.g. liver, blood, brain) were achieved within 1–2 hours after administration of high oral doses (76 and 152 mg/kg of body weight). In lesser perfused tissues (e.g. adipose and mammary tissue), maximum levels of this compound were reached in 3–4 hours (Bartosek et al., 1984). In male Wistar rats receiving a gavage dose of 2–15 mg of [^{14}C]-pyrene per kg of body weight, the fat had the highest levels of radioactivity, followed by the kidney, liver, and lungs (Withey et al., 1991). Orally absorbed DBAhA in rats was also widely distributed to several tissues. After continuous oral administration of 0.5 µg of [^{3}H]BaP daily to male rats for up to 7 days, the radioactivity persisted in liver, kidney, lung, and testis (Yamazaki & Kakiuchi, 1989). Orally administered BaP (200 mg/kg of body weight) has been shown to cross the placental barrier and has been detected in fetal tissues (2.77 µg/g) (Shendrikova & Aleksandrov, 1974). Using ^{14}C-tagged BaP, a BaP concentration 1–2 orders of magnitude lower in embryonic than in maternal tissues was determined after oral administration in mice (Neubert & Tapken, 1988). Differences in concentrations in the fetus among the various PAHs appeared to be highly dependent on the gastrointestinal absorption of the compound."

B.5.1.3. Metabolism

A short summary is provided in WHO (2003):

"The metabolism of PAHs is complex. Generally, the process involves epoxidation of double bonds, a reaction catalysed by the cytochrome P-450-dependent monooxygenase, the rearrangement or hydration of such epoxides to yield phenols or diols, respectively, and the conjugation of the hydroxylated derivatives. Reaction rates vary widely, and interindividual variations of up to 75-fold have been observed, for example, with human macrophages, mammary epithelial cells, and bronchial explants from different donors. Most metabolism results in detoxification, but some PAHs in some situations become activated to DNA-binding species, principally diol-epoxides, that can initiate tumours (WHO, 1997). Although the PAHs are similar, they have structural differences that are the basis for differences in metabolism and relative carcinogenicity. The metabolism of the more carcinogenic, alternant (equally distributed electron density) PAHs, such as BaP, BaA, and DBAhA, seems to differ in some ways from that of non-alternant (uneven electron density distribution)

PAHs, such as FA, BbFA, BkFA, BjFA, IP [Indeno[1,2,3-cd]pyrene]*, BghiP* [Benzo[ghi]perylene]*, and PY (Phillips & Grover, 1994; ATSDR, 1995). In general, little is known about the metabolism of most PAHs, particularly in non-rodent species. It should be noted that there appear to be species differences in the enzymes that activate PAHs (Michel et al., 1995) and in the formation of DNA adducts (Kulkarni et al., 1986).”*

It should be noted that metabolic activation is seen as a prerequisite for the carcinogenic potential of the PAHs covered by this dossier, as has been extensively discussed in other reviews of PAH toxicity. See also section B.7. on mutagenicity below.

B.5.1.4. Elimination

Extensive summaries of the available data on elimination have been provided a.o. by ATSDR (1995), WHO (1998 or 2003), or EFSA 2008.

A summary is provided by WHO (2003):

“PAH metabolites and their conjugates are excreted predominantly via the faeces and to a lesser extent in the urine. Conjugates excreted in the bile can be hydrolysed by enzymes of the gut flora and reabsorbed. It can be inferred from available data on total body burdens in humans that PAHs do not persist for long periods in the body and that turnover is rapid. This excludes those PAH moieties that become covalently bound to tissue constituents, in particular to nucleic acids, and are not removed by repair (WHO, 1997). The excretion of urinary metabolites is a method used to assess internal human exposure of PAHs.”

B.5.2. Acute toxicity

Not relevant for this dossier.

B.5.3. Irritation

Not relevant for this dossier.

B.5.4. Corrosivity

Not relevant for this dossier.

B.5.5. Sensitisation

Not relevant for this dossier. Of the eight PAHs evaluated in this dossier, only BaP has a harmonised classification for skin sensitisation in Annex VI of CLP (cf. section B.3.1.).

B.5.6. Repeated dosed toxicity

Not relevant for this dossier.

B.5.7. Mutagenicity

Of the eight PAHs evaluated in this 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 discussed the mutagenicity of these PAHs. The table below presents an overview.

Table B 5: Mutagenicity/carcinogenicity of polycyclic aromatic hydrocarbons: overall overview of regulatory evaluations

Chemical	**Mutagenicity**				**Carcinogenicity**	
	EC 1272/2008	**WHO/IPCS (1998)**	**EC (2002)**	**FAO/WHO (2006)**	**EC 1272/2008**	**IARC**
Benzo[a]pyrene (50-32-8)	Muta. 1B (H340)	Genotoxic	Genotoxic (positive results in vitro and in vivo for multiple end-points; positive also at germ cell level)	Genotoxic, both in vitro and in vivo	Carc. 1B (H350)	Group 1
Benzo[e]pyrene (192-97-2)	no	Genotoxic	Equivocal (mixed results in vitro, inconsistent results in vivo)	-	Carc. 1B (H350)	Group 3
Benzo[a]anthracene (56-55-3)	no	Genotoxic	Genotoxic (positive results in vitro and in vivo for multiple end-points; positive also at germ cell level)	Genotoxic, both in vitro and in vivo	Carc. 1B (H350)	Group 2B
Dibenzo[a,h]anthracene (53-70-3)	no	Genotoxic	Genotoxic (positive results in assays in vitro and in vivo for multiple end-points)	Genotoxic, both in vitro and in vivo	Carc. 1B (H350)	Group 2A
Benzo[b]fluoranthene (205-99-2)	no	Genotoxic	Genotoxic (positive results in assays in vitro and in vivo for different end-points)	Genotoxic, both in vitro and in vivo	Carc. 1B (H350)	Group 2B
Benzo[j]fluoranthene (205-82-3)	no	Genotoxic	Genotoxic (positive results in assays in vitro and for DNA binding in vivo)	Genotoxic, both in vitro and in vivo	Carc. 1B (H350)	Group 2B
Benzo[k]fluoranthene (207-08-9)	no	Genotoxic	Genotoxic (positive results in assays in vitro and for DNA binding in vivo)	Genotoxic, both in vitro and in vivo	Carc. 1B (H350)	Group 2B
Chrysene (218-01-9)	Muta. 2 (H341)	Genotoxic	Genotoxic (positive results in vitro and in vivo for multiple end-points; positive also at germ cell level)	Genotoxic, both in vitro and in vivo	Carc. 1B (H350)	Group 2B

As noted above, metabolic activation is seen as a prerequisite for the carcinogenic potential of the PAHs covered by this dossier.

The following description is taken from IARC (2010):
"PAHs are metabolized by phase I enzymes and peroxidases, which produce DNA-reactive metabolites, and phase II enzymes, which form polar conjugates. Phase I enzymes, such as cytochrome P450s, catalyse the mono-oxygenation of PAHs to form phenols and epoxides. Specific cytochrome P450 isozymes and epoxide hydrolase can form reactive diol epoxides that comprise one class of ultimate carcinogenic metabolites of many PAHs. Both cytochrome P450s and peroxidases can form radical cations by one electron oxidation that comprise another class of ultimate carcinogenic metabolites. Further oxidation of PAH phenols leads to the formation of PAH quinones. The major cytochrome P450s that are involved in the formation of diol epoxides are 1A1, 1A2 and 1B1, while 2C9 and 3A4 play a minor role in the activation of PAHs. PAHs induce increased expression of activating cytochrome P450s via enhanced aryl hydrocarbon receptor-mediated transcription. Polymorphisms in human cytochrome P450s have been identified, some of which may be associated with increased susceptibility. Additional enzymes that may play a role in the further activation of some PAH diols include members of the aldo-keto reductase family, among which polymorphisms that influence susceptibility have been identified. Nicotinamide adenine dinucleotide phosphate:quinone oxidoreductase 1 catalyses the reduction of PAH quinones to hydroquinones which may be re-oxidized and generate reactive oxygen species. Polymorphisms in this gene have also been described.

The major phase II enzymes include the glutathione S-transferases, uridine 5'-diphosphate glucuronosyltransferases and sulfotransferases. The major glutathione S-transferases involved in the conjugation of PAH metabolites are M1, P1 and T1. Multiple polymorphisms of these as well as polymorphisms in both uridine 5'-diphosphate glucuronosyl- and sulfotransferases have been identified, some of which can modulate susceptibility to cancer.

The current understanding of the carcinogenesis of PAHs in experimental animals is almost solely based on two complementary mechanisms: those of the diol epoxide and the radical cation. Each provides a different explanation for the data observed in experimental animals.

The diol epoxide mechanism features a sequence of metabolic transformations of PAHs, each of which leads to potentially reactive genotoxic forms. In general, PAHs are converted to oxides and dihydrodiols, which are in turn oxidized to diol epoxides. Both oxides and diol epoxides are ultimate DNA-reactive metabolites. PAH oxides can form stable DNA adducts and diol epoxides can form stable and depurinating adducts with DNA through electrophilic carbonium ions. The inherent reactivities of oxides and diol epoxides are dependent on topology (e.g. bay regions, fjord regions, cyclopenta rings), and the reactivity of diol epoxides is further dependent on factors such as stereochemistry and degree of planarity. Both stable and depurinating adducts are formed primarily with guanines and adenines, and induce mutations (e.g. in ras proto-oncogenes) that are strongly associated with the tumorigenic process. Some mutagenic PAH diols, oxides and diol epoxides are tumorigenic in experimental animals.

One-electron oxidation creates radical cations at a specific position on some PAHs. The ease of formation and relative stabilities of radical cations are related to the ionization potential of the PAH. Additional important factors in the radical cation mechanism are localization of charge in the PAH radical cation and optimal geometric configuration, particularly the presence of an angular ring. The radical cation mechanism results in the formation of *depurinating DNA adducts with guanines and adenines, which generate apurinic sites that can induce mutations in ras proto-oncogenes, which are strongly associated with tumorigenesis.*

There is strong evidence that the diol epoxide mechanism operates in the mouse lung tumorigenesis of many PAHs evaluated in this monograph. For some PAHs, there is strong evidence that both radical cation and diol epoxide mechanisms induce mouse skin carcinogenesis. Many of the pathways that lead to PAH carcinogenesis involve genotoxicity, and the genotoxic effects of PAHs and their metabolites were included in the overall evaluation of each PAH discussed.

The genotoxic effects of exposure to complex mixtures that contain PAHs have been studied in some populations exposed in industrial settings and in patients who undergo coal-tar therapy. Measured end-points include mutagenicity in urine and the presence of aromatic DNA adducts in the peripheral lymphocytes of exposed workers. In some studies, specific benzo[a]pyrene–DNA adducts have been measured. Cytogenetic effects such as micronucleus formation have also been reported.

Other mechanisms of carcinogenesis have been proposed for PAHs, but these are less well developed. The ortho-quinone/reactive oxygen species mechanism features enzymatic oxidation of non-K-region PAH diols to ortho-quinones by aldo-keto reductases, and has been studied only in in-vitro systems. These PAH ortho-quinones are highly reactive towards DNA; they yield DNA adducts and damage DNA. PAH ortho-quinones induce mutations in the p53 tumour-suppressor gene in vitro; they can also undergo repetitive redox cycling and generate reactive oxygen species, which have been associated with oxidative DNA-base damage as well as the induction of pro-oxidant signals that may have consequences on growth. Reactive oxygen species can also be produced by other mechanisms such as the formation of PAH quinones through peroxidase reactions. Thus, this pathway has the potential to contribute to the complete carcinogenicity of a parent PAH.

The mechanism of meso-region biomethylation and benzylic oxidation features biomethylation of parent PAHs to methyl PAHs. Methyl PAHs are further metabolized by cytochrome P450s to hydroxymethyl PAHs that are converted into reactive sulfate ester forms that are capable of forming DNA adducts. Studies on this mechanism have been limited to subcutaneous tissues in rats that are susceptible to PAH tumorigenesis.

Several of the biological effects of PAHs, such as enzyme induction of xenobiotic metabolizing enzymes, immunosuppression, teratogenicity and carcinogenicity, are thought to be mediated by activation of the aryl hydrocarbon receptor. This receptor is widely distributed and has been detected in most cells and tissues. There is also evidence that the aryl hydrocarbon receptor acts through a variety of pathways and, more recently, that cross-talk with other nuclear receptors enables cell type-specific and tissue-specific control of gene expression. Translocation of the activated aryl hydrocarbon receptor to the nucleus may require threshold concentrations of the ligand. Various oxidative and electrophilic PAH metabolites are also known to induce enzyme systems via anti-oxidant receptor elements. The biological effects of aryl hydrocarbon receptor and anti-oxidant receptor element signalling involve a variety of cellular responses, including regulation of phase I and II metabolism, lipid peroxidation, production of arachidonic acid-reactive metabolites, decreased levels of serum thyroxine and vitamin A and persistent activation of the thyroid hormone receptor. Aryl hydrocarbon receptor signalling may result in adaptive and toxic responses or perturbations of endogenous pathways. Furthermore, metabolic activation of

PAHs produces cellular stress. This in turn activates mitogenmediated protein kinase pathways, notably of Nrf2. The Nrf2 protein dimerizes with Mafoncoproteins to enable binding to an anti-oxidant/electrophilic response element, which has been identified in many phase I/II and other cellular defence enzymes and controls their expression. Therefore, cellular stress may be regulated independently of aryl hydrocarbon receptor-mediated xenobiotic metabolizing enzymes."

"PAHs must be metabolically activated in order to induce tumours. However, individuals differ in their ability to metabolize PAHs: people who are deficient in particular enzymes that activate PAHs to reactive metabolites may be at a lower risk for chemical carcinogenesis, whereas deficiencies in enzymes that detoxify reactive metabolites may increase this risk. Some of the epidemiological studies that have been conducted to date have shown positive relationships between genetic polymorphisms of drug-metabolizing enzymes and susceptibility to cancer, while others have been inconclusive. Many factors, including race, age, sex, tobacco smoking, alcohol intake and genetic factors, could induce or inhibit drug-metabolizing activities which indicates that a complex interaction exists. Multi-gene and exposure interactions may also play a complex role in the interpretation of any increases in risk."

In conclusion, given the ability to induce genotoxic effects there is no threshold value below which no health risk exist for mutagenic PAHs.

B.5.8. Carcinogenicity

The PAHs covered by this restriction proposal (benzo[a]pyrene (BaP), benzo[e]pyrene (BeP), benzo[a]anthracene (BaA), dibenzo[a,h]anthracene (DBAhA), benzo[b]fluoranthene (BbFA), benzo[j]fluoranthene (BjFA), benzo[k]fluoranthene (BkFA) and chrysene (CHR)) are classified for carcinogenicity (category 1B) according Regulation (EC) No 1272/2008. These eight PAHs have also been classified by the International Agency for Research on Cancer as well (IARC (2010, 2012), see for details Table B 5 in previous section.

Within the purpose of current restriction dossier it is not intended to re-evaluate the carcinogenic potential of the already classified eight PAHs. In fact, carcinogenicity studies were assessed with the main purpose of identifying the most suitable starting point(s) for the quantitative risk characterisation. Based on reviews by various international committees (ATSDR (1995); EFSA (2008); IARC (2010, 2012); WHO (1998, 2003), Health Council of the Netherlands (2006), EU (2008)), the previous Annex XV restriction report for 8 PAHs in consumer products prepared by BAuA (BAuA 2010) and the note on CTPHT by ECHAs RAC (ECHA, 2017c), key studies were selected and presented in the table below. Summaries of the key oral, dermal and inhalation carcinogenicity studies are presented in sections B.5.8.1., B.5.8.2. and B.5.8.3., respectively.

Table B 6: Overview of key studies for PAH-mixtures for the endpoint carcinogenicity.

Species, strain, sex, no/group	Test substance, duration of exposure	Reference
ORAL		
Rat, Wistar 52/sex/group	BaP Vehicle: soybean oil Via gavage: 5 d/wk for 104 wk	Kroese et al. (2001); Wester et al. (2012)
Mouse, B6C3F1, female 48/group	1. BaP 2. two coal tar mixtures containing various PAHs including BaP Via diet for 104 weeks	Culp et al. (1998)
Mouse, A/J, female 30/group	1. BaP 2. PAH-rich manufactured gas plant residu Via diet for 104 weeks	Weyand et al. (1995)
DERMAL		
Mouse, NMRI, female 100/group	1. BaP 2. a mixture of known carcinogenic PAHs ('C PAH', including BaP) 3. a mixture of PAHs not considered carcinogenic by the study authors ('NC PAH') 4. a combination of the latter two ('C PAH + NC PAH'). Dermal (back area), twice weekly during entire lifespan	Schmähl et al. (1977)
Mouse, NMRI, female 40/group	BaP and other PAHs tested individually Dermal (dorsal skin in the interscapular area), twice weekly, during entire lifespan	Habs et al. (1980)
Mouse, NMRI, female 20/group	BaP and a condensate containing various PAHs Dermal, twice weekly, during entire lifespan	Habs et al. (1984)
Mouse, C3H/HeJ, male 50/group	BaP Dermal, twice weekly, 99 weeks	Warshawsky and Barkley (1987)
Mouse, SENCAR, male and female 40/sex/group	BaP and extracts of soot from various sources Dermal 1×/week, 50-52 weeks	Nesnow et al. (1983)
INHALATION		
Rat, Wistar, female 72/group	Coal tar pitch (aerosol) 17 h/d, 5 d/wk fo 10 or 20 months; followed by a clean air period of up to 20 or 10 months, respectively.	Heinrich et al. (1994)
Mouse, NMRI/BR, female (newborns) 40/group	Coal tar pitch volatile aerosols Whole body 16 h/d, 5 d/wk, 44 weeks	Schulte et al. (1994)
Hamster, Syrian golden, male 25-27/group	BaP Nose only 4.5 h/d, 7 d/wk, for the first 10 weeks, then for 3 h/d for up to 2 years.	Thyssen et al. (1981)

B.5.8.1. Carcinogenicity: oral

Three oral carcinogenicity studies were identified as key studies: one in rats with BaP exposure via gavage (Kroese et al. (2001); Wester et al. (2012)) and two in mice, each with both BaP- as well as PAH-mixture exposure via the diet (Culp et al. (1998) and Weyand et al. (1995)).

B.5.8.1.1 Lifetime gavage study in rats: Kroese et al. (2001); Wester et al. (2012)

A combined chronic and carcinogenicity study in Wistar rats clearly showed BaP to be a potent carcinogen upon chronic oral administration. Groups of male and female Wistar rats

(n = 52/group) were administered oral doses of 0, 3, 10, or 30 mg BaP/kg bw/d by gavage (vehicle: soybean oil) on 5 days per week for 104 weeks. The most potent carcinogenic effects of BaP under these testing conditions were observed in the liver and forestomach, while for both organs a low spontaneous incidence was noted in this rat strain. Papillomas and carcinomas were observed in the forestomach, and adenomas and carcinomas in the liver of both female and male rats. Tumours were found at the lowest dose tested (3 mg/kg bw/d), though at a (borderline) non-significant incidence. Statistically significant incidences were observed at 10 mg/kg bw/d and above. Other tumours observed in this study were tumours of the auditory canal, skin and appendages, oral cavity, small intestine, kidney and soft tissue sarcomas.
Liver tumours were also responsible for morbidity and the high mortality rate at the highest dose level in both sexes (100 % after about 70 weeks). Mortality was mainly due to sacrifice for humane reasons when rats became emaciated, often with distended abdomen in which frequently one or more palpable masses were present in the cranial area (liver). In control animals, survival after 104 weeks was about 65 % and 50 % in males and females, respectively. The main cause of death in these animals was tumour development in the pituitary, which was consistent with earlier findings in historical controls of this laboratory (Kroese et al. (2001); Wester et al. (2012)).

Table B 7: Incidences of tumours in liver and forestomach in male and female Wistar rats following treatment with pure BaP (5 days per week, for 104 weeks) (Kroese et al. 2001; Wester et al. 2012)

		Dose (mg/kg bw/d)			
		0	**3**	**10**	**30** [a]
females					
Forestomach	*examined*	*52*	*51*	*51*	*52*
Squamous cell papilloma		1	3	20***	25***
Squamous cell carcinoma		0	3	10**	25***
Liver	*examined*	*52*	*52*	*52*	*52*
Hepatocellular adenoma		0	2	7*	1
Hepatocellular carcinoma		0	0	32***	50***
Auditory canal [b]	*examined*	*0*	*1*	*0*	*20*
Squamous cell papilloma		0	0	0	1
Carcinoma [c]		0	0	0	13**
males					
Forestomach	*examined*	*52*	*52*	*52*	*52*
Squamous cell papilloma		0	7*	18***	17***
Squamous cell carcinoma		0	1	25***	35***
Liver	*examined*	*52*	*52*	*52*	*52*
Hepatocellular adenoma		0	3	15***	4
Hepatocellular carcinoma		0	1	23***	45***
Auditory canal [b]	*examined*	*1*	*0*	*7*	*33*
Squamous cell papilloma		0	0	0	4
Carcinoma [c]		0	0	2	19***

[a] note that this group had a significantly shorter lifetime
[b] these tissues were examined only when abnormalities were observed upon macroscopic examination
[c] composite tumours of squamous and sebaceous cells apparently arisen from the pilosebaceous units / "Zymbal glands"
* p<0.01; ** p<0.001; *** p<0.00001, Fisher's exact test, analyses of tumour incidence of the auditory canal was based on n=52

B.5.8.1.2: Lifetime feeding study in mice: Culp et al. (1998)

In a 2-year carcinogenicity study, female B6C3F1 mice (n= 48/group) were fed pure BaP or two different coal tar mixtures containing high amounts of several PAHs (Culp et al., 1998). 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 diets were prepared by dissolving the appropriate amount of BaP in acetone and mixing the solution with the standard animal diet. The coal tar diets were prepared by freezing the coal tar mixtures in liquid nitrogen and blending with the appropriate amount of standard animal diet. The homogeneity of the coal tar diets was determined by measuring the amount of BaP in the sample by HPLC. Coal tar (CAS No 8007-45-2) mixture 1 was a standardised composite from seven manufactured gas plant waste sites and coal tar mixture 2 was a composite from two of the seven waste sites plus a third site having a very high BaP content. The PAH composition of the coal tar mixtures was assessed by gas chromatography/mass spectroscopy (see Table B 8). The BaP content was also analysed by high performance liquid chromatography (HPLC) with fluorescence detection and found to be 2240 ± 51 (mean ± SD, n=2) mg BaP per kg coal tar for coal tar Mixture 1 and 3669 ± 134 (n=4) mg BaP per kg coal tar for coal tar mixture 2.

Table B 8: Polycyclic aromatic hydrocarbon composition of coal tar mixtures [a]

Compound	**Coal tar mixture 1 (mg/kg)**	**Coal tar mixture 2 (mg/kg)**
Acenapthene	2049	1270
Acenaphtylene	3190	5710
Anthracene	2524	2900
Benz[*a*]anthracene	2374	3340
Benzo[*b*]fluoranthene	2097	2890
Benzo[*k*]fluoranthene	699	1010
Benzo[*g,h,i*]perylene	1493	2290
Benzo[*a*]pyrene	1837	2760
Chrysene	2379	2960
Dibenz[*a,h*]anthracene	267	370
Dibenzofuran	1504	1810
Fluoranthene	4965	6370
Fluorene	3692	4770
Indan	1133	490
Indeno[1,2,3-cd]pyrene	1353	1990
1-methylnaphtalene	6550	5660
2-methylnaphtalene	11289	10700
Naphthalene	22203	32300
Phenanthrene	7640	10100
Pyrene	5092	7220

[a] analyses are reported as the mean of three gas chromatography/mass spectroscopy analyses on a single sample of each mixture

The BaP-treated animals (n=48/group) received BaP via the diet in concentrations of 0, 5, 25 or 100 ppm (equivalent to doses of 0, 0.7, 3.6 or 14 mg/kg bw/d; assuming 1 mg/kg bw/d corresponds to 7 ppm for mice, cf. EFSA (2008)) for 2 years. In the same experiment, groups of 48 female B6C3F1 mice were fed diets containing 0, 0.01, 0.03, 0.1, 0.3, 0.6 or 1.0 % coal tar mixture 1, which contained benzo[a]pyrene at a concentration of 2240 mg/kg (equivalent to BaP doses 0.032, 0.096, 0.32, 0.96, 1.92 or 3.2 mg/kg bw/d), or 0, 0.03, 0.1 or 0.3 % of coal tar mixture 2, which contained benzo[a]pyrene at a concentration of 3669 mg/kg (equivalent to BaP doses of 0.16, 0.52 or 1.6 mg/kg bw/d).

Body weight and food consumption were evaluated. All mice, including those that died during the experiment, were examined grossly at necropsy. Organ weights were noted. A histopathological examination was made on the liver, lungs, small intestine, stomach, tongue and esophagus from all mice. In addition, a full histopathological examination was conducted on all animals in the following groups: 0.1, 0.3, 0.6 and 1.0 % coal tar mixture 1; 0.03, 0.1 and 0.3 % coal tar mixture 2; 5, 25, and 100 ppm BaP and both control groups. All gross lesions found in mice in the other dose groups were also examined histopathologically.

Food consumption, body weight and organ weights:

Food consumption was monitored every week for the first 12 weeks on dose and every 4 weeks thereafter. Mice fed 1.0 % coal tar Mixture 1 ate significantly less feed (~30 % less) than the control mice. Similarly, a significant decrease in food consumption was observed for mice fed 0.6 % coal tar Mixture 1 (~25 % less) and 0.3 % coal tar Mixture 2 (~20 % less). Intermittent decreases in food consumption were observed in the other groups fed coal tar Mixtures 1 and 2, with the effect occurring more frequently as the dose was increased. The food consumption of mice fed only BaP differed only sporadically from that of the control group.

Mice fed 0.6 % and 1.0 % coal tar Mixture 1 weighed significantly less than the control group after two weeks of treatment. The body weights of the other groups of mice fed coal tar Mixture 1 differed only sporadically from the control group throughout the entire experiment. Significant decreases in body weight were also observed in mice fed 0.3 % coal tar Mixture 2 and 100 ppm benzo[a]pyrene.

Liver, kidney and lung weights were determined in mice surviving to the end of the experiment. The livers of mice fed 0.3 % coal tar Mixture 1 or 0.3 % coal tar Mixture 2 weighed ~40 % more than the control group, a difference that was significant. None of the other treatment groups showed significant differences in liver weights. Mice fed 0.1 % coal tar Mixture 1 had decreased kidney weights compared to the controls. This trend was not evident at higher doses. Likewise, mice fed 0.03 % coal tar Mixture 1 had a significant decrease in lung weight. None of the other groups showed significant differences in lung weights.

Morbidity and mortality:

None of the mice fed 1.0 % coal tar Mixture 1 survived the treatment period. The early mortality rate for the mice fed 0.6 % coal tar Mixture 1 was also 100 %. Only 10 mice (21 %) in the 0.3 % coal tar Mixture 1 group survived to the end of the 2-year treatment, a difference that was significant (P = 0.00006) from the control group. The survival for the mice in the 0.0, 0.01, 0.03 and 0.1 % coal tar Mixture 1 dose groups was 65, 71, 69 and 63 %, respectively.

In mice fed coal tar Mixture 2, there was significantly (P = 0.00003) lower survival in the 0.3 % dose group (15 %) as compared to the control group (65 %). The survival in the remaining two dose groups was similar to the control group.

All of the mice fed 100 ppm BaP were removed from study due to morbidity or death. A significant (P = 0.0009) number of mice in the 25 ppm BaP dose group also died early. The percentage survival of mice fed 5 ppm BaP (56 %) was similar to the control group.

Tumorigenicity:

<u>BaP</u>

Significantly increased incidences of papillomas and carcinomas were observed in the forestomach, oesophagus, and tongue. The increase in incidence of neoplasms was related to dose, with high statistical significance in the 25 and 100 ppm groups. See further Table B 9 for details on the tumour incidences in the BaP-treated mice.

Table B 9: Incidences of neoplasms in female B6C3F1 mice fed BaP for 2 years (Culp et al., 1998)

	BaP concentration (ppm) in diet				*P*-value for dose-related trend
	0	**5**	**25**	**100**	
	Corresponding BaP dose (mg/kg bw/d) [a]				
	0	*0.7*	*3.6*	*14*	
	incidences (%)				
Liver (hepatocellular adenomas)	2/48 (4)	7/48 (15)	5/47 (11)	0/45 (0)	NS [c]
Lung –alveolar/bronchiolar adenomas and/or carcinomas	5/48 (10)	0/48 (0)	4/45 (9)	0/48 (0)	NS
Forestomach – papillomas and/or carcinomas	1/48 (2)	3/47 (6)	36/46 [b] (78)	46/47 [b] (98)	<0.00001
Esophagus – papillomas and/or carcinomas	0/48 (0)	0/48 (0)	2/45 (4)	27/46 [b] (59)	0.0014
Tongue - papillomas and/or carcinomas	0/48 (0)	0/48 (0)	2/46 (4)	23/48 [b] (48)	0.0003
Larynx - papillomas and/or carcinomas	0/35 (0)	0/35 (0)	3/34 (9)	5/38 (13)	0.014
Hemangiosarcomas [d]	1/48 (2)	2/48 (4)	3/47 (6)	0/48 (0)	NS
Histiocytic sarcomas [e]	2/48 (4)	2/48 (4)	1/47 (2)	0/48 (0)	NS
Sarcomas	1/48 (2)	2/47 (4)	7/47 (15)	0/48 (0)	NS

[a] BaP doses are calculated assuming 1 mg/kg bw/d = 7 ppm in the diet for a mouse (cf. EFSA (2008))
[b] Significantly different (*P*<0.05) from control group
[c] NS=not significant
[d] organs involved include liver, mesentery and spleen
[e] organs involved include forestomach, glandular stomach, skin and skeletal muscle

Coal tar mixtures

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. See further Table B 10 for details on the tumour incidences in the coal tar mixture-treated mice.

Lowest concentrations resulting in a statistically significantly increased tumour incidence was 0.3 % for mixture 1 and 0.1 % for mixture 2.

Schneider et al. (2002) used the original, unpublished raw data from Culp and co-workers in order to establish the total number of tumour-bearing animals at each dose level for the coal tar mixture-treated animals. The results can be found in Table B 11.

This study indicated that BaP alone induced only tumours of the alimentary tract, whereas the coal tar mixtures also induced liver and lung tumours.

Table B 10: Incidences of neoplasms in female B6C3F1 mice fed coal tar mixtures I and II for 2 years (Culp et al., 1998)

	Mixture	**Coal tar concentration (%)** 0.0	0.01	0.03	0.1	0.3	0.6	1.0	***P*-value for dose-related trend**
		Incidences (%):							
Liver - hepatocellular adenomas and/or carcinomas	1	0/47 (0)	4/48 (8)	2/46 (4)	3/48 (6)	14/45 [a] (31)	1/42 (2)	5/43 (12)	0.007
	2	0/47 (0)	_ [b]	7/47 (15)	4/47 (9)	10/45 [a] (22)	_	_	0.0004
Lung –alveolar/bronchiolar adenomas and/or carcinomas	1	2/47 (4)	3/48 (6)	4/48 (8)	4/48 (8)	27/47 [a] (57)	25/47 [a] (53)	21/45 [a] (47)	<0.00001
	2	2/47 (4)	_	4/48 (8)	10/48 [a] (21)	23/47 [a] (49)	_	_	<0.00001
Forestomach – papillomas and/or carcinomas	1	0/47 (0)	2/47 (4)	6/45 (13)	3/47 (6)	14/46 [a] (30)	15/45 [a] (33)	6/41 (15)	<0.00001
	2	0/47 (0)	_	3/47 (6)	2/47 (4)	13/44 [a] (30)	_	_	<0.00001
Small intestine - adenocarinomas	1	0/47 (0)	0/46 (0)	0/45 (0)	0/47 (0)	0/42 (0)	22/36 [a] (61)	36/41 [a] (88)	<0.00001
	2	0/47 (0)	_	0/47 (0)	0/47 (0)	1/37 (3)	_	_	NS [c]
Hemangiosarcomas [d]	1	1/48 (2)	0/48 (0)	1/48 (2)	1/48 (2)	11/48 [a] (23)	17/48 [a] (35)	1/45 (2)	<0.00001
	2	1/48 (2)	_	1/48 (2)	4/48 (8)	17/48 [a] (35)	_	_	<0.00001
Histiocytic sarcomas	1	1/48 (2)	0/48 (0)	0/48 (0)	1/48 (2)	7/48 (15)	5/48 (10)	0/45 (0)	<0.00001
	2	1/48 (2)	_	3/48 (6)	2/48 (4)	11/48 [a] (23)	_	_	0.00003
Sarcomas [e]	1	1/48 (2)	4/48 (8)	3/48 (6)	2/48 (4)	7/48 (15)	1/48 (2)	2/45 (4)	0.006
	2	1/48 (2)	_	0/48 (0)	4/48 (8)	5/48 (10)	_	_	0.003

[a] significantly different ($P<0.05$) from control group

[b] not tested

[c] NS=not significant

[d] organs involved include skin, mesentery, mesenteric lymph nodes, heart spleen, urinary bladder, liver, uterus, thoracic cavity, ovary and skeletal muscle

[f] organs involved include mesentery, forestomach, skin and kidney

Table B 11: Number of tumour-bearing animals in coal tar mixture treated groups (A: coal tar mixture 1, B: coal tar mixture 2). Analysis by Schneider et al. (2002), based on the study of Culp et al. (1998).

A

Coal tar mixture concentration in food (%)	0	0.01	0.03	0.1	0.3	0.01	1
BaP daily dose per animal (mg/kg bw/d) [a]	0	0.032	0.096	0.32	0.96	1.92	3.2
Tumour-bearing animals (%) [b]	5/48 (10)	12/48 (25)	14/48 (29)	12/48 (25)	40/48 (83)	42/48 (88)	43/48 (90)

[a] as calculated assuming 1 mg/kg bw/d corresponds to 7 ppm for mice

[b] calculated using individual animal data for tumours of the liver, lung, forestomach, small intestine, hemangiosarcomas, histiocytic sarcomas and sarcomas of the mesentery, forestomach, skin and kidney.

B

Coal tar mixture concentration in food (%)	0	0.03	0.1	0.3
BaP daily dose per animal (mg/kg bw/d) [a]	0	0.16	0.52	1.1
Tumour-bearing animals (%) [b]	5/48 (10)	17/48 (35)	23/48 (48)	44/48 (92)

[a] as calculated assuming 1 mg/kg bw/d corresponds to 7 ppm for mice

[b] calculated using individual animal data for tumours of the liver, lung, forestomach, small intestine, hemangiosarcomas, histiocytic sarcomas and sarcomas of the mesentery, forestomach, skin and kidney.

It is noted that this study of Culp et al. (1998) and the analysis of Schneider et al. (2002) were used by EFSA (2008) as basis for dose response modelling (BMDL calculation). BMD modelling was performed on the total number of tumour-bearing animals. The two tested coal tar mixtures did not produce significantly different dose-response curves and therefore the data were combined by EFSA (2008). However, the results for the animals receiving the two highest doses of coal tar mixture 1 were omitted due to premature death of all animals in these dose groups. In addition to using only BaP as marker for the carcinogenic PAHs, EFSA explored additionally the use of PAH2 (benzo[a]pyrene and chrysene), PAH4 (benzo[a]pyrene, chrysene, benzo[a]anthracene, benzo[b]fluoranthene) and PAH8 (benzo[a]pyrene, chrysene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[ghi]perylene, dibenz[ah]anthracene, indeno[1,2,3-cd]pyrene). The US EPA BMD software (BMDS) was used for modelling the total tumour-bearing animals and BMD_{10} and $BMDL_{10}$ values were calculated. The Table B 12 below presents the $BMDL_{10}$-values for BaP, PAH2, PAH4 and PAH8. It is noted that the EFSA PAH8 differs from the eight PAHs under current evaluation (i.e. REACH-8 PAH, see for details section B.5.8.5.).

Table B 12: $BMDL_{10}$ for BaP, PAH2, PAH4 and PAH8 (calculated by EFSA (2008)) based on total tumour-bearing animals in the 2-year carcinogenicity study on coal tar mixtures by Culp et al. (1998).

Marker	$BMDL_{10}$ (mg/kg bw/d)
BaP	0.07
EFSA PAH2	0.17
EFSA PAH4	0.34
EFSA PAH8	0.49

B.5.8.1.3. Lifetime feeding study in Weyand et al. (1995)

In another study, groups of female A/J mice (n=30/group) were used for a similar feeding experiment with pure BaP and a PAH-rich manufactured gas plant residue. This mouse strain was chosen because of its sensitivity to chemical induction of pulmonary adenomas. A negative control group was fed the basal gel diet. In addition, a non-treated group of mice and a group dosed with vehicle only were fed with a NIH-07 pellet diet and used as negative controls. A further group served as positive control and was administered pure BaP (100 mg/kg) by i.p. injection in 0.25 mL of tricaprylin. After the last exposure day (= after 260 days of diet administration), the animals were sacrificed and their lungs and stomach removed for histology (Weyand et al., 1995).

In this study, the test item was denominated as 'Manufactured Gas Plant Residue' (MGP). MGPs, commonly also referred to as coal tar, are waste by-products formed in large quantities during coal gasification. It is noted that the BaP-content of MGP is similar to the BaP-content of the one designated 'coal tar mixture 2' by Culp et al. (1998, cf. above).

BaP

BaP was fed at concentrations of 16 or 98 ppm in the diet, resulting in an ingested amount of 40.6 or 256.6 µg BaP/day/mouse (according to study authors), respectively (equivalent to doses of 1.624 or 10.264 mg BaP/kg bw/d, respectively, assuming a 25 g bodyweight). The survival rate for both treatment groups was 25/30 and 27/30, respectively. In the control group 21/30 mice survived to the end of the study. Increased numbers of tumours in the forestomach and the lung were induced after treatment with pure BaP in feed for 260 days at both concentrations. In Table B 13, the incidence of forestomach and lung tumours is presented.

Table B 13: Incidences of forestomach and lung tumours in female A/J mice fed pure BaP for 260 days (Weyand et al. (1995)).

	BaP conc in food (ppm)		
	0	**16**	**98**
	BaP intake (mg/kg bw/d)		
	0	*1.624*	*10.264*
Forestomach	0/21 (0 %)	5/25 (20 %) *	27/27 (100 %) *
Lung	4/21 (19 %)	9/25 (36 %) *	14/27 (52 %) *

* significantly different ($p<0.05$) from control, determined by x^2 test

MGP

MGP, which contained BaP at a concentration of 2760 mg/kg (as determined by GC-MS), was given at concentrations of 0.1 or 0.25 % in the diet, resulting in ingested amounts of

6.9 or 16.3 µg BaP/mouse/d (according to study authors), respectively, (equivalent to doses of 0.276 or 0.652 mg BaP/kg bw/d, assuming a 25 g bodyweight). The survival rate for both treatment groups was 27/30 and 29/30, respectively. Treatment with MGP induced development of tumours in the lung. No local tumours in the forestomach were noted. The effect of MGP ingestion on the development of lung tumours is given in Table B 14.

Table B 14*:* Incidences of lung tumours in female A/J mice fed MGP for 260 days (Weyand et al. (1995)).

	MGP conc in food (%)		
	0	**0.10**	**0.25**
	BaP intake (mg/kg bw/d)		
	0	*0.276*	*0.652*
Lung	4/21 (19 %)	19/27 (70 %) *	29/29 (100 %) *

* significantly different (p<0.05) from control, determined by x^2 test

B.5.8.2. Carcinogenicity: dermal

Five dermal carcinogenicity studies were identified as key studies: one in NMRI mice using BaP and PAH-mixtures (Schmahl et al., 1977), two studies in NMRI mice using pure BaP and individual PAHs or a condensate containing various PAHs, respectively (Habs et al., 1980+1984), a study in C3H/HeJ mice using pure BaP (Warshawsky and Barkley, 1987) and finally a study in SENCAR mice using pure BaP and extracts of soot from various sources (Nesnow et al., 1983).

B.5.8.2.1 Dermal lifetime study in mice (Schmähl et al., 1977)

The carcinogenic action of PAH mixtures predominantly found in condensates of automobile exhaust were studied in this study. A total of four different test items was administered: pure BaP, a mixture of known carcinogenic PAHs ('C PAH', including BaP), a mixture of PAHs not considered carcinogenic by the study authors ('NC PAH'), and a combination of the latter two ('C PAH + NC PAH').

Female NMRI mice were dermally exposed (back area) to these test items (dissolved in 0.02 mL acetone) twice weekly for their entire lifespan. Concentrations were adjusted in a way that treated animals of the BaP, C PAH, and C PAH + NC PAH groups received 1.0, 1.7, or 3.0 µg BaP (corresponding to 0.04, 0.068, or 0.12 mg BaP/kg bw/d, assuming a 25 g bodyweight) regardless of the test item used. For the NC PAH group, concentrations were used which corresponded to the proportions (by weight) of the respective PAHs relative to BaP as encountered in real-life exhaust gas condensates. In order to be able to register possible weak effects, higher doses of NC PAH were given. In addition, a concurrent control group was treated with the vehicle acetone alone. Table B 15 presents an overview of the doses applied.

Table B 15: Doses (in µg) applied in skin dropping experiments, in relation to benzo[a]pyrene (Schmähl et al., 1977).

Controls					
Acetone		as solvent			
Benzo[a]pyrene		1.0	1.7	3.0	
C PAH					
Benzo[a]pyrene		1.0	1.7	3.0	
Dibenz[a,h]anthracene		0.7	1.2	2.1	
Benz[a]anthracene		1.4	2.4	4.2	
Benzo[b]fluoranthene		0.9	1.5	2.7	
	total	*4.0*	*6.8*	*12.0*	
NC PAH					
(benzo[a]pyrene		1.0	3.0	9.0	27.0)
Phenanthrene		27.0	81.0	243.0	729.0
Anthracene		8.5	25.5	76.5	229.5
Fluoranthene		10.8	32.4	97.2	291.5
Pyrene		13.8	41.4	124.2	372.6
Chrysene		1.2	3.6	10.8	32.4
Benzo[e]pyrene		0.6	1.8	5.4	16.2
Benzo[ghi]perylene		3.1	9.3	27.9	83.7
	total	*65.0*	*195.0*	*585.0*	*1755.0*
C PAH + NC PAH					
(benzo[a]pyrene		1.0	1.7	3.0)	
Total C PAH		4.0	6.8	12.0	
Total NC PAH		65.0	110.5	195.0	
Total C PAH + NC PAH		69.0	117.3	207.0	
Relation of C PAH: NC PAH is constantly 1:16.25					

The test articles were administered to the shaved skin of mice until the natural death of the animals or until the animals developed a tumour. At the start of the study, each dose group consisted of 100 animals, but spontaneous deaths and autolysis reduced the total number of animals examined in each group (Schmähl et al., 1977).

Lifetime exposure of female NMRI mice to 1.0, 1.7, and 3.0 µg BaP/animal from various mixtures produced a dose-related increase in carcinomas and other tumours of the skin at the site of application. In Table B 16 the findings are presented in detail.

Table B 16: Incidencens of skin tumours (*percentages* in brackets) in female NMRI mice topically administered PAHs 2 d/wk for their entire lifespan (Schmähl et al., 1977)

Pure BaP:					
dose (µg)	**0**	**1.0**	**1.7**	**3.0**	
Skin carcinoma	0/81 (0 %)	10/77 (13 %)	25/88 (28 %)	43/81 (53 %)	
Any skin tumour	1/81 (1 %)	11/77 (14 %)	25/88 (28 %)	45/81 (56 %)	
C PAH:					
dose (µg) [a,b]	**0**	**4.0**	**6.8**	**12.0**	
Skin carcinoma	0/81 (0 %)	25/81 (31 %)	53/88 (60 %)	63/90 (70 %)	
Any skin tumour	1/81 (1 %)	29/81 (36 %)	57/88 (65 %)	65/90 (72 %)	
NC PAH:					
dose (µg) [a,c]	**0**	**65.0**	**195.0**	**585.0**	**1755.0**
Skin carcinoma	0/81 (0 %)	1/85 (1 %)	0/84 (0 %)	1/88 (1 %)	15/86 (17 %)
Any skin tumour	1/81 (1 %)	1/85 (1 %)	0/84 (0 %)	1/88 (1 %)	16/86 (19 %)
C PAH + NC PAH:					
dose (µg) [a,b]	**0**	**69.0**	**117.3**	**207.0**	
Skin carcinoma	0/81 (0 %)	44/89 (49 %)	54/93 (58 %)	64/93 (69 %)	
Any skin tumour	1/81 (1 %)	46/89 (52 %)	57/93 (61 %)	65/93 (70 %)	

[a] dose refers to the complete PAH mixture
[b] dose of individual PAHs are related to 0, 1.0, 1.7 and 3.0 µg BaP
[c] dose of individual PAHs are related to 0, 1.0, 3.0, 9.0 and 27.0 µg BaP

The results given in the above table show clearly that PAH mixtures containing BaP and certain other PAHs will cause a higher incidence of neoplasms when administered at the same BaP exposure level.

In this study, induction of local tumours was observed at all tested concentrations. The lowest tested concentration of 1.0 µg BaP/animal was equivalent to 0.04 mg BaP/kg bw/d (assuming a 25 g bodyweight).

B.5.8.2.2 Dermal lifetime study in mice (Habs et al., 1980)

In a dermal lifetime study, pure BaP and other PAHs (benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fuoranthene, indeno[1,2,3-cd]pyrene, cyclopentadieno-[cd]pyrene, coronene) were tested with regard to local carcinogenicity by topical application to mouse skin. Groups of female NMRI mice (n=40) were topically administered 2d/wk for up to 130 weeks (except for coronene wit a 4d/wk frequency), with the individual PAHs dissolved in acetone (or DMSO in case of coronene). Table B 17 presents an overview of the applied dose levels. Controls received the vehicle alone. The solutions were applied by topical dropping to the clipped dorsal skin in the interscapular area. Each application comprised 0.02 mL. All experimental animals were checked twice daily and the occurrence of tumours at the site of application was recorded. Animals at an advanced stage of macroscopically clearly infiltrative tumour growth were killed prior to their natural death (Habs et al., 1980).

Table B 17: Dose levels of the individual PAHs tested topically on mice (Habs et al., 1980)

PAH	solvent	Individual dose (µg/animal/day)			Frequency of application
		I	II	III	
Benzo[a]pyrene	acetone	1.7	2.8	4.6	2d/wk
Benzo[b]fluoranthene	acetone	3.4	5.6	9.2	2d/wk
Benzo[j]fluoranthene	acetone	3.4	5.6	9.2	2d/wk
Benzo[k]fuoranthene	acetone	3.4	5.6	9.2	2d/wk
Indeno[1,2,3-cd]pyrene	acetone	3.4	5.6	9.2	2d/wk
Cyclopentadieno-[cd]pyrene	acetone	1.7	6.8	27.2	2d/wk
Coronene	DMSO	5.0	15.0		4d/wk

A clear dose-response relationship could be established for the carcinogenic activity of pure BaP at the site of application. Control animals did not develop tumours at the site of application. Study results are summarised in Table B 18.

Table B 18: Incidence of skin tumours in female NMRI mice topically administered with various PAHs (Habs et al., 1980). See Table B 15 for details on the applied dose levels

		Animals with local tumours		
		incidence	percentage	Age standardized tumour frequencies (%)
Acetone		0/35	0	0.0
DMSO		0/36	0	0.0
Benzo[a]pyrene	I	8/34	23.5	24.8
	II	24/35	68.6	89.3
	III	22/36	61.1	91.7
Benzo[b]fluoranthene	I	2/38	5.3	4.6
	II	5/34	14.7	14.0
	III	20/37	54.1	65.4
Benzo[j]fluoranthene	I	1/38	2.6	1.6
	II	1/35	2.9	2.6
	III	2/38	5.3	3.5
Benzo[k]fuoranthene	I	1/39	2.6	1.7
	II	0/38	0.0	0.0
	III	0/38	0.0	0.0
Indeno[1,2,3-cd]pyrene	I	1/36	2.8	1.4
	II	0/37	0.0	0.0
	III	0/37	0.0	0.0
Cyclopentadieno-[cd]pyrene	I	0/34	0.0	0.0
	II	0/35	0.0	0.0
	III	3/38	7.9	11.0
Coronene	I	1/39	2.6	3.1
	II	2/40	5.0	6.1

It is noted that the lowest tested concentration of 1.7 µg BaP/animal topically administered (2d/wk) for up to 130 weeks was associated with a significant increase in local tumours in female NMRI mice. Also benzo[b]fluoranthene induced local tumour formation. The dose of 1.7 µg BaP/animal is equivalent to 0.068 mg/kg bw/d (assuming a body weight of 25 g).

B.5.8.2.3 Dermal lifetime study in mice (Habs et al., 1984)

In a third life-time study, the carcinogenicity of condensates of the seed of *Citrullus colocynthis* was examined. See Table B 19 for details on the PAH-content of this condensate. BaP was used as positive control. Groups of female NMRI mice were treated 2d/wk with 2 or 4 µg BaP/mouse in acetone or 15 or 60 µg condensate/mouse (corresponding to 78 or 312 pg BaP/mouse) and one solvent–treated control, each group containing 20 animals. The individual dose in the control group was 0.01 mL acetone. The solutions (0.01 mL) were applied by topical dropping to the clipped dorsal skin in the interscapular area twice a week for life. All animals were monitored twice daily and the occurrence of skin tumours was recorded. Animals in an advanced stage of macroscopically clearly invasive tumour growth were killed, all other animals were observed until their natural death (Habs et al., 1984).

Table B 19: Concentration of PAHs in a condensate of Citrullus colocynthis seed used (Habs et al., 1984).

PAH	**Concentration (µg/g)**
Benz[a]anthracene	9.2
Chrysene and triphenylene	13.0
Fluoranthene	28.1
Pyrene	30.4
Benzofluoranthene (b+j+k)	6.7
Benzo[e]pyrene	3.8
Benzo[a]pyrene	5.2
Perylene	1.0
Indeno[1,2,3-cd]pyrene	1.6
Benzo[ghi]perylene	1.7
Anthanthrene	0.6

Treatment was tolerated without signs of acute or subacute toxicity. Weight development in test compound-treated mice did not differ from that in controls. Mean survival time was 691 (95 % CI: 600-763) days in the acetone control, 648 (440-729) days in the 2 µg BaP/mouse, 528 (480-555) days in the 4 µg BaP/mouse groups, 572 (407-644) in the low dose condensate group and 611 (430-673) in the high dose condensate group.

BaP was found to be clearly carcinogenic in both tested concentrations. No skin tumours were seen in vehicle controls. The carcinogenic activity of BaP and the tested condensate after chronic epicutaneous application to female NMRI mice is presented in Table B 20.

Table B 20: Incidences of skin tumours in female NMRI mice topically administered with BaP for 2d/wk (Habs et al., 1984).

Treatment	**Number (%) of animals with skin tumours**		
	total	**papillomas**	**Carcinomas**
Control	0 (0)	0 (0)	0 (0)
BaP- low dose	9 (45)	2 (10)	7 (35)
BaP – high dose	17 (85)	0 (0)	17 (85)
Condensate – low dose	1 (5)	0 (0)	1 (5)
Condensate - high dose	5 (25)	2 (10)	3 (15)

In summary, the lowest topically administered concentration of 2 µg BaP/mouse to female NMRI mice throughout their lifetime induced statistically significant skin tumours in 9/20 animals (45 %). The concentration of 2 µg BaP/animal is equivalent to 0.08 mg/kg bw/d (assuming 25 g bodyweight).

B.5.8.2.4 Dermal lifetime study in mice (Warshawsky and Barkley 1987)

In a further study, relative carcinogenic potencies of three combustion products of fossil fuels (including BaP and two *N*-heterocyclic compounds 7H-dibenzo[cg]carbazole and dibenz[aj]acridine) were compared in carcinogenicity mouse skin bioassays (skin painting studies). In the exposure groups, 50 male C3H/HeJ mice were treated twice a week with a 0.025 % solution of the tested compounds (12.5 µg compound/animal delivered in 50 µl of acetone) applied to the interscapular region of the back for up to 99 weeks. The animals of the control group were treated with 50 µL of distilled acetone twice weekly. Hair from the backs of mice was removed with electric clippers at least two days before the first treatment and every two weeks after the first treatment. During the course of the experiment animals were observed twice daily (Warshawsky and Barkley 1987).

Table B 21: Incidences of skin tumours in male C3H/HeJ mice (Warshawsky and Barkley, 1987).

	No. mice examined	**No. mice with malignant tumours**	**No. mice with benign tumours (only)**	**Average latency period (wks)**
No treatment	50	0	0	-
Acetone	50	0	0	-
0.025 % dibenz[aj]acridine	50	22	3	80.3
0.025 % 7H-dibenzo[cg]carbazole	50	47	1	36.6
0.025 % BaP	50	47	1	32.4

Male C3H/HeJ mice administered with 12.5 µg BaP/animal for 99 weeks produced skin tumours in 48/50 mice. While in one instance a benign tumour was found, tumours were malignant in all other cases. The mean latency period in the BaP-group was 32.4 weeks.

Assuming a body weight of 30 g/male mouse, the concentration of 12.5 µg BaP/animal is equivalent to 0.417 mg/kg bw/d.

B.5.8.2.5 Dermal 52-week mouse study (Nesnow et al. 1983)

Nesnow et al. (1983) studied carcinogenic risks following skin exposure of mice to extracts of soots of various sources, namely coal chimney soot, coke oven materials, industrial carbon black, oil shale soot, and gasoline vehicle exhaust materials. Also pure BaP was tested. This study also addressed tumour initiation and tumour promotion activity of the extracts and BaP. Below only the data of the complete carcinogenesis protocol (i.e. evaluation of the production of tumours after repeated application of a carcinogen of up to 1 year) are described.

Male and female SENCAR mice (40/sex/group) were treated topically 1/week (or twice weekly for the highest dose level). Samples of soot extracts or BaP were administered in 0.2 ml acetone for 50 to 52 weeks. Four agents were examined for their ability to act as complete carcinogens, i.e. BaP, coke over main extract, roofing tar extract, and gasoline vehicle exhaust extract.

Weekly application of 50.5 µg BaP produced a carcinoma incidence of greater than 93 %, with almost one carcinoma per mouse. Higher doses did not increase the tumour multiplicity. No carcinomas were observed in the control animals. The coke oven main sample also produced a strong complete carcinogen response in both male and female mice. Male mice seemed to be more sensitive; 98 % of the males bore approximately one carcinoma, while only 75 % of the females responded. The roofing tar sample produced a significant response only at the highest dose applied (4 mg/mouse/week), with 25 % to 28 % of the mice bearing tumours. The gasoline vehicle exhaust extract was essentially inactive as a complete carcinogen at the doses applied. The results are presented in Table B 22/Table B 23.

Table B 22: Tumours observed following administration of BaP to SENCAR mice in the complete carcinogenesis protocol (Nesnow et al., 1983)

Dose BaP (µg/mouse/week)	sex	Mice with carcinomas (%)[a]
0	M	0
0	F	0
12.6	M	10
12.6	F	8
25.2	M	63
25.2	F	43
50.5	M	93
50.5	F	98
101	M	80
101	F	90
202	M	80
202	F	93

[a] Cumulative score after one year

Table B 23:. Tumours observed following administration of coke oven main extract, roofing tar extract, and gasoline vehicle exhaust extract to SENCAR mice in the complete carcinogenesis protocol (Nesnow et al., 1983)

Dose extract (µg/mouse/week)	sex	Mice with carcinomas[a]		
		Coke over main	Roofing tar	Gasoline vehicle
100	M	5	0	0
100	F	5	0	0
500	M	36	0	0
500	F	30	0	0
1000	M	48	3	0
1000	F	60	0	0
2000	M	82	3	0
2000	F	78	8	0
4000	M	98	25	3
4000	F	75	28	5

[a] Cumulative score after one year

It is noted that this skin painting experiment with BaP (in acetone as solvent) of Nesnow et al. (1983) and the analysis of Knafla (2011) were used by ECHAs RAC as basis for establishing a dose-response relationship for the dermal route for the carcinogenicity of coal tar pitch - high temperature (ECHA 2017c).

B.5.8.3. Carcinogenicity: inhalation

Three inhalation carcinogenicity studies were identified as key studies: one study with exposure to coal tar pitch aerosol in rats (Heinrich et al., 1994), one with exposure to coal tar pitch aerosol in mice (Schulte et al., 1994) and one with exposure to BaP in hamsters (Thyssen et al., 1981).

B.5.8.3.1 Chronic inhalation study in rats (Heinrich et al., 1994)

In a chronic inhalation study, female Wistar rats were exposed to coal tar pitch (CTP) aerosol in order to estimate lifetime unit lung cancer risk for BaP. A total of five experimental groups, each consisting of 72 females, seven weeks of age at the start of the experiment, were used in this inhalation study. Two different concentrations of CTP aerosol were used, 1.1 and 2.6 mg/m^3, which contained a.o. 20 and 46 µg BaP/m^3, respectively. The concentrations of some other particle-bound and gaseous PAHs, as they occurred in the 2.6 mg CTP/m^3 exposure atmosphere, are listed in Table B 24.

Table B 24: Concentration of some particle-bound and gaseous PAHs in the exposure chamber containing 2.6 mg CTP aerosol/m^3 (Heinrich et al., 1994).

PAHs and PAH-related compound	Concentration of particle-bound PAHs (µg/m^3)	Concentration of gaseous PAHs (µg/m^3)
Acenapthene		38
Acenaphtylene		9
Anthracene	11	3
Benz[a]anthracene	58	
Benzo[a]fluorene	20	
Benzo[a]pyrene	46	
Benzo[b]fluorene	23	
Benzo[c]phenanthrene	7	
Benzo[e]pyrene	39	
Benzo[g,h,i]fluoranthene	8	
Benzo[g,h,i]perylene	27	
Benzofluoranthenes	93	
Benzonaphthothiophene	12	
Carbazole	6	
Chrysene	59	
Coronene	7	
Cyclopenta[d,ed]phen.	8	1
Dibenzofurane		14
Dibenzothiophene	3	2
Fluoranthene	87	1
Fluorene		17
Indeno[1,2,3-c,d]pyrene	29	
Methylbiphenyl		7
Methyldibenzofurane		5
Methylfluorene		3
Perylene	11	
Phenanthrene	50	13
Pyrene	67	

Animals were exposed to filtered clean air or the aerosols of CTP, free of any carbon black carrier particles, for 17 hours per day, 5 days per week for 10 or 20 months, followed by a clean air period of up to 20 or 10 months, respectively. Thus, the total experimental time for all groups was 30 months. The mass median aerodynamic diameter of the CTP aerosol was 0.5 µm (Heinrich et al., 1994).

A clear dose-dependent increase in lung tumour incidence was observed. Most tumours were classified as keratinising squamous cell tumours, but also some bronchio-alveolar adenomas and adenocarcinomas were found. The incidence of lung tumours in female rats chronically exposed to the aerosols of CTP is given in Table B 25.

Table B 25: Incidences of lung tumours in female Wistar rats chronically exposed to CTP by inhalation (related to BaP concentrations) (Heinrich et al., 1994).

CTP aerosol (mg/m^3)	BaP (µg/m^3)	Exposure (months)	Post exposure (months)	Cumulative exposure (mg BaP/m^3 x h)	Lung tumour incidence
0	0	0	30	0	0/72 (0 %)
1.1	20	10	20	71	3/72 (4.2 %)
1.1	20	20	10	142	24/72 (33.3 %)
2.6	46	10	20	158	28/72 (38.9 %)
2.6	46	20	10	321	70/72 (97.2 %)

When compared to controls, increased mortality rates were observed in the groups exposed to 2.6 mg/m^3 CTP aerosol (46 µg/m^3 BaP) for 10 or 20 months. In particular, the animals exposed for 20 months had to be sacrificed because of the development of large, multiple tumours in the lung. No lung tumours were found in control animals.

In summary, the lowest tested concentration of 1.1 mg/m^3 CTP containing 20 $\mu g/m^3$ BaP, was associated with a significantly increased tumour response in the lung after exposure for 10 (4.2 %) or 20 months (33.3 %) in female Wistar rats.

B.5.8.3.2 Long-term inhalation study in new-born mice (Schulte et al., 1994)

In a long-term inhalation study, new-born female NMRI/BR mice were used to study carcinogenic effects of PAH-rich exhausts. The use of new-born animals was explained by their lower spontaneous lung tumour incidence and greater susceptibility to tumour induction. Exposure started at the first day after birth. The animals (n=40/group) were exposed to filtered room air or coal tar pitch volatile aerosols (mass median aerodynamic diameter, MMAD of 0.55 ± 0.03 µm), containing 50 or 90 µg BaP/m^3 (0.05 or 0.09 mg/m^3), for 16 hours per day, 5 days per week during 44 exposure weeks. The PAH-rich exhaust was produced by pyrolysing preheated (80 °C) coal tar pitch under a nitrogen atmosphere at 750-800 °C, which was then diluted with fresh air and was transferred into the exposure chambers. BaP served as the lead compound for standardising the exposure concentrations. The animals of the control group were exposed to filtered room air (Schulte 1994).

The number of surviving mice at termination of the experiment was slightly lower in the PAH-rich exhaust exposure groups [50 $\mu g/m^3$: 38/40 (95 %); 90 $\mu g/m^3$: 35/40 (87.5 %)] as compared to controls [39/40 (97.5 %)], but average lifetime was nearly the same in all groups (44.2 - 44.4 weeks).

Results of the macroscopic and microscopic analysis of the lung clearly demonstrated that exposure to PAH-rich exhausts caused a dose-dependent increase in lung tumours. As in the previous study, tumours in organs other than the lung were not investigated. Bronchiolo-alveolar adenomas were observed in all mice exposed to 50 or 90 µg BaP/m^3 BaP (40/40 each) as compared to 5/40 in the control group. Bronchiolar-alveolar adenocarcinomas had developed in 10/40 and in 33/40 mice (see detailed study results in Table B 26).

Table B 26: Macrospcopic and microscopic results of long-term exposure of female NMRI/BR mice to PAH-rich exhausts (Schulte et al., 1994))

Exposure (µg BaP/m^3)	Lung cancer mortality abs. (%)	Average no. of nodules per lung	Number of adenomas abs. (%)	Number of adenocarcinomas abs. (%)	No. of squamous cell carcinomas abs. (%)	No. of adenosquamous carc.
0	0/40	0.1	5/40 (12.5 %)	0/40	0/40	0/40
50	1/40 (2.5 %)	24.7	40/40 *** (100 %)	10/40 ** (25 %)	0/40	0/40
90	4/40 (10.0 %)	37.1	40/40 *** (100 %)	33/40 *** (82.5 %)	6/40 * (15 %)	1/40 (2.5 %)

Note: *, $p<0.05$; **, $p<0.01$; ***, $p<0.001$ (compared to controls, pair wise Fisher test).

The lowest tested concentration of PAH-enriched exhaust containing 50 µg BaP/m^3, was associated with a significant increase in lung adenomas and a dose-dependent increase in malignant lung tumours for female NMRI/BR mice exposed for 44 weeks (5 d/wk, 16 h/d).

B.5.8.3.3 Chronic inhalation study in hamsters (Thyssen et al., 1981)

In another chronic inhalation study, groups of male Syrian golden hamsters (n = 25-27) were exposed by inhalation to BaP concentrations of 2.2, 9.5, and 46.5 mg/m^3 air for 4.5

h/d, 7 days/week for the first 10 weeks, then for 3 h/d for up to 2 years. Exposure was by nose breathing only. The total average dose of BaP per animal was 29, 127, and 383 mg, respectively. Controls were exposed to aerosol with 240 µg NaCl/m^3 air. The particle sizes were reported to be within the respirable range: more than 99 % of the BaP particles had diameters between 0.2 and 0.5 µm, and over 80 % were between 0.2 and 0.3 µm (Thyssen et al., 1981).

The chronic inhalation study in hamsters provides clear-cut evidence of a dose-response relationship between inhaled BaP particles and respiratory tract tumourigenesis. Survival time was significantly decreased from 96 weeks for controls to 59.5 weeks for animals in the 46.5 mg/m^3 BaP exposure group; survival times were not altered in the other exposure groups. Respiratory tract tumours were induced in the nasal cavity, pharynx, larynx, and trachea in hamsters exposed to 9.5 or 46.5 mg BaP/m^3. Exposure-related tumours were also found in the oesophagus and forestomach following exposure to 9.5 or 46.5 mg/m^3 (presumably as a consequence of mucocilliary particle clearance and swallowing of particles). These tumours were papillomas, papillary polyps, and squamous cell carcinomas. No respiratory tract tumours and no upper digestive tract tumours were found in the controls and in animals exposed to 2.2 mg BaP/m^3.

In contrast to lung tumours observed in rats and mice, no BaP-related tumours were found in the lungs of hamsters. An overview of tumour incidences in hamsters exposed to BaP is presented in Table B 27.

Table B 27: Incidence of tumours in male Syrian golden hamsters after long-term exposure to BaP (Thyssen et al. 1981)

	Conc (mg BaP/m^3)			
	0	**2.2**	**9.5**	**46.5**
Nasal cavity	0/27	0/27	12/26 (12 %)	1/25 (4 %)
Larynx	0/27	0/27	8/26 (31 %)	13/25 (52 %)
Trachea	0/27	0/27	1/26 (4 %)	3/25 (12 %)
Pharynx	0/27	0/27	6/26 (23 %)	14/25 (56 %)
Oesophagus	0/27	0/27	0/26 (0 %)	2/25 (8 %)
Forestomach	0/27	0/27	1/26 (4 %)	1/25 (4 %)
Tumour incidence (all tumours)	52 %	63 %	77 %	60 %
No. of tumours/tumour bearing animals	1.1	1.3	1.7	2.5

In male Syrian golden hamsters long-term inhalation exposure to ≥ 9.5 mg/m^3 BaP induced tumours in the respiratory and the upper digestive tract. It is noted that survival was drastically reduced in the high concentration group.

B.5.8.4. Carcinogenicity: human data

Information as presented below is taken primarily from the EU RAR (2008), the restriction dossier on eight PAHs in consumer products (BAuA, 2010) and the RAC note on CTPHT (ECHA 2017c).

Already in the 19th century, reports on the induction of cancer in persons occupationally exposed to combustion products containing PAHs have been published. Evidence that mixtures of PAHs are carcinogenic to humans is primarily derived from occupational studies of workers following inhalation and dermal exposure. No data were located regarding cancer in humans following inhalation of individual PAH compounds. Exposure of humans to PAHs is characterised by a mixture of these compounds and other substances in either occupational or environmental situations. For oral exposure to single PAHs or PAH mixtures in humans no adequate long-term data are available.

There is a large body of epidemiological studies of PAH-exposed workers, especially in coke ovens and aluminium smelters supporting a clear excess of lung cancer, and highly suggestive of an excess of bladder cancer. Skin cancer in man is well known to have occurred following exposure to poorly refined lubricating and cutting oils. The epidemiological studies include cohort and case-control studies with various PAH-rich sources. Exposure–response relationships for occupational PAH exposure and cancer in humans have been reviewed by several working groups of IARC (2010), US EPA (1984), WHO (1987, 1998, 2000, and 2003), and by the UK Health and Safety Executive (HSE, Armstrong et al., 2003, 2004). In addition to these evaluations by international committees, several additional studies have been published (Armstrong et al., 2009; Boffetta et al., 1997; Bosetti et al., 2007; Costantino et al., 1995; Mastrangelo et al., 1996; Moolgavkar et al., 1998). All of them confirm that heavy occupational exposure to mixtures of PAHs entails a substantial risk of lung, skin, or bladder cancer. BaP has been chosen as a lead compound for carcinogenic PAHs, although the limitations and uncertainties of the approach were recognised. The epidemiological data relevant for this report are summarised in the following section.

In the 1980s, IARC reviewed numerous epidemiological studies on PAH-exposed workers whose occupational exposure was assessed on the basis of type of employment or industrial process involved. Given the long latency between first exposure and cancer, these workers were exposed mainly during the first half of the century, when data on industrial hygiene were scarce. A definite risk of cancer was found in workers employed in the coke (lung cancer), aluminium (lung and bladder cancer), and steel industries (lung cancer), which were subsequently considered Group 1 carcinogens along with coal tar pitch, untreated and mildly treated mineral oils, and soot. On the other hand, inconsistencies between studies, lack of control of confounding factors, potential bias, and uncertainty regarding a dose-response relationship precluded any definitive conclusions for other occupational settings: roofers and asphalt workers, mechanics exposed to engine exhaust, bus and truck drivers, railroad workers, and excavator operators exposed to diesel exhaust in mines and tunnels (IARC 1983, 1984, 1985, 1989). These evaluations were updated in 2010 and further confirmed in 2012 and included also occupational exposure during coal gasification, coal tar distillation, paving and roofing with coal-tar pitch, and occupational exposure as a chimney sweep as Group 1 carcinogens (IARC 2010, 2012).

An increased risk of lung cancer among coke-oven workers was used for the quantitative risk assessment of PAHs with BaP as the lead substance in the Air Quality Guidelines for Europe (WHO 1987, 2000) and the current EU air limit for PAHs (EU 2001). According to WHO (1987), a strongly increased risk of death from cancer of the respiratory system had been demonstrated among workers at coke ovens in Allegheny County, Pennsylvania, USA, for 1953–1970, especially in top-oven workers (relative risk [RR] = 6.6–15.7 for 300 topside, full-time workers, divided into different categories according to the years of exposure). WHO (1987) further refers to a risk assessment by the US EPA in 1984 which applied a linearised multistage mathematical model to the individual exposure estimates, thereby generating an upper-bound risk estimate expressed in terms of benzene-extractable material. The US EPA estimate was converted in terms of BaP levels by assuming a 0.71 % content of BaP in the benzene extract, thus estimating the lung cancer risk from a lifetime exposure to PAHs in ambient air at 8.7×10^{-5} per ng BaP/m^3 (WHO 1987, 2000).

Armstrong 2003, 2004

The meta-analysis on lung and bladder cancer risk following PAH-exposure and funded by the UK HSE (Armstrong 2003, 2004) is described in more detail in this section. For the inhalation route, the meta-analysis of Armstrong et al. (2003, 2004) is considered to provide a robust, appropriate and reliable basis for assessment of the inhalation exposure. Moreover, it is noted that recently dose-response relations for lung (and bladder) cancer for workers were developed by ECHA (2017c), using the URR from this meta-analysis, in combination with a more recent value for reference lifetime risk based on the latest data on incidence of lung and bladder cancer from the year 2012 being available for most of the EU28 countries. See further section B.5.11.

This study of Armstrong (2003, 2004) was well-performed and quantified the relationships between occupational PAH exposure and lung and bladder cancer. This meta-analysis combined studies conducted in the industries that share (almost exclusive) exposure to PAHs. By combining a much larger body of data, the risk estimates become statistically much more stable. 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. Only epidemiological studies on occupational exposure by inhalation were included. Biomarker studies, studies only reporting proportional cancer analyses, non-English publications and non-primary research papers (e.g. reviews) were excluded. Studies in which PAH was considered unlikely to be the predominant lung or bladder carcinogen (because of the presence of other known, possibly confounding tissue specific carcinogenic substances, e.g. in workplaces including those in the rubber industry and foundries and those involving exposure to diesel exhaust) were excluded as well. Also studies for which assessment of exposure was not possible (e.g. case-control and registry studies) were excluded. To avoid double counting of information from the same workforce reported in several papers, only the last reported results were included.

The cohorts included in the meta-analysis were occupationally exposed to PAHs in several industries (aluminium smelting, carbon anode plants, asphalt, and tar distillation, coke ovens, coal gas production and carbon black production), where the main cause of cancer induction is their exposure to PAHs. Although it is likely that the composition (PAH profile) and therefore the carcinogenic potential of the exposures is not exactly similar across industries, deriving a statistically stable risk estimate based on all PAH-exposed cohorts is still considered superior to deriving industry-specific but very uncertain estimates. In a meta-analysis, exposures have to be defined as the same metric on the same scale.

The underlying studies, however, 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. Furthermore, the exposure variables were converted to cumulative exposure (duration × time-weighted mean concentration), if necessary. Where risk by cumulative exposure was not published, it was derived as the product of mean estimated concentration of exposure in each group for which risk was reported and the mean duration of exposure in that group. In absence of information on duration of exposure, 20 years was assumed, representing the average found in studies for which the duration was reported.

Concerning studies with cumulative exposure, the mean cumulative exposure in each group or the midpoint of interval was chosen as an estimate for the average cumulative BaP exposure. Overall, the cumulative exposure in the highest exposure groups ranged across three orders of magnitude, from 0.75 to 805 µg BaP /m^3 -years (≈ average air concentration of 0.04 to 40 µg/m^3 BaP).

In the meta-analyses, relative risks (RRs) were estimated for each study for a benchmark exposure level of 100 µg/m^3 year cumulative BaP, in which 100 µg/m^3 BaP -years corresponds to a concentration of 2.5 µg BaP/m^3 over 40 years. The authors had chosen this benchmark level such that it was comprised within the exposure ranges of the studies included in the meta-analyses. These Unit Relative Risks (URRs) were estimated by fitting an exposure-risk model to the data with Poisson regression. For determining URR two models were used: the log-linear relative risk model (exponential) as normally used in epidemiological studies and meta-analyses [RR=exp(b_{loglin}x)] and the linear relative risk model (RR)=1+b_{lin}x), where "x" is the cumulative exposure (µg/m^3 years) and "b" is the slope of the exposure-risk relationship. Meta-regression was applied to assess the impact of study characteristics on the final risk estimate.

- *Lung cancer*

There were 39 cohorts for which risk estimates were published for lung cancer. An overall relative risk estimate (URR) of 1.20 (95 % confidence interval (CI): 1.11-1.29) per unit of 100 µg/m^3 -year cumulative BaP exposure was calculated for lung cancer. This implies that the risk for lung cancer was 20 % higher in workers exposed to 100 µg/m^3 -year cumulative BaP (~ 40 years exposure to an average concentration of 2.5 µg/m^3 BaP). In a meta-analysis, it is common practice to investigate whether the data from the studies included are sufficiently in agreement with each other by testing for heterogeneity. In the current meta-analysis, a statistically significant heterogeneity in URRs between the individual studies was observed, indicating that some studies (mainly the smallest, *i.e.* least precise studies) had deviating estimates. Nevertheless, statistical significant heterogeneity was observed between industry groups, but not between and within the major contributing groups, *i.e.* coke ovens, gas works and aluminium smelters. Meta-regression analysis revealed that the URR for coke ovens, gas works and aluminium smelters were consistent and relatively precisely estimated (combined URR 1.17, 95 % CI: 1.12-1.22).

For other characteristics (such as study design, region or type of exposure measurement) no statistically significant heterogeneity was detected.

Although limited, information on total dust exposure did not suggest that dust exposure was an important confounder or effect modifier.

A requirement for establishing and quantifying an association between PAH exposure and lung cancer is that confounding due to other risk factors of lung cancer, such as smoking, are unlikely to explain the results. Confounding can arise from smoking habits that differ between the exposed and unexposed groups. In general, in occupational epidemiological studies the effect is limited, but unpredictable, as there is no systematic and consistent association between exposure and smoking (unlike studies on e.g. lifestyle and cancer, where smoking is always prevalent in persons with the least healthy lifestyle habits).

Regarding the meta-analysis of Armstrong et al. (2003, 2004), only in four out of 39 studies (mainly nested case-control studies from cokes ovens and aluminium smelters) in the meta-analysis for lung cancer, adjustment of risk estimates for confounding due to smoking was performed; the meta-analysis observed borderline statistically significant higher estimates for the studies adjusted for smoking than for those that had not (URR = 1.31, 95 % CI: 1.16-1.48 versus 1.16, 95 % CI: 1.11-1.21, respectively). Failure to adjust for smoking in the majority of the studies is, if anything, therefore more likely to underestimate than to overestimate the true risk estimate. This higher risk estimated from studies that did control for smoking prove at least that the risk of cancer is not always overestimated when no adjustment is made.

- *Bladder cancer*

There were 27 cohorts for which risk estimates were published for bladder cancer. An overall relative risk estimate (URR) of 1.33 (95 % confidence interval: 1.16-1.52) per unit of 100 µg/m^3 -year cumulative BaP exposure was calculated for bladder cancer (Armstrong et al. 2003, 2004). Although the results support a PAH-bladder cancer association, this finding was less robust than that for lung cancer. Only for the aluminium production industry was the evidence for an association strong. On the other hand the data from the other industries were weak rather than negative - and were compatible with a generic PAH risk of the same magnitude per unit BaP across cohorts. In addition, it cannot be excluded that bladder cancer is induced by other substances (not PAHs), which are suspected to be specific bladder carcinogens (e.g., 2-naphthylamine), and are found in the types of industries under investigation.

Overall, the meta-analysis supports the conclusions of previous reviews that lung cancer and bladder cancer are associated with PAH exposure. On average, relative risk predicted for lung cancer at 100 µg/m^3 BaP -years (URR) was 1.20 (95 %CI:1.11-1.29), but this varied significantly across industries. Coke ovens (1.17; CI:1.12-1.22), gasworks (1.15; CI:1.11-1.20), and aluminium production (1.16; CI:1.05-1.28) were slightly lower than the mean, and asphalt (17.50; CI:4.21-72.78) and chimney sweeping (16.2; CI:1.64-160.7) were much higher but imprecisely estimated. There was also an association of PAHs with bladder cancer (mean URR=1.33; 95 %CI: 1.16-1.52, no significant heterogeneity), but this finding was less robust than that for PAH-lung cancer, being largely dependent on two studies of aluminium production workers. The overall URR represents risk at fairly common exposures historically, but high for today.

<u>Further studies</u>

In a continuative study, the exposure–response function associating PAH exposure and lung cancer, with consideration of smoking, was estimated (Armstrong et al., 2009). Mortality, occupational exposure and smoking histories were ascertained for a cohort of 16431 persons (15703 men and 728 women) who had worked in one of four aluminium smelters in Quebec from 1950 to 1999. A variety of exposure–response functions were fitted to the cohort data using generalised relative risk models. In 677 lung cancer cases there was a clear trend of increasing risk with increasing cumulative exposure to PAH measured as BaP. A linear model predicted a relative risk of 1.35 (95 % CI 1.22 to 1.51) at 100 µg/m^{-3} BaP -years, but there was a significant departure from linearity in the direction of decreasing slope with increasing exposures. Among the models tried, the best fitting were a two-knot cubic spline and a power curve ($RR= (1+bx)^p$), the latter predicting a relative risk of 2.68 at 100 µg/m^{-3} BaP years. Additive and multiplicative models for combining risks from occupational PAHs and smoking fitted almost equally well, with a slight advantage to the additive. Despite the large cohort with a long follow-up, the shape of the exposure–response function and the mode of combination of risks due to occupational PAHs and smoking remain uncertain. If a linear exposure–response function is assumed, the estimated slope is broadly in line with the estimate from a previous follow-up of the same cohort (Armstrong et al., 1994) and somewhat higher than the average found in a recent meta-analysis of BaP exposed populations in a variety of industries (Armstrong et al., 2003, 2004).

In another review, the results from cohort studies conducted on workers exposed to PAHs in several industries, including those of the aluminium production, coal gasification, coke production, iron and steel foundries, coal tar and related products, carbon black and carbon electrodes production, were evaluated, with a focus on cancers of the respiratory and urinary tract (Bosetti et al., 2007). The main results from cohort studies conducted on workers from PAH-related occupations, with emphasis on study results reported after the review by Boffetta et al. (1997) were described. An excess risk of lung/respiratory cancer was found in most of the examined industries, whereas the pooled relative risk (RR) for workers in coal gasification was extensively increased. The evidence for cancer of the bladder and of the urinary system is less consistent, with a modest increase in risk only for workers of aluminium production, coal gasification, iron and steel foundries.

A review by Gibbs and Labreche (2014) of epidemiological evidence (cohort study) of lung and bladder cancer risks in aluminium industry confirmed an increased risk with cumulative exposure to benzo(a)pyrene, used as an index of coal tar pitch volatiles exposure, adjusted for smoking. The risk of tumours at other sites including stomach, pancreas, rectum/rectosigmoid junction, larynx, buccal cavity/pharynx, kidney, brain/nervous system, prostate, and lymphatic/hematopoietic tissues (in particular non-Hodgkin lymphoma, Hodgkin disease, and leukemia) was not found.

The study of Gibbs et al. (2014) focusing on mortality/incidence in aluminium smelter workers (17,089 workers between 1920-2004) found significant relationships between BaP exposure and lung and bladder cancers incidence and mortality. Digestive, lung, and bladder cancer mortality and lung, bladder, and buccal cancer incidence increased significantly with BaP exposure. Bladder cancer incidence was not increased at BaP exposures below 40 $\mu g/m^3$ - years.

Wagner et al. (2015) performed a systematic review and meta-analysis (16 studies) on PAH exposures and larynx malignancies (incidence and/or mortality). The aim was to clarify the potential aetiological role of PAH on the risk of larynx cancer by applying the principles of evidence-based medicine and examining existing evidence regarding a dose-response relationship. The analysis confirmed significant effect both on incidence and a little smaller effect on mortality. Only few studies allowing for dose-response analysis indicated a positive dose-response effect.

<u>Epi-studies on rubber infill</u>

Though at present no epidemiological studies focussing primarily on the relationship between playing sports on synthetic turf pitches with rubber infill and human health effects are available, recently, some first explorations were done by Washington State (2017) and Bleyer and Keegan (2018). Washington State (2017) concluded, based on a database of a football coach, that there was no increased number of cancer diagnoses among football players compared to what would be expected if football players experienced the same cancer rates as Washington residents of the same ages. However, they acknowledged that the data were limited, especially with respect to exposure, and recommended further research. Moreover, they considered that their investigation was not designed to determine if soccer players in general were at increased risk of cancer due to exposures from crumb rubber in artificial turf. Bleyer and Keegan (2018) recently examined, using data from California, the state with the greatest number of synthetic turf pitches, whether the incidence of lymphoma in 14 to 30 year-olds is higher or increasing to a greater extent in regions with higher density of synthetic turf pitches. No association between annual lymphoma county incidence and county-level synthetic turf field density was found. These authors recommended further studies assessing individual-level exposures among football players, most desirably a case-control analysis.

B.5.8.5. Carcinogenicity: markers of exposure

In contact with consumer articles and mixtures, consumers are exposed to a multitude of PAH mixtures of different composition. A main issue in the risk assessment of PAHs is the quantification of the carcinogenic potency of PAH mixtures. The composition of the PAH mixtures encountered in food, consumer products, mixtures such as rubber granules and the environment varies, resulting in varying carcinogenic potencies. Each of the (sometimes up to several hundred) different PAH mixture components possesses its own toxicity profile, absorption behaviour, and may potentially be carcinogenic. For risk assessment of PAH mixtures, various approaches have been described such as the Toxicity Equivalence Factor (TEF) approach, or the marker approach. EFSA (2008) concluded that "the TEF approach to the risk characterisation for PAHs in food was not considered to be scientifically valid because of the lack of data from oral carcinogenicity studies on different PAHs, their different modes of action and the evidence of poor predictability of the carcinogenic potency of PAH mixtures based on the currently proposed TEF values".

BaP has in general mostly been used as a marker of occurrence and effect of the carcinogenic PAHs. Based on the data available, it seems indeed appropriate to assess occupational risks by using BaP as relevant indicator of inhalation exposure of the PAH mixture (with dermal-systemic exposure implicit, see B.5.8.6. – Human data). In the absence of specific data for the general population, this approach is also taken for consumers for this route of exposure. This pragmatic approach allows to use epidemiologic data where exposure to the PAH mixture is expressed using BaP as an exposure indicator as well.

For the oral route, EFSA (2008) concluded that BaP is not a suitable indicator for the occurrence of PAHs in, and thus the exposure to PAHs via, food. The relative concentrations of the PAHs in food were found to be variable, and BaP was not detected in some samples when other PAHs were measurable. By expanding the marker method to two PAHs (BaP and CHR), four PAHs (BaP, CHR, BaA and BbFA) and 8 PAHs (BaP, CHR, BaA, BbFA, BkFA, BghiP, DBAhA and IP), i.e. the PAHs that were measured in the carcinogenicity study of Culp et al. (1998), EFSA found the PAH4 and PAH8 markers to be more suitable indicators of PAHs in food, with PAH8 not providing much added value compared to PAH4.

As the relative concentrations of PAHs in rubber granules varies with BaP being not detectable in all samples, it may be considered that BaP is also not a suitable indicator for the occurrence in, and exposure to PAHs via, rubber granules. As the EFSA PAH8 group largely corresponds with the eight PAHs under current evaluation and thus are largely included in the study of Culp et al. (1998) which was used by EFSA for BMDL-derivation for the PAH8 marker group (see B.5.8.1.2, EFSAs approach is followed for current evaluation of the risks for consumer upon oral exposure. In this marker approach, the total carcinogenicity of the PAH mixtures tested in the Culp et al. (1998) study is assumed to correspond with the PAH8 marker group. So, it is possible to sum the exposures to the eight specified PAHs, and relate the summed exposure to the $BMDL_{10}$ for this marker group.

It is noted that the EFSA PAH8 differs from the eight PAHs under current evaluation (i.e. REACH-8 PAH, see Table B 28, two of the eight PAHs from the REACH-8 PAH group are not reported to be present in the mixtures tested in the Culp et al.(1998) study (unclear if measured and not detectable, or not measured at all). Hence, to assess the carcinogenicity of the REACH-8 PAH, we assumed that the concentrations of the deviating two PAHs benzo[e]pyrene and benzo[j]fluoranthene were present in the mixtures applied by Culp in similar concentrations to benzo[ghi]perylene and indeno[1,2,3-cd]pyrene[57]. In this case, the dose-response (and hence the $BMDL_{10}$) will be the same, regardless of the choice of PAH8 group. Subsequently, the toxicity of the EFSA PAH8 group can be applied in the current assessment to estimate the excess cancer risk of exposure to the REACH-8 PAH from rubber granules. However, it is noted that this assumption is accompanied with some uncertainty, as a direct verification of the reliability of this assumption is not possible. There is some information though of the concentrations of PAHs in two other coal tar pitch mixtures described in the EU RAR on CTPHT (EU, 2008). This EU RAR document shows that concentrations of REACH PAH benzo[e]pyrene in the coal tar pitch mixtures (11 891 and 8 976 mg/kg) are similar to concentrations of EFSA PAHs benzo[ghi]perylene (9 945 and 8 664 mg/kg) and indeno[1,2,3-cd]pyrene (11 106 and 9 061 mg/kg) in these mixtures. Unfortunately, the REACH PAH benzo[j]fluoranthene was not analysed. Nevertheless, the available information indicates that the assumption on similar concentrations of the deviating PAHs in the two PAH8 groups is defendable (RIVM, 2016).

It is noted that recently, ECHAs Risk Assessment Committee (RAC) established a dose-response relationship for the carcinogenicity of coal tar pitch - high temperature (ECHA 2017c). For the oral route, this was done based on the data of Culp et al. (1998) using BaP as marker. Another option suggested by RAC was to apply a PAH4 or PAH8 approach.

[57] Note that it is not necessary to assume that these substances have a similar potency and contribution to the carcinogenic potency, because the potency of the entire mixture is considered. When marker PAHs are exchanged, the BMD(L) stays the same if the concentrations of marker PAHs are the same.

Table B 28: Overview of PAH marker groups.

EFSA PAH8*	REACH-8 PAH#	CAS
Benzo[a]pyrene	Benzo[a]pyrene	50-32-8
Benz[a]anthracene	Benz[a]anthracene	56-55-3
Benzo[b]fluoranthene	Benzo[b]fluoranthene	205-99-2
Chrysene	Chrysene	218-01-9
Benzo[k]fluoranthene	Benzo[k]fluoranthene	207-08-9
Dibenz[a,h]anthracene	Dibenz[a,h]anthracene	53-70-3
Benzo[ghi]perylene		191-24-2
Indeno[1,2,3-cd]pyrene		193-39-5
	Benzo[e]pyrene	192-97-2
	Benzo[j]fluoranthene	205-82-3

* it is noted that all eight EFSA PAHs were included in the coal tar mixtures as tested by Culp et al. (1998) whereas two out of the eight ECHA PAHs (*i.e.* benzo[e]pyrene and benzo[j]fluoranthene) were not.
# this concerns the eight PAHs as currently included in entry 50 and under current evaluation

B.5.8.6. Carcinogenicity: summary, discussion and conclusion

Animal data

In numerous animal studies, the carcinogenic effects of PAHs, as single compounds or as various complex PAH-containing mixtures to which humans may be exposed, were examined by various routes of exposure. Of the PAHs under evaluation, BaP is the best-studied PAH. It is carcinogenic by all routes tested in a number of animal species. The majority of carcinogenicity studies in experimental animals were conducted as skin painting studies, a limited number of studies following ingestion were available, and only a few animal studies have been published on inhalation exposure. Oral studies with pure BaP or PAH mixtures resulted in increased tumour incidences in the gastrointestinal tract, liver, and respiratory tract in rats and mice. Long-term inhalation of PAH mixtures or pure BaP induced tumours in the lung in rats and mice. In hamster inhalation of BaP caused tumours in the respiratory tract, but not in the lung. Dermal exposure to relative low BaP or various PAH concentrations induced benign and malign skin tumours in various strains of mice. It is noted that experimental data on the combined carcinogenicity of exact these eight PAHs under current evaluation are not available. However, most of the eight PAHs under current evaluation have implicitly been tested as part of the PAH mixtures in the various studies.

Human data

No data are available on the carcinogenic effects of single PAHs in humans. In contrast, most of the human studies have addressed the carcinogenicity of PAH mixtures with BaP as marker compound. A considerable number of epidemiological studies have demonstrated that occupational exposure to soot, coal tar, and other PAH-containing mixtures is carcinogenic to humans. However, interpretation and comparison of these data is partly hampered due to differences in study design (case control versus cohort); differences in exposure measurements; not taking into account lifestyle factors; unawareness of co-exposure; and, incomplete data presentation. Nevertheless, despite these confounding factors, the majority of the epidemiological data associated airborne PAH exposures with increased lung cancer risk. In addition, exposed workers, particularly at coke ovens and aluminium smelters, have shown excess bladder cancer for which a relationship to PAH exposure was highly suggestive. From the most robust meta-analysis by Armstrong (2003, 2004) which included 39 different cohorts for lung cancer and 27 cohort for bladder cancer, URRs of 1.20 (95 % CI, 1.11-1.29, $p<0.001$; log-linear model) for lung cancer and 1.33 (95

%CI: 1.16-1.52, no significant heterogeneity) for bladder cancer could be derived at inhalation exposure of 100 µg/m^3 years BaP. By using the Armstrong et al. (2003, 2004) inhalation exposure data it is implicitly assumed that the dermal exposure will be as in the occupational settings that were covered by Armstrong et al. (2003, 2004). Although this assumption inevitably introduces some uncertainties, systemic exposure via the dermal route is taken to be reflected in these URRs. Locally, skin cancer has been reported to be positively associated with dermal PAH exposure, but not with inhalation exposure.

B.5.9. Toxicity for reproduction

In its criteria document, the WHO discussed the reproductive toxicity of several individual PAHs, among which benzo[a]pyrene. It was concluded that this PAH had adverse effects on female fertility and reproduction (WHO, 1998).

BaP is classified for effects on fertility and developmental toxicity, according to Regulation (EC) No 1272/2008. However, the observed effects are threshold effects and it is considered that these thresholds will be orders of magnitude higher than potential DMELs for carcinogenicity.

B.5.10. Other effects

Not relevant for this dossier.

B.5.11. Derivation of DNEL(s)/DMEL(s)

The human health endpoint of utmost concern for the PAHs is their potential for genotoxic carcinogenicity. Carcinogenicity of PAHs will presumably be exerted in humans and is being regarded as the critical effect for the purpose of this restriction proposal. Given the ability to induce genotoxic effects, a non-threshold approach is applied.

<u>Selection of key studies</u>

Taking into account the scope of current restriction proposal (*i.e.* eight PAHs in rubber granules), the anticipated exposure routes (*i.e.* oral, dermal and inhalation, cf section B.9.), the exposure route with highest contribution to the total PAH-exposure upon contact with rubber granules for consumers (*i.e.* oral (RIVM, 2017)) and the preference for the PAH8 marker group approach (as detailed above), selection criteria for prioritisation of (animal) carcinogenicity data were further established:

- the experimental animal study should include one or more group(s) with exposure to a PAH-mixture, in various dose or concentration levels;
- the composition (qualitative and quantitative) of the PAH-mixture as applied in the experimental animal study should be known;
- the PAH-mixture as applied in the experimental animal study should contain all/as much as possible of the eight PAHs under current evaluation.
- if human data with exposure to PAH mixtures are available that can be used for a quantitative assessment, these are given preference over the animal data.

- *Oral*

Experimental data on the toxicity of the REACH-8 PAH group upon oral exposure are not available, while the toxicity of the EFSA PAH8 group can be assessed using the data from Culp et al. (1998). See section B.5.8.5. for a discussion on the relevant markers of exposure.

Based on the criteria set, the mouse oral carcinogenicity study of Culp et al. (1998) (see section B.5.8.1.2 for a detailed summary of this study) was selected as key study, taking the $BMDL_{10}$ for PAH8 of 0.49 mg/kg bw/day (as derived by EFSA (2008), see section B.5.8.1.2 as point of departure.

Linear extrapolation is subsequently used to express the estimated exposure in terms of excess cancer risk[58]. This is done in accordance with the REACH Guidance (ECHA 2012). First the $BMDL_{10}$ is converted into a 'human' $BMDL_{10}$ (by adjusting for allometric scaling, applying a factor of 7 for mouse-human extrapolation), which is then divided by a high-to-low dosage factor, in order to reach a low risk level (e.g. dividing the 'human' $BMDL_{10}$ by 100,000 results in the dosage at which the excess cancer risk is one in a million (10^{-6})). The excess cancer risk from PAH8 at 1 in 10^{-6} corresponds therefore to 0.49 : 7 : 100,000 is 0.0007 μg/kg bw/d. In other words, the excess cancer risk per μg/kg bw/d is 1.43×10^{-3}. This dose-response relationship will be used for the risk characterisation when calculating the excess cancer risk upon oral PAH-exposure via contact with rubber granules for the general population (see section B.10).

A complicating factor when using an animal study to calculate cancer risks for young children is that a standard carcinogenicity study only exposes the laboratory animals to the substance starting from the age of around 6-8 weeks. This corresponds approximately to the period of adolescence in the case of humans. The consequence is that such a study does not provide any information about exposure in the preceding period. In the US, EPA and OEHHA apply an 'age-dependent adjustment factor' (ADAF) to calculate the cancer risk when using linear extrapolation based on a standard animal study (OEHHA 2009; US EPA 2005). The value of the ADAF should preferably be determined based on substance-specific information; otherwise it is, by default, 10 for the 0 to 2 years old group and three for the 2 to 16 years old group. The default ADAF for people aged 16 and up is one (OEHHA 2009; US EPA 2005).

This issue has also been noted by the EU Scientific Committees in their evaluation of the existing risk assessment methodologies and approaches for genotoxic carcinogens (SCHER/SCCP/SCENIHR (2009)), though no clear decision or recommendation was presented. EFSA (2005) has also taken this issue into consideration in their opinion on the Margin of Exposure (MoE)-approach (EFSA, 2005) and concludes that the usual default factor for inter- and intra-species differences of 10×10 for non-genotoxic substances would also be relevant for substances which are both genotoxic and carcinogenic. According to

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[58] The term excess cancer risk for the oral and dermal route is in fact erroneous. EFSA (2008) determined the extra cancer risk based on the Culp et al. 1998 study. Extra risk places greater weight upon the same increase in rate for a common lesion than for a rare lesion, compared to excess risk estimates and is therefore in general a more conservative risk estimate. Using the extra risk estimate as the excess risk estimate in the subsequent risk assessment slightly overestimates the risk from the oral and dermal route by a factor of approximately 1.2.

EFSA, these default factors could be reduced or increased when appropriate chemical specific data are available. The MOE approach does however not lead to explicit conclusions (quantitatively) about the excess cancer risk. However, EFSA does assert that an MOE of 10,000 or higher would indicate a 'low concern from a public health point of view'.

When using the linear extrapolation method, it is generally assumed that applying the high-to-low dosage factor results in an assessment which is sufficiently conservative to cover intraspecies differences as well. From a scientific perspective, some doubts have been expressed on this assumption. For example, the high-to-low dosage factor is argued to only correct for a 10 % risk in animals to e.g. a 0.0001 % risk in animals. Recommendations have therefore been made to apply the interspecies and intraspecies factors to carcinogenic substances by default, similarly to the risk assessment of non-carcinogenic substances, in addition to the high-to-low dosage factor (Slob et al. 2014). As is the case for non-carcinogenic substances, the default intraspecies factor of 10 should in that case be included to cover also any differences in sensitivity as a consequence of 'early-life exposure'.

However, within Europe, there is no general agreement (based on any regulatory framework, including REACH) on how to deal with the issue of 'early-life exposure' in the quantitative risk assessment of carcinogenic substances based on an animal study. For that reason, it was decided to follow the approach as described in the ECHA Guidance (ECHA 2012) and also followed by RIVM (2017) and ECHA (2017a) in their recent evaluations of the human health risks of exposure to substances in rubber granules, *i.e.* using the standard linear extrapolation method to assess the risks of PAHs in rubber granules – *i.e.* without an additional factor to account for any intraspecies differences as a consequence of 'early-life exposure'. The issue will however be further taken into consideration in the section on Uncertainties in the risk assessment (section B.10.4). It is further considered that a broad and general discussion on these assessment factors is urgently needed. That discussion should focus on the question whether and in which cases AFs for inter- and intraspecies may need to be applied for non-threshold carcinogens. It is considered that this discussion should not be limited to REACH but should also include other risk assessment frameworks.

- *Dermal*

Experimental data on the carcinogenicity of the PAH8 group upon dermal exposure are not available. For the purpose of assessing dermal (systemic) exposure to PAHs, the oral $BMDL_{10}$ value for PAH8 was converted to a dermal $BMDL_{10}$ value using route-to-route extrapolations. It is acknowledged that this may introduce uncertainties. The route-to-route extrapolation was done by using absorption fractions for the oral route of 0.3 and for the dermal route of 0.2 (see section B.5.1.1. for details), resulting in a dermal $BMDL_{10}$ of 0.74 mg/kg bw/d. Following linear extrapolation, the excess cancer risk per µg/kg bw/d is estimated at $9.46x10^{-4}$ for the dermal route. This dose-response relationship will be used for the risk characterisation when calculating the excess cancer risk upon dermal PAH-exposure via contact with rubber granules for the general population (as described in section B.10.). For the workers (i.e. installation and maintenance of the pitches), an adjustment factor of 0.38 (*i.e.* 5/7 × 48/52 × 40/70) is applied to correct for difference in exposure conditions between worker and general population.

It is noted that selecting the oral study of Culp et al. (1998) for evaluation of the dermal (systemic) route may introduce uncertainty to the risk assessment as route-to-route extrapolation is needed. Further, it is noted that dermal (systemic) exposure is reflected in the dose-response relationship derived from the epidemiological studies (see section B.5.8.4.).

With respect to dermal-local exposure, carcinogenicity data on PAHs are available. It is noted that ECHAs RAC established also for the dermal-local route a dose-response relationship for the carcinogenicity of CTPHT (ECHA 2017c). This was based on an analysis of Knafla (2011) which used a mouse skin painting study with a single PAH (i.e. BaP) dissolved in acetone (Nesnow et al., 1983) as basis to derive a dermal cancer slope factor for epidermal tumour formation. Also experimental data on PAH mixtures (i.e. different soot extracts) were obtained by Nesnow et al. (1983), however the PAH-content of the PAH-mixtures was not quantified. Taking into account the scope of current restriction proposal, i.e. PAHs in rubber granules focussing on the eight ECHA PAHs, using these experimental data would provide no information on the potency of the PAH mixture, as other PAHs were not included in this toxicity experiment. Therefore, the Dossier Submitter gives preference to the study of Culp et al. (1998) as basis for evaluation of the dermal exposure to the REACH-8 PAH.

- *Inhalation*

For the inhalation route, the meta-analysis of Armstrong et al. (2003, 2004) is considered to provide a robust, appropriate and reliable basis for assessment of the inhalation exposure, and is therefore selected as key study. It is noted that recently dose-response relations for lung (and bladder) cancer for workers were developed by ECHA (2017c), using the URR from this meta-analysis, in combination with a more recent value for reference lifetime risk based on the latest data on incidence of lung and bladder cancer from the year 2012 being available for most of the EU28 countries. In short, relative risk predictions for lung cancer at given cumulative exposure values can be made using the formulae:

$RR_x = 1 + (URR − 1) \times x/100 = 1 + (1.20 − 1) \times x/100$ (linear model)

where x is cumulative exposure in µg BaP/m^3-years. Excess lifetime cancer risk (ELCR) is calculated from the relative risks at given exposure with the formula:

$ELCR = P_{ref} \times (RRx − 1)$

where P_{ref} is cancer risk in the reference group (background risk in the unexposed target population), *i.e.* 0.07 for lung cancer.

The excess lung cancer risk per µg/m^3 -years is 0.00014 for workers.

By transforming the equations for occupational exposure to continuous exposure for the general population, also dose-response relationships for lung (and bladder) cancer for the general population were developed, by correcting the ELCR for differences in exposure conditions between workers and general population, using an adjustment factor of 5.3 (*i.e.* $20m^3/d/10m^3/d \times 7d/5d \times 52w/48w \times 70y/40y= 5.3$) (ECHA 2017c).

The excess lung cancer risk per µg/m^3 -year is 0.00042 for the general population.

For the present report, these dose-response relationships will be adopted and used for the risk characterisation when calculating the excess lung cancer risk for workers and consumers, respectively, upon inhalation PAH-exposure via contact with rubber granules (as described in section B.10.).

B.6. Human health hazard assessment of physicochemical properties

Not relevant for the dossier.

B.6.1. Explosivity

Not relevant for the dossier.

B.6.2. Flammability

Not relevant for the dossier.

B.6.3. Oxidising potential

Not relevant for the dossier.

B.7. Environmental hazard assessment

Also this whole section is not relevant for the PAHs as the scope of the assessment is on human health risks.

B.7.1. Aquatic compartment (including sediments)

Not relevant for the dossier.

B.7.2. Terrestrial compartment

Not relevant for the dossier.

B.7.3. Atmospheric compartment

Not relevant for the dossier.

B.7.4. Microbiological activity in sewage treatment systems

Not relevant for the dossier.

B.7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

Not relevant for the dossier.

B.8. PBT and vPvB assessment

The PBT assessment (B.8.) of PAHs is not relevant within the scope of the Annex XV report.

B.8.1. Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

Not relevant for the dossier.

B.8.2. Emission Characterisation

Not relevant for this dossier.

B.9. Exposure assessment

B.9.1. General discussion on releases and exposure

Exposure information on formulation[59] of rubber granules in public literature is scarce (and outside of scope for this dossier). Research has primarily focused on the use of rubber granules on synthetic (or artificial) turf or the installation of those turfs. In addition, some information is available from the use of rubber tiles, which are sometimes made from rubber granules by gluing the granules together to create the tile. As the function of rubber tiles as a shock absorber is the same for rubber granules in playgrounds, the information regarding contact information and behavioural information in playgrounds was considered in the exposure assessment below.

Less is known about the influence of coating of the granules on the exposure to PAHs, however the tendency is that exposures to PAHs are supposedly less as they are less easily released from the coated granules. This is supported by the findings by Fraunhofer ITEM (2016) showing lower migration rates to a simulant for dermal exposure for coated granules (see Section B.9.3.2. for results on uncoated granules). However, the use of coated granules on artificial turf for sports is thought to be limited. Currently, a Commission project STANPAH is ongoing focusing on acquiring dermal migration and analytical techniques suitable to measure PAH content or migration from rubber matrices.

There are quite a number of publications available describing the exposure to substances from rubber infill materials. Important routes of exposure are inhalation, dermal exposure and for playing and playing sports on artificial pitches the oral route is proven to be important (RIVM 2017, ECHA 2017a). In this dossier the focus lies on PAHs. The inhalation exposure of these PAHs is driven predominantly through inhalation of particulate matter (PM) containing rubber dust particles and thus also PAHs, especially during installation. Therefore, studies involving particulate matter measurements in relation to synthetic turf and rubber granules are within the focus of the dossier submitter for this chapter. Note

[59] Rubber granules have been classified as a mixture and for that reason the term formulation is used when the rubber granules are made. Typically the rubber granules are made from end of life tyres and no actual formulation takes place, which might cause confusion.

however that this exposure and risk assessment will not consider dust exposure on its own, where it is noted that during installation dust exposure limits should be safeguarded as well.

Exposure of synthetic turf installation and maintenance workers (IndusTox 2009, Ecopneus 2016), coaches (Castellano, 2008) and athletes (Van Rooij 2010, Menichini 2011, Simcox 2011, Ecopneus 2016) to substances/PAHs in rubber granules has been investigated in several studies. An estimation of the exposure of sporters (by taking Football players as an example) to the substances in rubber infill on synthetic turf pitches was most recently described by ECHA (2017a) and RIVM (2017).

Annex B.9. will not provide an exhaustive description of all the available literature on exposure to PAHs from rubber granules, but instead will focus on the exposure assessment. Selections of exposure data, exposure parameters, assumptions, and the applied calculations will be carefully explained. The starting points for the exposure assessment are the recent reports by ECHA and RIVM.

B.9.1.2. Summary of the effectiveness of the implemented operational conditions and risk management measures

To our knowledge, the operational conditions can differ amongst the manufacturing sites of the rubber granules, and can differ as to how they are being installed on the pitches. Manufacture of rubber granules is outside of scope for this restriction dossier. Regarding installation, the pitch size and its location (indoor or outdoor) has influence as to how the rubber granules are put on the artificial turfs. Especially for the smaller pitches manual labour is more difficult to avoid for installing the rubber granules and as a consequence contact with rubber granules becomes more evident. There are no set standards for operational conditions and risk management measures. The effectiveness of OC and RMMs will be described in the following sections, if appropriate.

B.9.2. Manufacturing

The formulation of the rubber granules (manufacturing process from end of life tyres (ELT) to the rubber granules) is not within the scope of this restriction proposal (please refer to Annex A for more information).

B.9.2.1. Occupational exposure

Not relevant for this dossier

B.9.2.2. Environmental release

Not relevant for this dossier

B.9.3. Use 1: Use of rubber granules on artificial turf

B.9.3.1. General information

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. 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*

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

* Professional players, coaches, referees etc. are in a legal sense 'Workers'. However, their exposure profile is the same as for consumers sporting on artificial turf and therefore the exposure of these 'workers' is considered in the same way as the adult players from the general population.

ES1: installation of synthetic pitches with rubber infill – workers

The way of installing rubber granules on synthetic pitches can vary depending on the size and pile height of the synthetic pitches and where the pitches are installed (location indoor and outdoor, country, and contractor). ETRMA (2016) has stated that the outdoor and indoor installation procedures are similar; however indoor locations may require the use of approach taken for smaller areas as larger machinery cannot access the indoor locations.

In case of large areas, companies will mainly use specialised spreading machines to distribute the infill and brush into the synthetic turf carpet. For smaller areas, companies typically load one tonne (or 1.5 m^3) big-bags into a small tractor unit (open driving space), which distributes the infill across the pitch. The amount of infill used in the field during installation depends on the size of the field and pile height of the carpet. The most commonly used pile height is 60 mm and this will typically need approximately 15 kg/m^2, that means use of approximately 110-120 tonnes of infill on a full size football field (120 big bags). With a shorter pile height, the infill quantity could be as low as 40 tonnes for the same area. According to ETRMA, a smaller quantity of rubber per square metre is also used on smaller pitches (ca. 5-10 kg/m^2).

Distribution of the rubber infill is normally done by one or two team units per field (two machines and workers that operate them). Big-bags are unloaded directly in the cargo bed of the truck, however if problems arise, workers can break the bags manually and then manual filling of trucks can occur. Some companies by default manually fill the trucks. Once distributed the infill is then brushed into the carpet using another tractor. Manual raking might occur as well.

Typically, there may be between two to four workers present on the field during installation and in total on average six workers are needed to install the pitches. Infilling a full-size football pitch normally takes two to three days (hence distribution of approximately 40-60 big-bags per day). Workers use protective masks (simple dust masks) to prevent inhalation of dust and protective clothing to prevent dermal exposure. According to ETRMA, workers sometimes don't use any type of PPEs during the rubber infill operations (except earmuffs because of the truck noise).

According to ETRMA (2016), the installation of a new field takes a total of 30-35 working days. The duration of the rubber infill procedure is 6 hours per day and lasts 2-3 days per week.

If the same workers are installing the new pitches, it is assumed that, as a worst-case, workers do the infill procedure for approximately 6 months per year.

Other tasks during installation are the preparation of the base such as placing aggregates with the right gradation, compaction etc. (20 days), laying down the synthetic turf (elastic layer underneath and the turf) (8 days) and spreading the sand layer (2-3 days) after which the granules are distributed.

Pitches are normally built during the summer months (6 months with the highest temperature of the year). The synthetic turf carpet and infill need to be dry to allow the infill to flow into the carpet pile. The temperature of the synthetic turf field with ELT rubber can reach in excess of 80 ^{o}C during very warm and sunny periods. It will be unusual for installation work to proceed in such hot conditions (over 30 ^{o}C ambient temperature) (see Annex A for more information).

ES2: Maintenance of synthetic pitches with rubber infill – workers

Different types of maintenance activities occur on the pitches, i.e. large maintenance typically at the end of each sporting season and regular maintenance with up to a weekly frequency dependent on the type of maintenance that is required (see below).

Refilling of infill material typically happens each year; 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) 3-5 tonnes is used. Refilling is done once per year with similar machines than what are used during the installations. Some of the 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 typically is considered small maintenance.

Other types of maintenance work include brushing or raking the rubber granules after the games. Brushing can be done with machines designed for this purpose, but manual brushing also occurs when a smaller area needs to be fixed.

According to Salonen et al. (2015) the frequency of brushing varies from once per week to once every 2-3 months. Shovelling of the rubber granules from the big-bags occurs as well. Nilsson et al. (2008) refers to a maintenance guide that states that the regular maintenance consists of cleaning, marking, deep-cleaning, surface loosening, filling up and watering. Watering can be relevant during the summer months with respect to cooling down and reduced friction. Salting of synthetic turfs may occur during the winter and snowy periods. Cleaning of machines is conducted regularly.

The maintenance guidance provides the frequencies for the maintenance:

- Raking: once every 4-6 weeks (indoors: as needed);

- Brushing: once every 4-6 weeks (indoors: 2-3 weeks);

- Aerating: maximum of three times per year, ideally after every sport season, and after snow clearing, if applicable (beginning in second year) (same for indoors); and

- Sweeping: as needed (same for indoors).

For the maintenance work, assumptions were used to estimate the duration and the frequency of the exposure.

ES3: playing sports on synthetic pitches with rubber infill - workers

Theoretically, professional sportspersons are in fact workers and therefore a separate exposure scenario was created in this restriction dossier. However, the behaviour is largely similar to amateur sportspersons, differing mainly in frequency and duration of training activities. Hence, the scenarios for amateur sportspersons (see under ES4 for description) largely apply. Their lifelong exposure was built up in the same way as for the consumers meaning that contributing scenarios (CS) during playing at playgrounds, playing sports in their youth, the CS during their professional career, and playing sports as a veteran is taken into account.

ES4: playing and playing sports on synthetic pitches with rubber infill - consumers

Exposure scenario 4 deals with children playing on playgrounds with synthetic turf and rubber infill, and with children and adults playing sports on synthetic turf pitches. The latter is described using playing football as the main sport utility of those synthetic pitches with rubber infill. It is supposed to cover for other sports as well, like rugby, American football, Gaelic sports, and other. Note that from the age of 11 playing sports is considered to be at a performance oriented level rather than a purely recreational one, thereby covering for what is perceived as the potentially highest exposed subjects due to higher frequency and duration of contact.

Playgrounds are increasingly constructed with rubber tiles or rubber granules (or rubber mulch or flakes) to provide a shock absorbing surface beneath the playground utilities, such as swings, slides, etc. Since children start playing at these playgrounds at a very young age (at first with their parents) and continue to play at these playgrounds during their childhood it was considered a relevant exposure scenario for the consumers. In this scenario, playing at playgrounds at random locations in the city and at day cares and schools is considered, and may also include public sports pitches. It is difficult to estimate the number of children playing at these playgrounds, but it is anticipated that it applies to the majority of the children population.

Football is commonly played in all EU Member States. It is assumed that there are millions of players in the EU, with around 15.4 million registered players. Including the other sports, such as rugby and Gaelic sports the total registered players mounts up to 20 million (see Annex A.2.3.1.).

In this report, several exposure scenarios are considered. Children typically start to play football at the age of 4 to 6 years, but then they will start with training courses and irregular frequency of training and playing). When children grow older, the frequency and the duration of the training and playing time increases. Whereas only a small percentage of players will become a professional player in the end, the absolute number of professional players in the EU is still relatively high.

In order to describe the PAH exposure to consumers several contributing scenarios have been created to ultimately derive a lifelong exposure to PAHs resulting from both playing on rubber infill materials at playgrounds and sporting on synthetic pitches. These contributing scenarios are valid for a specified period in a lifetime and are added up to obtain the lifelong exposure. It is foreseen that during childhood up to a certain age children will simultaneously play at playgrounds and play sports. The scenarios were elaborated in such a way that they calculate a realistic worst case exposure to PAHs from rubber granules for those exposed. This means that, based on actual situations, the exposure is calculated for the highest exposed individuals playing at playgrounds or playing sports. Thus, the majority of the population will be less exposed.

The scenarios for playing at playgrounds are based on the RIVM report on shock absorbing rubber tiles (RIVM 2016) as they are used for the same purpose and lead to more or less similar exposure profiles. As there are obvious differences between tiles and granules, these have been taken into account where possible, e.g. in the mouthing behaviour.

In the scenarios for sports, a distinction was made between playing sports for recreational purposes and performance-oriented sports (top level amateurs). To overcome differences in exposure, a further distinction was made by age, based on categories as they are now used by the Dutch football association. Information in the RIVM (2017) report and information received from the Finnish Football Association (2017; as cited by ECHA 2017a) has been used to estimate the duration and frequency of the exposure. For bodyweight, the default parameters have been taken from the General Fact Sheet prepared by RIVM (2014) including anthropometric data, representing worst-case default values. It is further assumed that goalkeepers starting from the age of seven are using gloves.

The following contributing scenarios (CS) have been created:

1. Child, 2 year old playing on playground
2. Child, 3-6 year old playing on playground
3. Child, 6-11 year old playing on playground
4. Child, 11-13 year old playing on playground
5. Children aged 4 to 11 years playing sports (outfield player)
6. Goalkeepers starting at 7 years of age
7. Children aged 11 to 18 years, performance-oriented sports (both outfield player and goalkeeper)
8. Adults (18 to 35 years of age), performance-oriented sports (both outfield player and goalkeeper)
9. Veterans (36 to 50 years of age), recreational level (both outfield player and goalkeeper)
10. Lifelong exposure (combination of aforementioned CS)

The above scenarios provide a picture of possible ways of coming into contact with rubber granules while playing at playground or playing football. For each scenario, parameter values were chosen for factors such as body weight and the frequency and duration of playing sports. In addition, for each route of exposure, the relevant values were selected such as body surface area in contact with granules, amount of granules in contact with the skin, respiratory rate and amount of granules that might be ingested. The exposure scenarios cover both females and males.

It is assumed that these scenarios are worst-case scenarios. Furthermore, it is noted that these scenarios may only describe a small population for whom the scenarios should cover, i.e. football player and for other sports players, like rugby, American football, and Gaelic sports. We acknowledge that in real life not all players are exercising and playing with such a heavy frequency on synthetic turf pitches so that the actual exposure is probably much lower. Besides that, pitches with other infill material and natural grass pitches are used as well.

An exposure scenario representing small children being exposed while watching (with their parents) the training or games of an older brother or sister and playing with the granules, is not considered further but assumed to be covered by the playground scenarios even though it could lead to a higher frequency of contact. Spectators, also including coaches, press-photographers etc., are also not considered separately here as their exposure is regarded to be much lower compared to the players and hence covered by those scenarios.

B.9.3.2. Exposure estimation

Availability of PAH for exposure – migration from the rubber granule matrix

In order to be exposed to PAH from rubber granules, these substances have to be released from the rubber granule matrix upon contact with the skin or sweat, upon contact with gastro-intestinal fluids, and lung fluids. To account for the release from the matrix, RIVM (2017) performed migration studies to assess the availability for exposure through dermal and oral contact.

Oral migration was studied using the Tiny-TIM model[60] to simulate the digestion of rubber granules in the gastro-intestinal tract. This model is an in vitro system consisting of two compartments that simulate the conditions in the stomach and the small intestine. During the experiment, peristalsis is simulated in both compartments for a total of four hours at 37°C, upon addition of artificial saliva, gastric and intestinal juices. To check for possible adherence to tubings used in the initial experiment, a repeat study was performed (Verschoor et al., 2018). The results of both studies were very similar, showing that approximately 9 % of the PAHs contained in the rubber granules are released from the granules into the gastrointestinal tract (RIVM 2017). This value is adopted for the exposure estimation in the present report.

A two-hour dermal migration study at 37°C was performed using artificial sweat, without a lipid fraction. This experiment indicated that only approximately 0.02 % of the PAHs in rubber granules are released into sweat (RIVM 2017). Although the study duration mimics the real life exposure durations, artificial sweat is not considered to be an appropriate testing fluid to assess the release of PAH. PAHs are lipophilic compounds, so migration in a more lipophilic medium than aqueous artificial sweat will be higher. So, whereas migration into sweat appears to offer the best representation of PAH exposure in relation to the

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[60] http://www.triskelion.nl/food-feed/adme-dmpk-food-feed/tim-services/

sweat-covered skin of an athlete, it will be less accurate for non-sweaty skin which contains natural skin oil and sebum and is therefore greasy (and may well be covered with skin care products that may have lipophilic characteristics, such as body lotion or sun cream). The dermal migration fraction of 0.02 % may therefore be an underestimation. In a study by Fraunhofer ITEM (2016) Tenax® was used to determine the migration of PAH from rubber granules. Tenax®, a powder with more lipophilic properties than artificial sweat, is considered to be a better alternative as migration simulant for lipophilic substances. Based on this study a dermal migration fraction of 0.05 % could be obtained, where it is noted that longer durations and a slightly higher temperature (10 days and 40°C) were used compared to the RIVM study. The migration study by Fraunhofer also showed that after 1 day at 20°C the content in migration receptor was below the limit of detection (LOD), but showed a higher migration fraction at 10 days and 60°C. For current evaluation, it was decided to use the migration fraction derived with 10 days and 40°C, i.e. 0.05 %, for the dermal exposure estimations as it approaches the skin temperature best.

In the absence of data on migration of PAHs out of rubber granulate dust into artificial lung fluid, as a worst case assumption it was assumed that all PAH inhaled via rubber dust would become available for exposure.

B.9.3.2.1. Workers exposure

There are three scenarios for workers, i.e. for the installation workers, maintenance workers and for the professional sportspersons also covering for trainers/coaches. The 'lifelong' exposure for the installation and maintenance workers is set at a 40 years working life. A different approach is taken for the professional players for whom it is unlikely to be a professional player for 40 years, but for which the pre- and post-professional life on the pitch is much more relevant. In a legal sense the professional sportspersons are considered workers, but from a risk assessment view it makes more sense to regard them as consumers. Therefore, the lifelong exposure for professional players is assessed in the same way as for the consumers (see CS10 on lifelong exposure).

ES1 and ES2 Installation and maintenance – workers

As described in Section B.9.3.1. the exposure during installation and maintenance are most likely related to dust formations and via direct dermal contact when emptying the big-bags containing rubber granules and the manual distribution of the rubber granules over the synthetic pitches. Though the activities during installation can take place with automated processes it is foreseen that manual labour involving potential direct contact will take place when emptying big bags, loading into tractors and during the distribution on the synthetic pitches. Manual labour is also foreseen during maintenance work, whether that relates to large maintenance or the more regular small maintenance.

There are two known exposure studies regarding the installation of synthetic pitches with rubber granules (IndusTox 2009, Ecopneus 2016) that also considered exposure to PAHs (both studies) or BaP (Ecopneus 2016) in particular. In addition, ECHA (2017a) estimated the exposure for workers during installation and maintenance based on literature on sporting activities. The IndusTox study included nine workers, whereas the Ecopneus study included in total around eight workers (exact number unclear based on the information provided, but this number can be lower for specific measurements). In both studies the respirable dust concentrations were determined and both studies included biomonitoring focussing on the metabolite 1-hydroxypyrene (1-OHP; as biomarker for BaP) in urine. In addition, the Ecopneus study included measurements of BaP in the breathing zone (as aerosol or part of PM) of the workers and BaP concentrations on four pads on four different locations (shoulder, chest, wrist and calf) of the worker to assess dermal exposure.

The biomonitoring data of both studies give insight in the exposure to PAHs from all sources and routes of exposure. Interesting to note is that 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. What these biological values of 1-OHP mean in terms of risks to the workers involved is not clear. The ECHA note (2017c) on coal tar pitch presents an approach to estimate the excess lifetime lung cancer risk for workers, however if we use the data from aforementioned studies in the equation to derive a converted BaP concentration a negative result is obtained (the measured concentrations fall outside the concentration range for conversion to BaP). Following the latest SCOEL recommendation on PAHs containing BaP the biological guideline value (BGV) of 0.5 µmol 1-OHP /mol creatinine (SCOEL, 2016) is slightly exceeded in the IndusTox study. The BGV is not a health-based limit, but indicates a level which non-occupationally exposed subjects (consumers) typically do not exceed. Unfortunately, the biomonitoring data cannot be used to derive a link between PAH content in rubber granules, worker activities and a risk estimate, since other sources cannot be excluded. Therefore, the biomonitoring data were not used in the exposure assessment.

ECHA (2017a) assessed the worker exposure during installation and maintenance based on measured maximum air concentrations at synthetic turf with rubber infill (inhalation) and based on contact with rubber granules of sportspersons (dermal). The inhalation exposure was assessed in a similar way as for sportspersons where it was assumed that worker inhaled dust containing rubber particles. The PM10 value as measured at a synthetic turf indoors was used as a starting point (based on NILU, 2006; see CS 5 to 9 under ES4 for clarification of this value)), but assumed that all PM10 originated from rubber granules in contrast to what NILU (2006) published (i.e. 35 %). As for dermal exposure, the assumption was made that there was similar dermal contact compared to outfield players, where additionally an extrapolation was made to account for longer contact durations during a work shift (six hours during installation work as opposed to one hour during sport).

Oral

Oral exposure was considered not relevant for workers during installation and maintenance. This exposure route was therefore not further taken into account.

Dermal

With respect to the dermal exposure, only the Ecopneus study provides limited measurement data. In the Ecopneus study the dermal load on the skin is estimated by summing up the BaP concentration on the four pads. The maximum sum of four measured values was 0.19 ng BaP/cm^2. Based on the available information, it is difficult to assess whether the method used by Ecopneus (2016) is adequate to measure the exposure to the skin. For example, exposure via dermal contact with the hands was not assessed (but was approximated by the wrist pad), whereas one would expect for workers to have dermal contact mainly through their hands and lower arms. As gloves are not typically worn according to occupational hygiene standards (wearing gloves in combination with short sleeved shirts may cause rubber granules going into the glove), the exposure to the hands may be highest. Also, the pads only allow a relatively small area for contact and thus may not catch a representative portion of the exposure.

For the reasons above, the approach taken for current evaluation is to use the highest measured dermal concentration of the cumulative dermal load (0.19 ng BaP/cm^2) and to extrapolate this to a total amount of PAH8 and rubber granules in contact with the skin over 6 hours of work (assuming contact with hands and lower arms and half of the legs; 5150 cm^2 (RIVM 2014)). To do so, information is required on the typical BaP content in the REACH-8 PAH (fraction is 0.15, see Appendix B1, which describes the contribution of each individual PAH from the REACH-8 PAH mixture) and the typical REACH-8 PAH content in rubber granules (11 mg REACH-8 PAH/kg granules, see Appendix B1). As the monitoring in the Ecopneus study took place for approximately 2 hours, a factor of 3 is applied to extrapolate to a 6 hour work shift. Further, as in the Ecopneus study only work on small pitches (half the size of a normal football pitch) was monitored, an additional factor of 2 was applied in current evaluation to account for the much lower amounts of rubber infill dealt with during those installations at those small pitches in the Ecopneus study. The 0.19 ng/cm^2 BaP measured in the Ecopneus study can be extrapolated to appr. 3.6 grams of rubber granules in contact with the skin during the installation, i.e. 0.19/1x10E-3 x 5150 x (100/15) x (1/11) x 3 x 2 = 3.6 gram.

Subsequently, the year average exposure is calculated using the information on frequency and duration.

The same calculations are performed for maintenance, corrected for frequency and duration of the tasks.

Inhalation

Data on respirable dust concentrations (PM10) could be derived from Ecopneus (2016), IndusTox (2009) and ECHA (2017a). IndusTox (2009) noted however that most of the dust was related to sand filling as the bottom layer of the synthetic turf and stated that the contribution from rubber infill installation is limited. ECHA (2017a) took the value from NILU (2006) which is based on measurements during sport events at an indoor location. It can be hypothesized that most of the PM10 value would result from rubber infill, which according to NILU (2006) was approximately 35 % of the measured PM10 during sports. This approach was not adopted for the current assessment, as these measurements do not represent the exposure during installation. Ecopneus (2016) however measured BaP in the breathing zone of the worker during installation. Based on their data a 90^{th} percentile of 23.24 ng BaP/m^3 could be derived. These measurements seem to represent the exposure to PAH from rubber infill installation most reliably even though the sample size is rather limited and in fact only BaP was measured as a marker for PAH. Moreover, the measurement data can be used directly in the equation to derive the cumulative exposure over 40 years of working life. To derive the year average inhalation exposure, the amount of BaP/m^3 (i.e. 23.24 ng BaP/m^3) is multiplied by the frequency, duration per day and by the number of months per 12 months.

Since no information is available for maintenance, the inhalation exposure is derived in the same way and thus using the Ecopneus measurement data, but corrected for frequency, duration and number of months.

To obtain the inhalation exposure for the worker over a 40 years working life, the year average exposure was multiplied by 40 years which in fact provides an exposure in terms of $\mu g/m^3$-years. The remaining parameters for exposure are given in Table B 29 below. Resulting exposure estimates are provided in Table B 30.

As noted by Ecopneus (2016), the measured BaP concentration in the breathing zones of the workers are the result of environmental exposure from traffic, from vehicles used during the installation, and from the rubber granules itself. An attempt to link the measured BaP concentrations in the breathing zone to rubber content in the air (by using content information of BaP in PAH mixture in rubber granules) resulted in unrealistic values much higher than the theoretical concentration limits (>1 g/kg). Therefore, the Dossier Submitter considered that the BaP must have come from several sources as noted by Ecopneus (2016) and of which rubber granule installation on the field even may be a minor source. In any case, the Dossier Submitter was unable to make a realistic link between the PAH content in rubber granules and the inhalation exposure of workers during installation and maintenance.

Table B 29: input parameters for the worker exposure of installation and maintenance workers.

Exposure parameters	Worker - installation	Worker – Large maintenance	Worker – Small maintenance
General			
Duration of exposure (h/d)	6	6	2
Frequency of exposure (d/week)	3	1	1
Months per year	6	1	10
Body weight (kg)[a]	68.8	68.8	68.8
Dermal			
Dermal load BaP (ng/cm^2)*	0.19	0.19	0.19
Skin contact area (cm^2)[a,*]	5150	5150	5150
Extrapolation factors (for size and duration)*	6	6	2
Fraction BaP in REACH-8 PAH[b,*]	0.15	0.15	0.15
Assumed content in Ecopneus study (mg/kg)[b,*]	11	11	11
Amount rubber granules on skin (g)	3.6	3.6	1.2
Inhalation			
BaP in breathing zone (ng/m^3)**	23.24	23.24	23.24

[a] from RIVM 2014; [b] from Annex D; * Required parameters to calculate the amount on skin

** This value cannot be extrapolated to a PAH content in rubber granules

Lifelong cumulative exposure estimates for the workers is derived as follows:

Dermal exposure: (Amount of granules on skin x REACH-8 PAH content x frequency/year x frequency/week x dermal migration fraction/ body weight) x working years (40 years)

Inhalation exposure: (BaP air concentration x frequency/year x frequency/week x hours/8hours) x working years (40 years)

Table B 30: exposure estimates for the dermal and inhalation route for workers in ES1 and ES2, based on REACH-8 PAH content of 17 mg/kg; P95).

Worker scenario	Dermal exposure estimate (µg/kg bw/d)	Inhalation exposure estimate (µg/m^3-year BaP)
Installation	0.00013	0.21
Large maintenance	7.3x10^{-6}	0.012
Small maintenance	2.4x10^{-5}	0.039

ES3: sporting on synthetic pitches with rubber infill - workers

In this section, the scenarios for the professional players (outfield players and goalkeeper) are briefly described with respect to playing frequencies and durations. The focus is mainly on those parameters that differ from performance-oriented amateur play in the age range 18-35 years as described under ES4. The same exposure contributing scenarios are adopted from the amateur situation as described under ES4, including the playground scenarios.

Please refer to ES4, where the consumer contributing scenarios are described for amateurs and how the lifelong exposure is calculated.

Contributing scenario W1: professional outfield player
Please refer to the scenario of the performance oriented outfield player in age category 18-35 years. The frequency of training and match increased to six times per week, with a duration of four hours per day in total compared to the performance oriented player (consumer).

Contributing Scenario W2: professional goalkeeper
Please refer to the scenario of the performance oriented goalkeeper in age category 18-35 years. The frequency of training and match increased to six times per week, with a duration of four hours per day in total.

B.9.3.2.2. Consumer exposure[1]

ES4: playing and sporting on synthetic pitches with rubber infill – consumers

The following contributing scenarios (CS) have been created:

1. Child, 2 year old playing on playground
2. Child, 3-6 year old playing on playground
3. Child, 6-11 year old playing on playground
4. Child, 11-13 year old playing on playground
5. Children aged 4 to 11 years playing sports (outfield player)

6. Goalkeepers starting at 7 years of age
7. Children aged 11 to 18 years, performance-oriented sports (both outfield player and goalkeeper)
8. Adults (18 to 35 years of age), performance-oriented sports (both outfield player and goalkeeper)
9. Veterans (36 to 50 years of age), recreational level (both outfield player and goalkeeper)
10. Lifelong exposure (sum of a combination of aforementioned CS)

Contributing Scenario CS1-4: children 2 to 13 years playing at playgrounds
The scenarios including children playing at playgrounds describe the habits of play for four age categories. Each age category is assumed to have exposure to PAHs from the rubber granules or rubber mulch (or flakes) that serve as shock absorption material. Notably, there is very little to no information available on the use of rubber granules at playgrounds and resulting exposure to PAHs. For this reason, due to the fact that the use of rubber tiles at playgrounds have the same purpose and function, the scenario descriptions were adopted from the RIVM evaluation of PAH exposure from shock absorbing rubber tiles that are used at playgrounds (RIVM 2016). To accommodate differences in exposure that might result from the different shape and form of granules compared to tiles, the assessment of the oral exposure was however adjusted.

It is anticipated that oral exposure via ingestion is much more likely to occur for granules compared to parts from worn rubber tiles. Therefore, the oral exposure during playing on playgrounds was approached similarly as for oral exposure during sports on artificial turf.

With respect to the dermal exposure, most input parameters were adopted from RIVM (2016), but calculations were performed differently as the exposure from tiles was based on a diffusion model assuming a slab like surface, which in the Dossier Submitters view is not applicable to PAH exposure from rubber granules. Therefore, the exposure estimation was brought in line with the dermal exposure assessment as done for playing sports on artificial turf (CS5-9). The input parameters for the frequency of contact with the rubber surface with either hands, legs and feet were used to derive a dermal load (amount of granules in contact with the skin). This is based on the assumption of a cumulated surface area of hands, legs, and feet corrected for frequency of contact (RIVM 2016), the amount of rubber granules per cm^2 (0.083 g/cm^2; RIVM 2017; see also below) and a derived fraction remaining on the skin of 1-1.5 % (based on RIVM 2017), which for each of the scenarios resulted in 0.21, 0.27, 0.56 and 0.87 g[61] rubber granule on the skin. This restructuring of the calculations was also needed later on to be able to calculate a maximum permissible PAH concentration in rubber granules (see section B.10.). The inhalation exposure was

[61] The amount on skin per scenario is derived by summing the amounts per skin part (surface area skin part x amount rubber granule per cm^2 x fraction remaining on skin x frequency of contact per skin part). Example Scenario 1: ((0.014 x 10000 x 0.01 x 0.083) x 261/365) +((0.072 x 10000 x 0.01 x 0.083) x 66/365)+ ((0.018 x 10000 x 0.01 x 0.083) x 66/365) = 0.21 g

considered negligible in the case of the rubber tiles, because the REACH-8 PAH substances are considered low-volatile and the exposure would predominantly result from evaporation of REACH-8 PAH from those tiles. Here, it is much more likely that exposure to rubber dust can take place during playing on rubber granules. Therefore, the inhalation exposure was addressed similarly as for the inhalation exposure assessment during sports (see CS 5 to 9).

In the reasonable worst-case scenario used for the exposure assessment (aiming at a 95th percentile of the exposure, typically used percentile for consumer exposure), a child is assumed to visit a playground with rubber granules containing PAHs for a few hours per day, on a number of days per year, from the age of 2 up to and including 12. This age range was selected since children in this age range start walking, visit playgrounds, and go to a day care centre or elementary school where playground equipment accompanied by rubber granules can be present. During these visits, inhalation, dermal and oral exposure is possible, respectively, from inhaling particles, having dermal contact with rubber granules especially to hands, legs and feet, and by ingestion of the granules or via hand-to-mouth contact. Below the input parameters are provided for the calculations for the exposure to PAHs at playgrounds (Table B 31 and Table B 33).

Table B 31: 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

Table B 32: Input parameters for the dermal and oral exposure calculation (taken from RIVM (2016) with slight adjustments)

Parameter	Value	Unit	Reference
General			
Frequency of playground visit	261/365	day^{-1}	RIVM 2016; based on (Gallup 2003)
Duration of playground visit	2	h/day	BAuA 2010
Oral exposure			
Amount ingested (g)	0.09 (2-10 year) 0 (11-13 year)		US EPA 2017a
Frequency of ingestion	261 / 365	day^{-1}	Assumed
Dermal exposure			
Hands			
Frequency of playground visit with hand-ground contact	261 / 365	day^{-1}	RIVM 2016; based on (Gallup 2003)
Legs			
Frequency of playground visit with leg-ground contact	66 / 365	day^{-1}	RIVM (2016)
Feet			
Frequency of playground visit with feet-ground contact	66 / 365	day^{-1}	RIVM (2016)
Amount granules (g) per cm^2	0.083		RIVM (2017)
Fraction sticking to skin	0.01; 0.015		Derived from RIVM (2017), see above
Amount granules on skin (calculated)	0.21; 0.27; 0.56; 0.87	g	Calculated
Inhalation exposure			
PM10 – rubber dust	12	$\mu g/m^3$	RIVM (2017) (NILU, 2006)

Calculation of the exposure per contributing scenario (see below after description of CS 5 to 9)

Contributing Scenario 5 to 9 playing sports on synthetic turf with rubber granule infill

The contributing scenarios 5 to 9 are based on the exposure assessment as described in RIVM (2017), with some minor adjustments for some of the input parameters based on new information. As stated previously, the sports scenarios are based on the popular sport football, which is supposed to represent other sports as well, e.g. rugby, Gaelic sports and other.

In each scenario, exposure to PAHs from the rubber granules can occur via three routes: the dermal route via skin contact, the inhalation route via inhaling of rubber dust (airborne particles), and/or the oral route via ingestion. Accidental ingestion of rubber granules is likely, certainly in the case of young children. For this reason, oral exposure was also taken into account.

From the age of seven, the goalkeeper is introduced in football. The main difference between the outfield players and goalkeepers is the higher estimated dermal exposure across all age categories and higher oral exposure during adulthood for the goalkeepers (oral exposure between goalkeeper and outfield player is up until adulthood the same). The main drivers for exposure are the frequency and durations of contact to the amount of rubber granules contacted (dermal exposure), ingested (oral exposure), or inhaled as rubber dust. The latter is in fact the same across all age categories as it is assumed that they breathe the same air.

Durations and frequencies were based on training schedules at arbitrarily selected football clubs in the Netherlands. The frequency and duration may differ per club, because the clubs themselves decide how the activities are structured. The age categories including 11 years up to 35 years (contributing scenarios 7 and 8) are based on performance-oriented teams with higher frequency and duration than typical recreational teams. According to the Dutch Football Association they represent a top-amateur level. Frequency over the year (months per year) is set differently for the dermal route since during the winter period, sporters will train in suitable outfits that fully cover arms and legs. Please note that this assumption may not hold for all regions across the EU.

The age categories are 'under six', children aged 11-18, adults aged 18-35 and veterans. Goalkeepers are introduced to the game from seven-years old and for that reason an 'under eight' category was introduced as well.
The scenario of children aged from four to six, the 'under six' category, is based on a four-year-old child who trains once per week (for one hour) and participates once per week in a number of mini-matches which last a total of 1.5 hours, with the exception of the two summer months and three winter months. This is based on a training schedule at an arbitrarily selected football club in the Netherlands. As stated above, the frequency and duration may differ per club, because the clubs themselves decide how the activities for children 'under 6' are structured. The assumption is that the children always play on synthetic turf with rubber granules (this applies for all scenarios). The body weight of a four-year-old child is estimated as being 15.7 kg, based on the 25 percentile of the body weight distributions among children aged between 3 and 6 (RIVM 2014).

Specific for goalkeepers the 'under eight' category was drawn up. At this age, children play on half-size pitches with goalkeepers, who are introduced for the first time to the football game in this age category. This scenario assumes that there is a designated, regular goalkeeper. However, in practice, this role may be assigned to a different child each match. In addition to dermal and inhalation exposure, this scenario also includes oral exposure, since rubber grains may end up in goalkeepers' mouths during training sessions and matches.
The scenario of children aged 11 and up (44.8 kg (RIVM 2014)) describes those who have switched to playing on full-size pitches. One specific feature of this scenario is the performance-oriented players in the first team of this age group. This team places a stronger emphasis on performance-oriented sport than would be the case in recreational sport. This primarily has an effect on the number of training sessions per week, which can be held as often as four times per week. The training sessions last at least 1 to 1.5 hours. A match lasting at least 2x30 minutes is also played. It can be assumed that children spend 1.5 hours on the pitch during match days. With the exception of the summer season, the children play throughout the entire year. They continue training during the winter break, in contrast to the younger 'under six' children for whom this is not the case. This is based on a training schedule at an arbitrarily selected football club. The training schedule corresponds to that of an elite amateur club.

The adult scenario is based on adult men and women (18 years and older, 68.8 kg, 25th percentile (RIVM 2014)) who participate in performance-oriented sport. A specific factor in this scenario is the performance-oriented player in selection teams, where the number of training sessions each week can be as many as four, with training sessions lasting up to two hours each time. A match lasting 2x 45 minutes is also played every week. It can be assumed that adults spend 2 hours on the pitch during match days. Consequently, the adults will spend 10 hours on the pitch per week. With the exception of the summer season, the adults play throughout the entire year.

After playing performance-oriented sport, football players and goalkeepers often join the veterans. It is assumed that a player plays sport at a recreational level from age 36 to age 50.

Below the general principles of the exposure via the dermal, oral and inhalation route have been described based predominantly on the approach taken by RIVM (2017).

Oral

While playing football, the child's skin comes into contact with rubber granules via his/her hands. Young children may have oral exposure as a consequence of hand-mouth contact with chemicals present on the skin. Little is known about hand-mouth contact of rubber granules and various approaches are used to calculate the exposure. The simplest way is to assume that a fixed amount of rubber granules is ingested per occasion (training session or match) by hand-mouth contact. The literature contains a few figures, such as 1 gram of rubber granules per match (NIPH, 2006), as well as default assumptions based on the risk assessments for soil safety: 50 to 200 mg soil/day (E.g. US EPA 2011, Pavilonis et al. 2014, RIVM 2007).
The assumption of 1 gram of rubber granules ingestion per period of sport activity for a four-year-old child was considered as being too extreme. Therefore, the default value for soil ingestion of 0.2 gram as used by the US EPA (2011) was selected for children by RIVM (2017). This rationale is followed in this restriction dossier, however in 2017, after finalization of the RIVM research, the US EPA default for soil ingestion was updated. In fact, the old default of 0.2 gram remained the same for the combined exposure to soil and dust, but now US EPA (2017a) also made a distinction possible between the two sources and consequently derived an oral ingestion of soil of 90 mg/day for children up to 11-years old and of 50 mg/day for children from the age of 11 and adults (the value for adults was in fact unchanged from 2011).

In this restriction dossier, in line with the approach followed by RIVM (2017), the oral amounts ingested were set to an amount **per event**, rather than per day. The reason for this slight but important adjustment is that the amount per day as mentioned by US EPA (2011; 2017a) could be related to a single activity on a particular day also accounting for non-exposure days. The amount per day can be regarded as an average and hence it was assumed for current evaluation that it could be the result from one activity. The oral ingested amounts are 90 mg/event for children (<11 y) and 50 mg/event for children (11 y and up) and adults when assuming playing on playgrounds and playing sports as an outfield player. The goalkeepers are believed to have relatively higher oral amounts ingested even though there is no literature to support this assumption. The goalkeeper is more often close to the ground and considered more likely to accidently get granules in their mouth. The oral amount ingested, for all age categories, was set at 90 mg/event.

Dermal

The way the contacted amounts via skin contact were derived is the same across all age categories. Based on a number of exposure studies a range was obtained. As an example the age category 'under six' is shown, which also covers players up to 12 years: "*The amount of rubber granules with which a child can come into contact via the skin depends on the type of sport activity, the uncovered skin area, and any granules which end up in the clothing. The relevant estimates from the literature vary and are expressed in amounts per surface area (mg/cm^2) or in amounts per kilogram body weight per day (mg/kg bw/day). When converted into total amounts, the values vary between 0.45 g and 1.1 g of rubber granules, although it should be noted that these amounts were calculated for the age category of 6-11 years ([30, 31]). No information is currently available for younger children* (RIVM 2017)".

To get insight on the value of this estimate, RIVM made the following consideration, which was repeated for each age category: "*Another theoretical approach for obtaining amounts is to use data from the US EPA on 'solid adherence to skin' (soil which remains on the skin after activities) [29]. US EPA (2011) reports skin adherence factors (mg/cm^2) for exposure to soil during football (geometric mean (GM):0.11; geometric standard deviation (GSD):1.8 to GM:0.014; GSD:5.3) and rugby (GM:0.4; GSD:1.7). In view of the wide range of values, it should be noted that much higher dermal exposures could occur if the calculations are based on the US EPA data. However, the question is whether dermal exposure to soil is not too extreme for a scenario for rubber granules. Additionally, in view of the considerable range in skin adherence factors, it was decided to base the calculation on the 'dermal load of a substance' as reported in the Norwegian study (1.1 g for 1 mg/cm^2) [31]. This decision was made because the dermal load from that study specifically refers to rubber granules and because the value falls within the spread of the values reported by the US EPA.*

In view of the above considerations and based on the literature, 1 g of rubber granules that can come into contact with the skin during a sport activity (training session or match) would appear to be a realistic estimate for a 4-year-old child. In order to get a better idea of the estimate, a weighted amount of rubber granules of 10 g was spread out, after which the surface area was determined as being approximately 120 cm^2 and therefore 0.083 g/cm^2. The spread out layer was with little space between the grains and 1 grain deep. In the worst-case situation, where the skin would be covered in a layer of 1 grain, one could come into contact with (0.083 g/cm^2 x 1260 cm^2 (contact with quarter of legs, half of arms and hands)) 105 g of rubber granules. In the literature, the assumption is that 1 g of rubber granules leads to dermal exposure, which is approximately 1 % of the absolute maximum estimate of the amount of rubber granules. If the contact with rubber granules were to be concentrated on one area of the body, 1 g of rubber granules would represent 12 cm^2 of skin contact. These appear to be reasonable values. Calculations of the dermal exposure will therefore be based on 1 g of rubber granules for the 4-year-old child."[62]

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[62] Reference number [29]: US EPA, Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F. 2011.
Reference number [30]: Pavilonis, B.T., et al., Bioaccessibility and Risk of Exposure to Metals and SVOCs in Artificial Turf Field Fill Materials and Fibers. Risk Anal, 2014. 34(1): p. 44-55.
Reference number [31]: NIPH, Artificial Turf Pitches: An Assessment of the Health Risks for Football Players. Norwegian Institute of Public Health and the Radium Hospital, Oslo, Norway. 2006.

The same approach was taken for all other age groups to derive the dermal amount contacted with the skin and to acquire the frequency and durations. As shown in RIVM 2017, this resulted in the estimates of 3.3 and 6 grams for children aged 11 to 19 years and for adults, respectively. Please refer to Table B 33 for the input parameters per age category. The goalkeeper (age 7 to 50) is assumed to have a different dermal contact compared to outfield players. The fact that gloves are worn means there is no dermal exposure via the hands, but it is assumed that goalkeepers will have more contact through arms and legs with rubber granules. Unfortunately, no information is available and thus RIVM (2017) assumed that the goalkeeper is exposed to 10 g of rubber granules per period of sport activity, which is 10-fold higher than exposure for an outfield player. This value is kept constant for all other age categories for the goalkeeper.

Inhalation

NILU (2006) measured the PM10 in indoor halls where rubber granules are used. In this study they measured a concentration of 40 µg/m^3 PM10 in air of which it was estimated to consist maximally 35 % of rubber. Hence, based on NILU (2006) an air concentration of rubber dust (measured as PM10) of 12 µg/m^3 was derived in a sports hall with SBR rubber granules. In this Norwegian study, the influence of PM10 from the outside air can be assumed to be negligible, meaning that this value is relevant for determining the contribution of inhalable rubber dust to the total exposure. The air concentration of PAH can be determined by multiplying the PM10 value of 12 µg/m^3 by the content fraction in the rubber granules. The inhalation exposure is further driven by the duration of sports per event, the number of events per year and over a lifetime (summing all contributing scenarios).

Marsili et al. (2014) looked at possible PAH vapour exposure resulting from rubber granules under laboratory conditions. The granules were heated to 60°C representing hot summer days and analysed the vapours released from the rubber granules for PAHs. In a subsequent worst case exposure and risk assessment, assuming that the PAH released remain directly above the pitch and are available for inhalation, resulted in risk estimates of $1x10^{-6}$ for carcinogenic effects. The worst case approach and conditions that are unlikely to take place the entire year and the low vapour pressures of the PAHs have led to the conclusion of the dossier submitter to disregard the possible very low contribution of PAHs in vapour phase to the inhalation exposure.

Table B 33: input parameters for contributing scenarios 5 to 9

	CS 5	**CS 6 (goal keeper)**	**CS 7**	**CS 8**	**CS 9**
	Age 4-11	**Age 7-10**	**Age 11-18**	**Adults**	**Veteran**
			Performance oriented	**Performance oriented**	
General					
Body weight (kg)	15.7	24.3	44.8	68.8	68.8
Frequency (days/week)	2/7	3/7	5/7	5/7	2/7
Frequency (months/year; oral and inhalation)	7/12	10/12	10/12	10/12	10/12
Frequency (months/year; dermal)	7/12	7/12	7/12	7/12	7/12
Duration hours/day	1.5	1.5	1.5	2	2
Oral exposure					
Oral amount ingested (g)	0.09	0.09 (for all GK)	0.05	0.05	0.05
Migration (fraction)	0.09	0.09	0.09	0.09	0.09
Dermal exposure					
Dermal amount contacted (g)	1	10 (for all GK)	3.3	6	6
Migration (fraction)	0.0005	0.0005	0.0005	0.0005	0.0005
Inhalation exposure					
PM10 – rubber dust (μg/m^3)	12	12	12	12	12
Fraction BaP in REACH-8 PAH*	0.15	0.15	0.15	0.15	0.15

* See Annex D.

Oral exposure: Amount granules ingested x REACH-8 PAH content x frequency/year x frequency/week x oral migration fraction/ body weight

Dermal exposure: Amount granules on skin x REACH-8 PAH content x frequency/year x frequency/week x dermal migration fraction/ body weight

Inhalation exposure: PM10 rubber dust in air x REACH-8 PAH content x Fraction BaP x hours/d x frequency/year x frequency/week

Scenario 10: lifelong exposure

The lifelong exposure is determined by multiplying the year average exposure by the number of years that the year average exposure can take place per contributing scenario, compared to a lifespan of 70 years. In other words, the 4-year-old scenario for sports lasts for 7 years (covering the years up to the age of 10, in what is a worst-case approach as lower body weights are used to derive the exposure), while the year average exposure for the 4-year-old scenario is multiplied by a factor of 0.1 (=7/70). The exposure is determined in the same way for the other scenarios and then added up.

To determine 'lifelong' exposure for goalkeepers, the assumption is that they have been an outfield player since age 4, and have played as a goalkeeper on the pitch from age 7. For that reason, goalkeepers' scenarios for 11-year-olds, adults and veterans were drawn up that are otherwise the same as for the outfield players, but taking into account the higher dermal and oral exposure (as described for the seven-year-old goalkeeper; CS6).

During childhood years from the age of four, simultaneous exposure can take place during both playing at playgrounds and during sport activities. Looking at the frequency of play and frequency of sport it is noticed that they may overlap and combined have a frequency higher than once per day. This is not an issue for the dermal and inhalation route of exposure as the input parameters are event-based rather being based on a daily exposure. This is however not the case for the oral amount ingested as presented by US EPA (2017a). The original data represents an amount per day, which was conveniently converted to an amount per event as explained above. To avoid an overly conservative approach, in case of multiple events within one day for a prolonged period of time as indicated by a combined frequency > 1/d, the approach taken was to limit the amount ingested to the default of 90 mg/day.
In the underlying calculations, the frequency of playing at playgrounds in the contributing scenarios 2 and 3 the frequency of oral contact was corrected to once per day (hence increased from the original input parameter) with an amount ingested of 90 mg/day; while at the same time the frequency of oral contact was set to zero (hence lowered) for the sports in the same age categories.

The calculation of lifelong exposures for professional and consumer players, both outfield players as goalkeeper, is presented below:

Calculation of 'lifelong' exposure for an outfield player:
Year average exposure for 2-year-old (scenario 1) x 1 years / 70 years +
Year average exposure for 3-year-old (scenario 2) x 3 years / 70 years +
Year average exposure for 6-year-old (scenario 3) x 5 years / 70 years +
Year average exposure for 11-year-old (scenario 4) x 2 years / 70 years +
Year average exposure scenario for 4-year-old (scenario 5) x 7 years / 70 years +
Year average exposure scenario for 11-year-old (scenario 7) x 7 years / 70 years +
Year average exposure scenario for adult (scenario 8) x 18 years / 70 years +
Year average exposure scenario for veterans (scenario 9) x 16 years / 70 years
= 'lifelong' exposure for an outfield player

Calculation of 'lifelong' exposure for a goalkeeper:
Playground scenarios
Year average exposure for 2-year-old (scenario 1) x 1 years / 70 years +
Year average exposure for 3-year-old (scenario 2) x 3 years / 70 years +
Year average exposure for 6-year-old (scenario 3) x 5 years / 70 years +
Year average exposure for 11-year-old (scenario 4) x 2 years / 70 years +
Sports'field scenarios
Year average exposure scenario for 4-year-old (scenario 5) x 3 years / 70 years +

Year average exposure scenario for 7-year-old goalkeeper (scenario 6) x 4 years / 70 years +
Year average exposure scenario for 11-year-old goalkeeper (scenario 7) x 7 years / 70 years +
Year average exposure scenario for adult goalkeeper (scenario 8) x 18 years / 70 years +
Year average exposure scenario for veteran goalkeeper (scenario 9) x 16 years / 70 years = 'lifelong' exposure for a goalkeeper

The lifelong exposure for professional players is obtained by replacing the year average exposure of scenario 8 by scenarios W1 for the outfield player or W2 for the goalkeeper. In Table B 34 and Table B 35 the exposure eestimates per route per contributing scenarios are presented together with the lifelong exposure estimates. The content of the REACH-8 PAHs was set at the P95 of the measured content in Europe, i.e. 17 mg/kg.

Table B 34: Exposure estimates per route for the playground scenarios and the outfield player (based on REACH-8 PAH content of 17 mg/kg; P95)

Contributing scenario	**Oral exposure estimate (µg/kg bw/d)**	**Dermal exposure estimate (µg/kg bw/d)**	**Inhalation exposure estimate (µg/m^3-year BaP)**
1	0.00011	2.1×10^{-6}	1.8×10^{-6}
2	0.00038	6.2×10^{-6}	5.5×10^{-6}
3	0.00040	1.4×10^{-5}	9.1×10^{-6}
4	0	4.7×10^{-6}	3.6×10^{-6}
5	0*	9.0×10^{-6}	2.2×10^{-6}
7	0.00010	2.6×10^{-5}	8.0×10^{-6}
8	0.00017	7.9×10^{-5}	2.7×10^{-5}
9	5.7×10^{-5}	2.6×10^{-5}	9.1×10^{-6}
W1	0.00020	9.5×10^{-5}	6.6×10^{-5}
Total			
Lifelong prof. player	0.0013	0.00018	1.1×10^{-4}
Lifelong consumer	0.0012	0.00017	6.7×10^{-5}

*Oral exposure covered by playground scenario
W= worker

Table B 35: Exposure estimates per route for the playground scenarios and the goalkeeper (based on REACH-8 PAH content of 17 mg/kg; P95)

Contributing scenario	Oral exposure estimate (µg/kg bw/d)	Dermal exposure estimate (µg/kg bw/d)	Inhalation exposure estimate (µg BaP /m^3-year)
1	0.00011	2.1×10^{-6}	1.8×10^{-6}
2	0.00038	6.2×10^{-6}	5.5×10^{-6}
3	0.00040	1.4×10^{-5}	9.1×10^{-6}
4	0	4.7×10^{-6}	3.6×10^{-6}
5 – 3 yrs in cat.	0*	3.9×10^{-6}	9.6×10^{-7}
6 – GK	0*	5.0×10^{-5}	2.7×10^{-6}
7 – GK	0.00018	7.9×10^{-5}	8.0×10^{-6}
8 – GK	0.00031	0.00013	2.7×10^{-5}
9 – GK	0.00010	4.4×10^{-5}	9.1×10^{-6}
W2	0.00037	0.00016	6.6×10^{-5}
Total			
Lifelong prof. player	0.0015	0.00036	1.1×10^{-4}
Lifelong consumer	0.0015	0.00034	6.8×10^{-5}

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

B 9.3.2.3. Indirect exposure of humans via the environment

Indirect exposure of humans via the environment was not considered for this dossier. It is noted that PAHs in rubber dust particles could become airborne through abrasion of the granules and may contribute to exposure via air. Other routes, through food or drinking water that seem less likely. However the indirect exposure routes have not been investigated

B.9.3.2.4. Environmental exposure[1]

Environmental exposure was not considered for this dossier.

B.10. Risk characterisation

B.10.1. Manufacturing

Not relevant for this dossier

B.10.1.1. Human health

Not relevant for this dossier

B.10.1.1.1. Workers

Not relevant for this dossier

B.10.1.1.2. Consumers

Not relevant for this dossier

B.10.1.1.3. Indirect exposure of humans via the environment

Not relevant for this dossier

B.10.1.1.4. Combined exposure

Not relevant for this dossier

B.10.1.2. Environment

Not relevant for this dossier

B.10.1.2.1. Aquatic compartment (including sediment and secondary poisoning)

Not relevant for this dossier

B.10.1.2.2. Terrestrial compartment (including secondary poisoning)

Not relevant for this dossier

B.10.1.2.3. Atmospheric compartment

Not relevant for this dossier

B.10.1.2.4. Microbiological activity in sewage treatment systems

Not relevant for this dossier

B.10.2. Use 1: Use of rubber granules on artificial turf

B.10.2.1. Human health

Previously, RIVM (2017) concluded that the health risks for people playing sports from exposure to substances (including PAHs) in rubber granules on synthetic turf pitches are virtually negligible. That study focused on exposure of consumers and showed that the excess cancer risk for the PAHs in rubber granules (based on a maximum content of 19.8 mg REACH-8 PAH/kg rubber granules) is around the negligible risk level of 1×10^{-6} (1.2×10^{-6} for an outfield player and 3.0×10^{-6} for a goalkeeper). Based on rather similar consumer exposure scenarios and REACH-8 PAH content (20 mg/kg), ECHA concluded that there is at most a very low level of concern from exposure to recycled rubber granules (ECHA 2017a). ECHA also included an evaluation of the health risks for workers (*i.e.* professional sports players and workers involved in the installation and maintenance of the pitches), resulting in the same conclusion as for consumers.

The results of the sampling study of RIVM (2017) showed that PAH content of the rubber granules on 100 Dutch pitches is currently well below the concentration limits set for mixtures in entry 28 of Annex XVII of REACH (*i.e.* 1000 mg/kg for benzo[e]pyrene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene and chrysene, and 100 mg/kg for benzo[a]pyrene and dibenzo[a,h]anthracene). This is in line with the analysis of concentration data of PAHs in ELT granules as provided by industry, authorities, other stakeholders and obtained from public literature sampled (from a granules production site or a sports field) in the EU in the year 2010 or later (see Appendix B1 for details). This analysis 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. However, RIVM (2017) and ECHA (2017a) also considered that if rubber granules would contain the 8 PAHs up to their maximum concentration to conform with the concentration limit for mixtures in Annex XVII of REACH, this would probably not provide an adequate level of protection.

As indicated in section B.9.3., the risks concerning exposure to PAHs related to the use of rubber granules on artificial turf and playgrounds will be characterized for the exposures estimated for the four exposure scenarios for workers and consumers (ES1-4), using the dose-response relationships as derived in section.B.5.11

Three types of risk characterisation will be performed:

1. For rubber granules currently in use in the EU (see Appendix B1 for overview of the EU content data), taking the P95 of the REACH-8 PAH content (17 mg/kg) as realistic worst case.
2. For the hypothetical situation that rubber granules would contain the REACH-8 PAH up to their maximum concentration to conform with the concentration limit for mixtures in Annex XVII of REACH.
   It is noted that the concentration limits of the individual PAHs cannot simply be summed up. By establishing this maximum concentration limit for the sum of the 8 ECHA PAHs, an additivity approach should be applied. Section 1.6.3.3.3 of the CLP-

guidance states that "*If the mode of action (MoA) of two substances is the same, additivity can reasonably be assumed*" (ECHA 2017b). Following the corresponding additivity rule as described in the CLP-Guidance (i.e. *(ConcA / clA) + (ConcB / clB) + …. + (ConcZ / clZ) = 1, where ConcA is the concentration of substance A in the mixture, clA is the concentration limit (either specific or generic) for substance A*), and taking into account the relative contribution of the different PAHs to the REACH-8 PAH content in the rubber granules (see Appendix B1 for details), the maximum concentration limit can be calculated and would be 387 mg/kg for the sum of the REACH-8 PAH.

3. Calculating backwards, an acceptable level of PAH in rubber granules will be derived based on the above mentioned exposure scenarios and an acceptable risk level. PAHs are genotoxic carcinogens for which in principle no safe level of exposure can be derived. However, a policy-based, acceptable risk level is often applied, for example for enforcement purposes. An excess risk of one in a million (10^{-6}, *i.e.* one additional case of cancer per one million lifelong exposed individuals) is often regarded as an acceptable risk level in the risk assessment of non-threshold carcinogens for the general population. This risk level will therefore be applied in the current evaluation for consumers (ES4). A higher risk level is often, from a policy point of view, accepted for workers. The REACH Guidance mentions that 10^{-5} could be seen as indicative tolerable risk level when setting DMELs for workers for a working life of 40 years (ECHA 2012). This risk level will be applied in the current evaluation for workers in ES1 and ES2 (installation and maintenance of the pitches, respectively). As for the workers in ES3 (professional outfield players and goalkeepers) the time period of their professional football career (which is assumed to cover the age of 18 to 35 years) forms only a small part of their lifelong exposure, for these workers it was considered more appropriate to use same risk level as for consumers.

B.10.2.1.1. Workers

1. Risks associated with exposure to rubber granules with PAH content as currently measured in EU: 17 mg REACH-8 PAH/kg

Table B 38 presents for exposure scenarios ES1 (installation), ES2 (maintenance) and ES3 (professional outfield player/goalkeeper) the lifelong exposure to PAHs and the associated excess cancer risks based on current EU situation (P95 of 17 mg/kg for the sum of the REACH-8 PAH).

The excess cancer risk for lifelong exposure (*i.e.* 40 years) 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 that is often considered acceptable by policy makers for 40 years worker exposure (*i.e.* 10^{-5}). The results show that the contribution of the dermal exposure route to the total risk for ES1 (installation) and ES2 (maintenance) is relatively low compared to the inhalation route. As mentioned before, it was not possible to link the PAH content in rubber granules to the inhalation exposure of workers during installation and maintenance (see section B.9.3.). The inhalation exposure of workers during installation and maintenance was primarily based on the study of Ecopneus (2016). It was noted that the REACH-8 PAH content of the rubber granules in this Ecopneus (2016) study amounted 8-13 mg/kg. This range corresponds well with the REACH-8 PAH content of ELT granules in the EU in the years ≥2010 (see Appendix

B1), *i.e.* values ranging from 2.9 to 21 mg/kg, with a geometric mean of 11 mg/kg and a P95 of 17 mg/kg (See Appendix B1). Therefore, it was considered acceptable to calculate the inhalation exposure for workers during installation and maintenance *for current EU situation* using the data of Ecopneus (2016).

For the professional player (ES3), the excess cancer risks based on current PAH-content levels in rubber granules in the EU are 2.0×10^{-6} and 2.6×10^{-6} for the outfield player and goalkeeper, respectively. The professional players have similar exposures thoughout their lifes compared to the amateur players, where only the exposure differs during their professional career. Therefore, it is considered more appropriate to compare their lifelong exposure to the acceptable risk level for the general population. These are slightly above what is considered acceptable for the general population for lifelong exposure (*i.e.* 10^{-6}). The contribution to the total risk for ES3 is highest for the oral route (predominantly during child years), followed by the dermal and inhalation route.

2. Risks associated with exposure to rubber granules with PAH content corresponding to current concentration limit for mixtures: 387 mg/kg for sum of REACH-8 PAH

The total risks for exposure scenarios ES1 and ES2 (installation and maintenance of the pitches), assuming that the PAH content in rubber granules would correspond to current concentration limit for mixtures (*i.e.* 387 mg/kg for the sum of REACH-8 PAH), cannot be calculated (see below for explanation). As indicated, 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 primarily based on the study of Ecopneus (2016). As the current concentration limit of 387 mg/kg for the sum of the REACH-8 PAH is far above what was measured as PAH content in the rubber granules in the Ecopneus (2016) study (*i.e.* 8-13 mg REACH-8 PAH /kg), the data of Ecopneus (2016) could not be used for the calculation of the inhalation exposure as this would lead to a large underestimation of the exposure. A calculation of the risks associated with the dermal exposure can however be made (Table B 38). This calculation shows that the excess cancer risk related to the dermal exposure would be 1.1×10^{-6}, 5.9×10^{-8} and 2.0×10^{-7} for installation, large maintenance and small maintenance, respectively. This is below the risk level that is considered acceptable for 40 year worker exposure (*i.e.* 10^{-5}). Nevertheless, as the inhalation exposure contributes most to the total risk for workers involved in installation and maintenance, the total risk (upon combined dermal and inhalation exposure) may be hypothesized to exceed the acceptable 10^{-5} risk level.

For the professional player (ES3), the excess cancer risk based on current concentration limit for mixtures can be calculated. For the outfield player and goalkeeper, excess cancer risks of 4.6×10^{-5} and 5.9×10^{-5} were calculated, respectively. These are far above the risk level that is considered acceptable for lifelong exposure (*i.e.* 10^{-6}), and, therefore, the health risks for the professional players (outfield player and goalkeeper) are not acceptable in case the PAH content of rubber granules would be as high as the current legally concentration limit for mixtures.

3. Maximum permissible PAH content in rubber granules

The maximum permissible content level for PAHs in rubber granules can be calculated for the professional football player and goalkeeper, based on the exposure scenarios as described in Section B.9.3., assuming that a risk level of 10^{-6} is considered as acceptable

(Table B 39). The maximum permissible REACH-8 PAH content in rubber granules (for the sum of the REACH-8 PAH) would be 8.4 mg/kg for the professional outfield player and 6.5 mg/kg for the professional goalkeeper.

The maximum permissible REACH-8 PAHs content in rubber granules is calculated as follows:

Maximum permissible level = $1x10^{-6}$ / ((oral exposure factor X oral unit risk) + (dermal exposure factor X dermal unit risk) + (inhalation exposure factor X inhalation unit risk)

The exposure factors basically describe the product of all the exposure parameters (combining them into one 'exposure factor'), except for the content value. Multiplying the exposure factor with the content value gives the exposure estimate for a specific route. The exposure factors were derived for each contributing scenario (including the lifelong scenario, which is the sum of exposure factors from contributing scenarios relevant for the lifelong scenario) and for each route of exposure. The exposure factors per route of exposure and per lifelong exposure scenario are given in Table B 36.

Table B 36: Exposure factors for lifelong exposure scenarios

	Oral route	**Dermal route**	**Inhalation route**
Professional player	$7.4x10^{-5}$	$1.1x10^{-5}$	$6.2x10^{-6}$
Professional goalkeeper	$9.1x10^{-5}$	$2.1x10^{-5}$	$6.3x10^{-6}$
Consumer	$7.2x10^{-5}$	$9.9x10^{-6}$	$3.9x10^{-6}$
Consumer goalkeeper	$8.7x10^{-5}$	$2.0x10^{-5}$	$4.0x10^{-6}$

The maximum permissible content level for PAHs in rubber granules cannot be calculated for workers involved in installation and maintenance, as inhalation exposure cannot be linked to the PAH content. Note however, that the professional players and consumers have higher exposure estimates compared to the installation and maintenance workers. Moreover, the installation and maintenance workers can be protected through technical, operational and personal risk management measures. It is therefore foreseen that maximum permissible PAH content in rubber granules derived for professional and consumer players will also cover for the installation and maintenance workers.

Table B 37: Results of the risk assessment for workers (exposure scenarios ES1, ES2 and ES3) according to the linear extrapolation; based on current PAH content values in EU (P95; 17 mg/kg)

Worker		**lifelong exposure (µg/kg bw/d or µg/m³-year)**	**Excess cancer risk per µg/kg bw/d or µg/m³-year**	**Excess cancer risk**
ES1: Installation				
	Dermal	0.00013	$3.56x10^{-4}$	$4.7x10^{-8}$
	Inhalation	0.21	0.00014	$2.9x10^{-5}$
	Total			*$2.9x10^{-5}$*
ES2: Maintenance - large				
	Dermal	$7.3x10^{-6}$	$3.56x10^{-4}$	$2.6x10^{-9}$
	Inhalation	0.012	0.00014	$1.6x10^{-6}$
	Total			*$1.6x10^{-6}$*
ES2: Maintenance - small				
	Dermal	$2.4x10^{-5}$	$3.56x10^{-4}$	$8.7x10^{-9}$
	Inhalation	0.039	0.00014	$5.4x10^{-6}$
	Total			*$5.4x10^{-6}$*
Professional player		**lifelong exposure (µg/kg bw/d or µg/m³-year)**	**Excess cancer risk per µg/kg bw/d or µg/m³-year**	**Excess cancer risk**
ES3: Outfield player				
	Oral	0.0013	$1.43x10^{-3}$	$1.8x10^{-6}$
	Dermal	0.00019	$9.46x10^{-4}$	$1.7x10^{-7}$
	Inhalation	$1.1x10^{-4}$	0.0004242	$4.5x10^{-8}$
	Total			*$2.0x10^{-6}$*
ES3: Goalkeeper				
	Oral	0.0015	$1.43x10^{-3}$	$2.2x10^{-6}$
	Dermal	0.00037	$9.46x10^{-4}$	$3.4x10^{-7}$
	Inhalation	$1.1x10^{-4}$	0.0004242	$4.5 x10^{-8}$
	Total			*$2.6 x10^{-6}$*

Table B 38: Results of the risk assessment for workers (exposure scenarios ES1, ES2 and ES3) according to the linear extrapolation; based on current concentration limit for mixtures (i.e. 387 mg/kg for the sum of REACH-8 PAH)*

Worker		**lifelong exposure (µg/kg bw/d)**	**Excess cancer risk per µg/kg bw/d**	**Excess cancer risk**
ES1: Installation				
	Dermal	0.0030	$3.56x10^{-4}$	$1.1x10^{-6}$
ES2: Maintenance - large				
	Dermal	0.00017	$3.56x10^{-4}$	$5.9x10^{-8}$
ES2: Maintenance - small				
	Dermal	0.00055	$3.56x10^{-4}$	$2.0\ x10^{-7}$
Professional player		**lifelong exposure (µg/kg bw/d or µg/m^3-year)**	**Excess cancer risk per µg/kg bw/d or µg/m^3-year**	**Excess cancer risk**
ES3: Outfield player				
	Oral	0.029	$1.43x10^{-3}$	$4.1\ x10^{-5}$
	Dermal	0.0042	$9.46x10^{-4}$	$4.0\ x10^{-6}$
	Inhalation	0.0024	0.0004242	$1.0\ x10^{-6}$
	Total			*$4.6\ x10^{-5}$*
ES3: Goalkeeper				
	Oral	0.035	$1.43x10^{-3}$	$5.0\ x10^{-5}$
	Dermal	0.0083	$9.46x10^{-4}$	$7.8\ x10^{-6}$
	Inhalation	0.0024	0.0004242	$1.0\ x10^{-6}$
	Total			*$5.9\ x10^{-5}$*

* Following the additivity rule as described in the CLP-Guidance and taking into account the relative contribution of the different PAHs to the REACH-8 PAH content in the rubber granules

Table B 39: Maximum permissible PAH content in rubber granules (as sum of REACH-8 PAH; expressed in mg/kg), calculated for the exposure scenario for the professional football player, based on an acceptable risk level of 10^{-6}

professional	**Maximum permissible PAH content for REACH-8 PAH (mg/kg)**
Outfield player	8.4
Goalkeeper	6.5

B.10.2.1.2. Consumers

1. Risks associated with exposure to rubber granules with PAH content as currently measured in EU: 17 mg REACH-8 PAH/kg

Table B 40 presents for exposure scenario ES4 the lifelong exposure to PAHs and the associated excess cancer risks based on current EU situation (P95 of 17 mg/kg for the sum of the REACH-8 PAH).

The excess cancer risk for lifelong exposure is 1.9×10^{-6} for the outfield player and 2.5×10^{-6} for the goalkeeper. These risks are slightly above the risk level that is considered acceptable for lifelong consumer exposure (*i.e.* 10^{-6}). The results show that, when playing and sporting on synthetic turf pitches, the oral exposure route contributes highest to the total exposure, followed by the dermal and inhalation exposure route.

2. Risks associated with exposure to rubber granules with PAH content corresponding to current concentration limit for mixtures: 387 mg/kg for sum of REACH-8 PAH

Assuming that the PAH content in rubber granules would correspond to current concentration limit for mixtures (*i.e.* sum of REACH-8 PAH of 387 mg/kg), the excess cancer risks for exposure scenario ES4 are presented in Table B 41. The excess cancer risk for lifelong exposure to PAHs via playing and sporting on synthetic pitches with infill with rubber granules are 4.4×10^{-5} and 5.6×10^{-5} for outfield player and goalkeeper, respectively. These are above the risk level that is considered acceptable for consumer exposure (*i.e.* 10^{-6}), and, therefore, risks for the consumer (outfield player and goalkeeper) are not acceptable in case the PAH content of rubber granules would be as high as the current legally concentration limit for mixtures.

3. Maximum permissible PAH content in rubber granules

The maximum permissible content level for PAHs in rubber granules can be calculated, based on the exposure scenarios as described for the amateur outfield player and goalkeeper in section B.9.3., assuming that a risk level of 10^{-6} can be considered as acceptable for consumers (Table B 42). The maximum PAH content in rubber granules (for the sum of the eight PAHs under current evaluation) would be 8.8 mg/kg for the amateur outfield player and 6.9 mg/kg for the amateur goalkeeper.

Table B 40: Results of the risk assessment for consumers (exposure scenarios ES4) according to the linear extrapolation; based on current PAH content values in EU (P95; 17 mg/kg for the sum of REACH-8 PAH)

Consumer		**lifelong exposure (µg/kg bw/d or µg/m^3-year)**	**Excess cancer risk per µg/kg bw/d or µg/m^3-year**	**Excess cancer risk**
ES4: Outfield player				
	oral	0.0012	1.43×10^{-3}	1.7×10^{-6}
	dermal	0.00017	9.46×10^{-4}	1.6×10^{-7}
	inhalation	6.7×10^{-5}	0.0004242	2.8×10^{-8}
	Total			*1.9×10^{-6}*
ES4: Goalkeeper				
	oral	0.0015	1.43×10^{-3}	2.1×10^{-6}
	dermal	0.00034	9.46×10^{-4}	3.2×10^{-7}
	inhalation	6.8×10^{-5}	0.0004242	2.9×10^{-8}
	Total			*2.5×10^{-6}*

Table B 41: Results of the risk assessment for consumers (exposure scenarios ES4) according to the linear extrapolation; based on current concentration limit for mixtures (i.e. 387 mg/kg for the sum of REACH-8 PAH)*

Consumer		**lifelong exposure (µg/kg bw/d or µg/m^3-year)**	**Excess cancer risk per µg/kg bw/d or µg/m^3-year**	**Excess cancer risk**
ES4: Outfield player				
	oral	0.028	1.43×10^{-3}	4.0×10^{-5}
	dermal	0.0038	9.46×10^{-4}	3.6×10^{-6}
	inhalation	*0.0015*	0.0004242	6.4×10^{-7}
	Total			*4.4×10^{-5}*
ES4: Goalkeeper				
	oral	0.034	1.43×10^{-3}	4.8×10^{-5}
	dermal	0.0077	9.46×10^{-4}	7.2×10^{-6}
	inhalation	*0.0016*	0.0004242	6.6×10^{-7}
	Total			*5.6×10^{-5}*

* Following the additivity rule as described in the CLP-Guidance and taking into account the relative contribution of the different PAHs to the REACH-8 PAH content in the rubber granules

Table B 42: Maximum permissible PAH content in rubber granules (as sum of REACH-8 PAH; expressed in mg/kg), calculated for the exposure scenario for the amateur football player, based on an acceptable risk level of 10^{-6}.

mateur	**Maximum permissible PAH content for REACH-8 PAH (mg/kg)**
Outfield player	8.8
Goalkeeper	6.9

B.10.2.1.3. Indirect exposure of humans via the environment

Not relevant for this dossier

B.10.2.1.4. Combined exposure

Not relevant for this dossier

B.10.2.2. Environment

Not relevant for this dossier

B.10.2.2.1. Aquatic compartment (including sediment and secondary poisoning)

Not relevant for this dossier

B.10.2.2.2. Terrestrial compartment (including secondary poisoning)

Not relevant for this dossier

B.10.2.2.3. Atmospheric compartment

Not relevant for this dossier

B.10.2.2.4. Microbiological activity in sewage treatment systems

Not relevant for this dossier

B.10.3. Summary on risk characterisation

The risk characterisation showed that, based on the actual PAH level in rubber granules in EU from ≥2010, the excess cancer risks for workers are just below to very slightly above the 10^{-5} risk level that is considered acceptable for 40 years worker exposure (*i.e.* 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). For the professional football player, excess cancer risks are slightly above the 10^{-6} risk a level that is considered acceptable for the general population for lifelong exposure (*i.e.* 2.0×10^{-6} and 2.6×10^{-6} for the outfield player and goalkeeper, respectively). Finally, the excess cancer risk for lifelong exposure for the amateur football player is slightly above the risk level that is considered acceptable for lifelong consumer exposure (*i.e.* 1.9×10^{-6} for the amateur outfield player and 2.5×10^{-6} for the goalkeeper).

In comparison to previous exposure assessments of PAH exposure from rubber granules by RIVM (2016, 2017) and ECHA (2017a) for consumers, the current exposure scenarios were slightly adapted. The main changes were: 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), and the inhalation exposure and subsequent risk estimate was added to the total risk estimate per scenario, whereas RIVM (2017) did not. Further, in current restriction dossier additional exposure scenarios were added to the lifelong exposure, i.e. playing at playgrounds. This resulted in a longer exposure period (starting from the age of 2 for current evaluation versus the age of 4 as done by RIVM (2017)) and simultaneous exposure via playing and playing sports at the age of 4-13 years. A minor change is that RIVM (2017) based the evaluation on the maximum value of 100 sampled Dutch pitches of 19.8 mg/kg for the sum of the REACH-8 PAH, whereas for current evaluation the P95 of 17 mg/kg of the total EU dataset ≥2010 was used. Taken together, it is noted that the calculated excess cancer risks for the consumer are slightly higher than was calculated by RIVM (2017) and ECHA (2017a) for the scenario of the amateur outfield player. In contrast, calculated excess cancer risks for the amateur goalkeeper are slightly lower than was calculated by RIVM (2017). This can be explained by the lower oral ingestion rate for goalkeepers based on the updated chapter 5 of the US EPA factors handbook (US EPA, 2017a), which has a major influence on the outcome for goalkeepers.

The exposure assessments for the installation and maintenance workers were changed from the evaluation performed by ECHA (2017a) as explained in section B.9.3.2.1. It should be noted that the data are rather limited with only two studies covering exposure for installation workers. Assuming similar contact rates for the maintenance workers as for the installation workers is likely to result in an overestimation of the former, even though the work will entail more manual labour such as raking the granules across the pitch. No information was available on installation of rubber granules at playgrounds. It is expected, due to their relatively small sizes compared to football pitches that the exposures of the workers are lower during installation and maintenance at playgrounds. It is supposed to be covered by the worker exposure scenarios.

The calculations based on the assumption that the PAH content in rubber granules would correspond to current concentration limit for mixtures in Annex XVII of REACH (*i.e.* 387 mg/kg for the sum of REACH-8 PAH, taking into account the additivity rule conform the CLP-Guidance (ECHA 2017b)) clearly showed that the excess cancer risks are not acceptable, both for the professional and amateur football player (outfield player and goalkeeper). This would support the conclusion of RIVM (2017) and ECHA (2017a) that the current concentration limit for mixtures do not provide an adequate level of protection against the development of cancer, and this would support the proposal for reducing the PAH concentration limit for rubber granules. Due to limited data on inhalation exposure for workers during installation and maintenance of the pitches, no reliable calculation of the total excess cancer risks (covering all exposure routes) can be done for these exposure scenarios.

Calculation of the maximum permissible concentration limit of PAHs in rubber granules showed that this value ranged from 6.5-8.4 mg/kg for the professional players to 6.9-8.8 mg/kg for the consumers. The most conservative value of 6.5 mg/kg was based on the exposure scenario of the professional goalkeeper, using an acceptable risk level of 10^{-6}.

B.10.4 Uncertainties in the risk characterisation

This risk characterisation includes a number of uncertainties. In Table B 43 the main sources of uncertainty in the risk are presented. Taken together, the Dossier Submitter considers that the uncertainties point to an overestimation of the risks, 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.

Table B 43: Overview of main sources of uncertainty in the PAH risk assessment and influence on estimated risk (↓ towards a lower true risk, ↑ towards a higher true risk)

Source	Description	Effect on risk
Hazard		
Marker approach (REACH-8 PAH) for oral exposure (consumer): underlying mouse oral carcinogenicity data	The composition and perhaps potency between the tested coal tar mixture and the PAH mixture present in rubber granules may differ. Two of the eight PAHs from the REACH-8 PAH group are not reported to be present in the mixtures tested in the mouse oral carcinogenicity study of Culp et al. (1998). Available data from the EU RAR on CTPHT indicates that the assumption on similar concentrations of the deviating PAHs in the two REACH-8 PAH groups is defendable.	↑↓
Dose-response relation inhalation: general issue	Exposure to PAHs in rubber granules may differ from exposure to PAHs in CTPHT, i.e. the exposure routes, the composition of the PAH mixtures in rubber granules, and physical form during PAH exposure via inhalation (dust vs. vapour) will differ from that in the occupational settings that served as basis for the dose-response setting. This results in an uncertain dose-response relationship.	↑↓
Dose-response relation inhalation: dermal exposure implicit	Dermal-systemic exposure is reflected in the dose-response relationship derived from the epidemiological studies based on Armstrong et al. (2003, 2004), resulting in an overestimation of the dermal exposure and thus the risk upon dermal exposure.	↓
Dose-response relation dermal (systemic): route-to-route extrapolation, route-specific differences in kinetics	Only allowance has been made for difference in route-specific absorption. It is difficult to quantify differences in metabolism, these have not been taken into account. This results in an uncertain dose-response relationship.	↑↓
Dose-response relation dermal (systemic): route-to-route extrapolation, underlying mouse oral carcinogenicity data	The dose-response for the oral route is based on the total number of tumour-bearing animals of the study of Culp et al. (1998), which includes all tumours, i.e. systemic and local. The raw animal data were not available to the Dossier Submitter and it is not clear whether the local tumours (in the GI-tract) occurred in the same animals which also presented the systemic tumours. This may have resulted in an overestimation of the dermal-systemic dose-response.	↓
Dose-response relation dermal (local):	As appropriate dermal carcinogenicity data for the PAH mixture under current evaluation are not available, local-dermal carcinogenicity is not accounted for. This may have resulted in an underestimation of the risk.	↑
Linear extrapolation without additional intra- and interspecies assessment factors	Application of intraspecies and interspecies assessment factors, in addition to the high-to-low dose extrapolation, would result in higher estimated excess cancer risks	↑
Sensitisation effect	Of the eight PAHs evaluated in this dossier, only BaP has a harmonised classification for skin sensitisation in Annex VI of CLP.	-
Effects on reproductive toxicity	Of the eight PAHs evaluated in this dossier, BaP has a harmonised classification for reproductive toxicity in Annex VI of CLP. However, the effects are threshold effects and it is considered that these thresholds will be orders of magnitude higher than DMELs for carcinogenicity	-
Exposure - worker	Limited information on worker exposure (installation), for which only a few workers were monitored in two studies.	↑↓

Source	Description	Effect on risk
	Variability in the measurement data was relatively high and as a result a conservative input parameter was selected. In addition, it is unclear if all activities related to installation of rubber granules on artificial turf are covered, e.g. emptying of big bags, spreading of the granules etc. No information available on maintenance activities. Extrapolation based on frequency and duration of activity compared to installation.	
	No RMMs were taken into account even though some PPE are prescribed. Pictures taken during installation consistently show workers without PPE.	↑↓
Exposure - consumer	In the ES it is estimated that people play 100 % of their playing and playing sports time on artificial turf with ELT-derived infill containing PAHs in a specific concentration. However, not all sport pitches and playgrounds in the EU are artificial turf filled with ELT-derived granules. People also play e.g. on natural grass and artificial turf with other types of infill material may be used.	↓
	In real life, not all players are expected to be exercising and playing at the frequency as assumed in the ES, so that the actual exposure for part of the population may be lower.	↓
	The number of play and sports activities described by the contributing scenarios for playing on playgrounds and while playing football should also cover for other play and sports activities, and exposures to by-standers. For example: trainers, parents, siblings, etc. as observers that still play themselves. Persons exercising multiple sports	-
	The exposure for consumers on playgrounds is based on rubber granules, whereas rubber mulch or flakes are used as well. In case mulch or flakes are used the exposure is likely to be lower as the rubber in this shape is less likely to be ingested and rubber dust formation is expected to be lower.	↓
Exposure - general	The exposure assessment is aimed at a 95th percentile of the exposed general population or 90th percentile of the exposed worker population, which is commonly accepted as being representative (realistic) worst case estimations for the respective populations.	-
	Extrapolation steps from rubber granule in the air to BaP concentration in the air were needed as the dose-response relationship for inhalation toxicity is based on BaP in PAH-mixtures. The extrapolation steps were performed using the median fraction of BaP in the REACH-8 PAH mixture and median fraction of REACH-8 PAH in rubber granules. These extrapolation steps come with an unknown uncertainty as the study from which the rubber fraction in air was taken from did not provide information on PAH content in those rubber granules present.	↑↓
	Migration data of PAH from rubber granules to relevant receptors is based on limited set of measurements (oral exposure) or data (dermal exposure), where for the latter it is unclear if the use of Tenax in the dermal migration study represents a worst case.	↑↓

Source	Description	Effect on risk
Other	The relative oral migration (migration from rubber granules as compared to migration from food matrices used in animal studies) is unknown. The risk is underestimated if migration from food is also relatively low (order of 10 %).	↑

An arrow pointing upwards (↑) indicates that uncertainties suggest that the risk may be higher and thus underestimated. An arrow pointing downwards (↓) suggests risks may be lower and thus overestimated. An uncertainty with minimal impact on the risk is indicated with a dash (-). Where arrows are pointing in both directions (↑ ↓), this indicates that uncertainties may have an impact on the estimated risk, but it is not possible to evaluate whether the parameter leads to under- or overestimation of the risks.

One of the uncertainties is the use of the derived $BMDL_{10}$ value based on a study with coal tar to assess the risk of PAH mixtures in rubber for the oral and dermal routes of exposure. This is inherently inaccurate due to the difference in content and perhaps potency between the tested coal tar mixture and the PAH mixture present in rubber granules. It is not clear what the exact effect of this difference is and whether it results in an underestimation or overestimation of the calculated maximal permissible concentration.

This would also apply to what is done for the inhalation route. An additional uncertainty for the inhalation route is that the epidemiological information on exposure to BaP from coal tar pitch may have included exposures to BaP vapours as processes took place under elevated temperatures. The BaP exposure from rubber granules is most likely to BaP contained in rubber dust. It is unknown if this could cause under- or overestimations of the risk.

For the inhalation route, the risk assessment was based on the dose-response relation derived from a meta-analysis of occupational epidemiology studies. It is noted that the dermal-systemic exposure is reflected in the dose-response relationship derived from the epidemiological studies. This may have led to an unknown double-counting and thus overestimation of the exposure and risks of the dermal exposure, which is possibly integrated in the inhalation risk estimate and is separately estimated for the dermal-systemic route.

Another uncertainty is associated with the fact that the limited data set on oral migration levels derived from RIVM (2017) has been extrapolated to apply to all pitch samples in general. However, within the limited number of samples of RIVM (2017), there appeared to be a fairly constant relationship between the total PAH concentration in the rubber granules and the migration into gastric juice/intestinal juice, so the uncertainty introduced by the small data set may well be minor.

More important is the uncertainty about the oral migration of PAH from food matrices in toxicity studies. It is assumed that the oral migration of PAHs from food in experimental animals is 100 %, whereas in reality this value could be lower. If so, it means that applying the oral migration fraction to the oral exposure route is in fact an underestimation. To date there have been no studies that describe the oral migration of PAHs from food, though it is hypothesized that it can be lower than 100 %. In that case, it means that the migration factor of 9 % currently used for the oral route should be adjusted for the fact that in the animal study there was no 100 % migration from food (the so-called relative migration factor should then be used, which is determined by percentage released in animal study vs. percentage released in migration study). The assumption of 100 % may lead to an underestimation of the exposure as the relative migration fraction could be higher than the currently used 9 %.

In this evaluation, the standard linear extrapolation method was applied to assess the risks of PAHs in rubber granules – *i.e.* without any intraspecies factor (in accordance with standard practice in EU). So, no additional factor to account for any intraspecies differences as a consequence of 'early-life exposure' was applied. At this moment, there is no agreement within Europe on the use of extra assessment factors for genotoxic carcinogens. For this reason, the Dossier Submitter considers that a broad and general discussion on these assessment factors is urgently needed. That discussion should focus on the question whether and in which cases AFs for inter- and intraspecies may need to be applied for non-threshold carcinogens. It is considered that this discussion should not be limited to REACH but should also include other risk assessment frameworks. The application of an extra factor for age-dependent differences in sensitivity (for example a factor of 3, as proposed by US EPA (2005) and used by Ginsberg and Toal (2010) in their risk assessment of PAHs in rubber crumb infill on artificial turf pitches in Connecticut, and by US EPA in their toxicological review of BaP (2017b)) would lead to calculated risks which are higher than those currently calculated. It is however noted that the linear extrapolation of a 10 % risk to a low percentage risk in animals is indeed conservative, as shown by (probabilistic) modelling. When probabilistically addressing the uncertainties in the toxicological data in the risk calculation, the confidence interval around the excess cancer risk reveals that the cancer risk calculated with the linear method is a worst-case scenario and corresponds to the upper boundary of the confidence interval. The cancer risk at the lower boundary of the confidence interval is one order of magnitude lower (RIVM 2016).

The exposure assessment represents a worst case realistic estimate for (only a very) a small population that is either a performance oriented sports player or even a player at a professional level and includes the life-long exposures including during their youth and as a veteran. The frequency of contact disregards the fact that individuals will not always play on artificial turf with rubber granules or will not play sports their 'entire' life. Based on data from Finland 75 % of the sporting occasions (Football) take place on artificial turf, but this is likely an overestimation for most other countries across the EU (Finnish Football Association, (2017; as cited in ECHA, 2017a)). ESTO estimates that synthetic turf pitches represent less than 15 % of the entire sports market in EU, however the share varies across the Member States (see Annex A). The 75 % assumption would cover for a potential trend of increasing pitches with rubber granule infill material, but is at this moment not realistic. The information available on exposure to PAHs from activities on artificial turf with rubber granules do not allow the Dossier Submitter to further refine the exposure assessment nor to provide a realistic exposure assessment for a typical individual in the exposed population.

Rubber granules are one of the many sources of exposure to PAHs. Others include, for example, exhaust fumes, tyre particulates, cigarette smoke, burned wood (open fire) and meat (barbecue). In general, food is the main source for the general population. Exposure via food may even be significantly higher when the person eats large amounts of barbecued meat on a regular basis (EFSA 2008). RIVM (2017) considered that compared to food as the most important source of PAHs for the (non-smoking) general population, the estimated exposure via rubber granules was marginal. Current evaluation focussed solely on exposure to PAHs via contact with rubber granules. This may lead to an underestimation of the risk.

B.10.5. Conclusion on hazard, exposure and risk

PAHs are genotoxic carcinogens. Given the ability to induce genotoxic effects there is no threshold value below which no health risk exist for mutagenic PAHs.

The risk characterisation showed that, based on the actual PAH level in rubber granules in EU from ≥2010 (i.e. 17 mg/kg), the excess cancer risks for workers are just below to very slightly above the 10^{-5} risk level that is considered acceptable (from a policy point of view) for 40 years worker exposure (*i.e.* 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). For the professional football player, excess cancer risks are slightly above the 10^{-6} risk level that is considered acceptable for the general population for lifelong exposure (*i.e.* 2.0×10^{-6} and 2.6×10^{-6} for the outfield player and goalkeeper, respectively). Finally, the excess cancer risk for lifelong exposure for the amateur football player is slightly above the risk level that is considered acceptable for lifelong consumer exposure (*i.e.* 1.9×10^{-6} for the amateur outfield player and 2.5×10^{-6} for the goalkeeper). This risk characterisation includes a number of uncertainties. Taken together, the Dossier Submitter considers that the uncertainties point to an overestimation of the risks, 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.

The calculations based on the assumption that the PAH content in rubber granules would correspond to current concentration limit for mixtures in Annex XVII of REACH (*i.e.* 387 mg/kg for the sum of REACH-8 PAH, taking into account the additivity rule conform the CLP-Guidance (ECHA 2017b)) showed that the excess cancer risks are not acceptable, both for the professional and amateur football player (outfield player and goalkeeper). This indicates that the current concentration limit for mixtures does not provide an adequate level of protection against the development of cancer, and this would support the proposal for reducing the PAH concentration limit for rubber granules.

Based on the evaluation of the hazard of PAHs and the assessment of the relevant exposure scenarios for worker and consumer, and taking into account a policy-based risk level of 10^{-5} for workers and 10^{-6} for the general population, a maximum permissible concentration for PAHs in rubber granules of 6.5 mg/kg for the sum of the REACH-8 PAHs was derived.

Annex C: Justification for action on a Union-wide basis

The justification for action on a Union-wide basis is provided in the Annex XV restriction report (main report).

Annex D: Baseline

This restriction proposal covers the REACH-8 PAH concentrations in granules used as performance infill material on artificial turf pitches, as well as the use of loose infill and mulch, used in playing and sport applications in Europe.

The Dossier Submitter has assessed in Annex B that the current generic limit value for the REACH-8 PAHs in mixtures according the restriction entry 28 of Annex XVII to REACH (either 100 or 1000 mg/kg per each of the PAHs) is not ensuring adequate protection of individuals (e.g. football players and small children) playing on these surfaces. To be able to estimate the expected impact of the restriction proposal, it is important to know the current situation in terms of the use of artificial turf and infill/mulch in the EU and to describe the expected trends that would occur without the introduction of any new regulatory measure.

For this dossier, the following elements are important when describing the baseline situation:

1. The number of artificial turf pitches and sport/play areas with loose infill/mulch installed across the EU that make use of performance infill and the expected trends in the number of pitches installed over the next decade;
2. The share/proportions of various types of infill used on artificial turf pitches, the quantities used and the expected trends related to the application of the different types of infill over the next decade;
3. The current distribution in REACH-8 PAHs concentrations in ELT-derived infill material and other infill materials and the expected trends therein;
4. The number of individuals that come into contact with infill material and the different exposure groups that may currently be at risk due to PAH concentrations above the proposed limit value.

D.1. Number of artificial turf pitches in Europe

The use of synthetic turf pitches in the EU started around 1970 with first and second generation synthetic turf used for football and other sports such as cricket and field hockey. Only after 1996 these pitches were developed to better suit the needs for football. Third generation long pile (50-70 mm) artificial turf that makes use of performance infill material was introduced in the late 1990s and is used for various purposes. In the Netherlands the broad use of synthetic turf for football started around 2000 (KNVB, as reported in RIVM 2017). The Dossier Submitter has very limited information on the share of synthetic turf football pitches relative to the number of natural grass pitches in EU countries.

According to ESTO, football is by far the largest sport played on long pile synthetic turfs. Examples of other sports played on this type of synthetic turf pitches are: rugby, Gaelic sports, baseball, lacrosse and American football. Artificial turf using infill material is also used for the installation of so-called ‘mini-pitches’. Mini-pitches may be indoor courts or outdoor pitches. Mini-pitches are smaller compared to football pitches and are used for various purposes by both adults and children. According to ESTO in its reply to ECHA’s questions (2016) 95 % of these mini-pitches are outdoor pitches. Like football pitches, they are often owned by local authorities (e.g. municipalities) but may also be privately owned.

D.1.1. Synthetic turf football pitches and mini-pitches

In 2012, there were over 13 000 synthetic turf football pitches and over 45 000 mini-pitches in the EU (ESTO Market Report Vision 2020). ESTO has estimated that the number of artificial turf pitches is expected to grow continuously. By 2020 the number of synthetic turf football pitches is expected to be about 21 000 and the number of mini-pitches about 70 000. Half of these mini-pitches are assumed to be pitches with performance infill. From 2012 to 2020 the increase is thus expected to be about 1 000 football pitches and about 1 600 mini-pitches per year. This equals annual growth rates of respectively 6.2 and 5.6 % for football pitches and mini-pitches. The ESTO estimates are based on newly installed pitches only. Based on this information, the Dossier Submitter estimates the number of full size synthetic turf pitches to be around 34 000 in 2028. This is in line with what was indicated during the 24 November 2017 workshop. There it was said that the number of pitches are expected to grow over the coming years, especially for mini-pitches.

ETRMA in its reply to ECHA's question (2016) estimates that around 1 200 - 1 400 new football pitches are nowadays installed every year in the EU. This includes replacement of old pitches. The ETRMA figures are in the same range as the 1 200 full size pitches estimated to be installed annually between 2012 and 2020 as used by the Dossier Submitter.

Assuming an average 10 year service life of synthetic turf pitches (personal communication synthetic turf sector) the Dossier Submitter assumes that 10 % of the pitches will be re-installed (re-surfaced) yearly. This means that on average between 2018 and 2028 annually 2 600 pitches and 4 300 mini-pitches will be resurfaced in the EU, including the replacement of infill material. Hence, the total number of full pitch (re-)installations between 2018 and 2028 will be on average 4 300 and the total number of mini-pitch (re-) installations will be on average around 6 700 annually.

D.1.2. Synthetic turf pitches used for rugby and other sports

ESTO's Market Report Vision 2020 reports that 232 synthetic turf rugby pitches were in use in 2012. Rugby Europe (Rugby Turf Performance Specification 2016[63]) reports that a total of 558 synthetic rugby pitches were installed in 2016. The Dossier Submitter uses the 232 reported pitches in 2012 by ESTO and 558 pitches in 2016 reported by Rugby Europe as key data. Based on this key data, a linear growth of 82 pitches per year is estimated, which translates to 1 536 synthetic turf rugby pitches in 2028. Assuming a 10 year service life of synthetic turf pitches, the Dossier Submitter assumes that annually, on average, between 2018 and 2028, 65 pitches will be resurfaced including the change of infill material. It should be noted that according to ESTO it is possible for football and rugby to be played on the same artificial surface. However, the Dossier Submitter has no further information on such shared uses by football clubs and rugby clubs. Hence, in the scope of this Annex XV dossier, rugby pitches are considered to be separately used from football or other sports purposes.

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[63] http://www.smartconnection.net.au/wp-content/uploads/2017/06/2016-Rugby-Turf-Performance-Specification.pdf

The Dossier Submitter has limited information on the use of synthetic turf pitches for other sports. Some information has been obtained from the European Lacrosse Federation and the Gaelic Athletic Association. No information was available to the Dossier Submitter on baseball and American football. Gaelic Sports are primarily practiced in the Republic of Ireland and normally takes place on natural grass. The Gaelic Sports Association reported on one third generation synthetic turf pitch in Abbotstown of which 11 % of the registered members make use. Lacrosse is played across Europe with the largest player population in the UK. Between 25 and 80 % of Lacrosse activities take place on synthetic turf but the Dossier Submitter has no information on the number of pitches installed and expected trends.

D.1.3. Overall conclusion on synthetic turf pitches used for sports in the EU

In conclusion, the Dossier Submitter estimates an average number of annual installations between 2018 and 2028 of synthetic turf football pitches of 2 800 and mini-pitches of 8 900. The number of annual installations of synthetic rugby pitches between 2018 and 2028 is estimated to be 147, which is just over 1 % of the total football pitch installations. For this reason, and as football is by far the largest sport in the EU, this baseline section focusses on football pitches and mini-pitches assuming that this provides a sufficient approximation of the number of pitches in the EU using performance infill material.

As can be seen in Figure A 7 of Annex A, Germany, UK, France, the Netherlands, Spain, Portugal and Italy currently have the largest number of artificial grass pitches installed each year. In other Member States, less artificial turf is being used.

Based on the above assumptions, it is thus estimated that in the baseline situation the number of artificial turf football pitches grows from 13 000 in 2012 to 21 000 in 2020 and 34 000 in 2028. The average annual number of football pitch installations, including replacement, is expected to be 2 800 between 2018 and 2028.

When it comes to mini-pitches, it appears to be more difficult to make a well substantiated estimate of the expected growth after 2020 as this use is less known and may be more diverse compared to football pitches. The total number of mini-pitch installations, including replacement, is estimated to be around 8 900 annually in the period 2018-2028.

D.1.4. Use of loose granules and mulch in sport & play applications.

Annex A.2.4. reports on the use of loose granules or mulch in playgrounds. Similar to rubber granules, mulch (or flakes) is regarded as a mixture according to ECHA's Guidance on substances in articles. Rubber mulch is predominantly produced from recycled tyre buffings or nuggets of synthetic rubber. Other materials such as ethylene propylene diene rubbers (EPDM) are also used to produce rubber mulch, although, to a considerably less extent. Rubber mulch is used in playgrounds as low impact surface area. The material may be used in loose form and also in situ bonded by a PU based resin. According to ETRMA, rubber mulch is always PU coated and mixed with a binder. In the scope of this Annex XV dossier only loose granules or mulch used in playgrounds and in sport applications are considered as solid floors and tiles are not regarded as mixtures. Approximately 60 % of rubber mulch ends up being used in playgrounds, whereas the remaining 40 % goes into other applications such as landscaping and gardens. Uses other than loose applications in playgrounds and for sports are not considered in this dossier. In playgrounds around 10 kg of mulch is used per square meter. According to ETRMA and other rubber mulch formulators and distributors, there has been some use of mulch observed with prevalence in the UK, but also in France, Germany, Austria, the Netherlands, Belgium, Bulgaria and Switzerland. The use seems to be almost non-existent in Portugal, Spain, and Sweden. In the UK the demand has grown over the past 3 years and the application of mulch in play areas represents around 8 000 tonnes per year.

The Dossier Submitter has no information on the number of playgrounds or sport facilities where mulch is used per Member State and in the EU as a whole. For this reason, in this baseline section no quantitative estimate on the use of mulch in the EU could be provided. However, the volume of use is expected to be minimal compared to the use of infill in football pitches and mini-pitches.

D.2. Types of performance infill used on artificial turf pitches in the EU

Infill material which is manufactured from recycled, ELT is by far the most common form of performance infill used in the EU. Other materials used are infill material manufactured from other recycled rubber articles, EPDM, thermoplastic elastomers/thermoplastic rubbers (TPE), PE, cork and coconut fibre. The majority of these alternative infills are expected to be virgin material; however, some of it may be from recycled materials as well. More details on alternatives are reported in Annex E.2.

D.2.1. Market shares per infill material type

The share of other infill materials in the EU compared to rubber infill material originating from recycled tyres is not known in detail. According to ESTO (2017, consultation response) more than 90 % of the performance infill material used worldwide is currently made from ELT. According to ESTO, in 2015, EPDM represented 0.3 % of the infill material used in synthetic turf globally, while TPE represented 1 % (ESTO 2017, response to ECHA). According to ESTO (2018, response to ECHA and RIVM) EPDM and TPE represent both 4 of the infill material used in synthetic turf in EU, while organic material represents 2 %. According to the FIFA (2017), worldwide 83 % of the infill used on FIFA approved turf uses ELT-derived rubber infill, 6 % is TPE, 6 % is EPDM, and 3 % is organic (cork and coconut). Another source reports shares of infill types comparable with those of FIFA (EU association, 2017).

Throughout Europe ELT is by far the most common form of infill used. However, there appear to be some differences among Member States when it comes to the type of infill used. In some EU countries ELT is used in over 85-95 % of all installed pitches (e.g. UK, Ireland and France). According to ESTO (call for evidence 2017) and personal communication with the recycling sector, in Germany 50 % of all pitches use EPDM or TPE and those similar infills have significant usage in Scandinavia (whether these are recycled or virgin material is not known). However, it is to be noted that competent authorities from Finland and Sweden stated that rubber infill material used in their countries is mainly ELT. Italy is said to mainly use coated ELT granules or organic infill.

During the 24 November workshop, figures on shares of various types of infill materials were presented and discussed. The split of 90 % use of ELT-derived granules and 10%

other infill types used on synthetic turf pitches was deemed to best represent the current situation in the EU. In absence of EU specific information, it is assumed that these figures represent the current European average situation. The Dossier Submitter assumes that the current (2018) average market shares of TPE and EDPM are 4 % and the market share of natural infill materials is 2 %.

D.2.2. Trends in shares

Based on the concerns raised about the risks to human health caused by the use of recycled rubber granules in the EU (especially in the Netherlands and France), a declining trend of ELT-derived infill material is reported by three manufacturers in the EU in 2016 and 2017 (personal communication). One of these manufacturers stated to expect a 25 % drop in sales volume in 2017 compared to 2016, due to the public attention in the Netherlands and the societal debate about the risks for athletes. Various views exist whether this trend is temporary or will continue in the future. Two of the ELT infill producers interviewed by the Dossier Submitter expect an increase of the use of their material again in 2018. However, one turf manufacturer stated to expect that the reduction in use is permanent, at least in the Netherlands as all large municipalities (such as Amsterdam and Utrecht) decided to permanently shift to non-ELT infill (personal communication recycling and synthetic turf sectors). This supports the impression gained in the 24 November 2017 workshop that the share of non-ELT infill is indeed growing in Europe. Based on the comments received from the workshop participants, the recent market trends reported by some EU-based ELT-derived granule manufacturers and the societal debate in some EU countries, the Dossier Submitter assumes that for the newly installed pitches (new installations + re-installations) the market share of ELT infill used will be gradually reduced from 90 % 2018 to 70 % in 2028. In 2028, 70 % of the newly installed pitches would use ELT-derived infill material, 12 % TPE, 12 % EPDM and 6 % cork and other organic materials. This would mean that the share of ELT-derived granules on all synthetic turf pitches in use in 2028 would be 78 % and 9 % for EPDM, 9 % for TPE and 4 % for cork. The use of non-infill long pile turf was not considered in the baseline as this development is considered to be uncertain.

D.2.2.1. Quantities of infill material used

RIVM (2017) explains that the rubber granules on synthetic turf pitches are used to ensure that the pitch has similar characteristics to conventional grass pitches, making sure that balls do not roll too fast or bounce too high. In addition, synthetic turf with performance infill is suitable for making a sliding. Synthetic turf pitches require less maintenance than sports pitches with natural grass and can be used intensively throughout the year. The performance infill is evenly distributed over the pitch to fill up the space between the artificial grass-fibres, and increase the quality of the pitch to closely resemble natural grass.

The amount of infill material used on synthetic turf pitches depends on the height of the pile and the performance required (ESTO 2017 as reported in ECHA 2017, personal communication synthetic turf sector). In 60 mm long pile synthetic turf pitches, about 15 kg ELT-derived infill per square meter is used (ETRMA respons to ECHA, workshop 24 November 2017, personal communication synthetic turf sector). According to ETRMA a lower quantity of rubber per square meter is used on mini-pitches with shorter pile height (ca. 10 kg/m²).

Sizes of football pitches vary somewhat from 100-120 meters by 64-75 meters, giving a surface area between 6 400 and 9 000 m^2 per pitch. According to information obtained from the synthetic turf sector (personal communication) the Dossier Submitter uses 7 600 m^2 as the standard surface area of a full-size football pitch. This means that 96-135 tonnes of ELT-derived granules are used per football pitch with a central estimate based on the standard size of 7 600 m^2 of 114 tonnes of ELT-derived infill per pitch. This assumption is supported by ESTO (2017, call for evidence) which estimates that a full-size football field requires between 110 and 120 tonnes of ELT infill. If the system incorporates a shockpad (foam layer underneath the turf) the pile height may be lower and the infill quantity could be as low as 40 tons for a full-size football pitch, depending on the type of infill used (ESTO 2017 as reported in ECHA 2017). One synthetic turf producer and various installers explained that systems with shockpads, shorter pile length and lower quantities of infill are especially used for non-ELT infill to compensate for the higher price of the infill material (personal communication synthetic turf sector).

During the 24 November 2017 workshop it was stated by some attendants that mini-pitches measure around 1/10th of the area of an average football field and are expected to use around 10-14 tonnes of ELT-derived infill granules ($1/10^{th}$ of a full size pitch). Other sources state that mini-pitches may be much larger up to half the size of a football pitch. The Dossier Submitter considers there to be variability in sizes of mini-pitches in Europe. Furthermore, there is large variability in the technical design of mini-pitches and in the use of performance infill. Mini-pitches may be so-called Cruyff courts (42x28 m = 1 176 m^2), very small indoor or outdoor pitches ($1/10^{th}$ the size of a football pitch), or larger pitches (quarter or half the size of a football pitch). According to the rules of the European Minifootball Federation (EMF) the size of a minifootball pitch using synthetic turf is 61x26 m (1 586 m^2). Currently, 50 % of the mini-pitches is said to use sand as infill but there is an increasing trend towards the use of performance infill granules (ESTO response to ECHA and RIVM). For this Annex XV dossier it is assumed that 50 % of the mini-pitches are of the long pile type using performance infill granules. This share is kept constant, as no further information on a potential trend is available. Furthermore, we assume that on an average for a long pile mini-pitch 14 tonnes of ELT-derived granules are used, which back calculates to a mini-pitch standard surface area of 1 400 m^2. This area is used to calculate tonnages of other infill types used on mini-pitches.

According to ESTO, the quantity of infill applied annually through maintenance depends on the level of use a field is subjected to and the quality of the maintenance (both highly variable). Suppliers of long pile synthetic turf pitches suggest that on average a figure of one tonne per year of replenishment should be applied for a full size pitch. The Dossier Submitter assumes 100 kg per year for a mini-pitch. For other infill types, these figures are adjusted according to their bulk densities and the amounts applied on a pitch. According to ETRMA (response to ECHA) 3 - 5 tonnes are needed for replenishment, if winter service is needed. This is because infill material will be removed from the pitch as a consequence of snow removal. The Dossier Submitter did not further consider the effect of snow removal on maintenance volumes.

Based on the information provided the Dossier Submitter used the parameters listed in Table D 1 below to calculate the amounts of ELT-derived, EPDM, TPE and cork infill granules used in the EU (for detailed justification See Annex E.2.):

Table D 1: Parameters applied for estimation of the amounts per infill type use on full size football pitches and mini-pitches in the baseline scenario.

Infill type	ELT-derived rubber	EPDM	TPE	Cork
Amount used on full size pitch (kg/m^2)	15	6	7	1.3
Amount used on mini-pitch (kg/m^2)	10	4	4.7	0.9
Share of use (% of the total number of long pile synthetic turf pitches) 2018	90 %	4 %	4 %	2 %
Share of use (% of the total number of long pile synthetic turf pitches) 2028	70 %	12 %	12 %	6 %
Tonnage for maintenance (kg per year) full size pitch	1000	500	500	90
Tonnage for maintenance (kg per year) mini-pitch	100	50	50	5

In 2016, based on industry estimates (ETRMA, 2016 as reported in ECHA 2017), the quantity of rubber infill originated from recycled tyres used on the European sports pitches was said to be between 80 000 and 130 000 tonnes per year. The majority of this amount was stated to be used for new installations (around 90 %) whilst a minor proportion is used during the maintenance (around 10 %). Other sources report 200 000 tonnes per year (VACO 2015, as reported in ECHA 2017) or substantially higher use volumes (EU association 2018, figure claimed confidential). Based on the assumptions above the Dossier Submitter estimated that in 2016 the following tonnages of ELT-derived infill materials were used on full size pitches and mini-pitches in the EU:

- New installations: 105 000 and 20 000 tonnes
- Maintenance: 14 000 and 2 000 tonnes
- Re-installations (re-surfacing): 170 000 and 35 000 tonnes

These estimates of ELT-derived granules tonnages used in 2016 for new installations and maintenance (total 141 000 tonnes) are in line with the figures reported by ETRMA as discussed above. The total figure derived in this dossier for the baseline situation (346 000 tonnes in 2016) is comparable with an estimate of ELT granules used annually on all types of sport pitches given by an EU association (figures claimed confidential). Re-installations will have a large and increasing share in the total tonnage used annually and are not included in the ETRMA figures. Based on an average expected 10-year service life of synthetic turf pitches the Dossier Submitter calculates the tonnage for re-surfacing of old synthetic turf pitches in 2016 at 205 000 tonnes. This tonnage is expected to show an increasing trend in the 2018-2028 period as a growing number of pitches will require re-installation at the end of their expected service-life of ten years. During re-surfacing the pitch is removed and replaced by a new pitch. Used infill material can be re-used for a second time but based on information available to the Dossier Submitter re-use is currently very limited (workshop November 2017). Hence, the re-use of granules on synthetic turf pitches is assumed to be zero.

D.2.2.2. Trends in quantities

Figure D 1 shows the tonnages of ELT-derived infill material, EPDM, TPE and cork as expected in the baseline scenario. The total annual use tonnage of ELT-derived infill material is expected to grow from 346 000 tonnes in 2016, 389 000 tonnes in 2018 to 548 000 tonnes in 2028. Throughout the period approximately 60 % of the tonnage is used for re-surfacing of existing pitches.

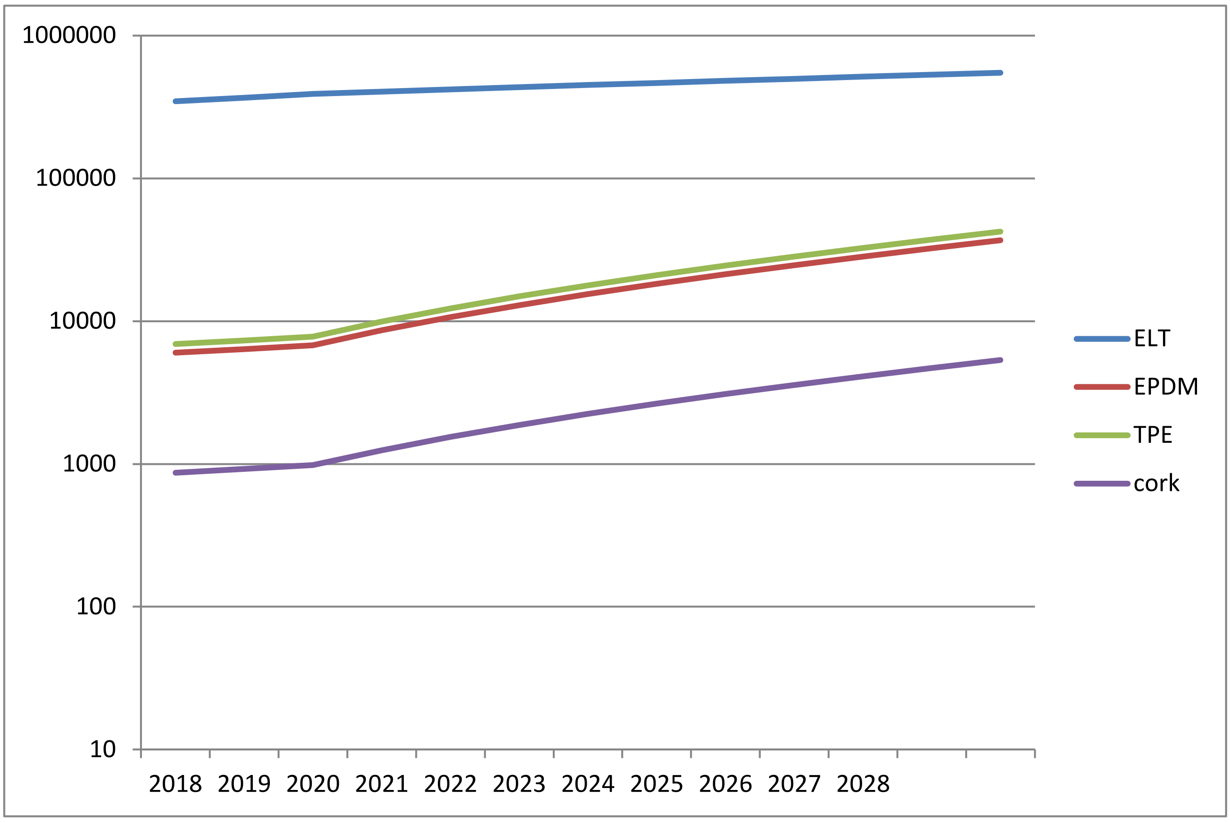

Figure D 1: Total annual use volumes (tonnes) of ELT, EPDM, TPE and cork infill materials applied in synthetic turf pitches and mini-pitches between 2018 and 2028. Estimations include newly installed pitches, granules added during annual maintenance of pitches and renewal of pitches at the end of service-life (re-installations).

D.3. PAHs concentrations in infill material

The ingredients of ELT crumb rubber find their basis in tyre manufacturing. To understand why PAHs are included in ELT (and to understand the possibilities to reduce PAH content in the material), it is important to have a general understanding of car and truck tyre chemistry. Petchkaew (2015) explains that car tyres are designed 'to have a good balance of three key properties including abrasion resistance, rolling resistance and wet skid resistance.' Tyres are generally made of Natural Rubber (NR), Styrene Butadiene Rubber (SBR) and Butadiene Rubber (BR). Other ingredients can be carbon black, accelerators, activators, anti-degradants, sulphur and process oil. Three basic types of oils can be distinguished: aromatic, naphthenic and paraffinic. The oils that are conventionally used in tyre manufacturing are Highly Aromatic (HA) oils due to the fact that they are compatible with both natural and synthetic rubbers. Oils in tyres have the functionality of improving processing properties, low temperature properties, dispersion of fillers and to reduce costs

(Petchkaew, 2015). Wypych, 2012 indicates the use of aromatic mineral oils as plasticizer in tyres. HA oils, also called Distillate Aromatic Extract (DEA) contain high concentrations of PAHs (Petchkaew, 2015). The use of these oils is one of the reasons why PAHs are present in tyres that can, after usage on a vehicle, be processed into ELT-derived rubber infill. According to the RIVM risk assessment on rubber granules (RIVM, 2017), ELT made infill material used in artificial turf pitches currently in the samples tested, have a median REACH-8 PAHs content of 5.8 mg/kg dry weight and a maximum of 19.8 mg/kg. ECHA (2017) found that new rubber granules manufactured from recycled tyres contain typically 0.2-22.8 mg/kg[64] of REACH-8 carcinogenic PAHs. For the purpose of this dossier, more information on PAH content of infill material has been collected. Concentration data of PAHs in ELT granules was provided by industry, authorities and other stakeholders and obtained from public literature. The collected data is restricted to uncoated granules produced from ELT rubber. It should however be noted that rubber granules in most cases originate from ELT, but may occasionally be mixed with other rubber waste streams on a pitch. Concentrations are only included when sampled (from a granules production site or a sport pitch) in the EU from the year 2010 onward. In total 1 373 samples with PAH information were obtained of which 1 234 included information on all REACH-8 carcinogenic PAHs. The 1 373 samples were taken in various European countries: Belgium (100), Denmark (17), Germany (143), Italy (23), the Netherlands (1 035), Portugal (5), Spain (15), Sweden (4), the UK (27) and other EU countries (4) and are deemed to be representative for ELT turfs in the EU. Samples from Eastern parts of the EU are missing. A large percentage of the samples originate from the Netherlands. Hence, the geographical spread of the PAH analytical data across the EU in our database is not perfect. On the other hand, we do cover one third of the EU countries. There may be some regional differences in tyres and hence scrap tyres on the European market in different regions (e.g. because of different technical requirements due to different climatic conditions). However, on the whole the tyre market acts on an EU-wide scale and the extender oil restriction applies in all EU countries. Therefore scrap tyres across the EU are expected to have similar PAH content. Differences in PAH concentrations in manufactured granules may appear due to differences in scrap tyre selection and granule manufacturing processes. This is acknowledged as an uncertainty. However, the Dossier Submitter has no indications that the PAHs information obtained is not a proper representation for the EU as a whole.

Various analytical methods were used to determine the PAH concentration in granules samples. Issues considering these methods are described in Annex E.9. and in Appendix E1. The analytical information on PAHs concentrations is presented in Appendix B1. In the section below, the main results of the analysis are summarized.

D.3.1. Current situation

The REACH-8 PAHs concentration in ELT infill samples available varied from 2.9 to 21 mg/kg with a 50th percentile of 11 mg/kg. Figure D 2 and Figure D 3 present a histogram and cumulative density function of all available measured REACH-8 PAH concentrations.

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[64] The minimum and maximum values are calculated from different samples measured in one study. This is done in order to get the worst-case values. Studies from almost 10 Member States covering more than 100 pitches (infill material already in use) and around 50 samples of new recycled rubber granules.

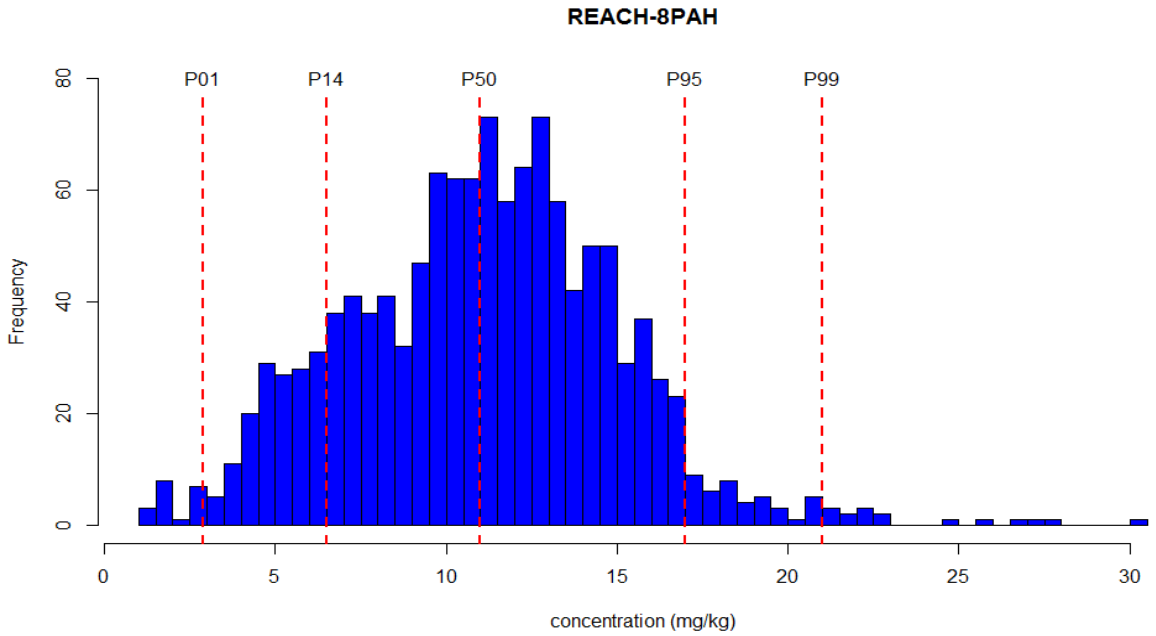

Figure D 2: Histogram of all available measured REACH-8 PAH concentrations (n=1 234). Vertical red lines indicate the 1st percentile (2.9 mg/kg), 14th percentile (6.5 mg/kg), 50th percentile (11 mg/kg), 95th percentile (17 mg/kg) and 99th percentile (21 mg/kg). In this figure, concentrations of individual congeners measured below LOD are set to equal LOD. This does not influence the obtained distribution. The percentiles obtained when setting values below LOD to zero are presented in Appendix B1.

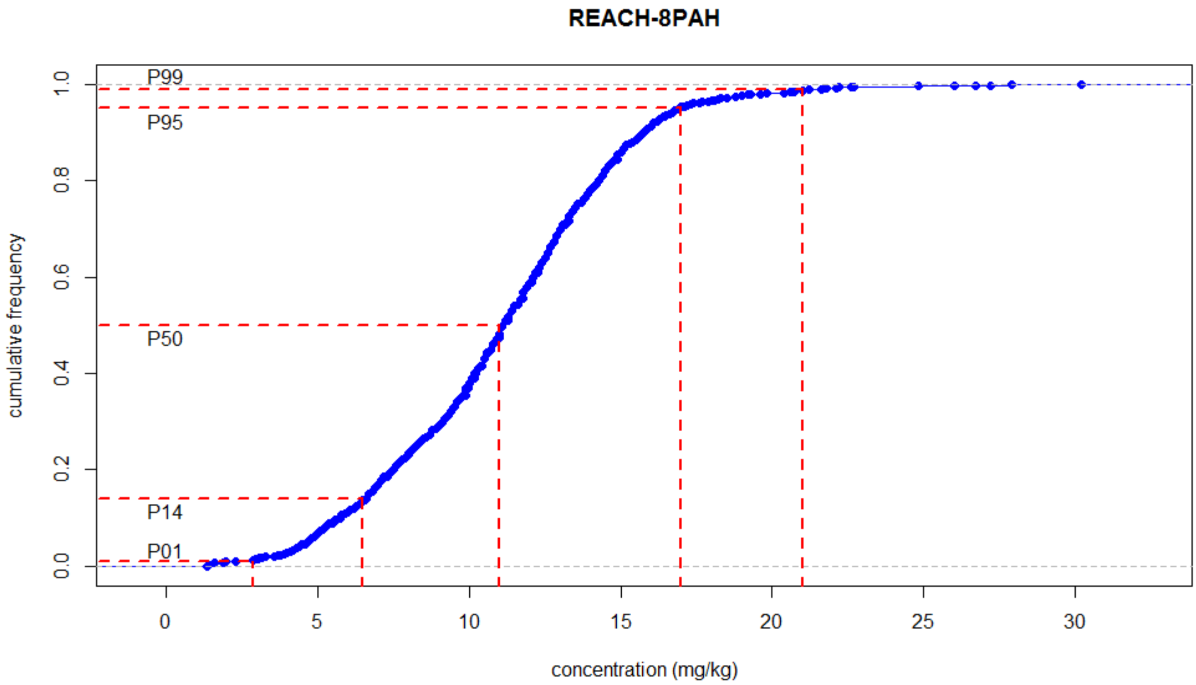

Figure D 3: Cumulative Density Function of all available measured REACH-8 PAH concentrations (n=1234). Red lines indicate the 1st percentile (2.9 mg/kg), 14th percentile (6.5 mg/kg), 50th percentile (11 mg/kg), 95th percentile (17 mg/kg) and 99th percentile (21 mg/kg).

The analysis in Appendix B1 focusses on PAHs in ELT. Only limited information is available on PAHs concentrations in rubber granules from other recycled material. In a study by Menichini et al. (2011) recycled scrap of vulcanised rubber and ground gaskets were between 0.1-4.1 mg/kg. However, these concentrations are from one study only, thus not representing all these types of material. In the ECHA report (2017) two samples were tested that contained around 3 000 mg/kg of the REACH-8 PAH. This rubber infill material was reported to originate from Asia and was not used in the reporting Member State.[65] However, it is not known whether or not this infill material is used in other EU Member States.

During the 24 November 2017 workshop and in personal communication with actors, various PAH concentration levels were mentioned. Concentration values by actors of 6, 9 and 15 mg/kg REACH-8 PAHs respectively have been indicated by different EU producers of infill material to be achievable at the moment. A concentration level of 20 mg/kg REACH-8 PAH seems to be achievable to the vast majority of actors consulted in the preparation of this dossier. Assuming that the available samples are representative for the EU, one may conclude that concentrations of 15-21 mg/kg are expected to be technically feasible for the majority of actors producing ELT infill. It was claimed during the November 2017 workshop that PAH level compliance would largely depend on the test method used as this influences the test results. Information on the various test methods available is given in Appendix E1.

D.3.2. Variability in PAHs content

During the November 2017 workshop, it was explained that PAHs concentrations in tyres and end-of-life tyre (ELT) granules appear to be relatively stable. However, differences in PAHs concentrations reported might occur for various reasons. First of all there will be variability of PAH recoveries from ELT-derived granules as it is dependent on the methods of extraction and analysis applied. Another issue might be that in addition to ELT also non-tyre rubber materials and waste articles may be used for manufacture of granules. This non-tyre waste may have other PAH content due to other composition of the rubber and due to the fact that the EU extender oils restriction does not apply to such materials. A third issue is that older scrap car or truck tyres or scrap non-automotive tyres (e.g. off-the-road tyres) may be used to manufacture granules (from before the entry into force of the EU extender oil restriction). Especially for truck tyres, this may be a factor of importance as retreating of truck tyres is common practice[66], other than of car tyres for which it is not economically feasible. A truck tyre may be retreated up to five times before the article reaches the end of its service life. Therefore, ELT material derived from truck tyres may be significantly older as the original tyre that is re-used several times may have been manufactured much earlier. A fourth source of variation may be the use of imported tyres[67] that do not comply with the

[65] Notably the concentrations of chrysene and benzo(a)pyrene were higher than the limit value set in entry 28 of Annex XVII to REACH, thus not complying with the existing restriction on PAHs.
[66] Although there are indications that retreading of truck tyres is declining (personal communication RIVM with recycling sector)
[67] Note that imported tyres should also comply with the EU extender oil restriction and because of that are expected to be low in PAHs, comparable to EU produced tyres. The difference in PAH content is especially expected in tyres that are produced for the non-EU market.

EU extender oil restriction to manufacture granules. Finally also import of waste tyres or granules from non-EU regions may be a source of variation.

ETRA (2017) taken from ECHA 2017 stated on this: "Based on the results of the research, we should consider producing infill material for artificial turf pitches exclusively from tyres manufactured in Europe since 2010, when the PAH in the rubber was radically reduced. Tyres produced outside of Europe, or those that do not comply with current requirements, or those previously produced in Europe in this regard, are much worse."

Depaolini et al. (2017) state that most of the existing studies on PAHs in ELT rubber refer to experiments on infill samples without any age classification, so it is possible that ELT material in these studies originated from tyres placed on the market before the entry into force of the REACH restriction on extender oil. Therefore, Depaolini et al. took a large number of ELTs that were assumed representative for the Italian market and classified by type, age and origin and analysed granules produced from these tyres e.g. on PAHs content. The study especially looked at the difference between before and after the EU 2010 extender oil restriction and at the difference between tyres produced within and outside the EU. The results of this study suggest that most of the ELT recycled today are compliant with the REACH extender oil restriction. Little more information is available to the Dossier Submitter on PAH concentrations in oils and tyres several years before the extender oil restriction became effective. As indicated in Annex A.1., CSTEE (2003) reports a total PAHs content in extender oils used in tyre manufacture in the range 300-700 mg/kg and estimates total PAH concentrations between 13 and 112 mg/kg in ELT particles due to the oils. Other sources referred to in the CSTEE opinion show ranges of 1-230 mg/kg, 30-360 mg/kg and a single reported value of 226 mg/kg in tyre material. These figures provide some indication of much higher PAH levels in oils and tyres on the EU market almost ten years prior to the restriction. Tyre manufacturers began to replace aromatic oils already before 2010 to guarantee compliance of the tyres sold from that year on. This is in line with signals the Dossier Submitter received during the 24 November 2017 workshop.

The results of the Depaolini et al. study indicate a generally lower amount of PAHs in EU recycled rubber samples compared to the non-EU ones. Moreover, for the non-EU material there was a difference in PAH content in samples taken before and after 2010, while this difference was less evident for the EU samples. The only significant difference was between EU and non-EU tyres.

D.3.3. Trend

The entering into force of the EU extender oil restriction in 2010 resulted in a gradual reduction of PAHs in tyres on the European market. Petchkaew (2015) investigated compatibility of various non-carcinogenic oils for car tyre manufacturing. Alternative oils that are mentioned are Treated Distillate Aromatic Extract (TDAE), Mild Extracted Solvate (MES), Naphthenic oils (NAP) and natural oils. TDAE currently appears to be the mostly used oil in tyre production for the EU market. Tyres produced for the EU market generally comply with the EU extender oil restriction (Depaolini et al., 2017).

Some ELT from before 2010 appears still to be placed on the EU recycling market.[68] However, the differences in PAHs content from before and after 2010 seems not significant. According to figures from ETRMA, imports of passenger car tyres and of bus and truck tyres have been growing over the last 5-8 years. This trend may slightly increase the PAHs content in ELT put on the EU market in the future. However, it is questionable whether this potential increase would be significant. Use of non-ELT crumb rubber from other sources has been indicated as a potential source of infill material that may contain higher PAHs content. However, no clear source could be found confirming this observation. Also no information is available that this use may be increasing in the EU.

To see whether there has been a trend over the past years, available measurements on PAHs content in granules taken from production facilities have been plotted against year of sampling (2010-2017, see Appendix B1, Figure B1-20). The analysis of measurements over time shows that from 2010 onwards, there is a (significant) decrease in REACH-8 PAH concentration. The decrease seems to level off in the last four years (2014-2017). It should be noted that the observed decrease is based on the limited number of (relatively high) samples from 2010 to 2013. Samples taken from the artificial turf pitches have been removed from this analysis as PAHs content may change over time while lying on the field (ageing) and as pitches are refilled every year and the infill that is available on the pitches will thus be a mixture of infill produced in different years.

Besides the use of oil, also carbon black will be a source of PAHs in the production of tyres. More information on the use of carbon black in tyre manufacturing is presented in Annex A.1.1.

Based on the available information, it is assumed that the PAH concentration in ELT will remain stable in the next decade, no further reduction or increase is expected in the baseline situation. The situation described above for ELT-derived granules used as infill is considered representative as well for the PAH concentrations in ELT-derived mulches and granules used in loose applications on playgrounds as the feedstock material (scrap tyres) is the same.

D.3.4. PAHs in other (non-ELT) infill materials

With respect to non-ELT infill, the majority of the infill will be virgin material (personal communication Professor Noordermeer and Dr. Dierkens, personal communication synthetic turf sector). These materials could in theory contain PAHs if for example carbon black or PAH containing oils are used in the production. The latter is deemed unlikely in case of EPDM as PAH containing oils do not match with the material. Carbon black could be used in in the production of EPDM. However, in practice this would probably not happen as customers prefer coloured infill. If alternative infill (e.g. EPDM) is made of recycled material, it probably contains carbon black and therefore may contain PAHs. A large proportion of EPDM articles used on the market contain black carbon (e.g. roofing sheets, floor mats etc.) and hence black carbon containing EPDM will be abundant in the waste stage. The analysis

[68] 15 % in Italy (Depaolini et al. 2017), for other countries no information is available. Not known whether this 15 % is representative for the EU.

of alternatives shows that some low quantities in PAHs have been found in EPDM based on limited information available (See Annex E.2.).

D.4. Number of people exposed and at risk

D.4.1 Football players and goalkeepers

Annex A.2.3. describes the main types of sports that are practiced on synthetic turf pitches. In relation with the use of synthetic turf, football is by far the largest sport with 15.4 million registered players in 2016 in the EU-28 and the EEA-3 as of 2015-2016 (UEFA, 2016[44]). The number of unregistered players in 2016 is a more uncertain figure but as indicated in Annex A it is assumed here that the population of unregistered football players in the EU may be 1.9 times larger than that of registered players. Of the 15.4 million registered players 71 049 are reported as professionals. For the sake of ease the Dossier Submitter assumes that one in each 11 (professional) players is a (professional) goalkeeper. Hence in 2016 we estimate a total of 64 590 professional players and 6 459 professional goalkeepers and likewise 13.9 million amateur players and 1.4 million amateur keepers. In Annex A it is estimated that there are about 20 million registered football, lacrosse, Gaelic games and rugby players in the EEA-31 (EU-28 plus Iceland, Norway and Liechtenstein) and 38 million registered and unregistered.

According to FIFA's 2006 latest published information on worldwide football statistics in the 55 UEFA countries have an active football playing population that makes up 7.3 % of the region's entire population (FIFA Big Count 2006[69]). Together with CONMEBOL (South-America) and CAF (Africa), UEFA is one of the confederations that show the highest growth rates. In each of these three regions, the number of active players has grown by more than 10 % from 2000 to 2006. According to FIFA these statistics reiterate the special importance of football in Europe and the Americas. FIFA in its report does not specifically mention growth prognosis in the European region. It should be noted that in recent years especially growth is seen in women's football. Worldwide FIFA reports a 19 % increase in the total number of female players and an 8 % increase in the total number of male players from 2000 to 2006. The Dossier Submitter concludes that the growth prognosis in the EU for the period 2018-2028 is uncertain. Demographic developments in the EU with a declining birth rate and ageing population will especially in some areas reduce the football playing population. UEFA runs a special programme in which it is looking to help national associations to increase the number of registered football players after there had been a reported decrease between 2010 and 2015 within some associations (UEFA 2018: A growth plan for European football[70]). This is a clear indication of recent developments that point towards a declined growth potential in the EU region as a whole primarily due to ageing of the general population. Other developments such as the growing interest in women's football may give rise to further growth in that sub population. As no clear prognosis is available to the Dossier Submitter, for the restriction dossier no further growth of the player population is assumed between 2018 and 2028. In the risk assessment of this dossier (See

[69] https://www.fifa.com/mm/document/fifafacts/bcoffsurv/bigcount.statspackage_7024.pdf
[70] https://www.uefa.com/insideuefa/news/newsid=2538043.html

Annex B) it is assumed that all football players make use of synthetic turf every time they play (both training and matches). This will be true for some players in some countries and therefore it is an appropriate assumption in the scope of a realistic worst case risk assessment. However, this frequency of use will not be reality in practice for most players. There will be football players that only make use of artificial turf with recycled rubber granules and there will be football players that never make use of artificial turf with recycled rubber granules. In between the two extremes, there will be players that make use of different types of pitches.

D.4.2. Players on mini-pitches

In the scope of this restriction dossier mini-pitches are understood to cover a broad range of synthetic turf pitches that are smaller than a standard football pitch and that may be used for football purposes (e.g. minifootball), other sports or as playing area for children. Mini-pitches may be located outdoors in urban areas (e.g. so-called Cruyff Courts or children's playgrounds) or indoors (mini-pitches for indoor soccer other than hard surface futsal).

The Dossier Submitter has insufficient information to define the actual number of individuals that make use of mini-pitches every year. Minifootball does not fall under the flag of FIFA or UEFA but in recent years it is being promoted by the European Minifootball Federation that organises a six-a-side competition and is supported by a growing number of national associations.

As a best-informed guess, the Dossier Submitter assumes that half of the European synthetic turf mini-pitches (45 000 in 2012, 63 000 in 2018 and 70 000 in 2020) are using performance infill. Based on this assumption the Dossier Submitter estimates 31 500 mini-pitches with infill are used in the EU in 2018. Furthermore, the assumption is made that all mini-pitches are multi-purpose pitches used for a variety of sports and leisure purposes, including playing and that all pitches are in public spaces.

To construct a proxy for the number of frequent users of mini-pitches, user estimates for Cruyff Courts in the Netherlands are used. The Cruyff Court is an example of a multi-purpose mini-. On a weekly basis, 65 000 children are active on one of the 233 Cruyff Courts in the Netherlands[71]. Hence, on average, 280 children are using a court in any given week. If we assume the use of these Cruyff Court mini-pitches to be representative for all mini-pitches in Europe and that all these children are different individuals (280 children times 31 500 mini-pitches in 2018) the potential group of users of mini-pitches in Europe is 8.8 million in one week. If we assume that of these children 9 out of 10 are frequent users of the pitch, we arrive at 252 children that fall in the group of frequent users per pitch. Add hoc users are not further considered in our estimations. Assuming 252 frequent users per pitch and 31 500 mini-pitches, the population users of mini-pitches in the EU is 7.9 million children. To put these numbers into perspective, as there are almost 80 million children from 0-14 years old in the EU[72], these estimates correspond to almost 10 % of the EU population in this age cohort.

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[71] https://www.cruyff-foundation.org/activiteiten/cruyff-courts

[72] Population: http://ec.europa.eu/eurostat/documents/2995521/8102195/3-10072017-AP-EN.pdf/a61ce1ca-1efd-41df-86a2-bb495daabdab; Age distribution: http://ec.europa.eu/eurostat/tgm/refreshTableAction.do?tab=table&plugin=1&pcode=tps00010&language=en

D.4.3. Installation and maintenance workers

There is no estimate available on the number of workers in Europe dealing with the installation and maintenance of artificial turf pitches. Therefore, estimates of the potential number of workers are derived based on the available information in Annex A, Annex B and Annex D and making additional assumptions. The calculations are presented in the textbox below. Based on this, an order of magnitude estimate of around 4 000 - 14 000 workers for installation and maintenance of artificial turf in the EU in 2018 is obtained.

Textbox D 1: Example calculation number of workers for installation and maintenance of artificial turf in the EU

Installation full size football pitches in Europe
It is estimated that there are on average 2 800 full field (re-)installations per year in the period 2018-2028. Assuming on average 5 days installation by 4 workers per field, gives an estimate of 56 000 worker days per year. Assuming 120 working days in 6 months period per worker gives 470 workers per year working (6 months a year) in installation.

Installation mini-pitches in Europe
It is estimated that there are on average 8 800 mini-pitch (re-)installations per year in the period 2018-2028. Assuming on average 3 days installation by 4 workers per pitch gives an estimate of 105 600 worker days per year. Assuming 120 working days in 6 month period per worker gives 880 workers per year working (6 months a year) in installation.

Maintenance of pitches
In the exposure scenario, the assumption is that regular maintenance takes 2 hours a day, 1 day a week by 1 worker. This implies that 1 worker maintains around 4 pitches a week for 10 months a year during the sport season assuming an 8 hour working day. Having 19 000 full size football pitches in 2018 in the EU thus requires 4 750 workers for maintenance. With respect to mini-pitches, it is assumed that maintenance also occurs once a week by 1 worker, but takes 1 hour instead of 2. For 63 000 mini-pitches installed in 2018 this thus requires 7 900 workers in the EU. If it is assumed that workers maintain pitches 5 days a week (deviate from the assumptions in the exposure scenario in Annex B), this means that respectively 20 and 40 pitches per week can be maintained per worker for full size football pitches and mini-pitches. This gives an estimate of 950 and 1 580 workers for maintenance in the EU for football pitches and mini-pitches. It is assumed that yearly maintenance occurs by the same workers as the regular weekly maintenance and that this does not add to the total numbers of workers involved with maintenance. This gives a total of 12 650 workers for maintenance in the high estimate (part-time maintenance) or 2 530 workers in the low estimate (full-time maintenance).

Total number of workers
In total, it is estimated that between 4 000 (470+880+2 530) - 14 000 (470+880+ 12 650) workers are involved in installation and maintenance of synthetic turf pitches. It is assumed that currently, 90 % of the synthetic turf contains ELT infill, that workers installing and maintaining pitches will do that for all types of infill used and, that all workers will thus come in to contact with ELT infill.

Annex E: Impact Assessment

E.1. Risk Management Options

E.1.1. Proposed restriction

The Dossier Submitter has assessed whether there is a risk to human health due to exposure to PAHs from the use of ELT-derived and other granules as 1) performance infill material in synthetic turf pitches and 2) from the use as loose granules or mulch on playgrounds and in sport applications. Specifically, the Dossier Submitter analysed whether existing maximum PAH content limits applicable to the granules applied as mixtures to the general public in accordance with REACH Annex XVII entry 28 are appropriate to guarantee control of risks and the need for reducing these maximum permissible levels to ensure risks are controlled. Both the risks for workers installing synthetic turf pitches and performing regular maintenance and for the general population making use of the synthetic turf pitches and playgrounds were assessed. The conclusion of this assessment is that there is a risk of the use of ELT-derived rubber granules as performance infill material on synthetic turf pitches if the concentration levels of carcinogenic PAHs in these granules are as high as permitted under the generic concentration limit for mixtures supplied to the general public (REACH Annex XVII, entry 28). Assuming the infill exposure scenarios are also applicable to the use of loose granules or mulches on playgrounds, this conclusion also applies to these other uses of ELT-derived materials. Based on our analysis of REACH-8 PAH concentrations in ELT-derived granules placed on the market and used on synthetic turf pitches, the Dossier Submitter conclude that there is a very low excess cancer risk in some of the scenarios (i.e. for professional goalkeepers). This conclusion is valid if an excess risk level of one additional cancer case per million exposed individuals during lifelong exposure is applied as an acceptable level (i.e. REACH guidance R8 DMEL). This conclusion is consistent with analyses performed by ECHA (2017) and RIVM (2017).

Therefore, it is proposed to restrict the concentration of PAHs in these granules to a level for which an appropriate level of risk control has been shown in the risk assessment and taking into account the technical and economic feasibility of the proposed limit values. The proposed restriction is presented in section 4 of the Restriction Dossier. The proposal is to restrict the maximum permitted concentration of the sum of REACH-8 PAHs in granules placed on the market for use as performance infill on synthetic turf pitches or as loose granules or mulch on playgrounds and in sport applications to a level of 17 mg/kg. The proposed transitional period is 12 months. The restriction applies to all types of granules or mulch that may be placed on the market and used to perform the function of performance infill on long pile synthetic turf systems or that are used in loose form on playgrounds or in sports applications. The restriction does not (directly) affect pitches that are already installed at the entry into force, except for any supplementary refill of granules (re-surfacing or re-installation). No derogations are proposed. This restriction option (or risk management option) is further evaluated in the impact assessment and indicated as R(M)O1

Discarded restriction options are presented in Section E.1.2. and other risk management options (RMOs) investigated are discussed in Section E.1.3.

In section E.9. and E.11. of this Dossier the suitability of the proposed restriction is evaluated based on an analysis of its effectiveness (risk reduction capacity and proportionality to the risk), practicality (implementability, enforceability and manageability) and monitorability.

E.1.1.1. Rationale for the proposed restriction

The proposed restriction is formulated taking into account the following:

- The risk of lifelong exposure to football players (including goalkeepers) from exposure to PAHs from the use of recycled rubber granules as performance infill in synthetic turf pitches is not controlled if PAH concentrations are as high as permitted in accordance with REACH Annex XVII entry 28 for supply of mixtures to the general public. Based on similar exposure scenarios it is assumed that the conclusion for football players also applies to other sports that make use of synthetic turf such as rugby, lacrosse and Gaelic Sports;

- A very low level of excess cancer risk in football players (especially goalkeepers), playing children and workers performing installation and maintenance activities based on their lifelong exposure to PAH concentrations that are currently found in ELT-derived performance infill granules used on synthetic turf pitches or playgrounds;

- On the basis of the identified risk, a need to establish a lower limit value for granules and mulch to ascertain risks for football players, goalkeepers, playing children, other athletes and workers are appropriately controlled for any current and future use of granules as performance infill in synthetic turf pitches and for loose application of granules and mulches on playgrounds;

- A trend since the year 2000 in Europe towards the increased application of synthetic turf systems using performance infill granules for football and other sports such as rugby and for recreational purposes;

- A main concern based on risks calculated due to the presence of PAHs in granules made from ELT-derived rubber granules along with the notion that in principle all granules used for this application should be equally safe for humans and the need for an equal treatment of stakeholders in the supply chain including suppliers of alternative granules based on other recycled or virgin materials.

- The technical and economic feasibility of the limit value proposed for stakeholders placing on the market granules or mulches for the uses in the scope of the proposed restriction.

E.1.1.2. Concentration limit

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

The risk assessment provides a basis for setting the limit value. The starting point is the magnitude of the risk for football players and goalkeepers and for children playing on mini-pitches due to lifelong exposure to granules with PAHs concentrations up to values of 100 mg/kg (BaP and DBAhA) or 1 000 mg/kg (other six of the REACH-8 PAHs) per individual

PAH (see Annex A.3.1). Excess cancer risk is estimated based on exposure to the eight carcinogenic PAHs that currently have a harmonised classification for this hazard class in CLP Annex VI. These REACH-8 PAHs are also covered in REACH Annex XVII entries 28 and 50. As the risk estimates are based on aggregated exposure of humans to these eight classified PAHs, the limit value should also be defined for the sum. The estimated risks were set against a maximum level of additional cancer risk that is considered acceptable. For the purpose of this Annex XV dossier the Dossier Submitter applied an acceptable excess risk level of one in a million as this has a basis in ECHA guidance R.8 for setting the Derived Minimal Exposure Levels (DMELs) for substances with a non-threshold toxicological effect. In setting the concentration limits based on the scenarios for football players and goalkeepers the Dossier Submitter argues that these scenarios can be used as a proper approximation for estimating exposure and risks for any other type of sport taking place on synthetic turf pitches (See Annex B). For estimating risk to small children playing on so-called mini-pitches or playgrounds on which granules or mulches (flakes) are used as infill material or in loose form, the Dossier Submitter used separate contributing exposure scenarios and hence these risks are also factored into the setting of the concentration limits.

Based on 95th percentile of the distribution of the current PAH levels in ELT-derived granules on synthetic turf pitches (baseline situation, Figure D 2), the excess lifetime cancer risk estimated for professional goalkeepers is at the level of $2.6x10^{-6}$. To reduce the risk to the level of $1x10^{-6}$, the limit value would be 6.5 mg/kg for the sum of REACH-8 PAHs (see Annex B). Taking into account that setting such a 'risk based' limit value would entail costs to society that are not deemed proportional in light of the estimated risk reduction, considerations on the achievability of the proposed limit values for the tyre recycling sector have to be accounted for together with the remaining risk levels. Based on information obtained in consultations with stakeholders the Dossier Submitter concluded that concentrations of 15-21 mg/kg are technically and economically feasible and achievable for a large part of actors producing ELT infill (see Appendix G1). Considering the above information, the Dossier Submitter uses the 95th percentile of the REACH-8 PAHs that are in currently placed on the market and used on synthetic turf pitches as the lowest value that is expected to be technically and economically feasible and achievable for manufacturers of ELT-derived granules and mulches in the EU that will result in acceptable risk values. The 95th percentile corresponds with a REACH-8 PAH concentration limit of 17 mg/kg.

E.1.1.3. Transitional period

The REACH restriction on PAHs in extender oils in tyres entered into force in January 2010. Based on information provided by ETRMA, the study by Depaolini et al. (2017), and the analysis of PAH content in ELT performed in the context of this dossier (see Annex D and Appendix B1), PAH levels in tyres available on the European market had decreased already prior to entry into force of this restriction and have since then been stabilised. This means that PAH concentrations in scrap tyres and manufactured granules and mulch on the EU market are expected to be relatively stable. Hence the development of PAH concentrations in granules is not a factor to consider in setting the transitional period for the restriction. The REACH-8 PAHs concentration in ELT infill samples available to the Dossier Submitter (1234 samples from 9 countries varied from 2.9-21 mg/kg with a 50 percentile of 11 mg/kg).

As the limit value of 17 mg/kg proposed is significantly lower than the 100-1000 mg/kg limit values[73] that are currently applicable to the granules, the restriction will mean for some ELT-derived granule manufacturers that they will have to increase the rate of compliance testing and switch to cleaner production input or cease the production of infill material. The restriction will render 5 % of the currently manufactured granules incompliant if entry into force of the restriction were to become effective immediately. A transitional period should allow a limited but reasonable period for downstream users (turf manufacturers, distributers and companies installing the turf) to switch to granules that have already been supplied to them (i.e. placed on the market prior to entry into force).

Another factor that is considered of importance is the possibility for ELT-derived granules manufacturers to implement and apply state of the art pre-production selection techniques on scrap tyres to reduce PAH concentrations in their products. During three site visits at ELT-derived granule manufacturers in the Netherlands and Germany, the Dossier Submitter noted that different techniques and principles are applied. One granule manufacturer used manual de-selection of tyres manufactured before 2010, another one manually de-selected truck tyres and off-road tyres (which often have a relatively long service life and hence may be much older). Automated de-selection of tyres was reported to be technically challenging (one sided tyre coding, difficulty to scan the black surface, equipment needs, etc.). Also the de-selection of non-ELT sources of recycled rubber may be a relevant measure. The Dossier Submitter considers selection of scrap tyres and other sources of rubber prior to ELT-derived granules manufacture a possibility for some recycling companies to lower PAH concentrations. We consider that some time should be allowed to implement such measures. However, not all recycling companies may find it feasible to implement such measures depending on the technical and organisational setup of their business. Furthermore, the effect may be limited based on the finding that there are only small reductions in PAH levels in tyres manufactured before and after 2010 and between EU and non-EU tyres (Depaolini et al. 2017). The Dossier Submitter is aware of the following options for de-selection:

- Tyres placed on the market prior to 2010 that only now become available as scrap tyres:
    - e.g. truck tyres that may have been retreaded up to five times and could contain higher PAH levels in the basic part of the tyre;
    - old land-filled tyres;
    - off- road tyres;
- Imported non-EU scrap tyres or granules made from non-EU tyres;
- Rubber waste originating from other sources (floor mats, conveyor belts, industrial piping etc.).

[73] Or 387 mg/kg if the limit value for mixtures is translated into a sum limit value. The concentration limits for the individual REACH-8 PAHs (in granules and mulches) set for mixtures in entry 28 of Annex XVII of REACH (i.e.1 000 mg/kg for benzo[e]pyrene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene and chrysene, and 100 mg/kg for benzo[a]pyrene and dibenzo[a,h]anthracene) can be translated to a sum limit of 387 mg/kg for the sum of the REACH-8 PAHs using the additivity approach (cf. CLP-Guidance section 1.6.3.3.3) and taking into account the relative contribution of the different PAHs to the REACH-8 PAH content in ELT infill found in the baseline situation in the EU (see Appendix B1). Note that this value should not be seen as an absolute value, as it may change depending on the concentrations and relative contribution of the individual PAHs in ELT infill.

During the November 2017 stakeholder workshop several stakeholders stated that because of the societal attention in some European countries to the use of ELT-derived granules on synthetic turf, any restriction imposed would have an immediate effect on the market for infill material. According to these stakeholders, a transitional period would therefore not be effective.

Considering the information provided above, the Dossier Submitter proposes a transitional period of 12 months for the placing on the market and use of granules as a reasonable timeframe to implement measures to reduce the PAH content in manufactured granules, to ensure compliance and, for downstream users, to use stocks that have already been placed on the market before entry into force.

E.1.1.4. Definitions and other enforcement considerations

The proposed restriction covers the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds if these materials contain more than 17 mg/kg (0.0017 %) by weight of this component of the sum of the listed PAHs. The restriction shall apply one year after its entry into force.

Types of synthetic turf and infill covered
The restriction covers the use of granules as infill material in synthetic turf. In the scope of the restriction proposal we define synthetic turf as any artificial turf requiring infill other than sand or water. In general, ELT-derived or other granules are used as so called 'performance infill' in 3rd generation long pile (4-6 cm) synthetic turf pitches that are used for football and other sports such as rugby, lacrosse, Gaelic Sports and baseball (list not exhaustive). Importantly, another type (short pile) of artificial turf is used for example for field hockey and requires sand or water as infill. Pitches show a broad variety between official UEFA-size football pitches and much smaller pitches such as so-called Cruyff courts and other types of mini-pitches. Indoor as well as outdoor pitches make use of synthetic turf and infill granules and are hence in the scope of the restriction proposal.

The concern that formed the basis for this restriction was related to ELT-derived rubber granules, some of which may contain high concentrations of PAHs. During the development of the restriction dossier information was gained on alternative infill materials (such as TPE, EPDM and natural cork), and on another type of ELT-derived material, rubber mulch, which has found its way into applications such as playgrounds where it may be used in loose form. Therefore, and based on the principle that the restriction on PAHs should equally apply to all types of granules and mulches used in synthetic turf infill applications and in loose form on playgrounds, the restriction covers all of these materials.

Mixtures versus articles
As indicated in Annex A.3.1. ELT-derived granules (rubber crumb) was concluded to fall under the scope of the REACH mixture definition. The same applies to rubber mulch and other types of infill granules, although it should be noted that for some alternatives the form may be less relevant to the function of the granule than the chemical composition (e.g. some of the alternatives have the shape of hollow tubes). This was also stated by some alternatives suppliers during the November 2017 workshop. It is outside the scope of this restriction dossier to further discuss the applicability of the mixture conclusion of rubber crumb to other infill types.

PAHs covered
The restriction proposes a limit value for eight PAHs that are currently covered by Annex XVII entry 50 and that have harmonised classifications as Carcinogenic Category 1B in Annex VI of the CLP Regulation. The limit value established applies to the sum of these REACH-8 PAHs which is consistent with the risk assessment approach in which consumers and workers are exposed to a cocktail of PAHs. The REACH-8 PAHs are hence applied as markers for a potentially larger group of carcinogenic PAHs that may be contained in granules or mulch (i.e. through extender oils and carbon black used in the manufacture of tyres). According to the harmonised classification in Annex VI of the CLP Regulation two PAHs BaP and DBAhA have a specific concentration limit for classification of mixtures that is a factor of 10 lower than the limit for the other six PAHs (100 instead of 1000 mg/kg). This difference in the specific concentration limit is accounted for in the risk assessment.

The Dossier Submitter considered the addition in the scope of the restriction of potential other carcinogenic PAHs that are now in the process of harmonised EU classification under the CLP Regulation. This option was however discarded as it would have no added value in terms of the risk reduction capacity of the restriction.

Loose granules and mulch versus bound materials
Mulches or granules may be used in loose applications on playgrounds and only these uses are covered by the restriction. Mulches or granules that are in situ bound (e.g. by applying a PU resin) and hence form a solid playground or sport flooring, or tiles are not covered by the restriction. Such applications are within the scope of the existing restriction on PAHs in articles supplied to the general public in entry 50 of the REACH Regulation. Loose uses of mulches or granules other than in playgrounds or sport applications are not covered by the restriction. These are for instance uses in gardening and landscaping, on shooting ranges or equestrian uses.

Analytical methods
At the time of writing this restriction dossier no standard methodology for extraction, clean-up and analysis of PAHs (often performed with a Gas Chromatography or High Performance Liquid Chromatography method) from rubber granules or mulches was available. In Appendix E1 an overview is provided on the extraction methods which were used to determine the PAH concentrations in rubber granulate samples obtained for this restriction dossier from literature and industry sources. The extraction step is assumed to be the most critical step in determining PAH concentrations. When the extraction is not complete, the PAH concentration is underestimated. The extraction solvents and techniques, clean-up procedures and methods used to perform the chemical analyses differ among the samples in the database developed for this dossier (see Appendix E1). Some of the extraction methods were specifically designed to analyse PAHs in rubber granules, while other methods were originally designed to determine PAH concentrations in other matrices, such as soil, building materials with and without bitumen or tyres. The methods also used various techniques to reduce the size of the granules and conditions during the extraction (durations, temperatures, pressure, etc.). As regards the size of the granules the methods ranged from no change to size reduction to 2-3 mm to cryogenic milling prior to extraction.

In general, the method should be able to extract even the PAHs present at the core of the particle. Based on a review by the Dossier Submitter, the AfPS GS 2014:01 PAH (i.e. ZEK 01.4-8) method seems to be the most rigorous and suitable standardised 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. The Dossier Submitter recommends that efforts be made to validate and optimise extraction methods to increase confidence in the extraction efficiency of measurement methods in general. We take note of the mandate given by the European Commission in December 2017 to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) to draft harmonised standards for analyses of REACH-8 PAHs listed in entry 50 of Annex XVII of REACH in the plastic and rubber components of articles. The standardisation work done by CEN and Cenelec is aimed to support the enforcement of the provisions in paragraphs 5 and 6 of the latter restriction but may also prove helpful for the current restriction proposal on granules and mulch.

E.1.2. Discarded restriction options

In addition to RMO1 described above, the following risk management options (RMO) were investigated:

- RMO2: Restriction as proposed, but setting the limit value for the REACH-8 PAH concentration at the value in which the excess lifetime cancer risk of all individuals exposed stays below $1x10^{-6}$ based on the realistic worst-case risk assessment

Proposing a limit value based on risk assessment ensuring a highest acceptable excess cancer risk for all exposed groups of 1 per million exposed, without taking into account technical and economic feasibility of the limit value introduced to actors in the supply chain would result in a restriction that would not be proportional. For the group exposed at the highest level considered in the risk assessment (professional goalkeepers), this restriction option would provide a very small additional risk reduction potential compared to the baseline, while the costs that would be incurred upon society would become very high as the restriction would have the effect that ELT-derived granules could not be used anymore as infill in synthetic turf. Turf manufacturers and installers would have to revert to more expensive alternative infill types. Costs would be incurred upon the end-users of the synthetic turf pitches, which are the municipalities and the players through their annual membership contribution (See Annex E.3. Restriction scenario(s)).

- RMO3: Restriction as proposed, but limiting the content of all PAHs that have a classification as Carcinogenic in Annex VI of the CLP Regulation

The Risk Assessment Committee (RAC) in 2016 drafted an opinion on the harmonised classification of two additional PAHs[74] as 'Carcinogenic Category 1B' and currently new proposals are underway. The Dossier Submitter has taken note of these developments but considers that the REACH-8 PAHs may be used as markers for a potentially much larger group of PAHs that are contained in ELT-derived granules or mulch as impurities in extender oils and carbon black which are used in the manufacturing of rubber tyres (for details reference is made to section 1.2.1. of this Restriction Dossier). This is also what has been concluded in the 24 November 2017 workshop. Expanding the scope of the restriction

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[74] benzo[rst]pentaphene: EC Number: 205-877-5, CAS Number: 189-55-9 (RAC opinion: Muta 2, Carc 1B) and dibenzo[b,def]chrysene, dibenzo[a,h]pyrene: EC Number: 205-878-0, CAS Number: 189-64-0 (RAC opinion: Muta 2, Carc 1B). RAC opinions: https://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling

proposal to other carcinogenic PAHs was not taken forward as this would have no added value in terms of the risk reduction capacity of the proposed restriction. Restricting the classified group of REACH-8 PAHs will be effective on a possibly larger group of PAHs as these are contained in ELT-derived rubber as impurities in extender oils and carbon black. The Dossier Submitter acknowledges that adding more classified carcinogenic PAHs in the risk assessment would reduce the uncertainty. The more classified carcinogenic PAHs would be covered, the better would the risk of total exposure to carcinogenic PAHs be estimated. However, the available information on any newly added PAHs (e.g. on their presence in granules) would be limited, which would hamper exposure assessment. Furthermore, the two newly classified PAHs currently have not yet undergone the legal procedure required for inclusion in Annex VI of CLP. Finally, expansion of the group of PAHs would increase the costs for compliance testing and would deviate from the existing restriction entry 50 paragraph 5 and 6 on PAHs in consumer articles.

- RMO4: Restriction as proposed, but defining a migration limit instead of a PAH content limit

This option was not taken forward based on several considerations. The general argument for a restriction based on migration and not on content is that migration better relates to the actual risk for human health of the use of granules. However, migration of PAHs from the mixture (e.g. rubber or plastic) matrix is a factor of importance in the toxicokinetic part of the risk assessment. Migration as such is taken into consideration in the risk assessment through the inclusion of oral, dermal and inhalation absorption factors allowing translation of external exposure to granules to internal doses in humans. Hence, based on the fact that the risk assessment takes into account 'migration' of PAHs in the various exposure scenarios, there is no added value in proposing a restriction based on migration limits. In addition, the Dossier Submitter considers that a content limit value for PAHs, a generally well understood and straightforward way of defining a restriction, is more practical and better enforceable compared to a migration based restriction.

The dossier submitter acknowledges that as regards migration of PAHs from rubber and plastics matrices work is in progress at European level. The Joint Research Centre (JRC) has been tasked by the European Commission to investigate migration of PAHs from rubber material surfaces through skin contact. This work is however targeted to articles that fall under the scope of REACH restriction entry 50, paragraph 5 and 6 and has no direct relevance for granules that are considered mixtures.

- RMO5: Restriction as proposed, but setting a limit value that is consistent with the limit value that applies to articles or toys in paragraphs 5 and 6 of Annex XVII of REACH and applies to individual PAHs (instead of the sum of REACH-8 PAHs)

This restriction option has not been taken forward as the exposure and risk assessment for plastic and rubber articles and toys differs from the risk assessment for mixtures and therefore the limit value of 1 mg/kg per PAH for articles and 0.5 mg/kg per PAH for toys cannot be compared with a limit value for PAHs in granules. The small particle size of the granules and mulches and their specific uses as infill material on synthetic turf pitches and as loose material on playgrounds result in different exposure scenarios for workers, playing children and athletes. These exposure scenarios have a scope that is different from the exposure situation for articles and toys to which the general public may come into contact through the skin. For granules and mulches, besides dermal contact, also oral exposure (swallowing) and inhalation exposure to dust is taken into account in our risk assessment.

Note that this restriction option has similarities with R(M)O2 and similar impacts are expected in practice.

E.1.3. Other Union-wide risk management options than restriction

RMO6: Limiting the PAH concentration in carbon black

Carbon black is used in the manufacture of tyres as filler for reinforcement of the vulcanised material and it also has a function to colour the tyres. Carbon black percentages in the tyre typically will be between 24 and 28 % in truck and car tyres respectively (See Annex A). Industrially manufactured carbon black is produced by pyrolysis of hydrocarbons at high temperatures under controlled process conditions, which results in the formation of unavoidable trace levels of organic impurities, such as PAHs. According to the International Carbon Black Association most carbon black products will typically have extractable PAH levels (REACH-8 PAHs) not exceeding 0.1 % (1000 mg/kg). Around 80 % of the carbon black on the market is used in tyre production (personal communication tyre sector). The Dossier Submitter has no information on the typical REACH-8 PAHs concentration in carbon blackblack used by tyre manufacturers for the EU market. In tyre manufacture different grades of carbon black may be used. Since early 1990s, a development started in the EU to design car tyres that have lower rolling resistance to reduce energy use of cars. To achieve this, the tread of EU tyres currently are reinforced with silica, replacing part of the carbon black used (personal communication Professor Noordermeer, personal communication tyre sector). In the tyre tread, carbon black percentages therefore are typically reduced to between 2-5 % weight to weight (personal communication tyre sector). The Dossier Submitter has no information on the contribution of the tread to the gross tyre weight. Assuming between 2 % (minimum level in the tread) and 28 % (maximum reported level in whole car tyre) of the tyre weight is carbon black with a maximum content of 1000 mg/kg REACH-8 PAHs, the maximum REACH-8 PAHs levels in ELT as a consequence of PAH impurities in carbon black would be between 20 and 280 mg/kg. The absence of minimum and typical PAH concentrations in tyres prevents the Dossier Submitter from estimating a PAH concentration range in ELT. It should be noted that silica-reinforced tyres contain about 1.5 times more extender oil than the carbon black-reinforced ones, which may also affect the PAHs concentration.

Based on the above analysis the Dossier Submitter cannot conclude on the question whether there would be an incentive to reduce the PAHs concentration in ELT material through restricting the level of PAHs in carbon black in tyre manufacture. No information is available on the typical concentration of carbon black products used by tyre manufacturers for the EU market. Based on the maximum amount of 1000 mg/kg REACH-8 PAHs in most carbon black products, the relative contribution of carbon black to the tyre and ELT content of REACH-8 PAHs may be significant or even form the major part in tyres manufactured after 2010. Technically, changing from a higher PAH contaminated carbon black to lower contaminated forms seems to be feasible as the Dossier Submitter has no indications that PAH levels influence the function of the carbon black in the vulcanised material. Because information is lacking about the carbon black grade(s) used by tyre manufacturers for EU tyres, and the price differences between various grades of carbon black, the Dossier Submitter does not have a basis to assess the economic feasibility of a shift between the grade of carbon black used by tyre manufacturers and the price effect on consumer prices of tyres.

A legal limitation of the PAH content in carbon black used in EU tyres if implemented would assert effect on the ELT market with a delay that is as a minimum equal to the average service life of car tyres, and likely larger as carbon black producers and tyre manufacturers may need time to adapt. In the EU truck tyres are re-treaded several times during service life, which has the effect that truck tyres on average have a much longer overall service life because of re-use of the core of the tyre. This re-use practice would have the result that a restriction on PAHs in carbon black used in tyres would have a much larger delayed effect on truck tyre derived ELT granules.

Based on the above the Dossier Submitter considers a legal measure limiting the PAH concentrations in carbon black used in tyre manufacture and tyres placed on the EU market not an appropriate EU-wide measure to address the risks of granules used in synthetic turf pitches, especially as it takes too much time to become effective.

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

As indicated in Annex A.1. extender oils are used in the manufacture of tyres as plasticiser. The typical concentration of extender oils in car tyres is 7 % and in truck tyres 1.6 %. The restriction on PAHs in extender oils used in manufacture of tyres that entered into force in January 2010 restricts BaP at a level below 1 mg/kg and REACH-8 PAHs at a level of 10 mg/kg in the oils. The Dossier Submitter notes that overall PAH concentrations in extender oil used in tyre manufacture must have been significantly reduced by industry to be able to meet the limit values. The Dossier Submitter has no information on current PAH levels in extender oils used in tyre manufacture and on the technical and economic feasibility of any further reduction of PAH levels in extender oils used for manufacture of EU tyres.

Assuming EU manufactured and imported tyres are compliant with the extender oil restriction (supported by Depaolini et al, 2017), the maximum contribution of extender oils to the total PAH concentration that is currently found in scrap tyres and ELT-derived granules can be estimated. If PAH concentrations were at the maximum allowed level in the oils, the maximum contribution of extender oils to the REACH-8 PAHs content would be 0.7 mg/kg and 0.016 mg/kg for car and truck tyres respectively. The REACH-8 PAHs concentration in ELT infill samples available to the Dossier Submitter ranged between 2.9 and 21 mg/kg with a geometric mean of 10 mg/kg. Hence, extender oils may currently contribute between 0.08 % and 24 % to the total concentration of REACH-8 PAHs in ELT-derived material. Therefore, we conclude any further reduction of the limit value for PAHs in extender oils used in tyre manufacture would probably have a limited effect on the PAH concentrations in future ELT-derived materials. Furthermore, as for measures on carbon black, such legal measure invoked upon the tyre manufacturers and importers would be relatively slow working. Any effect of such a restriction would be slow as scrap tyres meeting such requirements would become granules not before five to seven years from now. Therefore, the Dossier Submitter considered further reduction of the PAH limit value in extender oils not an appropriate EU-wide risk management option to address the risk of granules used in synthetic turf pitches.

RMO8: Classification and labelling

The CLP Regulation requires assignment of hazard categories to substances, based on available information, and subsequent labelling provisions to indicate the intrinsic hazard of the substance to the downstream users and consumers. These requirements already apply to granules and mulches at their placing on the market as these products are considered mixtures. The concentrations of the PAHs in general would however be too low to result in human health hazard classification of these products based on the existing specific concentration limits applicable for classification of mixtures. Furthermore, the requirements of the CLP Regulation do not in themselves restrict the placing on the market of mixtures containing these substances. As a risk management measure for PAHs therefore classification, labelling and packaging rules under CLP are considered not effective.

The Dossier Submitter considered the option of lowering the existing specific concentration limits for the REACH-8 PAHs through amendment of the harmonised classification in Annex VI of the CLP Regulation. This option was however discarded as the current CLP guidance on classification of Category 1B genotoxic carcinogens does not allow for setting specific concentration limits that are lower than 0.01 %. The guidance allows for setting specific concentration limits at 0.1 % (25 % tumour incidence (T25) in experimental animals exposed between 1 and 100 mg/kg body weight per day), at 0.01 % (T25 at doses of1 mg/kg body weight per day or below) and at 1 % (T25 at doses higher than 100 mg/kg body weight per day). Hence, currently this classification system does not foresee in setting lower specific concentration limits and therefore this RMO was not further considered a feasible option.

RMO9: Risk communication

Communication campaigns organised on a national or EU level could help to raise awareness by consumers and sporting federations, sports clubs and local communities that own the pitches. Advice could be given to athletes and other users of these facilities to adapt behaviour in order to minimise their exposure to the granules, e.g. to minimise oral intake of granules and shower after sporting to reduce dermal contact time with granules or dust. The effectiveness of risk management measures that act via voluntary behavioural adaptations by the general public is however considered to be limited.

E.2. Alternatives

E.2.2. Identification of potential alternative substances/materials and techniques fulfilling the function

To answer the question what potential alternatives are available to replace PAH containing infill material and mulch, starts with the actual scope of the restriction proposal. *For the scope of this Annex XV dossier we define an alternative as follows:*

Alternative to the placing on the market and use of granules as performance infill material in synthetic turf pitches or use in loose form of granules or mulches on playgrounds and in sports applications, containing PAHs above the limit value of 17 mg/kg for REACH-8 PAHs.

The alternatives assessment is performed with a broad focus taking as a main driver the functionalities delivered by the infill materials allowing the pitches and playgrounds to be used as intended.

Given the restriction text, *all options that comply with this limit value should be seen as alternatives*. During the workshop held at 24 November 2017, the use of the term 'alternative' was found somewhat confusing as also non-ELT infill materials with PAHs contents above the limit value are within the scope of the restriction. This was explained by the Dossier Submitter by referring to the goal of the Restriction proposal aiming to ascertain risks are controlled independent on the type of infill used. Similarly, ELT-derived granules with PAH concentrations below the limit value can be seen as alternative. One can thus not simply state that non-ELT infill options are alternatives and ELT derived infill is not and in that sense, it may be clearer to talk about various types of infill and various types of pitches instead of 'alternatives'. In this section the terms alternatives and various types of infill/pitches will both be used.

The analysis of alternatives focusses on functionality of performance infill granules. Although mulches and granules applied on playgrounds and sports applications (other than infill) may have other alternatives (like sand, bark/wood scrap and in-situ rubber floors or tiles), these are not further considered here as these uses seem to have a limited market volume in only a few EU Member States which is minor compared to the use of granules as performance infill.

E.2.2.1. Various types of infill and various types of pitches

For this restriction dossier, we distinguish three categories of alternatives.

1. The first group covers the various performance infill options that can be used on synthetic turf pitches with PAHs concentrations below the proposed limit value. This group consists of two sub-groups: infill made of synthetic materials and infill made of natural materials. Furthermore, we can distinguish infill produced from virgin and infill produced from recycled materials within this group.

2. The second group of alternatives includes various types of sport pitches. Natural grass pitches or other forms of synthetic pitches are thus assessed as potential alternatives to synthetic turf pitches requiring performance infill granules in a general sense.

3. As the restriction proposal does not propose a full ban on infill material containing PAHs, but rather proposes a limit value for REACH-8 PAHs in infill material, technologies to reduce the PAHs content in the infill material could also serve as 'technical' measures cq. 'alternatives'. The result of these measures (infill material with PAHs concentration below the limit value) in fact is included in the group 1 alternatives already, however, for the sake of transparency this group is presented as a separate group here as well, as it may require additional effort from the sector to achieve this.

Group 1. Various types of performance infill with PAHs concentrations below the limit value;

- Synthetic material
  - ELT-derived granules
  - Other recycled rubber materials
  - EPDM (Ethylene-Propylene-Diene rubbers)
  - TPE (Thermo Plastic Elastomer) or thermoplastic rubbers
  - PE (polyethylene)

    - Nike grind®
- Natural materials:
    - Cork
    - A mixture of natural fibres (e.g. coconut, vegetable fibres) and cork

Note that also combinations of various types of infill can be used in practice. For example, infill made of natural fibres may be mixed with synthetic infill to improve the technical performance.

Group 2: Alternative type of sport pitches

- Natural grass pitch
- Artificial turf pitch without the use of infill
- Hybrid pitch; artificial turf pitch filled with grass seed

Group 3: Technical measures to reduce PAHs content in crumb rubber infill material

- Mechanical measures to separate rubber waste with PAHs content above the limit value from rubber waste with PAHs content below the limit value before recycling and production of the rubber granules
- Chemical measures to reduce PAHs content in recycled rubber
- The use of low PAH ingredients in production of tyres (and other rubber products)

Table E 1: Brief explanation per alternative

Alternative	Explanation
Group 1. Various types of performance infill with PAHs concentrations below the limit value;	
ELT-derived infill (ambient, cryogenic and coated)	Majority of the infill granules currently on the EU market are produced from scrap tyres. ELT-derived granules and mulches in most cases are only milled and ground to reach the target particle size and placed on the market as such. The majority of ELT derived infill is produced at ambient temperature, however, it can also be produced at low temperatures (cryogenic process using liquid nitrogen). One actor claims that the cryogenic process amenable to lower PAH contents in the infill material, however, no further information is available to verify this claim. After granulation of ELT, granules can be coated with virgin polyurethane (PU) or latex. Coated ELT can be produced in various colours. Coated ELT is used in Europe, e.g. in Italy. Such coated granules and mulches are considered in the same way as untreated ELT-derived granules and mulches. There is extensive experience with use of ELT infill e.g. on sport pitches and this type of infill is most extensively researched. When stating ELT-derived granules in this dossier, we mean ELT granules derived from the ambient production process (unless otherwise stated).
Other recycled rubber materials	There are cases known where infill was made of other recycled rubber materials. Given the share of ELT versus other rubber products on the market, this may only be a minor part of potential produced infill. This material may potentially have high content of PAHs, however, only anecdotal information is available confirming this statement. E.g. as explained in the Baseline section, ECHA (2017) tested two samples that contained around 3 000 mg/kg of the REACH-8 PAH. Infill produced from other waste rubber materials may be mixed with ELT-derived rubber.
EPDM	EPDM is a terpolymer of ethylene propylene and a diene. It is a vulcanized rubber, meaning that it cannot be easily recycled. It is e.g. used in in automotive applications (weather strip profiles, coolant/brake hoses, seals) and in building and construction. The majority of EPDM infill on the market is expected to be virgin material, however, it may also be produced from waste materials. There are said to be quality differences between EPDM infill from various producers and some of the EPDM infill on the market may in fact

Alternative	Explanation
	contain other materials than EPDM. EPDM is one of the promising alternative infill materials on the market (24 November 2017 workshop).
TPE	TPE stands for thermoplastic elastomer, which is a general term for a large family of polymers that are usually not vulcanized during manufacturing, but instead form physical crosslinks when cooled. The material may be melted and can thus be recycled more easily. TPE infill expected to be produced from virgin material. Solid and hollow TPE infills are produced. There are said to be quality differences between TPE infill from various producers. These relate to the polymers used, impurities and the additives in the formulation such as fillers and stabilisers. TPE is one of the promising alternative infill materials on the market (24 November 2017 workshop). Also thermoplastic olefins (TPO), thermoplastic vulcanisates (TPV) are assumed to be covered within this group.
PE	PE stands for polyethylene and is a thermoplastic material that can be recycled. PE is also often the material used to produce the artificial turf (grass piles). PE infill is relatively rigid (inflexible) compared to e.g. EPDM and TPE[75]. It is said not to be used much as infill material currently (24 November 2017 workshop).
Nike grind®	Nike grind® is produced from recycled athletic shoes and Nike manufacturing scrap which are ground up and turned into infill crumb. It is not clear whether, and how much this infill material is used in the EU[76].
Group 2: Alternative type of sport pitches	
Cork	Cork is a natural product, which is derived from the bark of the cork oak. Infill produced from cork may be new material from the cork oak or recycled material from other uses of cork. Looking at natural infill options, cork is most often mentioned. Cork is also used in combination with a synthetic infill to improve the technical characteristics of the pitch.
Mixture of natural fibres materials	In addition to cork, also a mixture of various natural sources are said to be available for infill. Besides cork, coconut fibres can be used in these mixed infills.
Natural grass	Originally, natural grass pitches are used as sport pitches, as they provide e.g. more comfort and less risk of injuries compared to sand, dirt, or stone. Natural grass has different characteristics compared with artificial turf e.g. in terms of intensity of play and costs.
Artificial turf without infill	Artificial turf without infill is currently developed by some market actors. Ideas vary whether this type of turf is capable of meeting the technical performance requirements in the future. Recently, artificial turf without infill was said to be FIFA quality approved, and is currently used in test pitches in the Netherlands (Oldenkotte 2018, personal communication synthetic turf sector, [77]). Various actors in the field of synthetic turf expect an increase in use of this type of pitches in the future (personal communication synthetic turf sector).
Hybrid pitch	A hybrid pitch is based on a combination of artificial turf and natural grass. This system is also called reinforced grass. It is not clear how often this system is used in Europe. Some actors in the field state the use may become more important in case of a restriction with a low limit value (personal communication synthetic turf sector).
Group 3: Technical measures to reduce PAHs content in crumb rubber infill material	
Mechanical separation to reduce PAH content	The idea of mechanical separation is that recycling streams with PAH contents above the limit value are separated from streams with PAH contents below the limit value to make sure that the infill produced complies with the restriction. Precondition is that separation can be done visually e.g. not requiring actual testing on PAHs as that would be costly and require too much

[75] http://www.sportbelijning.nl/voetbal%20kunstgras%20instrooi%20infill.html
[76] http://www.nikegrind.com/
[77] http://www.fieldmanager.nl/nieuws.asp?id=17-19672

Alternative	Explanation
	time. Selection can for example be performed based on type of material (ELT/other rubber products), age and production origin of tyres. This selection cannot be made automated and thus needs to be made manually. Views vary among stakeholders vary whether this is possible in practice (24 November 2017 workshop). There are ELT recycling companies that in fact already have a manual selection step included in their recycling process, however, for others say this is impossible in practice.
Chemical measurements to reduce PAH content	The idea of this measure is that – in theory – measures could be taken to extract PAHs from the recycled material that is intended to be used as infill. According to the actors at the 24 November 2017 workshop, such a measure would not be possible in practice.
PAH reduction in tyre production	In preparation of the 2010 extender oil restriction, tyre manufacturers took an effort to redesign tyre composition to reduce the PAH content in tyres. According to professor Noordermeer (personal communication) this has been a complex process that took up to decades to fully replace high PAH containing oil in the sector. If technically/chemically possible, a further reduction in PAH content would presumably again require extensive effort from the tyre sector to redesign their formulations and would probably take substantial time to succeed (personal communication Professor Noordermeer). This measure may therefore not be very realistic on a foreseeable timeframe.

E 2.2.2 Selection of most promising alternatives

From the above, a selection of alternatives has been made for further investigation. Four alternatives will be reviewed in further detail below: natural grass, EPDM infill, TPE infill (solid) and cork infill. The following two criteria where used for the selection:

- Signals from the market on the use of other infill options and other pitches
- Variety in options included in the analysis, c.q. both natural and synthetic infill options as both natural and synthetic turf systems.

Besides the above 4 systems/infill types, also some attention will be paid to artificial turf without infill as these are expected to become important on the longer term (>5 years).

E.2.3. Introduction into the selected alternatives

E.2.3.1 Natural grass system

Originally, natural grass pitches are used as sport pitches, as they provide more comfort and less risk of injuries, compared to sand, dirt, or stone. Just like for artificial turf, installation of a natural grass pitch requires preparation of the topsoil to make it suitable for the natural grass system. What is required to prepare the top soil largely depends on the specific local conditions. A natural grass pitch can be installed using seed or sod. Installation of a pitch using seed takes more time compared to the use of sod, where the growing process already took place elsewhere. For sod, it takes about a month to be fully functional after installation, in case of seed considerably longer (Simon 2010). Required maintenance of natural grass systems e.g. depends on the type of grass used and the local (climate) conditions. Maintenance of natural grass systems involves regular mowing, fertilizing, irrigation, aeration, (re)painting of linings, and potential spraying with herbicides or pesticides (Simon 2010). In personal communication among actors in the field it was expressed that there is a wide variety in quality differences between natural grass pitches across Europe. According to actors in the field the lifetime of a natural grass system is approximately 10 years (personal communication synthetic turf sector). After that, it is assumed that the system needs renovation.

E.2.3.2. Artificial turf with non-ELT infill

Synthetic turf systems using other infill materials than ELT derived granules generally are of different design. Although the same system as used in case of ELT can be applied in theory, this is expected not to happen in practice for economic reasons. Non-ELT systems are expected to use shorter piles (30-40 mm instead of 60 mm) and hence lower quantities of infill are required. This is done to compensate the higher price of the infill material used. To obtain proper shock absorption in the system, a shockpad is used below the artificial grass system (personal communication synthetic turf sector).

E.2.3.3. EPDM

EPDM is a terpolymer of ethylene propylene and a diene. EPDM is a synthetic rubber or specialty elastomer: a polymer with elastic or rubber-like characteristics. EPDM has been available for over 40 years, and is mainly used in automotive applications (weather strip profiles, coolant/brake hoses, seals), in building and construction, in cable and wire as insulation and jacketing, and in a wide variety of moulded articles. Its properties can vary widely, depending on the operating conditions during polymerization and the catalyst system, peroxide or sulphur, which is used. (Noordermeer, 2002; Sportbelijning[78]).

The properties of EPDM depend on a number of parameters, including the fractions of ethylene-propylene copolymers, the average molecular weight, and molecular weight distribution. Various dienes have been tried as third monomer, but only two are currently used commercially in significant quantities, namely 5-ethylidene-2-norbornene (ENB) and dicyclopentadiene (DCPD). The resulting polymers are poly(ethylene-co-propylene-co-ENB) (25038-36-2) and poly(ethylene-co-propylene-co-DCPD) (25034-71-3).

E.2.3.4. TPE or thermoplastic rubbers

TPE stands for thermoplastic elastomer, which is a general term for a large family of polymers that are not vulcanized during manufacturing, but instead form physical crosslinks when cooled. These crosslinks are lost when TPE is heated, which means TPE can be melted and recycled[79]. During the workshop held on 24 November 2017 for the purpose of this dossier preparation, it was mentioned that the term TPE may be too broad and that it may be better to use the term thermoplastic rubbers, as this better covers the materials included here. However, as in the available (grey) literature the term TPE is widely used, it is not possible to replace the term fully in the context of this dossier.

TPE is combination of rubber and plastic. The chemical composition of TPE granules in general consists of copolymers of ethylene, butadiene, and styrene or polyurethane elastomers utilizing isocyanides, depending on the formula (VHB, 2015 [80]). A typical TPE is SEBS (Styrene Ethylene Butadiene Styrene) where the styrene segments form crystalline

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[78] http://www.sportbelijning.nl/voetbal%20kunstgras%20instrooi%20infill.html

[79] http://www.sportbelijning.nl/voetbal%20kunstgras%20instrooi%20infill.html

[80] https://winchesterskillingsproject.files.wordpress.com/2015/04/june-1-2015-memo-from-vhb-to-bos.pdf

domains. The chain structure of SEBS is saturated and it has been reported to yield good weather resistance (Nilsson et al., 2008[81]). SEBS soft gel granules are also available on the market. These are prepared by mixing high proportion of paraffinic oil in SEBS[82].

According to a manufacturer of TPE goods[83] there are six generic classes of thermoplastic polymers:

- Styrenic block copolymers (TPE-s or TPS compounds based on SBS, SEBS);
- Polyolefin blends (TPE-O or TPO);
- Elastomeric alloys (TPE-V or TPV);
- Thermoplastic polyurethanes (TPE-U or TPU);
- Thermoplastic copolyester (TPE-E or TPC);
- Thermoplastic polyamides (TPE-A or TPA).

TPE is used in the automotive, medical, construction, electrical, appliance, packaging and industrial markets and new uses for TPEs are being developed all the time (Source: Hexpol TPE website).

TPE used on artificial turf pitches is usually virgin material and is available in various shapes, compositions, and colours, however, in theory it could also be produced from recycled material. Like for EPDM, also for TPE it is noted that various qualities of TPE infill are available on the market with different chemical composition (personal communication synthetic turf sector; 24 November 2017 workshop).

E.2.3.5. Cork

Cork is a natural product, which is derived from the bark of the cork oak (Quercus suber L.). Cork oaks grow in the Mediterranean, in particular in Portugal and Spain, where they are cultivated in large plantations. Cork can first be harvested when the tree is about 25 years old and every nine years after that. The trees live approximately 200 years. Cork is mainly used in construction, for floors, and as wine stoppers. Cork infill can be made from virgin cork or from the waste of the wine stopper production, or old cork floors or stoppers [84].

E 2.4. General issues of the selected alternatives

E 2.4.1. Availability

For a potential increase in market of alternatives due to the restriction, it is important to have an idea of the availability of various alternatives. There are no signals that the availability of natural grass seed or sod is an issue in Europe. The assumption is that this market has the capacity to adapt to an increase in demand in Europe.

As indicated in the Baseline Annex D, around 6 500 and 7 500 tonnes EPDM and TPE infill are used in the EU in 2018 and 40 000 and 45 000 tonnes in 2028 respectively. EPDM and TPE infill may be produced in the EU or imported from other parts of the world. Currently

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[81] https://sportengemeenten.nl/wp-content/uploads/2016/10/Danish_investigations_of_artificial_turf-2008.pdf
[82] https://www.ijirset.com/upload/april/46_Thermoplastic.pdf
[83] See: http://www.hexpoltpe.com/en/index.htm

[84] http://www.sportbelijning.nl/voetbal%20kunstgras%20instrooi%20infill.html

within the EU, one Polish company formulates infill material from recycled EPDM and virgin EPDM infill material (2016, response to ECHA). Other European companies who formulate infill material from EPDM are from the Netherlands, Poland (three other companies), Germany, to name just a few. In total, there are about 16 main formulators of EPDM infill material in the EU, with German and Polish formulators playing a key role in the market. With respect to TPE, some of the key European formulators of TPE infill material are in UK, Italy (two companies)[85], Germany, Italy and Poland (two companies). During the 24 November 2017 workshop it was said that the alternative infill market is growing and that further increasing production capacity takes time. It was said that at current capacity, full replacement of ELT infill by alternatives is not yet possible, but within a few years this could be feasible.

Cork has been farmed for hundreds of years predominantly in Portugal and Spain for use as wine bottle stoppers. The cork industry in this region has been threatened due to competition in the market as alternatives such as plastic stoppers or screw tops have become popular. The conservation of the cork landscape is also important for conservation of biodiversity (FAO 2002[86]; FIFA 2017; WWF 2006). A tree that is 80 years old will produce 40-60kgs of natural cork. Each year, more than 100 000 tonnes of cork is produced in Portugal, from about 660 000 ha cork landscapes. Portugal produces more than 50 % of the world cork market. Other European cork producers are Spain (440 000 ha), France (110 000 ha) and Italy (90 000 ha) (FAO 2002[86]; Saomarcosdaserra[87]).

On a newly installed pitch with cork infill, 9.88 ton cork per pitch is used. For annual maintenance, 0.09 tonnes cork is used per pitch. Knowing that cork infill can be produced of waste of cork production (personal communication), and that the demand for cork decreases due to market completion of alternatives for cork, it seems that availability of cork is not a problem and this additional application of cork may be welcome to the cork production sector.

Table E 2: Overview of availability of the selected alternatives

Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Availability	Available	Available within some years	Available within some years	Available	Available

E 2.4.2. Recycled input material vs recyclability

EPDM used as infill material on artificial turf pitches can either be recycled or virgin material specifically made for this purpose. Recycled EPDM is usually derived from shredded weather strip profiles of car windows and doors and is often black. Virgin EPDM can have any colour[88]. In communication with Professor Noordermeer and Dr. Dierkes (personal communication) some doubts where expressed whether recycled EPDM infill will indeed be

[85] Acquired by Celanese (USA) in 2016.

[86] http://www.fao.org/docrep/005/y4351e/y4351e00.htm#Contents

[87] http://www.saomarcosdaserra.com/cork.php

[88] http://www.sportbelijning.nl/voetbal%20kunstgras%20instrooi%20infill.html

available on the market. An artificial grass producing company also mentioned that recycled EPDM is scarce on the Dutch market (personal communication). EPDM in 2010 is said to cover around 9 % of the total synthetic rubber market (Noordermeer, 2002). For comparison, Noordermeer estimates that tyres cover around 80 % of the rubber market (personal communication). It may thus be more challenging to have a feasible collection and recycling system in place for EPDM compared to tyres due to lower quantities and more diverse use of the material. Hence, the majority of EPDM infill on the EU market is expected to be virgin material. A Polish company (2016 response to ECHA) provided information that infill materials can also be formulated using ELT, EPDM and TPE rubber from mats, belts, sleeves, spouts and gaskets. They use also recycled tyres to formulate the infill material used for synthetic turfs. According to the company they sell infill materials mainly to Poland, Lithuania, Estonia and Latvia. Some EPDM and TPE-derived rubber granules are sold as refill material to Finland[89].

EPDM is a vulcanized material and thereby is difficult to recycle as it cannot be melted. EPDM infill however may be reused after service life. TPE is e thermoplastic material that can be melted and that is recyclable after service life.

As said, cork infill can be produced from both virgin as recycled cork material. What is more regular in practice is not known. Cork infill cannot be reused as it pulverizes during use.

Table E 3: Overview of the recycled/recyclability of the selected alternatives

Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Recycled input material	Recycles	Virgin, small part may be recycled	Virgin	Virgin/recycled	Not relevant
Recyclable	Potential reuse	Potential reuse	Recyclable	Not recyclable	Not relevant

E 2.5. Chemicals within the material

E 2.5.1. Hazardous substances in natural grass pitches

Grass is a plant that does not produce toxic components and thus there are no toxic substances expected in the natural grass itself.

E.2.5.2. Hazardous substances in EPDM

E.2.5.2.1. Composition of EPDM

Granules based on EPDM usually contain about 20 to 25 weight% EPDM rubber. The rest consists of chalk, processing oil, UV-stabilisers, anti-oxidants (e.g. zinc), pigments, and vulcanisation materials (sulphur and zinc-oxide or peroxide/starter) (Terra Sports Technology leaflet on EPDM and TPS[90]). Commonly used paraffinic extender oils contain

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[89] NH-Koneet Oy, personal communication (2016)

[90] http://docplayer.net/storage/71/64998494/1517830365/C1SbB-HG4jhtIisBJmelgQ/64998494.pdf

<0.1 wt% total PAHs (Noordermeer, 2002). Depending on the actual PAHs in the oil and the amount of oils used, this could lead to a concern.

EPDM can be vulcanized by means of peroxides or sulphur. In both cases, zinc oxide may be a constituent, but in greater volume in the sulphur vulcanisation (Nilsson et al., 2008). For the sulphur vulcanization, an accelerator has to be used that does not form carcinogenic secondary N-nitrosamines. The catalysts used in the polymerization usually include vanadium, aluminium, and chlorine. Catalyst residues in finished products are kept to a few parts per million.

Carbon black is usually used as filler. The semi-reinforcing types, such as FEF (fast extrusion furnace) and SRF (semi-reinforcing furnace), give the best performance. To lower the cost and improve the processability of light coloured compounds, or to reduce the cost of black compounds, calcined clay or fine-particle-size calcium carbonates are used. The most widely used plasticizers are paraffinic oils, sometimes blended with naphthenic oils. (Noordermeer 2002). Furthermore, professor Noordermeer states that phthalates will not be used in production of EPDM as these softeners are not compatible with the EPDM material. This is interesting as phthalates are in fact detected in EPDM samples obtained from artificial turf pitch (see Table E2-1, Appendix E2). EPDM was recorded as recycled EPDM. The maximum quantity found is <0.05 % of DEHP in a sample, which is not a functional quantity for phthalates. This may therefore very well be contamination.

When EPDM infill is produced from virgin feedstock, producers are expected not to use carbon black as filler as other colours are preferred for the higher price paid (personal communication synthetic turf sector). Prof. Noordermeer expressed his doubt whether all EPDM performance infill available on the market is indeed EPDM. It may also be EPDM mixed with other polymers/materials (personal communication Professor Noordermeer). An artificial turf producer explained that there is quite some quality difference between EPDM granules from various suppliers and that was also the signal given during the 24 November 2017 workshop. High quantities of chalk filler may be used in the production of EPDM infill to reduce cost price, but also reducing the quality of the infill (personal communication synthetic turf sector). Differences in quality are also mentioned by Sportbelijning[91]. Because of this, there only is a general impression of the likely composition of EPDM infill material. What is actually included in the material may vary among EPDM infill provided by various suppliers.

E.2.5.2.2. Safety Data Sheets

EPDM itself is not classified as a hazardous material in the EU. It is not considered carcinogenic according to OSHA Hazard Communications Standard and IARC Monographs. Most Safety Data Sheets found on the internet of EPDM rubber or EPDM infill report no hazard or hazardous components. Some SDS's that report content information are summarized below. Note that the Dossier Submitter does not know whether the EPDM in these SDS's is indeed also used as infill material. Federal Mogul reports a cancer risk caused by carbon black, which is present in EPDM rubber (MSDS Ethylene Propylene Diene Monomer (EPDM) Rubber 'Final', Federal Mogul, 29-6-2006). An Australian MSDS of Vulcanised Synthetic rubber (both SBR/ELT and EPDM) by Gulf reports as hazardous

[91] http://www.sportbelijning.nl/voetbal%20kunstgras%20instrooi%20infill.html

ingredients hydroxylamine (<0.01 %) and non-hazardous ingredients carbon black (35.5 %) and zinc oxide (3.5 %). This MSDS warns to prevent mixing the rubber with nitrates, nitrites, nitrogen oxides or other nitrosamines, to prevent the formation of nitrosamines (MSDS Vulcanised Synthetic Rubber (EPDM, SBR), Gulf engineered rubber and plastics, 22-2-2016). A Product Data Sheet of black EPDM infill reports content values of acetone extract (22-30 %), ash content (2-10%), carbon black content (30-40 %), and rubber hydrocarbon (30-45 %) (Product Data Sheet .5-1.25 mm Black EPDM (8 -18 MESH), Re-Tek products).

E.2.5.2.3. Measurements on EPDM infill material

Actual measurements of the composition/migration of EPDM artificial turf infill are scarce. However, several studies where found that provide information on hazardous substances found in EPDM infill. Table E2-1 in Appendix E2 provides an overview of the hazardous substances found in EPDM in the available studies compared to TPE and ELT.

E.2.5.2.4. Summary of the available studies

The RIVM risk assessment in 2017 included one sample that was indicated to be recycled EPDM. As it was a sample taken from an artificial turf pitch, it may well have contained EPDM and other types of infill that have been used for refilling the pitch. Another sample was claimed to be 'cleaned ELT' but showed very similar results compared to the recycled EPDM sample (and different compared to the other ELT samples analysed in this study). It was assumed that this second sample also contained EPDM, however, there is uncertainty whether this in fact is the case. These samples contained lower concentrations of most substances compared to ELT derived rubber, with the exception of phthalates, in particular DEHP (RIVM 2017, unpublished data).

A Danish study investigated content of chemical substances of 16 different artificial granules and pitches, including ELT derived rubber granules, EPDM rubber granules and TPE granules. The study did not analyse PAHs. (Nilsson et al., 2008).

A Norwegian study determined the chemical content of one sample of recycled EPDM infill granules, amongst others. Compared to three ELT derived rubber samples, the concentrations of most substances were lower. However, remarkably high levels of chromium (5 200 mg/kg) and zinc (9 500 mg/kg) were found, the latter falling within the zinc concentration range reported for ELT (i.e. between 118 and 20 000 mg/kg).

An investigation by TURI in Massachusetts reviewed information available on chemicals in EPDM infill. In addition to MSDS's (no substance data) and the aforementioned Norwegian study, this overview includes test results of the manufacturers themselves by Manufacturer Target Technologies International, Inc. (TTII), FieldTurf and Gezofill (TURI, 2017)

A recent report by the Norwegian Environmental Agency (Bauer et al., 2017) investigated 'environmentally friendly substitute products' for rubber granules as infill for artificial turf pitches. In the appendix a list is provided of substances detected in ELT derived rubber granules, EPDM rubber granules and TPE granules.

A Korean study determined lead content and extraction from EPDM granules (Kim et al., 2012). A French study to the environmental impact of several granules, found relatively high emissions of volatile organic compounds from virgin EPDM granules. Values found where higher than values in ELT rubber granules (Moretto, 2007).

E.2.5.3. Hazardous substances in TPE

E.2.5.3.1. Composition of TPE

As said, TPE is a generic term for extruded plastic pellets made from a rubber and plastic polymer with additives.

TPE is distinct from both ELT and EPDM rubber in that it is not vulcanised. Emission of vulcanisation chemicals is thus not expected[92]. This is the main reason that TPE leaches less zinc compared to most ELT and EPDM rubber, as zinc oxide is used in sulphur vulcanization (Terra XPS. Differences between EPDM based and TPE/TPV based infill systems for artificial turf).

TPE as such cannot be searched in ECHA's classification and labelling database. CAS numbers are not available for specific types of TPE that are used as infill material. A non-exhaustive search for TPE that could potentially be used for infill purposes yielded CAS number 66070-58-4. According one manufacturer the main application of this substances is: adhesives, sealants and coatings, automotive, sealing strip for buildings, toys, automobile parts, medical equipment, high-grade elastomer, high foaming materials, wires and cables, etc.[93] There is no harmonized classification for this substance.

E.2.5.3.2. Safety Data Sheets

So.F.teR reports for three types of TPE infill the following in the respective MSDS. Holo SP and Terra XPS granules are indicated not to have adverse physicochemical, human health and environmental effects. Calcium carbonate (≥50 - <60 %) is identified as hazardous substance and toxicity data is only provided, i.e.: LD50 (oral) for rat of >5000 mg/kg; 96-h LC50 for fish of >10 000 mg/L; 48-h EC50 for daphnia of >1 000 mg/L; and 72-h EC50 for algae of > 200 mg/L[94].

Forgrin granules are indicated not to have adverse physicochemical, human health and environmental effects. Hazardous substances identified are calcium carbonate (≥40 - <50 %), barium sulphate (≥1- <3 %) and titanium dioxide (≥1- <3 %). For calcium carbonate the same data is provided as for Holo SP and Terra XPS granules; for barium sulphate: 48-h EC50 for daphnia of 32; for titanium dioxide: 96-h LC50 of >1000 mg/L[95].

E.2.5.3.3. Measurements on TPE infill material

Actual measurements of the composition/migration of TPE infill are scarce. However, some studies where found that provide information on hazardous substances found in TPE infill. Table E2-1 in Appendix E2 provides an overview of the hazardous substances found in TPE in the available studies compared to EPDM and ELT.

Summary of the available studies

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[92] http://fieldturfbenelux.com/sporten/infill/
[93] http://www.sinopecgroup.com/group/en/products/Finechem/Product/SpecialRubber.shtml
[94] http://www.tpeinfill.com/media/files/171_holo_sp_verde_088vph470_-_en_(1).pdf
[95] http://www.tpeinfill.com/media/files/175_forgrin_gt_beige_085bt4075_-_en_(4).pdf

The Norwegian Institute for Air Research (NILU) investigated three indoor artificial turf pitches containing either recently laid ELT derived rubber granules, ELT derived rubber granules laid one year ago, or TPE granules (Dye et al., 2006). Examination of airborne dust from TPE granules showed absence of benzothiazoles while up to 2185 pg/m^3 benzothiazoles was detected in airborne dust from ELT derived rubber. Measurements of air concentrations did detect benzothiazole above turf pitches with TPE. This was lower than what was reported for turf pitches with ELT derived rubber (up to 31.7 µg/m^3). The authors noted that the benzothiazole concentrations could be affected by the rubber mat beneath the artificial turf. The report also measured phthalates and reported total phthalate levels in airborne dust from TPE 1.15 times higher compared to ELT derived rubber granules. The concentrations of diethylphthalate (DEP), diisobutylphthalate (DiBP), and dibutylphthalate (DBP) in air exceeded 0.005 µg/m^3 in all three halls, with small differences between the TPE and ELT derived rubber containing pitches. The report showed that halls with ELT derived granules had the highest PAH and total VOC concentrations being respectively 3 and 4.4 times higher compared to the hall with TPE granules.

Moretto (2007) measured the emissions of 9 volatile organic compounds (VOCs) and aldehyde from three artificial turfs containing either ELT derived rubber granules, EPDM rubber granules or TPE granules. Indoor situation was assessed using controlled emission chambers in accordance with standard protocols for evaluating emissions from construction materials. Total VOCs amounted after 28 days was lowest for TPE granules, results for ELT granules where 1.14 times higher and for EPDM 4.17 times.

Nilsson et al. (2008) performed leaching and content analyses of 16 types of infills from Danish artificial turf pitches, including three TPE pitches. Content analysis was determined after extraction with dichloromethane and leaching to ultrapure water. Notable was the difference between the three TPE infills. The substances found where all found in only one sample and not in the other two available samples. Octabenzone and bumetrizole are not considered hazardous, drometrizol and 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol have been self-classified for chronic aquatic toxicity. The most relevant hazardous substances found were phthalates. The values found were comparable with the ELT and EPDM infills analysed in this study. Zinc was not determined in TPE, because it was not expected that TPE contains zinc. Due to the low levels of hazardous substances, no health risk was expected by the authors.

Celanese SO.F.TER SPA, the manufacturer of Terra and Holo SP-D TPE granules refers to a report of SGS-Intron bv (A858170/R20110485/Uho/ILa, September 2011) that determined for their TPE granules the leaching of anorganic substances and the content of organic substances listed in the Dutch Soil Quality Regulation. None of the analysed substances were detected. Celanese also submitted information in the call for evidence for this dossier providing information on the (absence of) substances in TPE infill.

E.2.5.4. Hazardous substances in cork

There are reports that cork can be associated with several fungal species, most commonly with the *Penicillium glabrum* complex and *Chrysonilia sitophila*. While not being a hazardous substance, the *Penicillium glabrum* complex can result in respiratory diseases amongst workers, e.g. suberosis (Viegas et al., 2015).

An overview of the substances found in EPDM and TPE compared to ELT is provided in Table E2-1 in Appendix E2.

E.2.6. Chemicals in maintenance

E.2.6.1. Chemicals used in maintenance of natural grass pitches

Maintenance required to keep natural grass pitches in good shape, such as fertilization and pest management, can be of concern for human health and/or the environment.

E.2.6.1.1. Fertilizers

Natural grass pitches require fertilization. The grass pitch maintenance guide by Football NSW, i.e. the governing body for association football (soccer) in the Australian state of New South Wales, indicates that intensively used pitches may require fertilizing throughout the year (2 to 10 applications) in order to achieve suitable surface quality (Football NSW, 2015[96]). The Dutch football association (KNVB) recommends 2 to 7 fertilizing applications per year depending on the composition and release speed of the applied fertilizer. The number of applications is lower for slow releasing mineral and/or organic fertilizers (2 to 4), compared to quick releasing mineral fertilizers (4 to 7) (KNVB, 5th edition; accessed 16 February 2018[97]). A recent RIVM investigation confirms that higher nitrate, phosphate concentrations are found in soils and higher calcium, potassium, magnesium concentration in surface waters around natural grass pitches than around artificial turf which may very well come from the use of fertilizer (RIVM 2018).

E.2.6.1.2. Pest control

Turf quality can be reduced by pests and disease attacks as well as germination of annual weeds. In general, regardless of the type of pest, good maintenance practices, such as ensuring optimal growth conditions for grass and prevention of overexploitation, will reduce pest infestations.

Commonly encountered weeds in grass pitches encompass unwanted grasses (e.g. *Poa annua*, *Echinochloa crusgalli*, *Polygonum aviculare*), broadleaf plantain (*Plantago major*), dandelion (*Taraxacum officinale*), white clover (*Trifolum repens*), daisy (*Bellis perennis*, creeping buttercup (*Ranunculus repens*), creeping speedwell (*Veronica filiformis*) and mosses (*Bryophyta*) (KNVB brochure[98]). Depending on the weed different mechanical measures can be taken, i.e. the turf can be mowed low, organic matter from the topsoil can be removed (detatched), soil can be aerated, acidity and moisture levels of the soil can be adjusted, and sand can be added to the topsoil layer. Plants that are difficult to remove by these actions, e.g. dandelion and broadleaf plantain can be removed by pulling (Football NSW, 2015). The latter action is manually conducted and is thus labour intensive. Next to these mechanical and physical measures, weeds, moss and algae can be treated with selective or broad spectrum herbicides and algaecides, either preventively (=pre-emerging) or curatively (post-emerging) during different periods of the year (Bayer, 2016). The Dutch football association KNVB notes in their manual that preventive usage of plant protection products is not allowed in the Netherlands though (KNVB brochure).The German football association DFB published in 2017 a guideline on integrated pest management with the aim

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[96] http://www.footballfacilities.com.au/wp-content/uploads/2015/11/Grass-Field-Maintenance.pdf
[97] https://www.knvb.nl/downloads/bestand/1480/onderhoud-grasvelden
[98] https://www.knvb.nl/downloads/bestand/1490/ziekten-plagen-en-ongewenste-gewassen-brochure

to reduce the use of pesticides[99]. It recommends focusing during planning, construction and maintenance of pitches on mechanical/physical measures that can be taken to prevent pest infestation, and notes that chemical measures to control diseases and/or weeds should only be used when all other possibilities have been exploited.

E.2.6.1.3. Disease control

Intensively managed grass pitches can become susceptible to turf diseases caused by invading parasitic fungi, e.g. Dollar spot (*Rutstroemia floccosum*), Red thread (*Laetisaria fuciformis*, *Limonomyces roseipellis*), and Rust (*Puccina* spp.), or indirectly by fungi affecting the root zone, e.g. Localised Dry Spot (LDS) (Bayer, 2016 and KNVB brochure). Susceptibility will depend on the grass cultivar used, but is generally reduced by optimized maintenance practice, e.g. regular mowing but not too short, well-balanced nutrient levels and optimal pH in the soil, detatching to remove organic material from the topsoil, and good water management to control humidity and surface wetness. These measures can also be taken when the turf becomes diseased. In addition, for some diseases, e.g. Red thread, applying an additional fertilizer application that increases nitrogen levels can help turfs to naturally grow out of the problem (Football NSW, 2015; KNVB brochure). Diseased turfs can also be treated with fungicides, curative and preventative, all year round depending on the product (Bayer, 2016).

Turfs can get severely damaged by pests of insects and animals. Especially, chafer grubs (Chafer beetle larvae), leatherjackets (Crane fly larvae) and bibionid larvae can cause severe damage to turfs (Bayer, 2016; KNVB brochure). These insect larvae feed on organic matter and plant roots damaging the root system. Grass plants can display draught stress, but if ample water is available the grass will appear healthy but won’t be anchored to the soil. If heavily infested, entire sections of the turf can become loose, which can be worsened by predating birds and animals. Prevention includes removal of organic matter (dethatching) and maintaining good drainage. Treatment can consist of biological control by introduction of predatory nematodes that infect larvae with bacteria (Bayer, 2016; KNVB brochure), or spraying with *Bacillus thuringiensis* against leaf eating caterpillars[100]. Treatment with insecticides is also commonly applied. Even though the manual of the Dutch football association noted that once the damage is visible, i.e. loose turf, the damage has already occurred and the larvae do not feed that much more or at all (pupae), making treatment less effective (KNVB brochure). According to Bayer, only Merit turf, a granular insecticide, is allowed to treat these insect pests (Bayer, 2016). Other animals that can damage turf surface are rabbits and moles. Fencing can be successful to control rabbits, but is generally not sufficient for moles even when extending up to 1.2 meter below the surface (KNVB brochure). Rabbits and moles can be treated with aluminium phosphide (Bayer, 2016), but are generally deterred and/or caught.

E.2.6.1.4. Plant protection products

As laid down in Regulation (EC) No 1107/2009, approval of active substances to be used for plant protection products is done at EU level by the European Commission in a process that involves all Member States and the European Food Safety Authority (EFSA). The public and

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[99] http://www.ninobility.de/dfb/Pflanzenschutz/files/assets/common/downloads/publication.pdf
[100] https://agro.bayer.nl/Producten/Producten%20A-Z/XenTari/Aanbevelingen.aspx

other interested parties can also provide comments for consideration during the public consultation phase of the process. Once an active substance is approved, a national application for registration of a plant protection product containing the active substances can be submitted. Plant protection products have to be authorised on national level[101] and differences between Member States thus may occur when it comes to the use of plant protection products. Currently there are 83 plant protection products authorized on the Dutch market for use on sports pitches, of which 53 herbicides, 18 insecticides, 6 fungicides, 4 plant growth regulator, 1 acaricide (=ticks and mites), and 1 talpicide (= moles), and 1 additional insecticide for playgrounds[102]. This corresponds to 31 active ingredients that have been listed in the Table E 4 below. The associated hazard classifications have been added to this table (ECHA C&L database; accessed 19 February 2018). The table is not necessarily representative for the EU situation, however, it gives a first indication what chemicals may be used in pest control.

In addition to application of the regulated plant protection products, there appears to be an increasing interest in natural substances to control weeds, e.g. acetic acid (vinegar)[103]. This is often indicated as 'eco-friendly', but would need market authorization when applied as plant protection product. Furthermore, the efficacy of such treatments with regard to intensively played natural grass pitches is not clear.

The European Commission advocates a sustainable use of pesticides in the EU that will reduce the risks and impacts of pesticide use on human health and the environment. This can be achieved by applying an Integrated Pest Management (IPM) strategy and use of alternative approaches or techniques, such as non-chemical alternatives to pesticides (Directive 2009/128/EC, DG(SANTE) 2017-6291[104]). In Germany, it is prohibited to use plant protection products in areas designated for the public, such as public parks, sports grounds, school grounds and in proximity to health care facilities, except under a specific permit (DG(SANTE) 2017-6291). In the Netherlands, the Ministry of Economic Affairs, Agriculture and Innovation (currently the Ministry of Economic Affairs and Climate Policy) announced in 2013 its intention to forbid the use of chemical plant protection products on sports pitches by 2017. In response to several partners, including two ministries and seven sports organisations, municipality and industry associations, signed a Green Deal aiming to prevent usage of pesticides on sports pitches by 2020 (BSNC, 2014). The current status is that the sports sector has been granted an exception allowing the use of plant protection products on unpaved and semi-paved sports grounds such as grass, artificial grass and gravel until 2020. In the meanwhile, alternatives to chemical amenities in turfgrass systems are being investigated (Regensburg and Ospina Nieëto, 2017). In this report, physical, cultural and biological measures were compared, and it was advised to embed such measures in a sustainable turfgrass management plan to overcome unfavourable conditions that induce pests and diseases, in order to reduce the use of plant protection products.

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[101] https://english.ctgb.nl/plant-protection/active-substance-approval/active-substance-approval

[102] https://pesticidesdatabase.ctgb.nl/

[103] http://www.independent.co.uk/news/uk/home-news/bristol-smells-of-vinegar-as-council-uses-condiment-as-bizarre-weed-killer-a6999776.html; http://eartheasy.com/grow_lawn_care.htm

[104] doi:10.2875/846869

Table E 4: Market approved plant protection products in the Netherlands for use on sports pitches. One additional product is authorized for playgrounds (CTGB pesticide database and ECHA C&L database accessed on 20 February 2018)

Type	Active ingredient(s)	Harmonized classifications
Usage location: Sports pitch		
Herbicides	Bentazone [1]	Acute Tox.4 (H302); Eye Irrit. 2 (H319); Skin Sens. 1 (H317); Aquatic Chronic 3 (H412)
	Bifenox [1]	No harmonized classification. Self-classified by 71 of 74 notifiers as: Aquatic Acute 1 (H400); Aquatic Chronic 1
	Dicamba [2, 3]	Acute Tox.4 (H302); Eye Dam. 1 (H318); Aquatic Chronic 3 (H412
	Florasulam [1, 4, 5]	Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
	Fluroxypyr-meptyl [1, 4, 5]	Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
	Glyphosate [1]	Eye Dam. 1 (H318); Aquatic Chronic 2 (H411)
	Isoxaben [1]	Aquatic Chronic 4 (H413)
	Nonanoic acid [1]	Skin Irrit. 2 (H315); Eye Irrit. 2 (H319); Aquatic Chronic 3 (H412)
	2,4-D [2, 3]	Acute Tox.4 (H302), Eye Dam. 1 (H318), Skin Sens 1 (H317); STOT SE 3 (H335); Aquatic Chronic 3 (H412)
	MCPA [3]	Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
	Mecoprop-P [3]	Acute Tox.4 (H302); Eye Dam. 1 (H318); Aquatic Chronic 2 (H411)
	Clopyralid [5]	Eye Dam. 1 (H318);
Insecticides	Azadirachtin [1]	No harmonized classification. Self classification: Not classified (3 of 5 notifiers) / Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (1 of 5 notifiers) / Skin Sens. 1B (H317) (1 of 5 notifier).
	Bacillus thuringiensis subsp. Aizawai [1]	No harmonized classification. Self classified by 6 of 10 notifiers as: Skin Sens. 1 (H317); Eye Irrit.2 (H319); Resp. Sens 1 (H334); STOT SE 3 (H335) respiratory tract
	Bacillus thuringiensis subsp. kurstaki [1]	-
	Deltamethrin [1]	Acute Tox. 3 (H301) & (H331); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); M=1000000
	Esfenvalerate [1]	Acute Tox. 3 (H301) & (H331); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); M(Chronic)=10000
	Pirimicarb [1]	Acute Tox. 3 (H301) & (H331); Skin Sens. 1 (H317); Carc. 2 (H351); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); M(Chronic)=100; M=10
	spirodiclofen [1]	No harmonized classification. Self classified by 46 of 68 notifiers as: Skin Sens. 1 (H317); Carc. 2 (H351); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); M=10
	Thiacloprid [1]	Acute Tox. 3 (H301); Acute Tox. 4 (H332);STOT SE 3 (H336); Carc. 2 (H351); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); Repr. 1B (H360FD); M(Chronic)=100; M=100
Fungicides	Azoxystrobin [1]	
	Boscalid [6]	No harmonized classification. Self classified by 135 of 138 notifiers: Aquatic Chronic 2 (H411)
	Mepanipyrim [1]	Carc. 2 (H351); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
	Metconazole [1]	Acute Tox. 4 (H332); Aquatic Chronic 2 (H411); Repr. 2 (H361d)
	Pyraclostrobin [6]	No harmonized classification. Self classified by 189 notifiers, practically all classify as: Skin Irrit. 2

Type	Active ingredient(s)	Harmonized classifications
Usage location: Sports pitch		
		(H315); Acute Tox. 3 (H331); Aquatic Acute 1 (H400); Aquatic Chronic (H410) with differing M factors from 0 to 100.
	Trichoderma harzianum Rifai strain T-22 [1]	-
Acaricides	Acequinocyl [1]	Skin Sens. 1 (H317); STOT SE1 (H370); STOT RE2 (H373); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); M(Chronic)=1000
Plant growth regulators	Maleic hydrazide acid [1]	No harmonized classification. Self classified by 25 of 50 notifiers as: Skin Irrit. 2 (H315); Eye Irrit. 2 (H319); STOT SE 3 (H335)(lungs); Muta. 2 (h341). Not classified by 24 of 50 notifiers.
	Trinexapac-ethyl [1]	No harmonized classification. Self classified as Aquatic Chronic 1, 2 and 3.
Talpicides	Aluminium phosphide [1]	Water-react. 1 (H260); Acute Tox. 2 (H300); Acute Tox. 3 (H311); Acute Tox. 1 (H330); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
Usage location: Playgrounds		
Insecticides	Imidacloprid [1]	Acute Tox. 4 (H302); Aquatic Acute 1 (H400); M=100

Authorized product containing: [1] = one active substance; [2] = dicamba / 2,4D; [3] = dicamba / MCPA / 2,4-D / mecoprop-P; [4] = fluroxypyr-meptyl / florasulam; [5] = fluroxypyr-meptyl / clopyralid / florasulam; [6] = Boscalid / Pyraclostrobin

E.2.6.2. Chemicals used in maintenance of artificial turf pitches

Also artificial turf pitches need maintenance which includes the removal of bodily fluids and animal droppings, as well as the usage of sanitizing products (Claudio, 2008). Good pitch management also includes decompaction and regular brushing, often with automated sweepers, to even out the surface and redistribute the infill material, while at the same time preventing growth of algae, moss and even weeds (KNVB onderhoud kunstgrasvelden brochure[105]). Removal of leaves and twigs, especially in autumn, leads to a lower organic load and reduces the growth of vegetation. Nevertheless, algae, moss and weeds can grow in shady and less frequented parts of the pitch. According to the Dutch football association treatment is required 3 to 4 times a year (KNVB kunstgras onderhoudsbrochure[105]). However, there are also reports of more frequent treatments, i.e. Claudio (2008) refers to the Synthetic Turf Sports Pitches: A Construction and Maintenance Manual, published in 2006 by the American Sports Builders Association, and states that some synthetic turf owners *disinfect* their pitches as often as twice a month, with more frequent cleanings for sideline areas. The type of disinfectants/cleaning agents has not been specified. Treatment with hot water has been reported (BSNC, 2014), but generally chemicals are used. Comparison of pest controlling substances used on natural grass pitches and artificial turf pitches is not straight forward. Firstly, because products used on natural grass pitches are considered plant protection products, while products used to control moss, algae and/or weeds in artificial turf pitches fall under the biocide regulation (BSNC, 2016). According to FIFA the chemicals that can be used on synthetic surfaces for maintenance, after authorisation, include algaecides, mossicides, weedkillers and de-icers (FIFA, 2015).

[105] https://www.knvb.nl/downloads/bestand/1413/kunstgras-onderhoudsbrochure

In the Netherlands only two biocidal products containing the same active substance, i.e. Alkyl (C12-16) dimethylbenzylammonium chloride (ADBAC), are authorized to be used on wet and semi-wet artificial turf pitches (e.g. hockey) to control algal growth (search terms 'sportveld' and 'kunstgras' under usage info). This substance has no harmonized classification, and is self-classified by 1180 notifiers, the majority classifying as Aquatic Acute 1 (H400). From interviews with managers of especially wet artificial turf pitches (without infill) it appears that unauthorized substances are commonly used on artificial pitches, e.g. hydrogen peroxide, kitchen salt (=sodium chloride) and benzalkonium chloride (Broer, 2017). Note that this may not be relevant for this dossier as the pitches covered here are another type of artificial turf (not wet). Based on a recent publication in the Netherlands (BSNC/STOWA, 2018) the use of plant protection products and biocides primarily takes place on low pile pitch hockey and other pitches such as tennis courts in which water or sand or a combination of both are used as infill. Products such as hydrogen peroxide, salts, acetic acid, didecyldimethylammoniumchloride (DDAC), (2-methoxymethylethoxy)propanol (DPGME), Alkyl (C12-16) dimethylbenzylammoniumchloride (ADBAC), enzymes and occasionally glyphosate are mentioned to be used to treat against moss, algae and weed. On synthetic turf football pitches treatment is said to be practically non-existent as the rubber infill and intensive use of these pitches prevent problems from arising. The legal status of products allowed to be used is stated to be unclear for some of the products reported. Regular maintenance (i.e. weekly brushing) is said to prevent the need to revert to chemical products.

A questionnaire amongst 10 artificial turf pitches with ELT-infill in the Netherlands revealed that algae and weeds are removed mechanically on 7 out of 10 pitches, whereas on three pitches biocides were used to remove algae, especially along the edges of the pitch. This concerned acetic acid and salt on 1 pitch, DDAC on 1 pitch and ADBAC on 1 pitch (RIVM 2018).

E.2.7. Human health risks of alternatives

E.2.7.1. Human health risk related to chemicals in EPDM infill

The information on the concentration of substances in EPDM is limited, with a small number of studies that performed measurements, each including a few samples at most. The findings for the most relevant substance groups are discussed to indicate whether substances in EPDM may pose a human health concern.

E.2.7.1.1. PAHs and Carbon black

Overall, the levels of PAHs in EPDM seem to be lower than in ELT derived granules. Table E2-1, Appendix E.2. shows that two studies that determined total PAH (16) content found 1 mg/kg and 1.6 mg/kg. In the measurements by RIVM that investigated 2 samples of presumably recycled EPDM from pitches (potentially mixed with other types of infill) most PAH levels were below LOD, except fluoranthene (2.9 mg/kg) and pyrene (11.2 mg/kg) (RIVM, unpublished data). Fluoranthene and pyrene are not classified as carcinogenic and are not included in the REACH PAH 8. Based on the data available, there seems to be no indications PAHs from EPDM pose a hazard. However, it should be realized that the number of measurements are too limited (especially compared to ELT) to draw firm conclusions.

Carbon black is commonly used as filler in black rubber (both EPDM and tyres). The SDS's indicate that it is usually present in 30-40 % of the total mass in black EPDM. There are indications from high dose inhalation studies in animals that carbon black may be carcinogenic if inhaled in large quantities. On this basis, it is classified by IARC as possibly carcinogenic to humans (Group 2B). Also several notifiers classify the substance as Cat 2 carcinogen. As said in Annex A, carbon black may contain PAHs. Various grades of carbon black exist on the market and these may differ in PAH content. As mentioned earlier, with respect to EPDM, carbon black is said not to be used in virgin EPDM infill material (which is expected to cover the majority of the EPDM infill market) as other colours (than black) are preferred when it comes to this infill material. In that sense, carbon black may not be that relevant for EPDM infill material.

E.2.7.1.2. Phthalates

Relatively high levels of DEHP were found by RIVM in the 2 samples of presumably recycled EPDM from pitches (potentially mixed with other types of infill), with average pitch levels of 383 and 490 mg/kg infill (6 samples per pitch). This was well above the highest level found on the ELT pitches of 27.2 mg/kg infill. However, the concentration DEHP found in the Norwegian study was much lower (3.9 mg/kg), thus it is unclear how representative these findings are. During the 24 November 2017 workshop the presence of phthalates in EPDM samples was discussed. It was mentioned that phthalates are not compatible with EPDM and are not used in production. Looking at the measured quantities, 0.01-0.05 % of phthalates in the material is not a functional quantity for phthalates, and the phthalates measured may as well be contamination. However, it is unclear where this could contamination come from as also the synthetic turf piles are said not to contain phthalates (Personal communication synthetic turf sector). The main hazard of phthalates is reproductive toxicity through endocrine disruption, DEHP in particular has a harmonized classification as Repr. 1B. There is a restriction covering DBP, DEHP and BBP (entry 51) that prevents application in toys and children articles in concentrations greater than 0,1 % by weight of the plasticised material. A similar restriction (entry 52) prevents the use of DINP, DIDP and DNOP in toys and childcare articles in concentrations greater than 0,1 % by weight of the plasticised material. As the concentrations found in EPDM rubber were below 0.1 %, it is unlikely that phthalates from EPDM pose a hazard to human health based on the available information.

E.2.7.1.3. Lead

The concentrations of the lead measured vary from <LOD (0.1 mg/kg) to 17.3 mg/kg. Compared to the concentrations found in ELT derived granules, which also showed high variation, the concentrations in EPDM are on the lower end. The toxicological reference value for lead is 0.05 µg/kg bw/d, with (developmental) neurotoxicity as most sensitive endpoint. As the lead concentrations in EPDM are lower than in ELT, no exceedance of the reference value is expected as the year average exposure to lead from ELT was below the reference value (RIVM 2017).

E.2.7.1.4. Chromium

Chromium has been measured in various EPDM samples (Table E2-1, Appendix E2). Plesser and Lund (2004) reported high levels of chromium in EPDM rubber granules amounting to 5 200 mg/kg. Bauer et al (2017) reported much lower chromium concentration in EPDM rubber granules amounting to 0.43 ± 0.11 mg/kg. In the RIVM study chromium was not detected (<0.01 mg/kg) in granules consisting of 2 samples of presumably recycled EPDM from pitches (potentially mixed with other types of infill) (unpublished data). However, there is a large difference in human toxicity between the different forms of chromium.

Chromium VI is classified as Cat 1B carcinogen, while the most common form, chromium III, has no CMR classification. As no differentiation was made in the chromium detected in EPDM, it is not possible to indicate whether there is a health risk from chromium in EPDM.

E.2.7.1.5. Nitrosamines

A general issue in the production of rubber is the formation of carcinogenic nitrosamines in the vulcanization process. This can be prevented by using vulcanization accelerators which form no- or non-carcinogenic nitrosamines. Although this issue was raised in an MSDS and the Noordermeer publication (2002), there are no actual measurements that show nitrosamines occur in relevant quantities in EPDM infill.

E.2.7.1.6. Conclusion human health risks of EPDM

The data currently available on EPDM infill is still very limited, and carries a high level of uncertainty both on the identity of the substances in EPDM granules and their quantities. Generally, the PAHs and lead concentrations seem to be lower than those in ELT rubber granules. There are currently no indications that EPDM contains carcinogenic nitrosamines. Relatively high levels of phthalates have been found in one study, however, quantities indicate contamination and do not warrant an immediate concern.

E 2.7.2. Human health risks related to chemicals in TPE infill

There is only very limited information available on the presence and leaching of hazardous substances from TPE, which makes it difficult to assess the potential risk. Considering the broad definition of TPE, a high degree of variation is expected. This increases the uncertainty in the extrapolation from the few samples that have been analyzed to TPE infill in general. However, the general impression is that TPE contains no or fewer and lower concentrations of PAH's, metals, and VOC's compared to infill from ELT or EPDM rubber. The levels of phthalates found in TPE were comparable with the measurements in ELT and EPDM rubber in the same study. (see Table E2-1, Appendix E2). As the values were far below the limit of 0.1 % for phthalates in toys, no risk for human health is expected. Also for the other hazardous substances, there is no indication for concern based on the limited information available.

E 2.7.3. Human health risks related of cork infill

There are no reports on the types and concentrations of hazardous compounds in cork. The main human health concerns of cork are related to dust and fungi, in particular the *Penicillium glabrum* complex and *Chrysonilia sitophila.* The presence of the P. glabrum complex in the cork industry involves the risk of respiratory diseases such as suberosis, a type of hypersensitivity pneumonitis that is one of the most prevalent diseases among cork workers (Viegas et al. 2015; Pimentel and Avila. 1973). No reports could be found of human health hazards of cork as a final product. All cases described in literature concern workers in cork factories who have been chronically exposed to high air concentrations of cork particles and molds. It is unclear whether these studies are relevant for players on artificial turf pitches with a cork infill.

When it comes to dust, the cork as a final product is not expected to present problems as nothing has been reported and is commonly use in homes and schools due to the excellent thermal and acoustic isolation properties. However, there are actors in the field indicating that cork infill has the tendency to pulverize during service-life (personal communication synthetic turf sector). Overall, there is not enough information to conclude upon human health risks related to the use of cork as infill, however, these are not deemed very likely.

Table E 5: Overview of health risks related to the material of the selected alternatives

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Human health risk	*Health issues related the material*	PAHs and other hazardous substances	Lower concentration of PAHs, lower number of other hazardous chemicals compared to ELT, relatively high concentrations of phthalates, however limited measures available	No/low PAHs compared to ELT, no/limited other hazardous chemicals however, very limited information available	No hazardous chemicals expected, however, limited information available, issues related to dust/fungi however may not be relevant for infill	No concern

E.2.7.4. Human health risks related to maintenance of natural grass pitches

There are no human health risks associated with grass itself. However, as said, to maintain turf quality pesticides, herbicides, and/or fungicides may be used on natural grass pitches. Table E 4 gives an overview of plant protection products (PPP's) that are approved for use on sports pitches in the Netherlands. Although the approval system incorporates a risk assessment and all approved substances are deemed to be safe when used as intended and taking into account the appropriate safety measures, the human health hazards will be shortly discussed for every group of products, based on the classification of the active ingredients.

E.2.7.4.1. Herbicides

This is the largest group and appears to be the most frequently used group of PPP's. The classifications for this group are limited to acute endpoints and occasionally skin sensitization. Considering the low and intermittent exposure from the use on turf pitches, no human health risk is anticipated for players.

E.2.7.4.2. Insecticides

Several insecticides have been classified as acute toxic Category 3 and/or as skin sensitizers. Considering the low and intermittent exposure from the use on turf pitches, no human health risk is anticipated for players. Two active substances, spirodiclofen and thiacloprid have recently been evaluated by RAC, resulting in proposed harmonized classifications for CMR endpoints. Thiacloprid has been classified as Carc 2, Repr. 1B and spirodiclofen as Carc.1B and Repr. 2. Whether these two compounds pose a risk to the users of the pitch depends on amongst others their mechanism of action, potency, and the exposure. The latter in turn is influenced by the frequency of application, the amount used, the time after spraying etc. Moreover, there are no data available on how many clubs actually use these insecticides in their maintenance program. It is thus not possible to conclude about the potential risk of the use of these substances.

E.2.7.4.3. Fungicides

There are four fungicides for which (self) classifications are reported. Mepanipyrim has been classified as Carc. 2 and Metconazole as Repr. 2. Pyraclostrobin is self-classified as Acute tox 3 amongst others. Again, the risk depends mainly on the exposure to these substances. As there is no information about the actual use of these substances, it is currently not possible to conclude about the potential risk.

E.2.7.4.4. Acaricides (ticks and mites)

Acequinocyl is classified for sensitization and specific organ toxicity, both acute and chronic. This means that high exposure or long term exposure to this substance should be avoided. As there is no information about the actual use of this substance, it is currently not possible to conclude about the potential risk.

E.2.7.4.5. Talpicides (small mammals)

Aluminium phosphide has high acute toxicity to all mammals, including humans. This substance should be used in such manner that no accidental exposure can occur. As there is no information about the actual use of this substance, it is currently not possible to conclude about the potential risk.

E.2.7.4.6. Conclusion human health risk of maintenance of natural grass

The risk of PPP’s used on natural turf pitches to human health depends mainly on which products are used and to what extent. The most frequently used PPP’s are herbicides, which have low toxicity to humans. As there is no information about the actual use of PPP’s on natural grass sport pitches in Europe, it is currently not possible to conclude about the potential risk. The use also may differ among EU countries, as some countries have banned or are in the process of banning the use of PPP on sport pitches.

E.2.7.5. Human health risks related to maintenance of artificial turf pitches

Control of weeds, algae and moss is also required for artificial pitches and chemicals may be used for this, however, this is not deemed very likely in case of long pile artificial turf with performance infill. There is no information that suggests potential human health hazard because of the use of chemicals in maintenance. However, the available information is limited and some uncertainty around the use of chemicals on long pile artificial pitches remains.

Table E 6: Overview of health risks of chemicals used in maintenance of the selected alternatives

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Human health risk	*Health issues related to maintenance*	There are more potential harms to the system in case of natural grass than for artificial turf that may treated with chemicals and use of chemicals in maintenance of natural grass may be more likely compared to long pile artificial turf. This may imply that more and more hazardous chemicals are used during maintenance of natural grass than for artificial turf, however, there is uncertainty given the limited data available.				

E.2.7.6. Injury risk

The widespread use of synthetic paying surfaces have raised questions and concerns regarding the impact of artificial turf on the type and severity of sports-related injuries (Taylor et al., 2012) compared to natural grass. Many studies have been performed looking at injury risk of playing on artificial turf compared to natural grass. The scope of studies vary in terms of age, gender, professional or recreational player, country and types of injuries reviewed. Some studies look at injury incidence in general (Taylor et al., 2012, Bianco et al., 2016, Lanzetti et al., 2017), others look at specific types of injuries (knee injuries: Balazs et al., 2014, Hägglund and Waldén, 2016, Mansfield and Bucinel, 2016; Achilles raptures: Krill et al., 2017; Extremity fractures: Putter et al. 2015) or both (Meyer 2017, Rössler et al., 2017, Williams et al., 2013). All studies appear to look at third generation artificial turf using rubber infill, however, this is not always made explicit. No information is provided about the type of infill used.

The answer to the question whether there is a higher incidence of injuries on artificial pitches compared to natural grass is mixed. For example Rössler et al., 2017 and Tayler et al., 2012 concluded that injury risk was increased on artificial turf compared to natural grass. However, Meyer, 2017, O'Kane et al., 2016 and William et al., 2013 indicates lower incidence rates for playing and training on artificial turf compared to natural grass. Bianco et al., 2016, Lanzetti et al., 2017 observe no clear contribution of artificial turf or natural grass to injury risk. Putter et al., 2015 conclude that the effect of artificial turf on soccer-related injuries is still controversial due to inconsistent results from previous cohort studies addressing the injury risk during soccer played on artificial turf pitches and on natural grass.

Majority of injury studies look at soccer/football, however, also a few studies looking at Rugby were found. Lanzetti et al., 2017 concludes that in elite Italian rugby players, artificial turf seems to be safe in regards to traumatic injury while it seems to be a risk factor for overuse injuries. Williams et al., 2016 also looked at injury risk of playing surfaces in Rugby and concluded no differences between natural grass and artificial turf.

E.2.7.6.1. Perception

Public perception appears to be that artificial turf is more likely to cause injury compared to natural grass (Simon Rachel, 2010). Elite players all over the world also express a strong preference over the use of natural grass compared to artificial turf (Owen at al., 2017).

E.2.7.6.2. Conclusion injury risk

The effect of artificial grass on the risk of injuries is still debated in literature and the majority of published data seems to be contradictory. In public perception natural grass is safer compared to artificial turf.

Table E 7: Overview of health risks of the selected alternatives

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Human health risk	*Player safety*	Inconsistency in literature on injury risk of artificial turf compared to natural grass. In public perception natural grass is safer compared to artificial turf.				

E.2.8. Environmental risks

In the following sections the potential environmental risks of alternative infill material (EPDM, TPE and cork) are discussed, where possible compared to ELT. Note that environmental risk of ELT as such is not extensively discussed in this dossier as the dossier focusses on PAHs and human health (carcinogenicity). RIVM recently performed a study that indicates that the use of ELT infill can cause harm to the environment (RIVM 2018).

E.2.8.1. Environmental risk related to chemicals in artificial turf infill

Application of artificial turf systems involves the placement of materials on and in soil, which can lead to undesirable distribution of synthetic particles and leaching of substances into the environment.

E.2.8.1.1. Soil regulation

In the EU, soil protection is organized at Member State level. In the Netherlands, EPDM and TPE rubber granules fall within the (stony) granular building materials category of the Dutch Soil Quality Decree (*Besluit bodemkwaliteit)*, as the total levels of silicon, calcium or aluminium together generally exceed 10 percent by weight[106]. Therefore, EPDM and TPE rubber granules need to comply with the content and emission limit values for granular building materials that have been set for 19 organic and 19 inorganic parameters, as given in Tables 1 and 2 of Annex A of the Dutch Soil Quality Regulation (*Regeling bodemkwaliteit*)[107]. These emission requirements have been derived from the regulatory limit values that apply to substances in groundwater, surface water, drinking water and soil, and also take into account aspects, such as, gradual release of substances over a prolonged period of time (100 years), adsorption to different soil types, drainage to surface water, and leaching to groundwater at a depth of 1 m. (RIVM 2017). It is worth noting that ELT rubber granules are not considered as stony material and thus do not fall under the Dutch Soil Quality Decree, and that for their application as infill material it suffices to adhere to Article 13 of the Soil Protection Act (Wet bodembescherming), which states that care has to be taken to prevent soil pollution. There are no regulations defining what measures need to be taken, but recommendations have been published by tyre industry associations VACO and Band & Milieu/RecyBEM (VACO, 2014[108]). In a Norwegian Building Research Institute report, EPDM and ELT rubber granules were investigated and the results were compared to Norwegian and Canadian limits for soil and water (Plesser and Lund, 2004). The Norwegian Pollution Control Authority's normative values for 'most sensitive land use' covers areas intended for housing, gardens, nurseries, schools, etc. Normative values are available for, amongst others, zinc, lead, cadmium, and PAHs. As there were no values set for phthalates or phenols, these were taken from the "Canadian Environmental Quality Guidelines - Agricultural Soil". The values differ from the values used in the Netherlands. Unfortunately, information from other EU countries is not available to the Dossier Submitter.

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106 https://www.bodemplus.nl/onderwerpen/ zwet-regelgeving/bbk/vragen/bouwstof-kunstgras/faq/valt-toepassing/

107 http://wetten.overheid.nl/BWBR0023085/2017-02-01#BijlageA

108 http://sportengemeenten.nl/wp-content/uploads/2016/10/VACO-en-BEM-2014-Verantwoorde-toepassing-rubbergranulaat-vraag-en-antwoord.pdf

ELT infill

Table E2-1, Appendix E2 gives information on substances found in ELT infill compared to EPDM and TPE. The environmental impact of artificial turf pitches with ELT-infill was studied on 10 pitches (10-28 years old) in The Netherlands (RIVM 2018). The upper 10 cm of the soils in close vicinity of the pitches contained up to 35g rubber particles per kg soil. Concentrations of zinc, cobalt, and mineral oil were significantly higher than in soils surrounding natural turf pitches used as background controls. As a result soil quality criteria for these substances were exceeded. Elevated concentrations of PAHs and benzothiazoles were also observed, but these stayed well below the Dutch environmental quality criteria. In ditches near some of the pitches, elevated concentrations of cobalt, zinc, PAHs and mineral oil were observed in the sediment, and it was shown that this was the result of drainage from artificial turf. Near two pitches environmental quality criteria of zinc in sediment were exceeded. Extremely high concentrations were found near one pitch, were rubber granulate was also used in the supporting layer beneath the synthetic turf. The impact of ELT-infill was confirmed by bioassays with the same drainage water and sediment samples.

E.2.8.2. Environmental risk related to chemicals in EPDM

The sections below will discuss the hazardous substances detected in EPDM granules (see section E.2.5.2.) and where available the emission requirements will be given.

E.2.8.2.1. PAHs and carbon black

Table E2-1, Appendix E2 shows that some PAHs have been found in EPDM samples (PAH16, REACH PAH 8, fluoranthene and pyrene). The ECHA dissemination site (accessed 12-02-2018) shows that a majority of the notifiers, i.e. 40 of 60 notifiers for fluoranthene and 80 of 127 notifiers for pyrene, self-classified these substances as very toxic to aquatic life (Aquatic Acute 1, H400) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1, H410). For pyrene no maximum content value has been set in the Dutch Soil Quality Regulation, while the fluoranthene content is well below the maximum content value of 35 mg/kg d.w. This would imply low risk. However both substances have been concluded as PBT/vPvB substances in the Annex XV dossier that identified the UVCB coal tar pitch, high temperature (CTPHT) as a substance of very high concern (SVHC), because of its carcinogenic (category 2), PBT and vPvB properties[109]. Just recently SVHC intentions have been announced by Belgium for fluoranthene (04-12-2017) and by France for pyrene (22-09-2017) to identify them as SVHC substances based on their PBT/vPvB properties (expected submission date: 06-08-2018). Thus, pyrene and fluoranthene leaching from EPDM granules to drainage water pose a hazard to the environment due to their PBT/vPvB properties. In addition, fluoranthene has been placed on the list of priority substances of the Water Framework Directive (WFD, 2000/60/EC) with the proposed environmental quality standard (AA-EQS) for fresh water being set to 6.3 10^{-3} µg/L (Fluoranthene EQS dossier 2011). The available sum of PAHs values for EPDM is well below the maximum content value for sum of PAHs that has been set at 50 mg/kg in the Dutch Soil Quality Regulation. The Norwegian SFT’s normative value for PAH (16) has been set at 2 mg/kg. The overall picture is that EPDM rubber granules contain PAHs, but compared to granules of recycled

[109] https://echa.europa.eu/documents/10162/5d6c86db-67cc-4c6a-81b9-c812484e4b1c

ELT rubber the PAH levels are lower (See Table E2-1 in Appendix E2). However, it should be kept in mind that this observation is based upon only a very limited number of measurements for EPDM.

Carbon black has no harmonized classification, and only 11 out of 2594 notifiers (42 aggregated notification; accessed 12-02-2018) consider carbon black as Aquatic Chronic 1 or 4. However, carbon black may contain PAHs, and as such could pose a risk to the environment. However, it should be kept in mind that virgin EPDM can be produced in several colours, and that only the black pigmented granules that are likely to be primarily manufactured by recycling companies from EPDM waste streams will contain carbon black.

E.2.8.2.2. Phthalates

Table E2-1, Appendix E2 shows the measured phthalates in various samples of EPDM. There appears to be quite a large range between the available samples: e.g. 383-490 mg/kg DEHP measured by RIVM versus 3.9 mg/kg measured by Plesser et al., 2004. The DEHP concentrations found by RIVM were well above the highest level found on the ELT pitches of 27.2 mg/kg infill. However, it is unclear how representative these findings are. How the phthalate levels in EPDM rubber granules compare to ELT derived rubber granules is thus not so clear. Regarding environmental toxicity, DBP has a harmonized classification (index number 607-318-00-4) as Aquatic Acute 1 (H400: very toxic to aquatic life), and DIDP and DEHP have been self-classified as very toxic to aquatic life (Aquatic Acute 1; H400) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1; H410) by several notifiers (as of February 2018). The majority of the notifiers did, however, not self-classify DIDP nor DEHP for aquatic toxicity. No solid conclusion can be drawn with respect to the environmental risks associated with phthalates in EPDM rubber granules and how this compares to the environmental risk caused by phthalates in ELT rubber granules.

E.2.8.2.3. Zinc

EPDM rubber, just like ELT rubber, undergoes vulcanization during manufacture using zinc oxide as vulcanization enhancer (See Annex A.1.1.1. Tyre production). Consequently, both types of rubber contain zinc. Furthermore, some UV stabilisers that are added to protect against light degradation also contain zinc (e.g. Tinuvin 494; Nilsson et al 2008). As can be seen in Table E2-1 in Appendix E2, high zinc levels have been reported for EPDM rubber, from 3.5 – 9500 mg/kg. The RIVM study investigated the leaching of zinc from a mixture of ELT and EPDM rubber granules. The amount of zinc that leached from the material tested amounted 13 and 18 mg per kg granules (unpublished data, RIVM 2017). The emission limit value for zinc is set at 4.5 mg/kg in the Dutch Soil Quality Regulation, and the emission limit for granular building materials is thus exceeded in the RIVM study. Plesser and Lund (2004) determined the leaching of zinc from EPDM rubber granules to be 80 µg/L and concluded that the concentration of zinc in the leachate corresponds to the Norwegian Pollution Control Authority's Leaching Class IV (strongly polluted). The high level of zinc measured in EPDM rubber granules, i.e. 9500 mg/kg, exceeded the Norwegian Pollution Control Authority's normative values for most sensitive land use which is set at 100 mg/kg. For metal zinc there is a harmonized classification (index number 030-001-00-1 (pyrophoric zinc dust) and 030-001-00-1 (stabilised zinc dust)) classifying zinc as very toxic to aquatic life (Aquatic Acute 1, H400) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1, H410). It should be noted that leaching of zinc will be in the form of zinc ions (Zn^{2+}), and the hazard classification of the easily water soluble zinc salt zinc chloride is in that sense more relevant with respect to environment than massive zinc in dust form.

Zinc chloride also has a harmonized classification (index number 030-003-00-2) as very toxic to aquatic life (Aquatic Acute 1, H400) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1, H410). Leaching of zinc can thus adversely affect the growth, survival, and reproduction of aquatic species. Furthermore, zinc is also known to have toxic effects to benthic species and terrestrial species. In comparison with ELT derived rubber granules though, the amount of zinc in EPDM granules appears to be somewhat lower, however, especially for EPDM limited number of estimates is available. According to Professor Noordermeer, zinc concentrations in EPDM are expected to be in the same order of magnitude as ELT. Lower zinc concentrations in EPDM could imply that the infill material does not (only) contain (vulcanized) EPDM but may also contain other (unvulcanised) materials (personal communication Professor Noordermeer). Concluding, an environmental risk with respect to zinc leaching for EPDM rubber granules cannot be excluded and may be comparable to ELT.

E.2.8.2.4. Chromium

As can be seen in Table E2-1, Appendix E2, a variation in chromium has been measured in various EPDM samples. Plesser and Lund (2004) reported high levels of chromium in EPDM rubber granules amounting to 5 200 mg/kg, and determined leaching of chromium from artificial turf fibres and EPDM granules to be limited (<2 μg/L). It was concluded that the chromium concentration exceeds the Norwegian Pollution Control Authority's normative values for most sensitive land use. Bauer et al (2017) reported much lower chromium concentration in EPDM rubber granules amounting to 0.43 ± 0.11 mg/kg. In the RIVM study chromium was not detected (<0.01 mg/kg) in the 2 samples of presumably recycled EPDM from pitches (potentially mixed with other types of infill) (unpublished data). The emission limit value set in the Dutch Soil Quality Regulation of 0.63 mg/kg was thus not exceeded. The data regarding chromium concentrations in EPDM rubber granules are ambiguous and no firm conclusions can be drawn with regard to environmental risk associated with chromium in EPDM granules and how this compares to ELT rubber granules.

E.2.8.2.5. Lead

As can be seen from Table E2-1, Appendix E2 various concentrations of lead have been reported in EPDM samples. The emission limit value of lead that is set at 2.3 mg/kg in the Dutch Soil Quality Regulation, and the Norwegian Pollution Control Authority's normative value for most sensitive land use that is set at 60 mg/kg, are not exceeded in the available studies. For lead an EU harmonized classification exists in Annex VI of the CLP Regulation (index number 082-013-00-1 (particle diameter <1 mm) and 082-014-00-7 (particle diameter ≥1 mm)), but without environmental classifications. On the ECHA dissemination site there are 59 aggregated self-classifications for lead corresponding to 1 597 notifiers ((accessed 12-02-2018), with the majority classifying lead as very toxic to aquatic life (Aquatic Acute 1; 988 notifiers) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; 1 051 notifiers). The lead levels appear somewhat higher in ELT rubber granules, however, the available information is limited.

E.2.8.2.6. Alkylphenols

As can be seen from Table E2-1, Appendix E2, nonylphenols and octylphenols are measured in some samples of EPDM. Nonylphenols (including 4-n-nonylphenol and 4-iso-nonylphenol) have been harmonized classified (Index number 601-053-00-8) as very toxic to aquatic life (Aquatic Acute 1; H400) and very toxic to aquatic life with long-lasting effects (Aquatic

Chronic 1; H410). 4-t-octylphenol has also been harmonized classified (Index numbers 604-075-00-6) as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), but with an M-factor of 10, corresponding to higher toxicity. In the Water Framework Directive (WFD, 2000/60/EC) 4-Nonylphenol (branched) and nonylphenol have been classified as priority hazardous substance (= priority substance No. 24). The average annual quality standard (AA-QS) for all surface waters has been set at 0.33 µg/L and the quality standard accounting for transient concentration peaks (MAC-QS) at 2.1 µg/L (EQS dossier Nonylphenols, 2005). Octylphenols (para-tert-octylphenol) has been classified as a priority substance under review in the WFD (= priority substance No. 25), with an AA-QS for inland surface waters of 0.12 µg/L, AA-QS for other surface water covered by the WFD of 0.0122 µg/L, and a MAC-QS of 0.13 µg/L (EQS dossier Octylphenols, 2005). Available data shows that EPDM can contain low levels of nonyl- and or octylphenols. Considering the low environmental quality standards, leaching of nonyl- and/or octylphenol could result in an environmental risk. To what extent these substances can leach from EPDM rubber granules is not clear. In comparison with ELT rubber granules, the reported concentrations in EPDM rubber are lower.

E.2.8.2.7. 1,3-diacetylbenzene, 1,4-diacetylbenzene and p-isopropenylacetophenone

These substances were detected in relatively high levels in EPDM rubber leachate by Nilsson et al. (2008), see Table E2-1, Appendix E.2. . These substances are not registered under REACH, nor are they listed in ECHA C&L inventory. ECOSAR predicts low acute and chronic toxicity for 1,3 and 1,4-diacetylbenzene, and slightly higher toxicity for the more hydrophobic substance p-isopropenylacetophenone with the acute and chronic effect concentrations being predicted in the range of a few mg/L. These substances were not detected in the leachate of ELT derived rubber granules or TPE granules (Nilsson et al., 2008). Furthermore, they have only been reported by Nilsson et al. (2008). Considering the limited information available for these substances, the available toxicity estimates and the fact that these substances have been detected in a single study only, seems at this stage that the environmental risk associated with these substances is limited.

E.2.8.2.8. Nitrosamines

There are no indications that nitrosamines occur in relevant quantities in EPDM infill, while low levels have been detected in ELT derived rubber granules. Due to the limited information available, no conclusive comparisons can be made with regard to environmental risk of nitrosamines in EPDM and ELT derived rubber granules. Considering the carcinogenicity of these substances, concern appears to be primarily human health related though.

E.2.8.2.9. Conclusion environmental risk of EPDM

The data currently available on EPDM infill is still limited, and carries a high level of uncertainty both on the identity of the substances in EPDM granules and their quantities and migration levels. EPDM granules contain high levels of zinc (although lower compared with ELT-derived granules) and leaching can impact the environment. The PAHs fluoranthene and pyrene, as well as other PAHs, are found both in EPDM and ELT derived rubber granules. Fluoranthene and pyrene are likely to be identified as SVHC substances based on their PBT/vPvB properties, and as such, they may pose a hazard for the environment. Nonyl- and octylphenol are detected in low levels in EPDM as well as ELT derived rubber granules.

Considering the high toxicity of alkylphenols to aquatic species, leaching could pose and environmental risk. Generally, PAH and alkylphenol concentrations seem to be lower in EPDM granules compared to ELT derived rubber granules. Zinc concentrations also seem somewhat lower compared to ELT, however, if actually EPDM is used, concentrations are expected to be comparable. There is insufficient information to conclude on phthalates, but they appear to be present in at least some EPDM granules.

E.2.8.3. Environmental risk related to chemicals in TPE

Compared to EPDM rubber granules, and especially ELT derived rubber granules, the information available on hazardous substances in TPE granules is rather limited, and as said there appears to be a difference between different types of TPE granules (Nilsson et al., 2008). Nilsson showed that one of the three tested TPE granules contained drometrizol and 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol, substances that have been self-classified with respect to chronic aquatic toxicity (i.e. drometrizol as Aquatic Chronic 1 or 4, and 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol as Aquatic Chronic 3). Nonetheless, it appears that TPE granules contain fewer and less hazardous substances than ELT derived rubber and EPDM rubber granules. TPE is not vulcanized, and therefore should not contain zinc. This is a substantial difference with EPDM and ELT derived rubber granules. Unfortunately, as zinc is not expected most studies did not measure zinc levels. The PAH and phthalate levels vary between reports, but are either lower or around the same level as for EPDM and ELT derived rubber granules (Nilsson et al., 2008; Moretto, 2007). Overall, based on the currently available data, TPE appears to contain less hazardous substances than ELT derived rubber granules looking at the environment.

E.2.8.4. Environment risks related to cork infill

The information available with respect to cork infill is rather limited, especially from an environmental point of view. Presence of fungi is not expected to pose an environmental issue. There are no indications that cork contains substances hazardous, but recycled cork could have been treated with chemicals depending on its previous function. Regarding maintenance of cork infill, no information could be retrieved. But likely the same will apply as for the other types of artificial turfs.

Table E 8: Overview of environmental risks of chemicals within the material of the selected alternatives

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Environmental risk	Environmental issues related to chemicals in the material	Some concern e.g. related to zinc, cobalt and mineral oil	Some concerns related to zinc, alkylphenols, concentrations seem lower compared to ELT	Less hazardous chemical comparedcompared to ELT and EPDM, however, limited data	No information, however, no indication for concern	Not relevant

Note that the above analysis, compares chemicals in different types of infill. It does not account for the difference in artificial turf system used in case of EPDM, TPE and cork compared to ELT. In case of non-ELT infill generally a shockpad or e-layer will be used underneath the turf. If that layer makes use of ELT, the environmental impact of the full artificial turf system may look different and environmental impact of the alternative may be more comparable to the ELT based system. For more information on the potential environmental impact of artificial turf using ELT, see RIVM, 2018.

E.2.8.5. Environmental risks related to maintenance of natural grass

E.2.8.5.1. Eutrophication

Regular fertilization is required to keep natural grass pitches in optimal shape. When quick releasing mineral fertilizers are used, there is a risk of run off (KNVB manual). Subsequent increase of nitrate and/or phosphate levels in nearby water bodies can lead to eutrophication and disturbance of the ecosystem. A study by the Michigan State University where nitrogen leaching from a grass pitch was investigated for 15 years, shows that aged grass pitches can lead to increased nitrate leaching (Frank et al., 2016[110]). In general, proper fertilizing of grass pitches that accounts for playing and mowing frequencies, type and amount of fertilizer, as well as the application period, can reduce the risk of wash out and eutrophication. This issue is not relevant for artificial pitches, as they obviously do not need to be fertilized.

E.2.8.5.2. Pest, disease and weed control

Natural grass pitches are susceptible to pests, diseases and weeds. Adequate mechanical measures can be taken to ensure turf quality and reduce the need for plant protection products. Mechanical options do not contain a risk to the environment. Biological agents could produce toxic substances and market authorization is needed to evaluate the risks, as is the case for products containing *Bacillus thuringiensis*. The introduction of nematodes could affect the ecosystem, but considering that the nematodes are sensitive to soil temperature and moisture content, and do not survive long outside the larvae (KNVB brochure), spreading outside the grass pitch is not expected to represent a substantial risk to the ecosystem. The application of plant protection products, can pose a risk to the environment, as an intrinsic property of plant protection products is that they are detrimental to one or more target organisms, and often also to non-target organisms. Exposure to the environment can be minimized by following instructions on the label, e.g. using correct spraying nozzles, taking account of weather conditions such as wind and rain, keeping adequate distance from water bodies, and respecting a withholding period after application. However, a risk to the environment cannot be fully excluded, as run off and drainage can contaminate ground(water) and surface waters. From Table E 4, it is clear that many of the approved active substances are very toxic to the aquatic environment with and without long lasting effects, Aquatic Chronic and Acute 1, respectively. This is especially the case for insecticides that appear to be very potent with many of them having additional M-factors (up to 1 000 000 for Deltamethrin). It should be noted that classification and labelling only concerns the aquatic environment, but toxicity can also be exerted by these substances to terrestrial species that belong to the vulnerable taxa.

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[110] doi:10.2135/cropsci2016.03.0197

E.2.8.5.3. Conclusion environmental risk of maintenance of natural grass

Optimized management of natural grass pitches can protect water bodies from eutrophication and reduce the need for plant protection products. The latter is advocated by the European Commission, and in some Member States use of plant protection products on sport pitches is prohibited or will be prohibited. Current status is that several plant protection products are authorized to be used on natural grass pitches and may pose a risk to the environment.

E.2.8.6. Environmental risks related to maintenance of artificial turf

Also in case of artificial turf chemicals (biocides) may be used during maintenance e.g. to control for moss, algae and/or weeds in artificial turf pitches, to disinfect the pitch or to defrost the pitch. Besides salt and acetic acid, DDAC and ADBAC no information is available on the substances used in maintenance of artificial turf pitches. However, that chemicals are used in maintenance is stated by various sources. General risk reducing measures, e.g. using correct spraying nozzles, taking account of weather conditions such as wind and rain, keeping adequate distance from water bodies, and respecting a withholding period after application are important to reduce the potential environmental impact of biocide use during maintenance. Nevertheless, a risk to the environment cannot be fully excluded, as run off and drainage can contaminate ground- and surface waters. Furthermore, regular application of salt in maintenance can result in silting. Indeed, higher sodium concentrations were found in soils around artificial turf pitches compared to natural turf pitches (RIVM 2018). There is no difference to be expected between the different types of synthetic infill material, i.e. ELT derived rubber granules, EPDM rubber granules or TPE granules. No information could be found for pitches with cork as infill. Manufacturers of cork infill claim it is resistant to moulding and bacterial growth[111]. However, they also indicate that the level of exposure to water may influence this[112]. It can be expected that cork that is humid for prolonged periods of time may be prone to growth of fungi and/or algae. There is no data yet to confirm whether this is indeed the case, and if so, which measures have to be taken to counter this.

E.2.8.6.1. Conclusion environmental risk of maintenance of synthetic turf

Control of weeds, algae and moss is also required for artificial pitches, but especially for short pile pitches filled with sand and water, and less likely in artificial turf with performance infill. However, there are signals that chemical maintenance is used for long pile artificial turf pitches (RIVM 2018). Chemical maintenance of artificial turf with performance infill is deemed less likely compared to natural grass as there are less potential threads to the artificial turf system compared to natural grass. In addition, natural grass pitches are also susceptible to fungal disease, insects and other pests, in contrast to artificial turf pitches. Especially the insecticides are potent toxicants, with many of them being classified as very toxic to the aquatic environment with and without long lasting effects. Overall, based on the available information, the environmental impact associated with maintenance of grass pitches is expected to be higher than that of artificial pitches, but further reduction of plant

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[111] http://www.fieldturf.com/en/purefill
[112] https://cork-shop.com/artificial-grass-granules-cork

protection product usage will lead to lower environmental impact and much depends of course on the actual maintenance practice.

Table E 9: Overview of environmental risks of chemicals used during maintenance of the selected alternatives

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Environmental risk	Environmental issues related to chemicals in maintenance	Chemicals may be used during maintenance, of artificial turf. No information is available to deviate between different types of infill, however, cork may be prone to fungi and may be treated for that. Overall, there are expected to be lower potential threads to artificial turf compared to natural grass and therefore fewer chemicals may be used in maintenance of artificial turf compared to natural grass. Chemical maintenance of artificial turf is expected to pose lower environmental burden compared to the use of chemicals in maintenance of grass, however, limited information available and there is uncertainty around this.				Various types of plant protection products may be used and can pose environmental hazard.

E.2.8.7. Global warming[113]

This section is included to account for differences in energy and material use (i.e. recycling versus non-recycling) and consequently presents differences in greenhouse gas emissions between various systems. It is mainly based on a Canadian study of Meil and Bushi, 2007.

E.2.8.7.1. CO_2 emissions natural grass system

To estimate the CO_2 emissions of a natural turf pitch to have a net negative carbon footprint (-16.9 tons $C0_2$ equivalent over ten years) due mainlygrass system, we follow the boundaries and elements attributable to the natural turf systems based on Meil and Bushi (2007). The main phases of installing grass pitches are i) installation of the pitch; ii) use and maintenance and iii) transportation. For the dossier, we separated the 5 elements related to CO_2 emissions in natural grass (NG pitches) as in Meil and Bushi (2007); NG1) grass seed production, NG2) organic plant matter production, NG3) transport, NG4) natural grass carbon sequestration potential of the grass and NG5) natural grass itself.

Compared to the study of Meil and Bushi we made some adjustments. The first one is the size of a pitch. We assume that a football pitch in the EU is 7600 m^2. The second adjustment we made is for NG4, the level of carbon sequestration. Meil and Bushi applied a natural grass carbon sequestration factor of 0.95 tonne Carbon/ha/year. It is unclear where this assumption was based upon. In general, the level of carbon sequestration in grass lands depends largely on the type of grass land and the management techniques applied on it (e.g. Petri et al., 2010). Degraded unmanaged dry lands bind much less C than well managed moist grasslands. That is why large differences in sequestration levels are reported in literature. For this study, we assume that a natural grass sports pitch is a well-

[113] References: Batjes, 2004; Chang et al., 2015; Dickey, (date unknown); Meil and Bushi, 2007; Petri et al., 2010; Skenhall et al, 2012

moistured and well-managed pitch, so carbon sequestration will be relatively high. In general, carbon sequestration levels on temperate well managed soil range between 0,1-0,5 tC/ha/y (e.g. Batjes, 2004). In absence of further information, for this dossier we almost half the estimate of Meil and Bushi and use an estimate of 0,5 tC/ha/y. This however, is a factor of uncertainty in the estimate of greenhouse gas emissions.

Table E 10: Greenhouse-gas-emissions of a 7600 m^2 natural grass system (in ton CO2-equivalents, adapted from Meil and Bushi (2007), coloured boxes are adjusted)

Element identifier	NG1	NG2	NG3	NG4	NG5	Total
Element name	Grass seed: production	Organic plant; production matter	Transport	Natural grass; carbon sequestration	Natural grass system: maintenance (irrigation, grass cutting)	
scaling factor	0	1	211	7600	7600	
units	tons	tons	liters	m2	m2	
CO_2	0,0	0,0	0,7	-13,9	11,3	-1,9
CH_4	0,0	0,0	0,0	0,0	0,0	0,0
N2O	0,0	0,1	0,0	0,0	0,0	0,1
Total GHGs	0,0	0,1	0,7	-13,9	11,3	-1,8

E.2.8.7.2. CO_2 emissions artificial grass system

To estimate the CO_2 emissions of an artificial grass system, we follow the boundaries and elements attributable to the artificial turf systems based on Meil and Bushi (2007). The main phases are: i) production of the main components of the artificial turf system; ii) use and maintenance; iii) disposal phase (recycling) and iv) transportation.

As in Meil and Bushi, we include the following ten main components used to construct the artificial grass (AG) system; AG1) the synthetic turf pitch, on the other hand, emitted +55.6 tons of CO2 equivalent over ten years. This figureitself; AG2) primary backing material, AG3) joints and bonding (assembly of turf rolls); AG4) polyurethane production (secondary elastomeric coating) and AG5) rubber granule infill. The rubber infill granules are derived from recycled tyres. Other elements necessary to estimate the CO_2 emissions of an artificial grass system are AG6) PVC piping to provide pitch drainage, AG7) Top-soil excavation, AG8) synthetic turf maintenance system, AG9) recycling and AG10) transport.

Most turf components have an estimated service life of 10 years. Meil and Bushi assume a 100 % recycling rate to estimate AG9. The dossier submitters agree with Dickey (date unknown) that this is too optimistic. The overall estimate of CO_2 emissions would have been almost twice as high (108.2 tons CO_2) if the authors had not assumed that the pitch would be recycled at the end of life (which gave a carbon credit of 52.6 tons CO2 equivalent). Assuming that the pitch is eventually recycled, its greenhouse gas emissions (GHG) relative to those of natural turf (which are negative) could be offset. Recycling of synthetic turf is theoretically possible but not without further treatment and consequently additional CO_2 emissions. Furthermore, recycling of artificial turf systems is possible, however, it currently only happens on small scale in the EU. Therefore, for this dossier, the recycling step has been taken out of the analysis. As no further information on the balance of GHG emissions of end of life treatment of artificial turf is available, this stage was left out of this analysis.

As indicated in section D.2.2.1., around 114 tonnes rubber granules are used in a pitch of 7600 meter. Due to this, we assume for AG5 that 135 instead of 105 tonnes rubber granules are used on a 9000 meter pitch. The impact measured in CO_2 equivalents is adjusted linearly.

Another adjustment we made is related to the emissions due to transportation, AG10. As we are analysing the emissions in an EU context, and the turf is produced in Europe, we do not include the emissions related to transportation from Europe to the US[114]. Based on the emission factors for trucks (10-20 ton) and sea transport (average, 4080 TEU, panamax) on the Dutch webpage 'CO2 emissie factoren'[115], we recalculate the emissions related to transport.

Table E 11: Greenhouse-gas-emissions of a 7600 m^2 artificial grass system (in ton CO_2-equivalents, source Meil and Bushi (2007), coloured boxes are adjusted)

Element identifier	**AG1**	**AG2**	**AG3**	**AG4**	**AG5**	**AG6**	**AG7**	**AG8**	**AG9**	**AG10**	**total**
Element name	synthetic turf; polyethylene production	production primary backing material	joints and bonding (assembly of turf rolls)	production (secondary elastomeric	rubber granule production	PVC piping production	top soil excavation	maintenance	recycling	Transport	
scaling factor	13	1	0	7	114	3	3800	7600	24	7600	7600
units	tons	tons	tons	tons	tons	tons	tons	m^2	tons	m^2	m^2
CO2	23.6	2.20	0.00	27.0	11.4	6.76	1.5	3.38	0.00	7.81	83.7
CH4	1.69	0.17	0.00	2.53	0.00	0.46	0.02	0.00	0.00	0.01	4.9
N2O	0.00	0.04	0.00	0.07	0.00	0.01	0.02	0.00	0.00	0.01	0.2
Total GHGs	25.3	2.40	0.00	29.6	11.4	7.2	1.6	3.4	0.0	7.8	88.8

[114] In this correction, we assume equal CO_2 emissions per km transport over sea and over land. We know this is not correct, however, we do not have sufficient information to correct for this.
[115] https://co2emissiefactoren.nl/lijst-emissiefactoren/

Due to the fact that ELT granules are made of recycled tyres, and due to different production processes, the CO_2-emissions differ for each of the performance infill options. Skenhall et al. (2012) made a comparison between environmental effects of three different performance infill types used in Sweden. The amounts of infill used per pitch are not comparable with the estimates used for this dossier, most probably due to the fact that in the Swedish study a shockpad is assumed for all systems, while we excluded the impact of a shockpad in our analysis. By scaling the CO_2-equivalents in this study in ton CO_2-equivalents per ton infill, we came to the impacts as presented Table E 12. Assuming that the other impacts are comparable with the estimates for greenhouse-gas-emissions of a 7600 m^2 artificial grass system, based on Meil and Bushi, the total GHG-emissions per EPDM and per TPE pitch can be calculated.

Table E 12: Ton CO_2-equivalents per pitch for different types of performance infill used in Europe (based on Skenhall et al., 2012, Meil and Bushi, 2007)

	ELT	**EPDM**	**TPE**
Ton used in Skenhall et al., 2012	51	61	87
Ton CO2-equivalent per pitch	5	53	166
Ton CO2-equivalent per ton infill	0,10	0,87	1,91
Tonnages per pitch in dossier (baseline)	114	45,6	53,2
Ton CO2-equivalent per pitch in Europe	11	40	102

Note: cork was not included in the analysis of Skenhall et al., 2012

The CO_2 impact of EPDM and TPE infill materials is higher compared to ELT rubber. Note that this estimate does not correct for the difference in the artificial grass systems in case of alternative infill, e.g. shorter piles and a shockpad underneath the pitch.

E.2.8.7.3. Conclusion greenhouse gas emissions

Overall, from a CO_2 perspective, the CO_2 impact of an artificial pitch is considerably larger than the impact of a natural grass system. This impact is even larger if taken into account a replacement rate of 1 artificial pitch for 3 grass pitches, as will be explained in Section E.2.8.9. Land use. Table E 13 below gives an overview of the estimated GHG emissions of the various systems. In this estimate it is assumed that GHG emissions of the synthetic turf system of EPDM, TPE and cork are comparable to the GHG emissions of the synthetic turf system in case use of ELT.[116] In practice this may not be the case as shorter piles and a shockpad (or e-layer) are used in case of non-ELT infill.

Table E 13: Overview of greenhouse gas emissions of the selected alternatives

Impact category	**Sub-indicator**	**Artificial turf: ELT**	**Artificial turf: EPDM**	**Artificial turf: TPE**	**Artificial turf: Cork**	**Natural grass**
Greenhouse gas emissions	Ton CO_2-equivalents per pitch	89	118	180	n.a.	-2

Based on CO_2-emissions, the impact of an artificial pitch with EPDM and TPE infill is larger than the impact of an artificial pitch with ELT infill. The dossier submitter didn't have data on the CO_2 emissions related to artificial pitches with cork infill and pitches without infill.

[116] See table E 11: 88.9 minus 11.4 gives arount 78 ton CO_2 equivalents for an synthetic turf pitch without the infill.

E.2.8.8. Water use for irrigation

Natural grass requires water to grow and remain in good condition. The amount of water required for irrigation of a natural grass pitch depends on climate conditions, the conditions of the pitch and the way in which irrigation is carried out. Two US studies provide estimates of 2-11 million liter water each year per 7600 m^2 pitch per year (Simon Rachel, 2010; Cheng et al. 2014)[117]. The website of the Government of Western Australia provides an estimate of 4.8 million liter water for a 8000 m^2 soccer pitch. Unfortunately, no EU figures are available. Water use for sport pitches in the EU may differ from the US and Australia due to differences in climate, soil etc. Comparing natural grass with artificial turf it can be said that artificial turf essentially requires no irrigation. However, artificial turf pitches may need to be irrigated to cool and clean the playing surface on hot summer days (Cheng et al. 2014). It is not known how often this in practice happens and how much water is used for this purpose.

E.2.8.8.1. Conclusion water use for irrigation

The dossier submitter assumes that only a fraction of the water used in case of natural grass pitch will be used on an artificial pitch. Especially in areas where there is limited fresh water available, the use of artificial turf will be preferred when it comes to water use.

E.2.8.9. Land use (intensity of use)

Artificial grass is said to be the best alternative to natural grass pitches e.g. due to its ability to sustain more intensive use (FIFA, 2015). Natural grass is damaged by playing and needs time to recover, which is not the case for artificial turf. According to the European Seed Association (ESA, 2006), natural grass can be played on around 400 hours a year, compared to 900-1300 hours for artificial turf. Cheng et al. (2014) gives figures of 300-600 hours of play per year for natural grass compared to 1500 hours of play for artificial turf. Simon Rachel (2010) mentions 2000-3000 play hours compared to 300-816 hours for natural grass. In addition, for natural grass pitches it is recommended not to use the pitch more than 20-24 hours per week. There appears to be quite a range in the available estimates. Actors in the field state that estimates of 600-800 hours for the use of natural grass are not realistic; 400 hours may be the maximum. Estimates of 600-800 may however represent an extensively used hybrid pitch. A hybrid pitch is a natural grass pitch with reinforced artificial fibers. However, a lower estimate for play hours of a hybrid pitch may be more realistic. The dossier submitters assume an average use of 300 hours a year for natural grass pitches, and of 500 hours for a hybrid pitch.

In theory, the number of playing hours on an artificial turf can be up to 24 hours a day. This is however not the use in practice. The number of playing hours of one of the most used pitches in an average Dutch city is estimated at 1300 hours (personal communication synthetic turf actors). This is assumed to be a realistic estimate of what would maximally be achievable in practice. Most pitches are expected to be used less often (see box 1 for an example). For this dossier it is assumed that artificial turf pitches are used 1000 playing hours per year.

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[117] 1 Gallon = 3.785 liter, and 1 US gallon per square foot = 40.74 liters per m2

Textbox E 1: Illustration underlying the estimate of an intensive and realistic number of hours played per year on artificial grass pitches

A very intensively used pitch in the Netherlands (1580 hours): •Training hours of a football club: 5 hours a day, 5 days a week September till mid-December (about 16 weeks) and February till May (16 weeks): 5x5x16x2= 800 hours •Matchday Saturday: about 7 hours for 2x16 weeks: 2x16x7=224 hours •Matchday Sunday: about 5 hours for 2x16 weeks: 2x16x5=160 hours During day-time: • Schools: 4 hours a day * 5 days a week * 20 weeks (only in summer time) = 400 hours
An average used pitch in the Netherlands (about 1000 hours): •Training hours of a football club: 4 hours a day, 5 days a week September till mid-December (about 16 weeks) and February till may (16 weeks): 4x5x16x2= 640 hours •Match day Saturday: about 7 hours for 2x16 weeks: 2x16x7=224 hours •Match day Sunday: about 4 hours for 2x16 weeks: 2x16x4=128 hours

On average, it is assumed that o artificial turf pitch can replace three pitches of natural grass (see Table E 14). This is in line with what has been suggested by stakeholders at the 24 November 2017 workshop.

In other words, if artificial grass is used, 1/3 of the land is required compared to the use of natural grass in order to provide similar sporting facility. In situations where there is scarcity in land, e.g. in densely populated cities, the use of artificial turf can be preferred. In that case, by substituting natural grass for artificial pitches, more land will be/remain available for other purposes (housing, industry, nature, etc.). If a municipality has made the choice to substitute grass for artificial grass, and to use one of the grass pitches for other purposes most probable houses, this substitution is irreversible.

Table E 14: Number of playing hours per year per pitch

	Artificial turf pitch	**Natural grass pitch**	**Hybrid pitch**
Number of playing hours per year	1 000 (9 00-3 000)	300 (250-816)	500 (300-816)
Number of pitches substituted by one artificial turf system	1	3	2

E.2.8.9.1. Conclusion land use

In many cases, football pitches are located in densely populated cities. Due to extra demand for land in case of grass pitches compared to artificial pitches, in many cases a natural grass pitch isn’t an alternative for an artificial pitch.

Table E 15: Overview of land use impacts of the selected alternatives per pitch

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Land use	Number of playing hours per year	1 000				300
	Number of pitches substituted by one artificial turf system	1				3

E.2.8.10. Micro-plastics

In contrast with the use of natural grass, artificial turf introduces the problem of micro-plastics released to the environment if synthetic infill is used. By introducing an artificial pitch without infill, this problem will be solved. Cork is a natural product and as such not a micro-plastic.

Synthetic infill can be considered micro-plastics, i.e. plastic particles smaller than 5 mm in all directions. The following sizes have been reported for the various artificial granules: recycled ELT rubber granules 0.5-2.5 mm (standard), 0.5 – 2.5 mm (cryogen), 0.52 mm (coated); virgin EPDM rubber granules 0.25 – 4 mm; virgin TPE granules 0 – 2.5 mm (massive), 0 -3.5 mm (hollow); PE granules 1 – 2.5 mm (FM4 table comparing alternatives). The FIFA estimates that 1- 4% of plastic infill is lost and replaced every year (FIFA 2017 Environmental Impact assessment). Comparably, ESTO estimates that 1 ton of replenishment infill is needed for an artificial turf every year (see Annex D). Weijer and Knol (2017) studied the distribution of infill from five artificial turf pitches, three of which contained ELT derived rubber granules, one contained TPE granules and one cork granules. This study provided indicative mass balances, and concluded that of the annually replaced infill 20 to 50 % is lost to the environment, while the remainder is needed to compensate for compaction (i.e. settling of infill and compacting through use). For the dossier, we assume an annual refill of infill for maintenance of 1 ton for ELT and of 0.5 ton for EPDM and TPE. For ELT rubber granules biggest loss was to surrounding soil/grass (240-260 kg/year), while it was hardly lost to surface water (0-10 kg/year). For TPE granules the opposite was observed with a loss to surface water of 100 kg/year and to grass/soil of 15 kg/year. The loss of infill during sweeping of the pitch is 5 kg/year for TPE granules and 0-20 kg/year for ELT rubber granules. It was noted that the differences could be due to differences in material properties, without further elaboration. Compaction could result in 'losses', but good maintenance procedures can reduce compaction almost entirely (Fleming et al., 2015[118]).

[118] http://journals.sagepub.com/doi/pdf/10.1177/1754337114566480

Table E 16: Overview of micro-plastic lost to the environment in the selected alternatives per pitch

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Micro-plastics	Emitted micro-plastics per pitch (ton)	0,2-0,5	0,1-0,25	0,1-0,25	No issue	No issue

E.2.8.11. Ecosystem services

The provision of ecosystem services by natural grass is an advantage of natural grass over artificial grass pitches. Ecosystem services are the benefits people obtain from natural ecosystems (MEA, 2005[119]). Players extracting utility from playing on grass, benefit from the cultural ecosystem service provided by grass. The habitat function of grass is a supporting (intermediate) service, as grass could be a habitat and food source for a variety of species (Cheng et al., 2014). Grass could also provide the regulating ecosystem service water storage, due to the storage capacity of grass resulting in the prevention of water damage due to flooding. As there are many different grass systems, the dossier submitter will not include these impacts in the analysis of alternatives.

E.2.9. Technical feasibility

E.2.9.1. Sport technical performance

In discussing the following elements, we assume proper installation and maintenance of the pitches. Lack in maintenance of pitches will reduce e.g. the sport technical performance and the player safety of pitches, both for natural grass as for artificial turf.

E.2.9.1.1. Artificial grass pitch versus natural grass

As said, originally, natural grass have been used as sport pitch, as it provides more comfort and less risk of injuries, compared to sand, dirt, or stone. The characteristics of natural grass therefore may serve as a reference when looking at required sports technical performance of pitches.

According to FIFA, artificial grass is the best alternative to natural grass pitches. However, the product range of artificial turf shows significant quality differences between the various systems available. This is why FIFA developed a testing system for artificial pitches focusing on the needs of football players. This is the so-called FIFA Quality Programme. FIFA defines two quality marks in its program: FIFA QUALITY and FIFA QUALITY PRO[120]. The FIFA QUALITY mark is intended for recreational, community and municipal football, with typically 40-60 playing hours per week. The FIFA QUALITY PRO mark is intended for professional football for a typical usage of up to 20 playing hours per week. There are stricter

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[119] Millennium Ecosystem Assessment (2005) Ecosystems and human well-being; synthesis. Island Press, Washington, DC. https://www.millenniumassessment.org/documents/document.356.aspx.pdf

[120] The FIFA QUALITY and FIFA QUALITY PRO standards have replaced FIFA one star and FIFA two star standards. The latter two standards however, are sometimes still reported in references.

requirements for international match pitches covered in the quality mark IMS: International Match Standard.

Producers of artificial turf have the possibility to certify their installations. FIFA approval of a football turf pitch incorporates laboratory testing of the system and pitch testing after installation of the actual pitch of which the latter should be repeated periodically (every 5 years for FIFA QUALITY PRO) to ensure proper installation and maintenance. Quality criteria from FIFA cover elements like playing performance, safety, durability and quality assurance. An extensive number of quantitative indicators are addressed in the FIFA testing program, e.g. looking at interaction between the player and the surface, interaction between the ball and the surface, product composition, weather resistance, seam strength, service life. (FIFA, 2015A, FIFA, 2015B[121]).

E.2.9.1.2. Technical feasibility of performance infill in artificial pitches

There is EPDM, TPE and cork infill on the European market that is FIFA quality certified, implying that the sport technical performance requirements can be met with these types of infill. However, the sector also indicates that there are differences in quality between EPDM infill and between TPE infill of various suppliers.

Cork infill is debated for its sport technical performance. Various actors in the field are not very enthusiastic about the sport technical performance of cork infill. Cork is a very light material that can float on water potentially giving problems in heavy rain and windy weather conditions. Furthermore, cork is said to compact more during use compared to synthetic infill and has the tendency to pulverize. To improve sport technical performance, cork is also applied in combination with synthetic infill (personal communication synthetic turf sector, [122]).

E.2.9.1.3. Conclusion sport technical performance

For this dossier, artificial turf pitches, inclusive the infill with a FIFA quality label are assumed to have good sport technical performance.

E.2.9.2. Characteristics in extreme climates

Natural grass and artificial turf respond differently to various climatic conditions. Natural grass for example may get soaky and muddy in wet conditions and cannot be used during frost because the grass will be damaged. Artificial grass can be used in almost all weather conditions. Snow can be removed from the pitch if necessary and precipitation is not a problem. On the other hand artificial turf has the tendency to heat up in warm/hot weather, this problem is not observed for natural grass (Cheng et al., 2014, Simon Rachel, 2010).

Various studies are available that look at heating of artificial turf systems and natural grass in warm weather. TURI, Nov 2016 (US focus, Physical and biological hazard) reviewed a number of studies looking at the heat of artificial turf systems. Increased temperatures of

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[121] FIFA, 2015A. FIFA Quality Programme for Football Turf; FIFA, 2015B. FIFA Quality Programme for Football Turf, Handbook of Test Methods, October 2015 edition

[122] http://www.sportbelijning.nl/voetbal%20kunstgras%20instrooi%20infill.html

35-42F (average) and 102F (peak) have been reported at the surface. Peak surface temperature of 156F (69°C) was reported for the artificial grass fibers itself (polyethylene and polypropylene) and 200F (93°C) on a 98F (37°C) day for artificial turf. The highest surface temperature observed for natural grass was 60F (16°C). Synthetic turf reaches higher temperatures than natural grass, regardless of the type of infill material used (Turi, 2016). Studies however differ in whether types of infill used affect the heating effect of artificial turf. Irrigation is said to be able to reduce the temperature increase on artificial turf, however, this effect was not maintained for the length of an average sport event. Heating of the surface is said to lead to heat stress and skin injuries (blisters and burned skin). (TURI, Nov 2016). Jim, 2017 (Asian study) shows that on a sunny day artificial turf materials heat to over 70°C, attained at noontime and maintained in the early afternoon. The retained heat is in turn transferred to near-ground air by conduction and convection to raise air temperature to above 40 °C. Their joint impact on athletes can induce heat stress to exceed the safety threshold and harm their health and performance.

Currently, technologically advanced cool climate synthetic products which claim to reduce surface temperature of synthetic turf are available. Petrass et al., 2015 (Australia) compared surface temperatures of typical third-generation synthetic turf with a cool climate product and to natural grass. Mean surface temperatures were significantly lower (40.79 °C) on a cool climate pitch compared to a typical third-generation pitch (44.91 °C), although both synthetic pitches were considerably warmer than natural grass at the same venue (by 12.46 °C at the metropolitan venue and 22.15 °C at the regional venue). Villacañas et al., 2017 says that improvements in third generation of artificial turf are still unable to prevent the turf from reaching higher temperatures than natural grass. This situation results in customer dissatisfaction, decreased performance and the possibility of causing heat-related injuries. Dissatisfaction in use of artificial turf in hot weather may also relate to smell of the ELT derived infill material.

Table E 17: Overview of technical feasibility of various alternatives

Impact category	Sub-indicator	Artificial turf: ELT	Artificial turf: EPDM	Artificial turf: TPE	Artificial turf: Cork	Natural grass
Sport technical performance	FIFA quality	Natural grass pitches and all artificial turf pitches, inclusive the infill with a FIFA quality label are assumed to have good sport technical performance.				
Characteristics in extreme climates	Heating					Lower temperatures than artificial turf, regardless of the type of infill material used

E.2.10. Economic feasibility

In analysing the differences in costs between the artificial turf system with ELT infill and natural grass systems, and in analysing the differences in costs of artificial grass systems with ELT infill and artificial grass systems with a shockpad and other types of infill, it is important to consider the complete life-cycle costs. We will give an indication of the costs, including installation, maintenance and end of life related to the different pitches. As we want to compare costs of an installed pitch, we include the price the end customer has to pay (municipalities/sports clubs, etc.). Independent of the pitch structure, the size of a standard football pitch is assumed to be 7 600 m^2. We assume a lifetime of 10 years both for the natural grass and synthetic turf systems.

Turf installed in year 0 will be replaced in 10 years. The end-of-life costs of that specific pitch are in year 10. Discounted recycling costs (discount rate = 4 %) are 15,5 thousand euro’s for ELT, EPDM and Cork and 13,5 thousand euro’s for TPE and no-infill pitches.

The substructure underneath natural grass and synthetic turf however may have a longer lifetime with estimates ranging between 10 and 40 years. The costs of the sub-structure depend largely of the climate and soil-type. Table E 18 gives an overview of the different costs for the different artificial turf systems. As the costs of the substructure are equal for the four different types of artificial pitches, these will not be taken into account in Table 20. Due to this, the estimated costs of replacement in this Dossier are equal to the estimated costs of installing new pitches.

Table E 18: Cost per artificial turf systems with infill (costs in *€1 000 over 10 years period; discount rate 4 %))

	Artificial turf with ELT granules		**Artificial turf with EPDM granules**		**Artificial turf with solid TPE granules**		**Artificial turf with cork granules**	
Shockpad				40 (30- 45)		40 (30- 45)		40 (30- 45)
Installation of the shockpad				5,5		5,5		5,5
Artificial carpet with long piles	*6 cm*	100 (75-115)						
Artificial carpet with short piles			*3-4 cm*	85	*3-4 cm*	85	*3-4 cm*	85
Installation of the artificial carpet		26,6		26,6		26,6		26,6
Sand infill		8,0		12,8		12,8		12,8
Cost per ton sand infill (€/ton)	*€ 70*		*€ 70*		*€ 70*		*€ 70*	
Sand infill needed (kg/m2)	*15 kg/m2*		*24 kg/m2*		*24 kg/m2*		*24 kg/m2*	
Installation of the sand infill		2,7		3,0		3,0		3,0
Performance Infill		25,1		79,8		85,1		13,3
Cost per ton infill (€/ton)	*220 (180-500)*		*1750 (1400-2000)*		*1600 (1200-2000)*		*1350 (1000-1700)*	
Infill needed (kg/m2)	*15 (15-16.5)*		*6 (6-9.75)*		*7 (7-12.75)*		*1.3 (1.3-2)*	
Installation of the performance infill		2,7		2,7		2,7		2,7
Maintenance over 10 years inclusive infill refill		42,2		50,6		50,6		67,5
End of life costs, carpet and infill[1]		15,5		15,5		13,5		15,5
Total installation		165		255		261		189
Total maintenance		42		51		51		67
Total end-of-life		16		16		14		16
Total 10 years, excl. substructure		**223**		**322**		**325**		**272**

Sources: call for evidence, personal communication synthetic turf sector, taxatiewijzer sport, 2015

[1]Transport to disposal is not included in these end-of-life costs. The total costs of total cost for removal and disposal of an artificial pitch would be higher. The dossier submitter assumes that these costs are comparable for the different systems, so this will not have an impact on the analysis.

Table E 19 presents an overview of the costs of artificial turf with ELT infill, compared to grass and artificial grass without infill. Note that this overview does not account for the differences in intensity of use of the various systems. The all-in costs of the substructure will differ between natural grass and artificial turf with ELT infill. These costs will depend on the type of soil, and the climate at the location of the pitch.The costs of the substructure of a natural grass pitch (about 60 000 euros) in the Netherlands are significantly lower than the substructure of artificial pitches (about 140 000 euros). The extra costs for an artificial turf pitch without infill are based on an estimate for the extra costs for an artificial turf field without infill compared to artificial pitches with ELT granules. These costs are estimated to be about € 16,- per m^2, implying € 121 600 extra per pitch compared to an artificial pitch with ELT granules. The Dossier Submitter assumes a distribution over the different elements of the artificial pitch, by assuming that the maintenance costs of no infill pitches equals maintenance costs of pitches with ELT infill and by assuming that end-of-life costs equals the end-of-life costs of pitches with TPE infill.

Table E 19: The costs of an artificial turf system with ELT infill compared with other systems (costs in *1000 € over 10 years period; discount rate 4 %). Note that this overview does not account for the differences in intensity of use of the various systems.

	Artificial turf with ELT granules		No -infill		Natural grass	
Substructure	*€ 140,000 (lifetime about 40 years)*		*€ 140,000 (lifetime about 40 years)*		*€ 60,000 (lifetime about 40 years)*	
Total installation		165		287		40
Total maintenance		42		42		81
Total end-of-life		16		14		0
Total 10 years, excl. substructure		223		343		121
Total 10 years, incl. substructure		363		483		181

Sources: call for evidence; personal communication synthetic turf sector; taxatiewijzer sport, 2015

E.3. Restriction scenarios

To analyze the impacts of possible restriction options, in this Dossier an impact assessment of the following two restriction options is carried out:

Restriction option 1 (RO1) ("17 mg/kg limit value"): this restriction option covers the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 17 mg/kg (0.0017 % by weight of this component) of the sum of the listed PAHs. The specific limit value reflects the 95^{th} percentile of the REACH-8 PAH concentration in measurements taken from synthetic turf pitches, i.e. at the moment 5 % of the ELT volume sold and hence 5 % of ELT pitches in the EU are expected to be above this concentration limit.

Restriction option 2 (RO2) ("6.5 mg/kg limit value"): this restriction option covers the placing on the market of granules and mulches as infill material for synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 6.5 mg/kg (0.00065 % by weight of this component) of the sum of the listed PAHs. The specific limit value reflects the REACH-8 PAH concentration below which the lifetime excess cancer of all individuals exposed stays below $1x10^{-6}$.

Table E 20 and Table E 21 present an extensive overview of the expected impacts of these two restriction options compared to the baseline situation per relevant actor. The tables also present an explanation of the expected impacts, sources used and assumptions made in defining the expected impacts. In this analysis, we want to be as complete as possible with respect to identification of the relevant effects. Per effect, we indicate whether and how it will be taken into account in the further analysis. Potential quantification and valuation of welfare effects is presented in the following sections. Note that the calculations were performed to get an idea of the order of magnitude of the expected welfare effects. The actual outcomes of the calculations are presented here to facilitate the reproducibility of calculations. In the Annex XV Restriction Dossier (main report) the estimates have been rounded.

E.3.1 Overview of the expected impacts of RO1 and RO2 compared to he baseline

Table E 20: Overview of the expected effects of RO1, a 17 mg/kg limit value, compared to the baseline situation

Actor	Actors' role	RO1: Expected effects in case of a 17 mg/kg limit value:	Explanation, sources and assumptions
Producers of recycled rubber mixtures	Producers of ELT/other recycled rubber granules, mulch for sport and play activities and other applications of ELT (material and energy recovery)	• Extra costs for measures to guarantee compliance	R1.1. As can be seen in Figure D 2 in Annex D: Baseline, 95 % of the ELT infill that is produced in the EU or that is found on the pitches currently is below the concentration of 17 mg/kg for the REACH-8 PAH. The Dossier Submitter assumes that this distribution of PAHs is representative for the EU. 5 % of the recycled granules currently are thus expected not to comply with the 17 mg/kg limit value and are not suitable for use in synthetic turf pitches. (Part of) the recycling companies will have to take measures to comply, e.g. by improved selection of material inflow. It may also be the case that measures to reduce PAH content show to be insufficient and that companies need other markets for this non-compliant part (other material reuse or energy recovery).
		• Increase in costs to test for PAH content to guarantee compliance	R1.2. It is assumed that the infill granules produced as performance infill will be tested per pitch for PAH content, as it is expected that the market/sector will ask for that. Part of the infill producers (assumption: 50 % of the producers) already test all batches of their infill granules on PAH content in the Baseline situation, due to societal demand. This is not the case for all European producers (assumption: 50 % of the producers), so implementation of the restriction will result in an increased frequency in testing for PAH content for these companies.
		• Potential change in company structure and jobs *(not further considered)*	R1.3. Extra costs could imply a change in company structure in the ELT waste managing sector. For example, as indicated by ETRMA (2018), smaller companies may have difficulties to survive in a higher cost situation and companies may try to reduce costs by increasing production efficiency, reducing the number of employees. Extra costs, however, could also be passed on to tyre manufacturers who are responsible for waste management of tyres. What will happen in practice will probably differ per company and per country and is difficult to estimate. As the percentage of ELT derived infill that may not comply with the limit value is at maximum 5 %, we assume that all companies are capable to remain in business.
		• No change in quantities of ELT infill sold *(not further considered)*	R1.4. The price of ELT infill is assumed to increase slightly due to the additional measures that are to be taken. This may make alternative infill somewhat more competitive. However, as alternatives remain significantly more expensive compared to ELT, this is assumed not to affect the quantities of ELT infill sold. The Dossier Submitter assumes that the trend in use of various types of infill is comparable to the baseline situation implying a slight reduction in the use of ELT and increase in the use of alternatives. (R1.1)
			R1.5. It is noted that companies depend on ELT tyres as input for producing ELT

Actor	Actors' role	RO1: Expected effects in case of a 17 mg/kg limit value:	Explanation, sources and assumptions
		• Increased business risk *(not further considered)*	granules. The companies have limited influence on their input material and may have limited possibility to make sure that the infill produced indeed complies with the limit value. This will result in some business risk for the infill producing companies. It will require a certain flexibility from companies, e.g. to make sure that they are flexible in selling their infill products on other markets, if the infill produced turns out not to be compliant. R1.6. According to actors in the field there is variation in the results of PAHs tests depending on the test method and the lab performing tests. They perceive this as an important uncertainty for the industry as it depends on the lab test whether they comply with the limit. However, there is no scientific study found showing this effect and the variation in the available information on PAHs content of the available samples appears to be limited. Currently, 95 % of the 1 234 samples are below the 17 mg/kg limit.
Tyre manufacturers	Actors responsible for the management of ELTs	• No effect	R1.7. Although waste management for the production of ELT infill may become somewhat more expensive, it is expected that this increase in price can be passed on to the buyers (owners) of sport and play facilities and not result in an increase in waste management costs for tyre manufacturers. Infill covers only 15 % of the total EU tyre recycling market (see Annex A). (R1.5)
Non-ELT performance infill producers	Producers of other types of infill: EPDM, TPE, cork, etc.	• No effect	R1.8. See above (R1.4).
Artificial turf producers	Actors that develop artificial turf systems, produce the turf (piles) and potentially other elements of the systems (shockpad, sand) and sell the complete artificial turf systems	• No effect	R1.9. The Dossier Submitter assumes no early replacement and no replacement to alternatives. The major question here is how the public and market actors will respond to a limit value based on proportionality considerations vs a 6.5 mg/kg limit value. Societal concern may remain in this scenario as ELT remains to be used. There is no information available to assess this potential effect of early replacement due to societal concern.
Artificial pitch	Companies and	• Reduction in health risk due to prevention of	R1.10. Exposure and health risk reduction due to a shift of the distribution of

Actor	Actors' role	RO1: Expected effects in case of a 17 mg/kg limit value:	Explanation, sources and assumptions
installation and maintenance companies	employees responsible for installation and maintenance. Maintenance may be done by maintenance companies or pitch owners/users	infill with PAH content above 17 mg/kg	PAH concentrations in ELT granules and mulches in the EU to below 17 mg/kg. Furthermore, high PAH concentrations are avoided that may occur in the baseline due to the high limit value for mixtures that currently applies to granules and mulches in sport and play applications, see Figure E 2.
Natural grass construction and maintenance companies	Companies and employees responsible for construction and maintenance. Maintenance may be done by pitch owners/users	• No effect	R1.11. See above (R1.4 and R1.9). The Dossier Submitter does not expect a change in turf systems due to the restriction.
Municipality/ sport clubs/ schools/ private-sector companies	Owners/tenants of the pitches and playgrounds	• (Slightly) increased price of artificial turf with ELT derived infill	R1.12. Due to a slightly higher price of ELT infill.
Athletes (e.g. football player, goalkeeper, including professionals), parents and little siblings, children playing	Users of the pitches and playgrounds	• Reduction in health risk due to prevention of infill with PAH content above 17 mg/kg • Change in societal concern related to potential health effects of the use of recycled rubber infill • No change in costs to sport/play *(not further considered)*	R1.13. See R1.10, exposure and health risk reduction due to a shift of the distribution of PAH concentrations in ELT granules and mulches in the EU to below 17 mg/kg. Furthermore, high PAH concentrations are avoided that may occur in the baseline due to the high limit value for mixtures that currently applies to granules and mulches in sport and play applications, see Figure E 2. R1.14. In some EU countries (e.g. Netherlands, France) there is societal concern linked to the use of ELT/recycled rubber infill material on artificial turf. Societal concern may be reduced by this restriction as high PAH concentrations are avoided. Societal concern could remain as ELT remains to be used and there may be societal concerns related to that e.g. linked to other (environmental) issues. The Dossier Submitter does not know whether this may result in early replacement of existing pitches and this is not further considered. R1.15. Sports (including football) in the EU are a merit good, local authorities support it by giving subsidies and providing access to publicly owned sport facilities for free or at a reduced price to stimulate sport and to reduce

Actor	Actors' role	RO1: Expected effects in case of a 17 mg/kg limit value:	Explanation, sources and assumptions
			inequalities in physical activity. The level in which this happens varies across different European countries (Breuer et al., 2017, Ibsen et al., 2017, Ward et al., 2017). Based on this information, the Dossier Submitter assumes that in the EU28, local authorities will finance the extra costs for the pitches which implies no extra cost for the users of pitches. The same is assumed for the playgrounds that make use of infill/loose granules/mulch.
Waste managers of artificial turf	Organizations dealing with artificial turf waste (landfilling, incineration or recycling)	• No effect	R1.16. The limit value is not expected to change waste handling activities of artificial turf.
Citizens /general EU population	Tax payers and 'users' of natural resources	• Change in societal concern related to potential health effects of the use of recycled rubber infill • Potential slight increase in costs for sport pitch and public playground	R1.17. See above (R1.14). R1.18. See above (R1.15): slightly increased price for artificial turf systems are assumed to be financed by local authorities. These costs may be passed on to the tax payers.
Car/truck drivers	Users of tyres	• No effect	R1.19. See above (R1.8)
National government	Actors responsible for enforcement	• Increased enforcement costs (compliance costs)	R1.20. Enforcement authorities may make extra costs to check compliance of market actor e.g. by performing checks on paper or by testing samples on PAH concentration.

Table E 21: Overview of the expected effects of RO2, a 6.5 mg/kg limit value, compared to the baseline situation

Actor	Actors' role	RO2: Expected effects in case of a 6.5 mg/kg limit value:	Explanation, sources and assumptions
Producers of recycled rubber mixtures	ELT waste managers and producers of granules, mulch for sport/play activities and potentially other ELT derived products	• End of market for rubber granules in artificial turf and lose applications on sport pitches and playgrounds • Increase of other options of ELT/rubber recycling • Increase in costs of tyre recycling	R2.1. Currently 14 % of the ELT derived infill is expected to comply with the 6.5 mg/kg value (see Appendix E1). It is expected not to be possible for recycling companies to assure stable PAH concentrations over time at or below the proposed limit value as recycling companies are expected to have limited possibilities to influence PAH concentrations in their recycling streams. R2.2. As can be seen in Annex A, various options for recycling of tyres are available. It is unclear, however, what the demand for these other options is. What is known is that these other options compared to ELT performance infill are less profitable. As landfilling is forbidden in the EU,

Actor	Actors' role	RO2: Expected effects in case of a 6.5 mg/kg limit value:	Explanation, sources and assumptions
		• Potential change in company structure and jobs	alternative use of ELT will either be other types of ELT material reuse or energy recovery (in cement kilns). For this assessment, three different scenarios are developed (energy recovery at a cost, energy recovery at a small price and material reuse at a price below ELT infill) to get an impression of the order of magnitude of these extra costs. R2.3. Extra costs could imply a change in company structure in the ELT waste managing sector. For example, as indicated by ETRMA (2018), smaller companies may have difficulties to survive in a higher cost situation and companies may try to reduce costs by increasing production efficiency, reducing the number of employees. Extra costs, however, could also be passed on to tyre manufacturers who are responsible for waste management of tyres. What will happen in practice will probably differ per company and per country and is difficult to predict.
Tyre manufacturers	Actors responsible for the management of ELTs	• Potential increase in price of new tyres	R2.4. Due to an increase in costs of tyre recycling. See above (R2.3)
Non-ELT performance infill producers	Producers of other types of infill: EPDM, TPE, cork, etc.	• Increased market for non-ELT performance infill in newly installed pitches, re-fill and in potential early replacement of existing pitches and in refill of existing pitches	R2.5. As no ELT derived infill can be used anymore (See R2.1.), alternative types of infill will be used for all newly installed artificial pitches and for refills. R2.6. Due to societal concern, some existing pitches may face early replacement (ETRMA 2018). In this impact analysis, the Dossier Submitter does not quantify early replacement and assumes that the total number of artificial turf pitches per year (including growth of pitches) is the same as in the baseline. Note that if early replacement will occur in practice as a consequence of this RO2, this may be a relevant effect that is not accounted for in this impact assessment. R2.7. For infill used in the newly installed (only no-ELT) pitches and refills, the following is assumed: 43 % EPDM, 43 % TPE, 14 % cork in the first year after the introduction of the restriction; gradual introduction up to 5 % no infill installation over 10 years (and 40 % EPDM, 40 % TPE, 15 % cork). Shares are the Dossier Submitters best estimate based upon responses received during the 24 November 2017 workshop and personal communication. R2.8. Increase in demand of these other types of infill materials could reduce price due to economies of scale or could increase price in case of market shortage. In the 24 November 2017 workshop it was said that within some years increased production capacity can be realized by the market and thus, market shortage is not to be expected. Whether price may be

Actor	Actors' role	RO2: Expected effects in case of a 6.5 mg/kg limit value:	Explanation, sources and assumptions
			reduced due to economies of scale is not known and is not further considered.
Artificial turf producers	Actors that develop artificial turf systems, produce the turf (piles) and potentially other elements of the systems (shockpad, sand) and sell the complete artificial turf systems	• Increase in artificial turf demand because of potential early replacement of existing pitches *(not further considered)* • Increase in demand of specific types of artificial turf systems and elements within that system • Market opportunity for innovative artificial turf structures, like turf without infill	R2.9. See above (R2.6) R2.10. Due to the fact that virgin infill is more expensive, artificial turf with alternative infill makes use of another system that require less infill (shorter pile + shockpad[123]). It is expected that in case of early replacement, this will happen for the complete artificial turf system and not only the infill. In this impact analysis, the Dossier Submitter does not quantify early replacement. R2.11. See above (R2.10). Another artificial turf system has other material requirements. Somewhat less material will be needed for the turf itself, a shockpad is needed below the turf that is not used in case of ELT and the system makes use of a larger amount of sand infill. R2.12. Artificial turf systems without infill are currently developed by artificial turf producers (personal communication synthetic turf sector). The first systems with a FIFA Quality Pro certificate is installed in 2018 (test pitches in NL, personal communication Municipality of Utrecht). For this dossier, we assume that these innovative systems without infill will enter the market gradually in the coming years: 5 % of the new installations over 10 years.
Artificial pitch installation and maintenance companies	Companies and employees responsible for installation and maintenance. Maintenance may be done by maintenance	• Increased market because of other installation requirements for artificial turf systems with alternative infill/no-infill • Increased market because of early replacement of existing pitches (*not further considered)* • Increased market due to (slightly) more frequent maintenance in case of cork (and EPDM and TPE infill)	R2.13. See above (R2.6 and R2.10) R2.14. Based on the information available on the maintenance costs in case of alternative infill, a slight increase in maintenance costs in case of EPDM and TPE and a substantial increase in case of cork is assumed[124]. Without

[123] A schokpad is used to obtain proper shock absorption in the system. Shockpads are mainly made of foam. ELT can be used in so called e-layers, which have a shock damping effect as well.
[124] Personal communication with installers and owners of fields (communication synthetic turf sector) and Bouwman consulting, 2016 (online: http://loudoun.granicus.com/MetaViewer.php?view_id=68&clip_id=4389&meta_id=96276).

Actor	Actors' role	RO2: Expected effects in case of a 6.5 mg/kg limit value:	Explanation, sources and assumptions
	companies or pitch owners/users	• Reduction in health risk for employees responsible for installation and maintenance due to reduction in PAHs content • Potential reduction of other human health risk for employees due reduction in other hazardous chemicals	having information, the Dossier Submitter assumes that artificial turf without infill require equal maintenance compared to ELT. R2.15. For new installations and maintenance, contact of employees with ELT derived infill will (gradually) be replaced by contact with alternative types of infill. Exposure and health risk due to PAHs in ELT granules and mulches in the EU are avoided for the newly installed pitches. Furthermore, high PAH concentrations are avoided that may occur in the baseline due to the high limit value for mixtures that currently applies to granules and mulches in sport and play applications, see Figure E 2. Although there is uncertainty around the actual composition of alternatives e.g. EPDM and TPE infill and there appears to be variation in composition between infill producers (see Annnex E.2.), in general virgin EPDM and TPE are expected to contain less hazardous chemicals (including PAHs) compared to ELT. With respect to cork, limited information is available to conclude upon potential health hazards of chemicals, however, these are deemed unlikely. Related to the potential use of pesticides/herbicides/fungicides during maintenance there is no information to conclude upon differences between various types of infill and potential related risks.
Natural grass construction and maintenance companies	Companies and employees responsible for construction and maintenance. Maintenance may be done by pitch owners/users	• No effect	R2.16. As can be seen in the Analysis of Alternatives section (Annex E.2.), natural grass has different characteristics compared to artificial turf. Especially, the intensity of play, i.e. the difference in hours that can be played on the different types of pitches resulting in different m^2 land use, is deemed important. Because of this, the Dossier Submitter assumes no substitution to natural grass in this scenario. This is in line with the signals received from stakeholders during the 24 November 2017 workshop.
Municipality/ sport clubs/ schools/ private-sector companies	Owners/tenants of the pitches and playgrounds	• Increased costs for newly installed (mini-) pitches and for replacement of (mini-) pitches and potential change in maintenance costs	R2.17. As indicated in Annex E.2., artificial turf systems with EPDM, TPE and cork infill and no-infill systems are more expensive compared to artificial turf with ELT-derived infill. R2.18. See above (R2.6, R2.10 and R2.14) and see below (R2.20)
Athletes (e.g. football players, goalkeepers, including professionals), parents and little	Users of the pitches and playgrounds	• Reduction in health risk due to reduction in PAHs for professional/amateur players, keepers, children/adults playing (sports) • Potential reduction of other human health risk due to reduction in other hazardous chemicals	R2.19. Contact of the users of pitches with ELT derived infill will gradually be replaced by contact with alternative types of infill. Exposure and health risk due to PAHs in ELT granules and mulches in the EU are avoided for the newly installed pitches. Furthermore, high PAH concentrations are avoided that may occur in the baseline due to the high limit value for mixtures that currently applies to granules and mulches in sport and play

Actor	Actors' role	RO2: Expected effects in case of a 6.5 mg/kg limit value:	Explanation, sources and assumptions
siblings, children playing			applications, see Figure E 2. Although there is uncertainty around the actual composition of e.g. EPDM and TPE infill and there appears to be variation in composition between infill producers (see Annex E.2.), in general virgin EPDM and TPE are expected to contain less hazardous chemicals (including PAHs) compared to ELT. With respect to cork, limited information is available to conclude upon potential health hazards of chemicals, however, these are deemed unlikely. Related to the potential use of pesticides/herbicides/fungicides during maintenance there is no information to conclude upon differences between various types of infill and potential related risks for end users of pitches.
		• No change in costs to sport/play *(not further considered)*	R2.20. As indicated in RO1 above, sports (including football) in the EU are a merit good, local authorities support it by giving subsidies and providing access to publicly owned sport facilities for free or at a reduced price to stimulate sport and to reduce inequalities in physical activity. The level in which this happens varies over different European countries (Breuer et al., 2017, Ibsen et al., 2017, Ward et al., 2017). Based on this information, the Dossier Submitter assumes that in the EU28, local authorities will finance the extra costs for the pitches which imply no extra cost for the users of pitches. Same is assumed for the playgrounds that make use of infill/loose granules/mulch.
		• Change in societal concern related to the use of recycled rubber infill	R2.21. In some EU countries (e.g. Netherlands, France) there is societal concern linked to the use of ELT/recycled rubber infill material on artificial turf. It is expected that in 10 years' time, all pitches using (ELT derived) recycled rubber will be replaced by artificial pitches using other types of infill, which will in time end the societal concern. The restriction is intended for the newly installed pitches and thereby intends not to affect the existing pitches. This may lead to a temporal increased societal concern related to the use of recycled granules on existing pitches. As said, this may lead to early replacement of existing pitches (see R2.6).
		• (Perceived) change in performance quality (depending of the system/infill change)	R2.22. Other types of infill or other types of artificial pitches (no infill) may have other (perceived) sport technical performance characteristics. Various actors in the field, for example are not very enthusiastic about the performance of cork. Or actors may have a preference for the performance of a specific type of infill or system. All types of infill and pitches included in this analysis, however, can comply with the FIFA Pro qualification and thus can meet this benchmark of performance quality.
Waste managers of artificial turf	Organizations dealing with	• Increase in recycled rubber infill and artificial turf waste due to early replacement of	R2.23. See above (R2.6 and R2.10)

Actor	Actors' role	RO2: Expected effects in case of a 6.5 mg/kg limit value:	Explanation, sources and assumptions
	artificial turf waste (landfilling, incineration or recycling)	artificial turf pitches *(not further considered)* • Change in waste composition may influence the waste handling possibilities	R2.24. Newly installed pitches will consist of different materials (infill, sand, shockpad) compared to systems with ELT. See above (R2.10 and R.2.11). R2.25. Existing pitches using ELT derived granules (if not early replaced) will be refilled every year with an alternative type of infill. This will have the consequence of waste managers facing mixed waste streams. R2.26. The Dossier Submitter assumes that the restriction does not affect the type of end of life treatment of artificial turf systems (landfilling, incineration or recycling) as no further information is available.
Citizens /general EU population	Tax payers, 'users' of natural resources	• Increase in costs for sports pitches and public playground *(not further considered)* • Reduction of environmental risk due to reduction in PAHs (and potentially other hazardous chemicals) • Change in other environmental effects (CO_2, microplastics)	R2.27. See above (R2.10 and R2.17): increased price for artificial turf systems are assumed to be financed by local authorities. Depending on the institutional system, this will e.g. lead to increase in local municipality tax and costs are thus expected to be (indirectly) paid by EU citizens. R2.28. ELT derived infill will (gradually) be replaced by alternative types of infill. There is environmental concern related to the use of ELT infill e.g. due to potential leakage of hazardous chemicals to soil and water systems (e.g. zinc). Although there is uncertainty around the actual composition of EPDM and TPE infill as alternatives and there appears to be variation in composition between infill producers (see Annex E.2.), in general virgin EPDM and TPE are expected to contain less hazardous chemicals (including PAHs) compared to ELT. With respect to cork, limited information is available to conclude upon potential environmental hazards of chemicals, however, these are deemed unlikely. Related to the potential use of pesticides/ herbicides/ fungicides during maintenance there is no information to conclude upon differences between various types of infill and potential related environmental risks. Environmental risks of hazardous substances in ELT are out of scope of this restriction proposal and have not been assessed in the risk assessment of Annex B. It may however be relevant in terms of impacts of RO2. Therefore, it will be discussed briefly in the impact assessment. R2.29. Replacement of ELT infill by cork or replacement of the artificial pitch by a no infill system will reduce the amount of microplastics that enter the environment. Also, replacement of ELT with EPDM or TPE is expected to reduce the emission of microplastics as lower quantities of infill are used in these systems and as these materials tend to spread less easily to the environment (Weijer and Knol, 2017). R2.30. Replacement of recycled rubber infill by virgin EPDM or TPE will increase CO_2 emissions (see Annex E.2.).

Actor	Actors' role	RO2: Expected effects in case of a 6.5 mg/kg limit value:	Explanation, sources and assumptions
		• Change in societal concern related to the use of recycled rubber infill	R2.31. See R2.21. Furthermore, some environmental issues may remain as majority of the alternatives are expected to be synthetic materials as well (EPDM and TPE; microplastics) and for example EPDM also contains (lower) quantities of zinc that may pose an environmental concern as well and as ELT may be used in an e-layer below artificial turf pitches using non-ELT infill material.
Car/truck drivers	Users of tyres	• Potential increase in price of new tyres *(not further considered for this actor)*	R2.32. Due to an increase in waste management costs. See above (R2.3)
National government	Actors responsible for enforcement	• Increased enforcement costs (compliance costs)	R2.33. As the difference between ELT derived infill and alternative types of infill is visual, no (expensive) tests are expected to be needed. Furthermore, at least in parts of the EU where there is a societal concern around the use of recycled rubber infill, actors in society may well check compliance. In other parts of the EU, some visual inspection may be performed.

Note: The Dossier Submitter is aware of the fact that sport pitches and playgrounds are (partly) financed by charity organizations and sponsors. For this analysis, we assume the budgets of these organizations as fixed implying that a change in costs has to be attributed to other actors (included in the Table 2 above, R2.17 and R2.20)

E.3.2 Numbers and types of newly installed pitches under different scenarios

In Annex D, the current (baseline) situation in terms of the use of artificial turf and infill in the EU and the expected trends that would occur without the introduction of any new regulatory measure are described. In the baseline, part of the newly installed pitches are moving away from ELT infill materials to alternative infill material. The number of new and total number of pitches installed per type of infill material will be the same in the baseline and RO1. To assess the impact of the limit value in RO2, the expected trend after the introduction of a limit value of 6.5 mg/kg is presented in this Section. The number of newly installed pitches is necessary to assess the economic impacts of such limit value. To estimate the health and environmental impacts, the total number of the different types of artificial pitches is needed as well.

The total number of new and overall artificial turf pitches and mini-pitches is assumed to equal the baseline situation. However, distributions over pitch and infill types are different in RO2. In RO2, all newly installed pitches will be pitches with alternative performance infill, or pitches without infill. The Dossier Submitter assumes that in the year after entry into force 43 % of the performance infill will be EPDM, 43% TPE and 14 % cork. After 10 years, 40 % will be EPDM, 40 % TPE, 15 % cork and 5 % no-infill. This distribution is assumed to be equal for pitches and mini-pitches. An overview of the types of pitches in the baseline scenario, RO1 and in RO2 is given in Table E 22, Table E 23, Table E 24 and Table E 25.

Table E 22: Number of (new and re-) installed artificial pitches, per type of infill in the EU in the baseline, RO1 and RO2

Year after entry into force	Total installed	Baseline and RO1				RO2				
		ELT	**EPDM**	**TPE**	**cork**	**ELT**	**EPDM**	**TPE**	**cork**	**No-infill**
1	3 215	2 829	154	154	77	0	1 383	1 383	450	0
2	3 415	2 937	191	191	96	0	1 457	1 457	482	19
3	3 626	3 046	232	232	116	0	1 535	1 535	516	40
4	3 851	3 158	277	277	139	0	1 618	1 618	552	64
5	4 090	3 272	327	327	164	0	1 704	1 704	591	91
6	4 344	3 388	382	382	191	0	1 796	1 796	632	121
7	4 614	3 506	443	443	221	0	1 892	1 892	677	154
8	4 900	3 626	510	510	255	0	1 993	1 993	724	191
9	5 204	3 747	583	583	291	0	2 099	2 099	775	231
10	5 527	3 869	663	663	332	0	2 211	2 211	829	276

Table E 23: Number of (new and re-) installed artificial mini-pitches, per type of infill in the EU in the baseline, RO1 and RO2

Year after entry into force	Total installed	Baseline and RO1				RO2				
		ELT	**EPDM**	**TPE**	**cork**	**ELT**	**EPDM**	**TPE**	**cork**	**No-infill**
1	4 925	4 433	197	197	99	0	2 237	2 237	728	0
2	5 203	4 578	250	250	125	0	2 345	2 345	775	31
3	5 496	4 726	308	308	154	0	2 457	2 457	826	65
4	5 805	4 876	372	372	186	0	2 575	2 575	879	102
5	6 132	5 028	442	442	221	0	2 699	2 699	936	144
6	6 477	5 182	518	518	259	0	2 828	2 828	996	190
7	6 842	5 337	602	602	301	0	2 963	2 963	1 060	241
8	7 227	5 493	694	694	347	0	3 105	3 105	1 128	297
9	7 634	5 649	794	794	397	0	3 253	3 253	1 201	358
10	8 064	5 806	903	903	452	0	3 407	3 407	1 278	426

Each year, the 10-year old pitches will be replaced. For the calculation of the distribution of the different types of infill in RO2, the Dossier Submitter assumes that all the ELT pitches in use in 2018 are replaced between 2019 and 2020, 10 % per year.

Table E 24: Number of artificial pitches, per type of infill in the EU in the baseline, RO1 and RO2

Year after entry into force	Total	Baseline and RO1				RO2				
		ELT	**EPDM**	**TPE**	**cork**	**ELT**	**EPDM**	**TPE**	**cork**	**No-infill**
1	19 841	17 460	952	952	476	15 132	1 974	1 974	760	0
2	21 072	18 122	1 180	1 180	590	13 451	3 212	3 212	1 163	34
3	22 380	18 799	1 432	1 432	716	11 770	4 461	4 461	1 585	103
4	23 768	19 490	1 711	1 711	856	10 088	5 723	5 723	2 024	209
5	25 243	20 194	2 019	2 019	1 010	8 407	6 999	6 999	2 484	353
6	26 809	20 911	2 359	2 359	1 180	6 726	8 291	8 291	2 964	537
7	28 472	21 639	2 733	2 733	1 367	5 044	9 600	9 600	3 466	762
8	30 239	22 377	3 145	3 145	1 572	3 363	10 927	10 927	3 991	1 031
9	32 115	23 123	3 597	3 597	1 798	1 681	12 274	12 274	4 541	1 344
10	34 107	23 875	4 093	4 093	2 046	0	13 643	13 643	5 116	1 705

Table E 25: Number of artificial mini-pitches with performance infill, per type of infill in the EU in the baseline, RO1 and RO2

Year after entry into force	Total	Baseline and RO1				RO2				
		ELT	**EPDM**	**TPE**	**cork**	**ELT**	**EPDM**	**TPE**	**cork**	**No-infill**
1	33 282	28 622	1 598	1 598	799	26 958	2 634	2 634	1 055	0
2	35 156	30 234	1 969	1 969	984	25 312	4 133	4 133	1 537	41
3	37 136	31 194	2 377	2 377	1 188	23 396	5 765	5 765	2 082	128
4	39 227	32 166	2 824	2 824	1 412	21 183	7 541	7 541	2 694	269
5	41 437	33 149	3 315	3 315	1 657	18 646	9 470	9 470	3 379	471
6	43 770	34 141	3 852	3 852	1 926	15 757	11 562	11 562	4 146	743
7	46 235	35 139	4 439	4 439	2 219	12 484	13 829	13 829	5 001	1 094
8	48 839	36 141	5 079	5 079	2 540	8 791	16 282	16 282	5 951	1 533
9	51 590	37 145	5 778	5 778	2 889	4 643	18 934	18 934	7 006	2 073
10	54 495	38 147	6 539	6 539	3 270	0	21 798	21 798	8 174	2 725

The Dossier Submitter is aware of the societal concern related to ELT granules. A limit value of 6.5 mg/kg may have the effect that some existing pitches face an early (i.e. unscheduled) replacement (ETRMA, 2018). In the impact analysis presented here, the Dossier Submitter does not consider the costs and benefits of such early replacements.

E.4. Economic impacts[125]

E.4.1 Economic impacts of RO1

An overview of the main economic impacts of RO1, based on a limit value of 17 mg PAHs per kg, are given in Table E 26

Table E 26: Main market impacts of RO1 compared to Baseline in the first 10 years after entry into force (in € million, discount rate 4 %)

Actors **Impacts**	*Producers of recycled rubber mixtures*	*Test companies (labs)*	*Municipalities/owners of pitches*	*EU citizens*	**Impacts to society**
Cost of compliance for ELT recyclers	-41 (-23 to -48)		(x[1])	x[1]	-41 (-23 to -48)
Increase in test costs for ELT recyclers		3	x[1]		-3
Total	-41 (-23 to -48)	3	x[1]	x[1]	-44 (-26 to -51)

Currently, 95 % of the recycled granules already comply with the 17 mg/kg concentration limit value (see Annex D, estimate based on 1 234 available samples). Based on these test results, around 5 % of the granules are expected not to comply and will not be suitable for use in synthetic turf pitches after implementation of RO1. According to rubber granules producers and test laboratories, there is a variation in the results of PAHs tests depending on the test method and the lab performing tests. They perceive this as an important uncertainty for the industry as it depends on the lab test whether they comply with the limit. However, no scientific study was found that would show this effect. Indeed, the Dossier Submitter perceives the variation in the available PAH samples to be limited.

Measures to reduce PAH content

Some of the recycling companies will have to take measures to comply to RO1, e.g. by improved selection of material inflow to ensure they fully comply with the limit value. The Dossier Submitter assumes that costs related to production could slightly increase, but evidence suggests that these costs will be less than the expected loss from placing the granules on other markets. Therefore, the former costs that will be taken into account in assessing the regulatory burden of the proposed restriction is likely to be partially passed

[125] In

Table E 18, the key parameters used in this section are given (e.g. the costs per ton infill, the total tonnes infill per pitch and the total costs per pitch).

through to the buyers (mostly communities and sport clubs) and this would imply a slight increase in the price of ELT derived infill material. It is thus reasonable to assume that tax payers will eventually have to bear a part of the restriction's implied costs.

Other market for ELT granules

However, it may also be that measures to reduce the PAH content show to be insufficient and that companies need other markets for the non-compliant part of the recycled material (i.e. other material reuse or energy recovery). As can be seen from Figure A 2 in Annex A, other applications for ELT are currently available. As explained in Annex E.4.2.1, the value of ELT on other markets will be lower than that of ELT performance infill. As most ELT producers sell their granules on different markets, the ELT infill that does not comply can be sold for alternative use and, as quantities are limited, losses would probably be marginal. Assuming that all non-compliant performance infill has to be sold on other markets, 5 % of the total performance infill has to be sold for a lower price. In Annex E.4.2.1 , different scenarios for alternative ELT markets are described and the possible impact stemming from each of these scenarios is quantified. As an indication, for the maximum costs of RO1[126], the costs in case of scenario 1 "granules sold on energy market, the price of tyre-derived fuel granules is slightly positive" are calculated. This implies that the costs 10 years after entry into force correspond to 5 % of the lost revenue of the ELT sector, sold at a lower price assumed to be 5 euro per ton ELT results in a loss of about 41 million € for the ELT sector. <u>The total loss of the ELT sector is hence estimated to be between 23 and 48 million € in the first 10 years after the restriction has come into force.</u>

Table E 27: Total value of ELT granules sold on other markets than ELT for the recycling sector in the baseline and in RO1 (discount rate 4 %)

	Selling price (€) per ton rubber granules	Total selling price of ELT granules in baseline and RO1 over 10 years after entry into force (€ million)	Lost revenue for the ELT sector over 10 years after entry into force (€ million)
Baseline: price of rubber granules for artificial pitches	220	42	
RO1, Scenario 1: Granules sold on energy market and the price of tyre derived fuels granules is slightly positive (2015 price)	5	1	-41
RO1, Scenario 2: Granules sold on energy market and the price of tyre derived fuels granules is negative (gate fee paid 1995-2015)	-30	-6	-48
RO1, Scenario 3: Granules sold on alternative material market, but at lower price	100	19	-23

[126] It is expected that the price of 5€ per ton ELT is at the low end of what ELT recycling companies can get for their material. They may as well be able to sell their material to other alternative material markets at higher prices. As the increase in supply of granules to the alternative market remains limited in RO1 (5 %), this is not expected to change the price at which the material can be sold for the alternative use in the baseline, the price for ELT infill used for energy recovery. Cost will therefore not be higher than this maximum estimate. Costs for the ELT sector may be lower.

Extra compliance testing
Besides the potential business losses described above, the Dossier Submitter assumes that potential extra costs for measures to guarantee compliance need to be taken. A rough estimate of the potential size of these costs is given below for illustrative purposes. The Dossier Submitter assumes that the infill granules produced as performance infill will be tested for PAH content before refilling a pitch, as it is expected that the market/sector will ask for that. Due to this, the costs for an artificial pitch with ELT infill will slightly increase. Some of the infill producers already test all batches of their infill granules on PAH content in the Baseline situation, due to societal concern with respect to ELT granules, and due to this concern, a societal demand for testing in some countries. As societal concern differs between countries, this is expected not to be the case for all European producers. It is assumed that implementation of the restriction will result in an increased frequency of testing for PAH content affecting 50 % of the producers (assumption that 50 % of producers do already perform tests regularly). The costs per test of one sample of ELT performance infill are estimated to be between 25 and 232 euro (personal communication test laboratory). The Dossier Submitter assumes one test per pitch, e.g. one sample is taken from the 114 tons of ELT performance infill needed on a newly installed pitch, or from the 21 tons of infill needed on a mini-pitch. The number of newly installed pitches and the distribution of newly installed artificial pitches in RO1 is equal to the number and distribution established for the baseline situation (see E.3.2.) Assuming an average cost per test of 130 euro per pitch, the total costs related to extra tests are a bit more than 3 million euro in the first 10 years after the restriction has come into force.

Based on the above, overall economic costs of RO1 are estimated to be in the range of €3-44 million in the first 10 years after the restriction came into force (discounted at 4 %).

E.4.2 Economic impacts of RO2

Overview of the main economic impacts of RO2, which sets a limit value of 6.5 mg PAHs per kg, are summarized in Table E 28. The assumptions and calculation underlying this table are explained in detail in Sections E.4.2.1 and E.4.2.2.

Table E 28: Main market impacts of RO2 compared to Baseline in the first 10 years after entry into force (in € million, discount rate 4 %)

	Artificial turf carpet	**ELT infill**	**Alternative infill**	**Sand infill**	**Artificial pitch installation**	**Maintenance cost**	**Waste management**	**Extra overall societal costs**
Alternative recycling of ELT		19						19
Change in artificial turf systems (incl. infill)	1028	-838	2480	172	213	150	-33	3072
TOTAL	1028	-819	2379	172	213	150	-33	3091

The net present value of a shift from the baseline to RO2 is estimated at 3091 million euro over 10 years.

One of the implications of RO2 is that due to a limit value of 6.5 mg/kg PAHs in ELT, ELT granules can no longer be sold as performance infill. In Section E.4.2.1, the Dossier Submitter describes this effect on the end-of-life market of ELT infill in RO2.

In Section E.4.2.2, the Dossier Submitter describes the economic impact of a shift from ELT derived infill to other types of infill and other types of artificial turf systems in RO2 compared to the baseline. Overall, higher social costs are expected due to higher prices of alternative infill material and alternative artificial turf systems and due to a slight increase in costs for maintenance of the pitches with alternative infill material. The cost items per element of an artificial field, and per type of artificial field are described in the analysis of alternatives, section (Annex E.2.). Based on the number of new and existing pitches (see section E.3.2) and the cost items per field, the total costs are calculated for the baseline situation and the restriction option RO2, a 6.5 mg/kg limit value. The difference between the two total costs represents the costs of shifting from the baseline to RO2.

E.4.2.1 Economic impacts RO2: costs for alternative recycling of ELT due to end-of-market ELT granules as performance infill

As ELT infill material is a recyclate, a ban on using it as performance infill (if concentrations exceed the limit value) makes it necessary to look for alternative uses (e.g. waste management) of ELT. Table E 28 gives an impression of the quantities of granules for which another application has to be found. To calculate the amount of ELT used in pitches and mini-pitches, the following assumptions are made: 114 tons performance infill per pitch and 21 ton per mini-pitch, the annual refill tonnages are 1 and 0.1 ton per year, respectively. Furthermore, as explained in Annex A, the Dossier Submitter assumes that 50 % of the mini-pitches use performance infill.

Table E 28: ELT used in the EU as performance infill in the baseline scenario (ton)

Year after entry into force	Total ELT used	Newly and re-installed pitches	Refill pitches	Newly installed mini-pitches	Refill mini-pitches
1	403 929	322 542	14 796	64 095	2 495
2	418 868	334 768	15 357	66 166	2 576
3	434 126	347 271	15 931	68 267	2 658
4	449 687	360 035	16 516	70 395	2 741
5	465 530	373 047	17 113	72 546	2 824
6	481 632	386 288	17 720	74 716	2 909
7	497 966	399 735	18 337	76 900	2 994
8	514 499	413 364	18 962	79 093	3 079
9	531 195	427 146	19 595	81 289	3 165
10	548 011	441 046	20 232	83 482	3 250

There are various applications currently for ELT (granules) as can be seen from Figure A 2 in Annex A. As the total amount of ELT tyres in the EU will be the same in RO2 as in the baseline, for all the ELT tyre granules currently sold as ELT infill another use has to be found. The question is what will happen with ELT that cannot be used as performance infill anymore. The value of the alternative use of ELT currently sold as ELT infill will be lower than the value of ELT performance infill, otherwise the recycler would have sold the granules for other purposes already. For example, until a few years ago, recyclers had to compensate the cement industry for use of their granules as fuel recovery. Currently, cement plants pay a slightly positive price for these granules (ETRMA 2018). To get an impression of the possible extra costs for society paid for tyre waste management/recycling, the Dossier Submitter calculated the total alternative selling price for the baseline and for three different scenarios. In the baseline, the selling price of rubber granules for artificial pitches is €220 per ton. In the first scenario, granules are sold on energy markets at a price of €5 per ton. In the second scenario, due to increased supply of ELT granules on the market, the price of ELT granules decreases and the ELT sector has to pay a compensation to deliver their granules to the energy market. In a third scenario, the ELT sector manages to find an alternative material market on which the ELT granules can be sold at a lower price compared to the current ELT granules market. By multiplying the total ELT used on pitches and mini-pitches with the selling price per ton of rubber granules, the total selling price of infill in the Baseline and for the three scenarios are calculated. The lost revenues for the ELT sector are made up of the difference between the revenues in the baseline, as ELT is sold as performance infill, and the revenues in the alternative scenarios. The different impacts of these scenarios for the ELT sector are reported in Table E 29.

Table E 29: Total value of ELT granules sold on other markets than ELT for the recycling sector in the baseline and in RO2 (discount rate 4 %)

	Selling price (€) per ton rubber granules	Total selling price of ELT granules in Baseline and RO2 over 10 years after entry into force (€ million)	Lost revenue for the ELT sector over 10 years after entry into force (€ million)
Baseline: price of rubber granules for artificial pitches	220	838	
RO2, Scenario 1: Granules sold on energy market and the price of tyre derived fuels granules is slightly positive (2015 price)	5	19	-819
RO2, Scenario 2: Granules sold on energy market and the price of tyre derived fuels granules is negative (gate fee paid 1995-2015)	-30	-114	-952
RO2, Scenario 3: Granules sold on alternative material market, but at lower price	100	381	-457

In all three scenarios, the revenues for the ELT sector will decrease. For the impact analysis, the Dossier Submitter included Scenario 1 as a medium estimate, see Table E 29 and Table E 30. To avoid double counting, the loss in revenues due to end-of-market ELT granules as ELT infill is taken into account in the impact assessment in Section E.4.2.2.

Table E 30: Impact of end-of-market ELT infill sector in RO2 compared to Baseline in the first 10 years after entry into force (in €million, discount rate 4 %)

	Artificial turf carpet	ELT infill	Alternative infill	Sand infill	Artificial pitch installation	Maintenance	Waste management	Overall social costs
Alternative recycling of ELT		19 (-114-381)						19 (-114-381)

Based on these assumptions, in Scenario 1 the new revenues for ELT granules are 12 million euros for the granules sold as performance infill for pitches in the baseline, and 3 million euro for the infill sold as infill on mini-pitches.

E.4.2.2 Economic impacts RO2: costs related to the change in artificial turf systems

In Annex E.2., economic feasibility, the cost structure of an artificial pitch is given. In this Section, the Dossier Submitter compares the cost difference of a change in artificial turf systems from ELT systems to alternative systems, as described in Section E.3.2. The cost differences can be attributed to i) the artificial turf system, consisting of the artificial carpet and for the systems with alternative performance infill, of the shockpad; ii) the difference in performance infill; iii) the difference in sand infill; iv) the difference in installation costs; v) the difference in maintenance costs, and vi) the difference in waste management of end-of-life artificial turf systems. In the following paragraphs, the Dossier Submitter describes the calculation of the costs of these different elements of an artificial pitch. At the end, the overall cost calculation for the baseline and RO is presented, even as the differences between these.

Artificial turf carpet (i)

The Dossier Submitter assumes other types of artificial carpets are used for alternative performance infill compared to pitches with ELT infill (see Annex A and E.2.). Based on the costs estimates of the different artificial carpets presented in Annex E.2. the Dossier Submitter calculated the total extra costs for artificial carpet in newly installed pitches and mini-pitches (for number of new pitches and mini-pitches, see Table E 22 and Table E 23) in the baseline situation and for RO2 (in 2018 euros, discount rate 4 %). The total extra costs related to other types of artificial carpet are estimated to be around € 1 028 million in the first 10 years after the restriction has come into force.

Performance infill (ii)

ELT performance infill

Baseline: The total costs for ELT performance infill are the costs for newly installed pitches with ELT infill and the costs for refill. Only in the baseline scenario, new ELT pitches will be constructed and ELT will be used for re-fill. The total costs for ELT infill in the baseline scenario are calculated based on the total ton of performance infill used in the EU (see Table

E 28) * costs per ton infill, discounted at a 4 % discount rate. As explained in Section 4.2.1, the total selling price of ELT granules in the Baseline is € 838 million. RO2 implies the end-of-market for ELT infill.

Alternative performance infill and no-infill

Comparable to the calculation of ELT infill, the total costs related to alternative performance infill are the costs of performance infill needed for newly installed pitches with alternative infill and the costs of infill needed for refill. Both in the baseline and in RO2, pitches with alternative types of infill will be installed. The total costs for performance infill (non-ELT) in these pitches are calculated for the Baseline and RO2 as:

- The number of newly installed artificial pitches with alternative infill (EPDM, TPE, cork, and in RO2 no infill) per year * tonnes needed per field * the costs per tonnes infill, discounted at a 4 % discount rate, plus
- The annual tonnage for maintenance * the costs per tonnes refill, discounted at a 4 % discount rate

To calculate the amount of alternative infill used, the assumptions in Table E 31 are made.

Table E 31: Assumptions used to calculate the quantity of alternative infill

		EPDM	TPE	Cork
Tonnages used for annual maintenance	Per pitch	0.5	0.5	0.09
	Per mini-pitch	0.05	0.05	0.005
Tonnages used for installing new pitches	per pitch	45.6	53.2	9.88
	Per mini-pitch	8.4	9.8	1.82
Cost (in €) per ton of infill		1 750	1 600	1 350

For RO2, the Dossier Submitter assumes that after the restriction will come into force, that in case of maintenance, the existing pitches with ELT infill will be refilled with EPDM (50 %) and TPE (50 %) infill (and not with cork).

The total extra societal costs related to other types of performance infill are estimated to be around € 2 379 million in the first 10 years after the restriction has come into force.

Sand infill (iii)

Alternative pitches (non-ELT) need more sand infill compared to the ELT system (24kg/m2 in alternative pitches compared to 15kg/m2 in pitches with ELT performance infill) which increases the costs in RO2 compared to the baseline. The sand-infill costs of a mini-pitch are assumed to be 20 % of the sand infill costs of a 7 600m^2 pitch.The total extra societal costs of sand infill are estimated to be around € 172 million.

Installation (iv)

Based on the cost estimates of the different types of pitches presented in Annex E.2., the installation costs of alternative artificial turf pitches (no ELT) is higher due to the installation of shockpads under the artificial grass piles. The Dossier Submitter calculated the total cost of installation for both the baseline and for RO2. The installation costs of a mini-pitch are assumed to be 20 % of the installation costs of a 7 600m^2 pitch. The total extra societal costs of installation are estimated to be around € 213 million.

Maintenance costs (v)

To calculate the maintenance costs, the total number of pitches per infill type in the baseline and for scenario RO2 (see Section E.3.2) is multiplied with the maintenance costs per field. The maintenance costs of the mini-pitches are scaled based on the square meters of the pitch. The maintenance costs of a mini-pitch are assumed to be 20 % of the maintenance costs of a 7 600m^2 pitch. The total extra societal costs of maintenance are estimated to be around € 150 million.

Waste management (vi)

The costs of waste management are assumed to be more or less equal for the different systems. The only exception is TPE, as better recycling options are expected. This results in a slightly lower cost for pitches with TPE infill. The waste management costs of a mini-pitch are assumed to be 20 % of the waste management costs of a 7 600m^2 pitch.The total extra societal benefits of waste management are estimated to be around € 33 million.

The above results in the following the overall estimate of the costs related to the artificial turf systems in the Baseline and for RO2 which is given in Table E 32 and Table E 33.

Table E 32: Cost calculation for all EU28 artificial turf systems in baseline 2019-2028 (in € million, discount rate 4 %)

	Artificial turf carpet	ELT infill	Alternative infill	Sand infill	Artificial pitch installation	Maintenance cost	Waste management	TOTAL
Pitches	3 729	702	560	319	1 177	1 113	544	8 143
Mini-pitches	1 084	135	101	93	342	335	158	2 247

Table E 33: Cost calculation of all EU28 artificial turf systems in RO2 (6.5 mg/kg limit value) 2019-2028 (in million €, discount rate 4 %)

	Artificial turf carpet	ELT infill	Alternative infill	Sand infill	Artificial pitch installation	Maintenance cost	Waste management	TOTAL
Pitches	4 525	0	2 549	452	1 342	1 233	518	10 619
Mini-pitches	1 315	0	490	131	390	365	151	2 843

By comparing the Baseline and RO2, the extra costs related to the change in artificial turf systems when the concentration limit value is set at 6.5 mg/kg are calculated over a 10-year period (Table E 34).

Table E 34: Difference in social costs (and benefits) over 10-year period (in € million, discount rate 4%)

	Artificial turf carpet	ELT infill	Alternative infill	Sand infill	Artificial pitch installation	Maintenance cost	Waste management	Extra Overall societal costs
Pitches	796	-702	1 989	133	165	120	-25	2 476
Mini-pitches	231	-135	389	39	48	30	-7	595
Total difference	1 028	-838	2 379	172	213	150	-33	3 072

The societal costs of the restriction presented in RO2 compared with the baseline related to the artificial turf system are estimated to be **3 072 million euro** (in 2018 €).

E.4.3 Enforcement costs (compliance costs)

Enforcement costs are administrative costs incurred by Member States enforcement agencies to ensure that economic actors on the EU28 market comply with the EU regulations. By evaluating data reported from European studies on inspection/enforcement costs of REACH restrictions (Milieu, 2012; RPA, 2012), ECHA assessed the administrative burden of enforcement for new restriction proposals. ECHA concluded that based on data reported by Member States, the average administrative cost of enforcing a restriction is approximately €55 000 a year per Member State. Assuming constant administrative costs of enforcement over time, the net present value of compliance costs over 10 years is € 14 million for EEA31. This estimate is assumed to be relevant both for RO1 as for RO2.

This value is estimated based on numbers of controls over the period 2010-2014 reported by Member States (reporting under REACH art. 117 / CLP art. 46). The calculation is based on an average cost per control (inspection) and an average number of controls per restriction. ECHA notes that, while the average enforcement costs may remain fairly similar over time as they are driven by budgetary constraints, the costs for individual restrictions would likely vary. It is often the practice that enforcement campaigns focus on newer restrictions or high-risk restrictions considered a priority by Member States, and fewer resources are allocated to restrictions industry is already familiar with.

For the purpose of the current assessment, the value of €55 000 per year, should be seen as only illustrative in terms of the potential order of magnitude of the cost. It has to be noted that the Member State Competent Authorities have generally established the infrastructures and experience in enforcing other restrictions covering PAHs (e.g. entry 50 of REACH Annex XVII for articles, toys and extender oils) so that the new restriction on PAHs in granules and mulches is not likely to significantly add to the existing administrative costs. Therefore, the ECHA general established value for the annual administrative burden of enforcing a new restriction is most likely an overestimate for this proposal.

E.4.3.1 Compliance costs of RO1

Under RO1 it is expected that there will be some increased enforcement costs compared to the baseline situation. Because the concentration limit under RO1 is significantly lowered to fall within the range of PAH concentrations that are actually measured in granules placed on the market at the time of writing the restriction proposal, compliance with the restriction will be more challenging for ELT derived granule formulators compared to the baseline legal situation. For the same reason, enforcement authorities are expected to make some additional costs to check compliance by actors in the supply chain. This may be done administratively but also by testing PAH concentration in samples. As indicated above, total compliance costs are estimated at € 14 million for the EU over a 10 year period.

E.4.3.2 Compliance costs of RO2

Under RO2 it is expected that because of the relatively low concentration limit for PAHs, ELT derived granules and mulches will not anymore be placed on the market or used in applications as targeted by the restriction. As ELT derived infill and alternative types of infill are easily distinguishable by eyesight (due to difference in color and shape), compliance control by national enforcement bodies at granule formulation or distribution sites, or on synthetic turf pitches, can take place by simple visual control in combination with administrative checks (i.e. by checking the safety datasheet of the material, if available). It is expected that no chemical analyses will normally be needed. In case of the use of alternative infill granule types of which it is known that these may contain a certain level of PAHs (i.e. EPDM), also chemical analyses may be required to ascertain compliance if administrative information is considered not sufficient by the inspecting body. As indicated above, total compliance costs are estimated at € 14 million for the EU over a 10 year period.Overall, neither of the restriction options is expected to pose any major additional administrative burden on public authorities in terms of cost for inspection and enforcement. Note however, that compliance costs for individual Member States may in practice be substantially larger compared to the above average estimate if countries decide to put more effort in enforcement of the restriction.

E.5. Wider economic impacts

E.5.1 Wider economic impacts of RO1

It is noted that companies depend on ELT tyres as input for producing ELT granules. These companies have limited influence on their input material and may have limited possibility to ensure that the infill produced indeed complies with the limit value. This will result in some business risk for the infill producing companies. It will require a certain flexibility from companies, e.g. to make sure that they are flexible in selling their infill products on other markets if the infill produced turns out not to be compliant. Extra costs could imply a change in company structure in the ELT waste managing sector. For example, as indicated by ETRMA (ETRMA, 2018), smaller companies may have difficulties to survive in a higher cost situation and companies may try to reduce costs by increasing production efficiency, reducing thereby the number of employees. This is deemed less likely in RO1 compared to RO2 as extra costs for tyre recycling are much smaller in this scenario. Extra costs might also be passed on to tyre manufacturers who are responsible for waste management of tyres, and to buyers of the infill material. What will happen in practice will probably differ by company and country and is difficult to predict with certainty. As the percentage of ELT derived infill that may not comply with the limit value should be no more than 5 % (i.e. it is assumed that the concentration data available is representative for the PAH content in infill material produced in the EU), we assume that all companies are capable to remain in business. Furthermore, the Dossier Submitter assumes that the same total quantities of ELT granules are sold in RO1 compared to the baseline. In other words, the producing companies are thought to be flexible enough to adapt to the new regulation and no impact on the number of jobs is expected under this scenario.

E.5.2 Wider economic impacts of RO2

The wider economic impact of RO2 compared to the baseline depends on the market development. Extra costs because of a lower price received for the ELT sold to other markets than the infill market could imply a change in company structure in the ELT waste managing sector. For example, as indicated by ETRMA (ETRMA, 2018), smaller companies may have difficulties to survive in the higher cost situation and companies may try to reduce costs by increasing production efficiency and reducing the number of employees. Extra costs, however, could also be passed on to tyre manufacturers who are responsible for waste management of tyres and these may be passed on to consumers buying new tyres. What will happen in practice will probably differ by company and country and is therefore difficult to predict with certainty. However, the Dossier Submitter assumes that any potential job losses in the tyre recycling sector are likely to be offset by an increase in jobs in the artificial turf sector, especially in the production of alternative infill material. Thus, any detrimental effect of jobs will at most result in temporal unemployment of some workers who may have to shift jobs because of the restriction. To calculate these jobs lost due to end-of-market ELT, The Dossier submitter assumes that 15 % of the total jobs in the ELT sector are related to ELT infill. The total number of fte in this sector is between 2500 and 2900 FTE (ETRMA, 2018), implying temporal loss of 405 jobs. The total present value of job losses is calculated by multiplying these fte's with the net present value of the social costs of one lost job in the EU-28 of € 95 500 (Dubourg, 2016[127], ECHA 2016). The total present value of job losses due to RO2 are estimated to be 39 million euro.

E.6. Human health impacts

As concluded in Annex B, exposure to PAHs related to the use of ELT derived granules on artificial turf and playgrounds results in an unacceptable health risk if concentrations were as high as the current concentration limit for mixtures in Annex XVII of REACH. It should however be noted that based on PAH concentrations found in ELT derived granules currently used as infill material in the EU, the health risks associated with this use seem to be relatively small. Introduction of a restriction focusing on the PAH concentration limit in ELT derived granules aims to prevent potential exposure to unacceptably high levels of carcinogenic PAHs and consequential unacceptable cancer risks. The section below describes the health gains that are expected from any of the two restriction options. This assessment relies on qualitative and (semi)quantitative arguments. It is important to take note that human PAH exposures are the result of many different sources and routes of exposure. As

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

explained in Annex B, such sources include among others exhaust fumes, tyre particulates, cigarette smoke, burned wood (open fire) and (scorched) food. RIVM (2017) considered that the estimated exposure from rubber granules was marginal compared to food which is the most important source of PAHs for the (non-smoking) general population.

E.6.1 Type of human health effects

E.6.1.1 Carcinogenicity and mutagenicity

The focus of this restriction dossier is limited to the eight PAHs included in entry 50 to Annex XVII (i.e. REACH-8 PAHs). These eight PAHs share the same genotoxic mode of action. Among the eight PAHs covered in this restriction proposal BaP is the most studied. However, all of them have a harmonized classification for carcinogenicity in Annex VI of CLP in category 1B. In addition, BaP and chrysene are classified for germ cell mutagenicity in category 1B and 2, respectively, according to Annex VI of CLP.

In animal studies, PAH exposure is associated with carcinogenic effects for all tested exposure routes (oral, inhalation, dermal). As explained in Annex B, various types of tumours are observed: Oral studies with pure BaP or PAH mixtures resulted in increased tumour incidences in the gastrointestinal tract, liver, and respiratory tract in rats and mice. Long-term inhalation of PAH mixtures or pure BaP induced tumours in the lung in rats and mice. In hamsters, inhalation of BaP caused tumours in the respiratory tract, but not in the lung. Dermal exposure to relative low BaP or various PAH concentrations induced benign and malign skin tumours in various strains of mice.

Besides animal studies, several human studies have addressed the carcinogenicity of PAH mixtures with BaP as a marker compound. Studies mainly include occupational exposure to soot, coal tar, and other PAH-containing mixtures in various industries. Despite difficulties in interpretation and comparison of the results of these human studies, the majority of the epidemiological data associates airborne PAH exposures with increased lung cancer risk. In addition, for exposed workers, particularly those working at coke ovens and aluminium smelters a relationship between excess bladder cancer risk and PAH exposure could well be established. Locally, skin cancer has been reported to be positively associated with dermal PAH exposure, but not with inhalation exposure.

These genotoxic carcinogenic effects are considered non-threshold effects and safe dose and exposure levels can thus not be considered. Effects are expected to be relevant for all groups of society (male, female, young, old).

E.6.1.2 Potential other health effects

Besides carcinogenicity and mutagenicity, BaP is classified as skin sensitizer (Skin Sens. 1 (H317)) and classified for its effects on reproduction (Repro. 1B (H360FD)) according Annex VI of CLP. The reproduction toxicity (both in terms of fertility impairment and developmental toxicity) is considered a threshold effect with a threshold that is expected to be in orders of magnitude higher than potential DMELs for carcinogenicity. For skin sensitization it is not known whether effects may occur to BaP concentrations found in ELT infill. These effects are not further considered in Annex B, as genotoxic carcinogenicity is the human health endpoint of main concern and the focus of the risk assessment in this Annex XV dossier.

E.6.2 Relevant population

People come into contact with ELT derived granules during sports and playing and as a consequence are exposed to PAHs present in the granules. In Annex B, various sub-groups of the general population are characterized by different exposure profiles. These exposure profiles determine the expected risk level within a sub-group. Some groups are expected to have higher average exposure levels than others. In real life, however, exposure levels within any individual from a particular sub-group may vary depending on the actual behaviour of the individual.

In order to define the population at risk, the first step is to define the relevant population units. This starts with the full EU population, as in theory all EU citizens may potentially come in contact with ELT granules/mulches during sports and play. Mini-pitches will often be public facilities that are open to everybody and that may be used both by children and adults. Football pitches and other sport pitches may also be used by a wide range of actors; besides the members of sport clubs, school children and children in child care centres (kindergarten) may make use of artificial turf. Hence, large parts of the EU population may come into frequent contact with ELT granules at least during a part of their lives. Although the actual population in contact with ELT granules and mulches is likely to be much smaller, the total EU population serves as an upper bound.

In a second step, we define the most relevant population units for this dossier as follows: workers during installation and maintenance of pitches using ELT infill, professional and amateur athletes and children playing on playgrounds. All of these specified groups are likely to come into frequent contact with ELT granules or mulches during installation and maintenance, sports and/or playing on pitches, mini-pitches and playgrounds. Some individuals within these populations may in practice not come into contact with ELT, e.g. some athletes may only make use of natural grass pitches, mini-pitches appear to often not make use of recycled (ELT) infill and some installation/maintenance workers may not be directly involved with the filling of pitches.

In a third step, ideally, one should define for each of these groups what part of the group population is indeed exposed to PAHs contained in granules or mulches. The absolute size of the population at risk due to exposure to PAHs contained in granules or mulches however, could not be quantified given the available information.

In a fourth step, population at (unacceptable) risk can be evaluated connecting exposure to the associated health endpoints. As outlined in Annex B, a dose-response relationship was defined for PAHs to estimate the expected response (risk) at a given exposure level. This dose-response relationship defines the increased excess lifetime cancer risk from lifelong exposure to various PAH concentrations. As PAHs are genotoxic carcinogens, it is assumed that every exposure to these substances may lead to an increment in risk. To derive an acceptable level of exposure of the general public and workers to PAHs, policy-based risk levels are often applied. There may be different policy views among Member States as regards these acceptable risk levels. In Annex B, the acceptable excess cancer risk level for the general population is set at 10^{-6} (i.e. 1 additional cancer case per 1 million individuals with lifelong exposure). Similarly, for workers an acceptable excess cancer risk level of 10^{-5} is applied. One could thus say that all actors exposed to concentrations that correspond to excess risk levels below these acceptable risk levels bear an acceptable risk while actors above will bear an unacceptable risk. Following this definition, the number of individuals at risk will be a fraction of the total group that comes into contact with ELT granules and who are exposed to PAHs. Note that this means that individuals exposed to (relatively) low PAHs concentrations, below the concentration corresponding to a 10^{-6} or 10^{-5} risk, do face an excess cancer risk. However, this excess risk is low and is deemed acceptable to (Dutch) policy makers.

An overview of the relevant (sub-)population described above and a graphic presentation of the possible size of the relevant populations is given in Figure E 1 below.

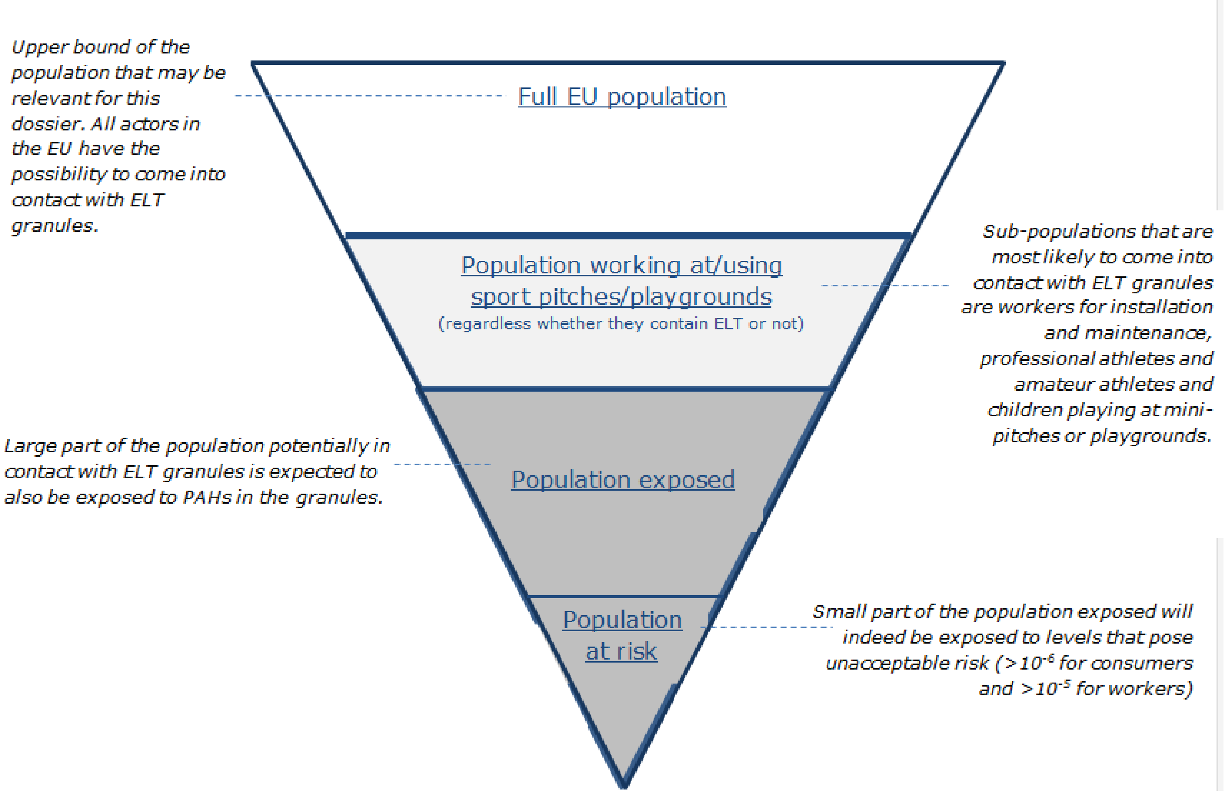

Figure E 1: Relevant population potentially exposed to PAHs via contact with ELT granules during sport and play applications (workers and general public)

E.6.2.1 Population working at/using sport pitches/playgrounds (that may come into contact with granules or mulches)

Annex D (Baseline) provides quantitative estimates of the number of individuals in the EU that may come into contact with granules or mulches in sport or playing applications.Table E 35 below gives an estimate of the major groups that are also presented in the upper two layers of Figure E 1. For simplicity, no trend estimate is made for the population size over the period 2016/18-2028. Because of that, it is assumed that the population is stable over these years. This may be an underestimation as, in the baseline situation, the total number of artificial pitches with ELT infill is expected to grow during this period implying an increase in the number of people that may come into contact with the material over the years. The full EU population has been included however as an upper bound of the potential population and serves as a sensitivity check.

Table E 35: Estimated number of individuals that are working at/using sport pitches/playgrounds and potentially come in contact with recycled granules and mulches; estimates in year 2016/2018 in the EU

	Group	Sub-group	Number of people
Population working at/using pitches for sport or play (regardless whether they contain ELT or not)	Workers	Installation and maintenance	4 000 – 14 000[a]
	Registered football	Professional field players	65 000[b]
		Professional goalkeepers	6 500[b]
		Amateur field players	13.9 million[b]
		Amateur goalkeepers	1.4 million[b]
	Registered athletes	Football, lacrosse, Gaelic games and Rugby players in the EEA-31	20 million[b]
	Registered and unregistered athletes	Football, lacrosse, Gaelic games and Rugby players in the EEA-31	38 million[b]
	Users of mini-pitches	Children(/adults)	8 million[a]
	Total of sub-populations (high)	Workers + registered and unregistered athletes + users of mini-pitches	46 million
	EU population	Including all groups below	512 million[b]

For further information and references on the number of individuals included in this table see Annex A and D
[a]2018 estimate
[b]2016 estimate

E.6.2.2 People exposed to PAHs in granules and mulches and people at risk

As indicated in Figure E 1, the population actually exposed to PAHs because of contact with granules/mulches in sport or play application and the population at risk are expected to be smaller than the numbers included in Table E 35. The actual size of the population exposed to PAHs is not known based on the data available to the Dossier Submitter. It may be only slightly smaller, however, compared to the populations that may be into contact with granules and mulches presented in Table E 35. Reasons for this are among others that a fraction of football players/children playing in the EU will not make use of artificial turf with ELT infill and that some maintenance workers are either involved in activities that do not entail exposure to ELT infill material or are protected against exposure to PAHs.

Whereas concise information to estimate the size of the population exposed is not available, it can be assumed that the realistic worst-case exposure estimates presented in B.9. are representative for only a (very) small part of the population exposed. Textbox E 1 gives some further explanation around this realistic worst-case exposure assessment to better understand the actual meaning of the results for the purpose of impact assessment. Large parts of the population will be exposed at lower levels than what has been estimated in the exposure scenarios (ES) and will therefore bear a lower excess cancer risk compared to the estimates in Annex B. The ES were designed by the Dossier Submitter in such a way that they intend to cover approximately 95 % of the population that is exposed to PAHs from ELT derived granules or mulches.

Textbox E 1: Interpretation of results of the exposure and risk assessment

In the risk assessment, a realistic worst-case approach is taken as it intends to protect all people that may come into contact with granules and may be exposed to PAHs from that, also the individuals that have higher than average levels of exposure. The highest exposed groups are driving the risk estimate and the 6.5 mg/kg concentration limit.

In section B.9. exposure estimates of various groups of people that may come into contact with recycled rubber granules/mulches in sport and play applications are developed. For each scenario, parameter values were chosen for factors such as body weight and the frequency and duration of playing sports. In addition, for each route of exposure, the relevant values were selected such as body surface area in contact with granules, quantities of granules in contact with the skin, respiratory rate and the quantity of granules that might be ingested. What is developed based on these models are lifelong exposure estimates of people over 70 (40) years of their (work) life by a combination of playing (children), sporting (children and adults) and/or working with rubber granules. The scenarios were elaborated in such a way that they calculate a realistic worst-case exposure to PAHs in rubber granules.

Using these exposure scenarios (ES), excess cancer risk is calculated for the various groups and based upon the exposure scenario with the highest lifelong exposure (professional goalkeeper), an acceptable risk level of one per million exposed is derived at or below a concentration of 6.5 mg/kg REACH-8 PAHs in granules.

ES overestimate the actual exposure for most individuals in the population that come into contact with ELT granules for several reasons:

- Assumptions made with respect to oral, dermal and inhalation are intended to be on the safe side, protecting all actors.
- In real life, not all players are expected to be exercising and playing at the frequency as assumed in the ES, so that the actual exposure for part of the population may be lower.
- In the ES it is estimated that people play 100 % of their playing and sporting time on artificial turf with ELT-derived infill containing PAHs in a specific concentration. However, not all sport pitches and playgrounds in the EU are artificial turf filled with ELT-derived granules. People also play e.g. on natural grass and artificial turf with other types of infill material may be used. For example, in Finland 75 % of all football pitches are artificial turf and 25 % is natural grass. For other EU countries information on the distribution is not available to the Dossier Submitter. In some countries it is expected that the share of artificial turf pitches is significantly lower.
- ES are developed to estimate lifelong exposure obtained by adding various activities over the lifetime of an individual, including childhood exposure from playing on artificial turf, exposure as a veteran playing football played on artificial turf and stages in between. In real life, only some people will in fact make use of artificial turf their whole active life. Many people may only make use of it for some years in their life and will consequently have significantly lower cumulative exposure profiles.

E.6.4 Risk levels and risk reduction in RO1 and RO2 compared to the baseline

In Annex B, risk levels for various lifelong exposure scenarios have been calculated at given PAH concentrations in ELT granules. These risk levels are presented in Table E 36. Based on these different risk values, risk reduction of both RO1 and RO2 can be calculated. Theoretical and reasonable maximum reduction in excess cancer risks of RO1 and RO2 for various lifelong exposure scenarios are presented in Table E 37. Note that, as stated earlier, the risk and the reasonable maximum risk reduction values included in Table E 36 and Table E 37 are expected to be representative for only a small part of the population exposed. Majority of the population will have lower risk values and consequently will have lower levels of risk reduction in respectively RO1 and RO2 compared to the baseline.

Table E 36: Excess cancer risk estimates for various lifelong exposure scenarios at different PAH concentrations in ELT granules as calculated in Annex B see Table B 34, Table B 35, Table B 37, Table B 38.

Sub-population	Excess cancer risk – Limit value mixtures (387 mg/kg*)	Excess cancer risk - P99 baseline (21 mg/kg)	Excess cancer risk – P95 baseline (17 mg/kg) = RO1	Excess cancer risk – P14 baseline (6.5 mg/kg) = RO2**	Excess cancer risk – non-use ELT (0 mg/kg) = RO2
Professional outfield player	$4.6x10^{-5}$	$2.5x10^{-6}$	$2.0\ x10^{-6}$	$7.7x10^{-7}$	0
Professional goalkeeper	$5.9\ x10^{-5}$	$3.2\ x10^{-6}$	$2.6\ x10^{-6}$	$9.9\ x10^{-7}$	0
Amateur outfield player	$4.4\ x10^{-5}$	$2.4\ x10^{-6}$	$1.9\ x10^{-6}$	$7.4\ x10^{-7}$	0
Amateur goalkeeper	$5.6\ x10^{-5}$	$3.1\ x10^{-6}$	$2.5\ x10^{-6}$	$9.5\ x10^{-7}$	0

* The concentration limits for the individual REACH-8 PAHs (in granules and mulches) set for mixtures in entry 28 of Annex XVII of REACH (i.e.1 000 mg/kg for benzo[e]pyrene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene and chrysene, and 100 mg/kg for benzo[a]pyrene and dibenzo[a,h]anthracene) can be translated to a sum limit of 387 mg/kg for the sum of the REACH-8 PAHs using the additivity approach (cf. CLP-Guidance section 1.6.3.3.3) and taking into account the relative contribution of the different PAHs to the REACH-8 PAH content in ELT infill found in the baseline situation in the EU (see Appendix B1). Note that this value should not be seen as an absolute value, as it may change depending on the concentrations and relative contribution of the individual PAHs in ELT infill.
** The content limit of 6.5 mg/kg is a rounded value such that the excess lifetime cancer risk estimate under RO2 for professional goalkeeper approximates the pre-set 1x10-6 risk level.

Table E 37: Theoretical and reasonable maximum reduction in excess cancer risk of RO1 and RO2 based on lifelong exposure (70 years)

- Theoretical reduction in excess cancer risk = excess cancer risk at limit value for mixtures – excess cancer risk at RO limit value
- Reasonable maximum reduction in excess cancer risk = excess cancer risk at P99 of the baseline – excess cancer risk at RO limit value
- For RO1 the risk value at 17 mg/kg is used, for RO2 the risk value at 6.5 mg/kg and 0 mg/kg are included. Note that the latter is expected to be the actual risk value after implementation of RO2 as it is assumed that ELT granules and mulches are not used anymore in this scenario
- Values in grey are used in further impact calculations

Sub-population	**Theoretical reduction in excess cancer risk**			**Reasonable maximum reduction in excess cancer risk**		
	RO1 (387 to 17 mg/kg)	RO2 (387 to 6.5 mg/kg)	RO2 (387 to 0 mg/kg)	RO1 (21 to 17 mg/kg)	RO2 (21 to 6.5 mg/kg)	RO2 (21 to 0 mg/kg)
Professional outfield player	$4.4x10^{-5}$	$4.5\ x10^{-5}$	$4.6\ x10^{-5}$	$4.7x10^{-7}$	$1.7x10^{-6}$	$2.5\ x10^{-6}$
Professional goalkeeper	$5.7\ x10^{-5}$	$5.8\ x10^{-5}$	$5.9\ x10^{-5}$	$6.1\ x10^{-7}$	$2.2\ x10^{-6}$	$3.2\ x10^{-6}$
Amateur outfield player	$4.2\ x10^{-5}$	$4.3\ x10^{-5}$	$4.4\ x10^{-5}$	$4.6\ x10^{-7}$	$1.6\ x10^{-6}$	$2.4\ x10^{-6}$
Amateur goalkeeper	$5.4\ x10^{-5}$	$5.5\ x10^{-5}$	$5.6\ x10^{-5}$	$5.8\ x10^{-7}$	$2.1\ x10^{-6}$	$3.1\ x10^{-6}$

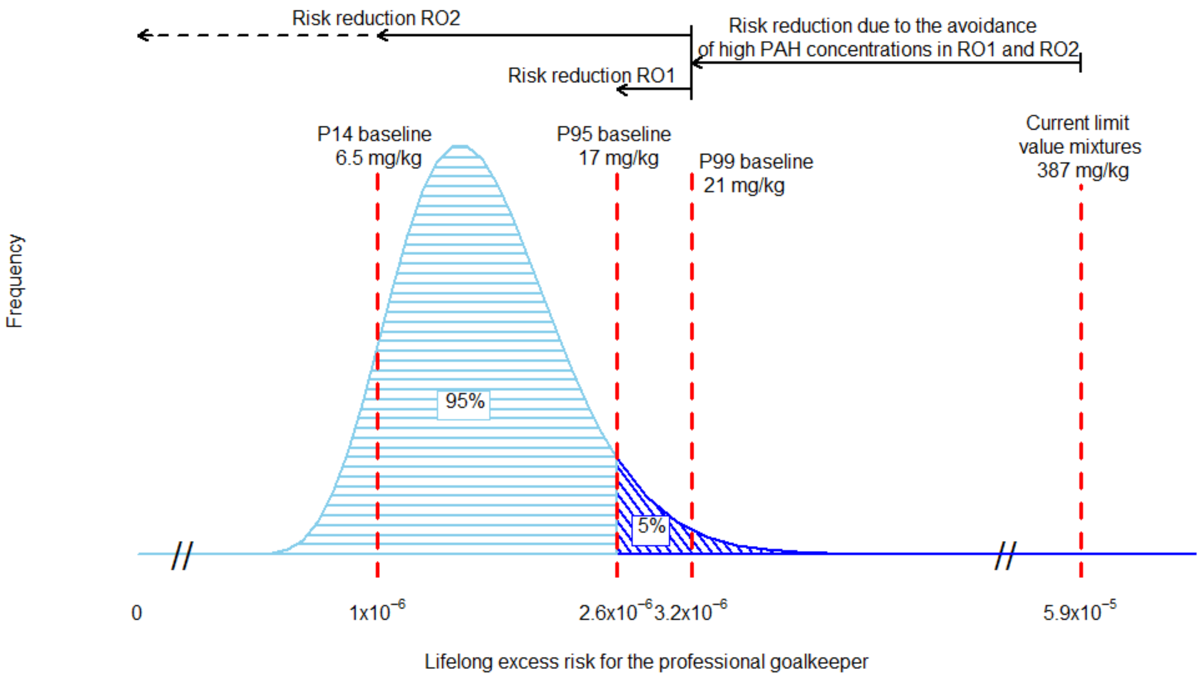

Figure E 2: Schematic presentation of the risk levels and risk reduction of RO1 and RO2 compared to the baseline situation. Risk values included in the figure represent the lifelong risk values of the professional goalkeeper at various sum REACH-8 PAH concentrations. Area under the curve represents the frequency of risk values in the sub-population of the professional goalkeepers. Note that the risk levels for a large part of the total population (including professional goal keepers) are expected to be (much) lower than the values indicated in the figure and that risks for these individuals are expected to be at acceptable levels in the baseline already. Avoidance of high risk situations is expected to be relevant for a small part of the population.

Figure E 2 gives a schematic representation of the risk levels and the risk reduction of RO1 and RO2 compared to the baseline situation. In this figure, lifelong risk values of the professional goalkeeper are included for illustrative purposes. Other lifelong exposure scenarios will give other (lower) risk and risk reduction values (see tables Table E 36 and Table E 37). The graph represents the distribution of risk given the distribution in PAH concentrations on artificial turf pitches in the EU in the baseline situation. In the baseline, 95 % of the professional keeper population is expected to have risk levels below 2.6x10^{-6} while 5 % may be above this value. This is indicated with the areas under the curve.

RO1 will reduce PAH concentration in ELT granules and mulches by setting a limit value of 17 mg/kg. This may have two possible consequences:

- It may result in a cut-off at 17 mg/kg, e.g. loss of the 5 % area above 17 mg/kg
- It may result in a shift of the curve to below 17 mg/kg resulting in a somewhat larger risk reduction than the 5 % area.

RO2 proposes a concentration limit value of 6.5 mg/kg and the excess cancer risks for that limit value has been calculated and is indicated in Figure E 2. However, as it is expected that ELT will not be used anymore in the RO2 situation and alternatives are expected to contain no (or very low) quantities of PAHs (see Annex E.2.), the actual risks of PAHs from ELT granules and mulches in sport and play applications will go to zero in RO2. The full area under the curve is thus to be avoided in this scenario.

Besides the risk reduction indicated by the area under the curve in Figure E 2, there is also a reduction in risk in RO1 and RO2 due to the avoidance of high PAH concentrations that may occur in the baseline situation because of the high limit value for PAH in mixtures that currently applies to recycled rubber granules and mulches. This is indicated by the arrow on the right side of Figure E 2. This would be a reduction in risks for individuals or clubs rather than for the full target population of the restriction, as high PAH concentrations in granules and mulches are expected to be incidents. The Dossier Submitter does not know how often such incidents occur in practice in the EU, only anecdotal information is available indicating that it may occur. As can be seen in Table E 36 and Table E 37, the risk and risk reduction levels for individuals due to high PAH concentrations can be substantial and should therefore be avoided to ensure risks remain at an acceptable level.

E.6.5 Theoretical maximum reduction in cancer cases in RO1 and RO2 compared to the baseline

In E.6.4 the risk reduction is calculated for various sub-populations exposed to PAHs in granules and mulches in sport and play applications of RO1 and RO2 compared to the baseline. As a first tier quantitative impact assessment, an estimate of the theoretical maximum number of cancer cases avoided are quantified by the Dossier Submitter based on the estimates of risk reduction of the professional keeper. Although further refinement of the analysis may be scientifically more sound, it is not deemed proportional for the purpose of this impact assessment. The approach taken is deemed sufficient to conclude on proportionality of the ROs later on in this Annex.

A theoretical maximum reduction in health impact is derived based as follows:

*Theoretical maximum reduction in health impact = Reasonable maximum risk reduction * Population * Share of pitches that still make use of ELT*

- Reasonable maximum risk reduction: the estimate of the reasonable maximum risk reduction for the professional keeper is selected as a high-end risk reduction value for consumer exposure, see Table E 37. It is estimated that other consumer groups have lower risk values and lower risk reduction. Note that although workers may have somewhat higher risk reduction, this is valued different compared to consumers as higher risk levels are accepted for workers. The lifelong risk reduction level derived in Table E 37 is divided by 70 years to come to an annualised risk reduction value.
- Total population: high-end estimate of the size of the population, for which risks are reduced, is achieved by adding the (upper bound estimate of the) worker population, the population of registered and unregistered athletes and the users of mini-pitches, see Table E 35, total of sub-populations (high). Note that this may imply some double counting, as part of the users of mini-pitches may very well also be athlete (football, lacrosse, Gaelic sports and rugby players).
- Share of pitches that still make use of ELT: as the restriction covers placing on the market of granules and mulch in sport and play applications, it will only affect new installations, replacements and refill. The health effect will therefore be gradually achieved over the years as more and more ELT pitches will be replaced over time. The lifetime of pitches is estimated to be around 10 years and it is expected that in a

period of 10 years all pitches and playgrounds with ELT are replaced by alternatives. This is accounted for by assuming linear reduction to zero from year 1 to year 10 after entry into force.

By selecting the above values, it is assumed that the total population exposed is exposed at levels comparable to realistic worst-case estimates of professional keepers and that this value is reduced to the risk level of connected to 17 mg/kg in RO1 and to zero in RO2. In real life, only a small part of the population exposed will indeed have this level of risk (and impact) reduction, for the majority of actors the risk (and impact) reduction is expected to be lower. Multiplying the above elements will provide a theoretical maximum health impact reduction of RO1 and RO2 compared to the baseline.

Table E 38 provides an overview of the expected number of cancer cases avoided in the first ten years after implementation of the restriction in RO1 and RO2. As said, the number of cases increase every year as the restriction only applies to new pitches installed and the effect of the restriction is thus gradually achieved over the 10-years period. It is estimated that after year 10 the health gain of the restriction is thus at maximum capacity. <u>Note that, as both the risk reduction levels and the population exposed are overestimates in this calculation, the actual number of cancer cases avoided in RO1 and RO2 is expected to be lower.</u>

Table E 38: Theoretical maximum estimate of the number of cancer cases avoided due to implementation of RO1 and RO2 assuming risk reduction at the level of professional keepers for 1. The total of sub populations that potentially come into contact with ELT; and 2. The total EU population

Year after entry into force	**Cancer cases avoided in RO1** Total of sub-populations exposed as professional keeper	**Cancer cases avoided in RO2** Total of sub-populations exposed as professional keeper
0	0	0
1	0	0.2
2	0.1	0.4
3	0.1	0.6
4	0.2	0.8
5	0.2	1.1
6	0.2	1.3
7	0.3	1.5
8	0.3	1.7
9	0.4	1.9
10	0.4	2.1
Total over 10 years	<2	<12
Size of the population exposed	46 million	46 million

The estimated theoretical maximum reduction in cancer cases avoided in RO1 and RO2 are small and logically RO1 is expected to result on a smaller number compared to RO2. Note that the risk reduction due to the avoidance of high PAH concentrations in granules or mulches that may be relevant for individuals or teams, are not included in the above theoretical maximum estimate of the number of cancer cases avoided. This is an additional and important benefit of the restriction.

Few studies have looked at cancer incidence specifically in populations that come into contact with rubber granules on artificial turf pitches. Washington State (2017) concluded, based on a database of a football coach, that there was no increased number of cancer diagnoses among football players compared to what would be expected if football players experienced the same cancer rates as Washington residents of the same ages. However, they acknowledged that the data were limited, especially with respect to exposure, and recommended further research. Moreover, they considered that their investigation was not designed to determine if soccer players in general were at increased risk of cancer due to exposures from crumb rubber in artificial turf.

Bleyer and Keegan (2018) recently examined, using data from California (the U.S. state with the greatest number of synthetic turf pitches), whether the incidence of lymphoma in individuals aged 14 to 30 is higher or increasing in regions with higher density of synthetic turf pitches. No association between annual lymphoma county incidence and county-level synthetic turf field density was found. Although the available information is still very limited, the findings of the two cited studies are in line with the outcomes of the theoretical maximum number of cancer cases avoided. The calculated cancer cases avoided are small and therefore it will be very difficult to show this in epidemiological studies.

E.6.6 Human health risks of other potential hazardous effects of PAHs, of other hazardous substances in ELT and of alternatives

In RO2, ELT granules and mulches are expected to be gradually replaced by alternatives. As PAHs may pose other hazards, ELT contains other hazardous substances and alternatives may contain less hazardous substances, a shift from ELT to alternatives may result in additional reduction in health risk. Note that this is not expected to be relevant for RO1 as in that scenario, ELT infill and granules remain to be used.

As mentioned in section E.6.1.2, BaP also is a skin sensitizer. It is not known whether this may give effects of skin sensitization in the baseline situation. It is also not known whether and to what extend the other PAHs may pose other hazards to the human population that may be avoided in RO2.

Table E2-1 in Appendix E1 shows that ELT infill may contain other hazardous substance besides the REACH-8 PAHs. Whether or not these may pose a health risk and potential impact due to the use of ELT infill, is currently not known and under review by ECHA in a separate project. These potential other impacts of ELT are out of scope of this restriction proposal and are not further considered in this health impact assessment

In RO2, ELT derived infill is expected to be replaced by alternative types of infill: EPDM, TPE, cork and by artificial turf systems without infill. Section E.2. discusses the potential human health risks of these alternatives. Information on the presence of hazardous substances in alternative types of infill is limited and there is said to be variation between alternatives from different producers. The information that was found suggests that, although there may be hazardous substances in EPDM and TPE, the number of different hazardous substances found and the concentration in which they are found are lower compared to ELT. EPDM is said to may contain concentrations of PAHs, however, these are mainly expected in case of recycled EPDM as this material contacts carbon black. Majority of EPDM infill on the market is expected to be virgin EPDM, which will be coloured and therefore cannot contain carbon black. TPE is not expected to contain PAHs. Overall, although there may be some hazardous substances in alternative infill materials and there are uncertainties related to the actual composition of alternatives, potential health concern is expected to be lower compared to ELT based on the available information.

E.7. Environmental impacts

E.7.1 Environmental impact gains of RO1

There are no differences in environmental impacts expected from RO1 compared to the baseline situation, as ELT derived infill is expected to remain to be used in this scenario. The environment however, may gain from the elimination of high PAH concentrations in infill material (from 17 to 387 mg/kg [128]) as PAHs pose a hazard to the environment as well. All 8 PAHs are classified as Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410).

E.7.2 Environmental impact gains of RO2

E.7.2.1 Environmental risk reduction of PAHs and other hazardous chemicals

A shift in RO2 from ELT to alternatives can have environmental benefits due to a reduction in PAHs and other hazardous chemicals. Although, this is out of scope of this restriction proposal and the risk assessment in Annex B, it may be relevant when analyzing the impacts of RO2 and is therefore briefly discussed here.

As said, all 8 PAHs are classified as Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410). In addition, as indicated in Appendix E2, ELT derived infill contains other substances that may be hazardous to the environment. Recently, RIVM investigated the environmental impact of 10 artificial turf pitches with ELT infill on the environment compared to natural grass (RIVM, 2018). Concentrations of zinc, cobalt, PAHs and mineral oil were significantly higher in soils and some ditch sediments around artificial turf pitches that make use of ELT infill than around surrounding natural turf pitches. As a result, NL environmental quality criteria for these substances were exceeded in some cases (ELT pitches) for cobalt, zinc and mineral oil. when an artificial turf pitch with ELT infill is replaced after end-of-life, a reservoir of leached substances is present in the supporting layer (substructure) beneath the artificial turf. This layer, when not removed, is a remaining source for further distribution of these substances in the environment (RIVM, 2018). Despite the limited available information on the actual composition of alternatives and the leaching of hazardous substances to the environment, the available data indicates that EPDM and TPE infill contain lower or no PAHs and cobalt compared to ELT and are expected to contain lower number and lower concentrations of other potential environmental hazardous substances compared to ELT. Concentrations of zinc in EPDM seem somewhat lower compared to ELT based on the available data (see Appendix E2), however, if actually EPDM is used to produced infill, zinc concentrations are expected to be comparable ELT (personal communication Professor Noordermeer). Environmental emissions of zinc could remain in RO2 if EPDM is used as

[128] The concentration limits for the individual REACH-8 PAHs (in granules and mulches) set for mixtures in entry 28 of Annex XVII of REACH (i.e.1 000 mg/kg for benzo[e]pyrene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene and chrysene, and 100 mg/kg for benzo[a]pyrene and dibenzo[a,h]anthracene) can be translated to a sum limit of 387 mg/kg for the sum of the REACH-8 PAHs using the additivity approach (cf. CLP-Guidance section 1.6.3.3.3) and taking into account the relative contribution of the different PAHs to the REACH-8 PAH content in ELT infill found in the baseline situation in the EU (see Appendix B1). Note that this value should not be seen as an absolute value, as it may change depending on the concentrations and relative contribution of the individual PAHs in ELT infill.

alternative. Information on chemicals in cork infill or non-infill artificial turf is limited, however, it is deemed less likely to be of concern to the environment. Overall, it is expected that the shift to alternatives in RO2 will lead to less exposure of hazardous substances to the environment and will result in a better environmental quality. The extent of the gain to the environment of RO2 is uncertain. Note that the above does not account for the shockpad or e-layer that is used below artificial turf systems without ELT infill. A shockpad is made of a foam, an e-layer is made of a rubber and could be made of ELT. Stakeholders say that alternative systems make use of a shockpad (personal communication synthetic turf sector) however, there are also actors indicating that e-layers may be used below artificial turf systems. The use of ELT in an e-layer could reduce/cancel out the environmental benefits of RO2.

E.7.2.2 GHG-emissions

The use of ELT-derived infill in artificial turf systems results in lower virgin material use. Because of this, GHG emissions of artificial turf system with ELT-derived infill compared to systems that make use of virgin infill materials like EPDM and TPE. To get an impression of the increase in GHG emissions caused by a shift from the Baseline situation to RO2, an LCA study by Skenhall et al., 2012[129] is used, see section E.2. Alternatives. The study only gives information on ELT, EPDM and TPE infill, no information in cork or no-infill systems is available to the Dossier Submitter. The calculated difference in the GHG emissions per system as presented in Table E 12, is the difference in GHG impact of the three different kinds of infill. The difference in the GHG emissions of the different artificial turf systems (with versus without shockpad and shorter pile vs longer pile length) is not included in any study known by the Dossier Submitter. The GHG impact of energy and material use for producing a shockpad is assumed to be higher compared with the relative gain of producing shorter piles compared with higher piles. Comparing GHG emissions of different kinds of infill only shows higher emissions of EPDM and TPE compared with ELT. As replacement by cork and non-infill systems has not been included in this analysis, there is an additional uncertainty in the difference in GHG emissions between the Baseline situation and RO2. For the calculation it is assumed that the GHGs of cork and no-infill equal the GHG emissions related to ELT infill. It is not known to the Dossier Submitter whether this results in an under- or over estimation.

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[129] Skenhall, S. A., L. Hallberg and T. Rydberg (2012) Livscykelanalys på återvinning av däck Jämförelser mellan däckmaterial och alternativa material i konstgräsplaner, dräneringslager och ridbanor. IVL, Stockholm.

Table E 39: CO_2 emissions in the baseline and RO2 of artificial turf systems (pitches and mini-pitches), based on CO_2 emissions related to performance infill (in ton CO_2 equivalents)

Year after entry into force	Baseline	RO2	Difference
1	65069	240112	175042
2	72934	253160	180225
3	81518	266907	185389
4	90878	281390	190511
5	101079	296647	195569
6	112187	312720	200533
7	124275	329651	205376
8	137423	347484	210061
9	151714	366268	214554
10	167240	386051	218811

The extra costs of carbon emissions in RO2 compared to the Baseline

To assess the impact of the GHGs in RO2 compared to the baseline, the difference in the total tons of CO2 emissions is multiplied by the costs of carbon expressed in Euro/ton. Estimates of the costs of carbon vary in the literature and between countries (see for example Smith and Braathen, 2015[130]). For the Dossier, an EU value is chosen, namely the central value of carbon as presented in the EU guide to cost-benefit analysis of investment projects (EC, 2014). The costs of carbon per ton increase over time as emissions in future years will have greater impacts than emissions today (see Table E 40). These EU estimates are lower compared to country specific estimates (see for example the values for different OECD countries in Smith and Braathen, 2015).

Table E 40: Costs per ton carbon applied in this Dossier

Year after entry into force[131]	Carbon value (€/ton)
1	34
2	35
3	36
4	37
5	38
6	39
7	40
8	41
9	42
10	43

Sources (OECD, 2015)

Based on these assumptions, the social costs of a change from the baseline to RO2, a change from ELT infill to alternative infill is calculated as the difference in tonnes CO_2-equivalenst (Table E 39* the social costs per tonnes carbon (Table E 40), resulting in a social cost of around 75 million euro in the first 10 years after the entry came into force (discount rate: 4 %), 12 million euro for mini-pitches and 64 million euro for full size pitches.

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[130] Smith, S. and N. Braathen (2015), "Monetary Carbon Values in Policy Appraisal: An overview of Current Practice and Key Issues", *OECD Environment Working Papers*, No. 92, OECD Publishing, Paris. http://dx.doi.org/10.1787/5jrs8st3ngvh-en

[131] Year after entry into force is assumed to be 2019

E.7.2.3 Microplastics

As explained in the analysis of alternatives section E.2., the use of synthetic infill material can result in environmental pollution by microplastics if the infill materials are lost from the pitches. Although the definition of microplastics is not formally set, rubber particles are generally considered microplastics (OSPAR 2017). Although measures can be taken to limit the loss of infill from pitches, e.g. by improved design of the field (edges), optimized management practices (leaf blowing inwards) or the use of cork as infill or non-infill artificial turf systems, this is not common practice in the EU. Microplastics that eventually end up in the aquatic environment can be ingested and distributed through the food chain, causing detrimental effects both due to leaching of substances from the microplastics as well as due to physical obstructions. It is generally agreed that pollution of the environment with microplastics should be reduced. Just recently, a report has been drafted for DG Environment of the European Commission that investigated options for reducing releases in the aquatic environment of microplastics emitted by products. In this report it is estimated that the total load of microplastics generated from artificial sports turf pitches in the EU is between 18 000 and 72 000 tons per year. In this estimate it is assumed that all refill is to replace lost infill to the environment (Hann et al., 2017). A study by RIVM (2018) shows that rubber crumbs are found in the vicinity of artificial turf pitches in concentrations upto 35 g crumbs/kg soil. This amount accumulated in a period of 12 years.

The shift from the baseline situation to RO2 is expected to result in a (slight) increase in the use of cork infill and artificial turf systems that do not make use of infill at all. As a consequence, no microplastics will be emitted from these pitches and this will result in a slight reduction in microplastics emissions from artificial turf pitches in general in the EU. Another impact is that the emissions of EPDM and TPE are assumed to be lower than emissions of ELT infill as lower quantities of infill are used and as these materials have lower tendency to spread as they are heavier (Weijer and Knol, 2017).

In Table E 41 the estimated emitted microplastics per pitch (in ton) are given, based on Annex E.2. (analysis of alternatives).

Table E 41: Estimated emitted microplastics (in tons) per pitch per year

	ELT	EPDM	TPE	Cork	No infill
Per pitch	0.35	0.175	0.175	0	0
per mini-pitch	0.06	0.03	0.03	0	0

Based on these estimates of the emitted microplastics per pitch, the total quantities of microplastics that are expected to be emitted are presented in Table E 42. The estimates of microplastics emitted to the environment made by the Dossier submitter are lower compared with the estimates in Hann et al. (2017).

Table E 42: Annual and total emitted infill over 10 years from pitches and mini-pitches with different types of infill (ton)

Year after entry into force	Baseline:					RO2				
	ELT	EPDM	TPE	Cork	No infill	ELT	EPDM	TPE	Cork	No infill
1	7 034	192	192	0	0	6 165	388	388	0	0
2	7 317	238	238	0	0	5 524	629	629	0	0
3	7 585	289	289	0	0	4 874	874	874	0	0
4	7 858	345	345	0	0	4 214	1 123	1 123	0	0
5	8 137	407	407	0	0	3 544	1 378	1 378	0	0
6	8 419	475	475	0	0	2 862	1 637	1 637	0	0
7	8 706	550	550	0	0	2 168	1 903	1 903	0	0
8	8 997	632	632	0	0	1 460	2 175	2 175	0	0
9	9 290	723	723	0	0	738	2 453	2 453	0	0
10	9 586	822	822	0	0	0	2 739	2 739	0	0
total emitted infill over 10 years from pitches					92 276					62 144

Restriction option 2 will have a positive impact on the amount of microplastics in the environment. Over ten years, in total more than 30 000 tons less performance infill will be emitted to the environment under RO2 compared to the baseline.

E.8. Social impacts

The use of artificial turf pitches with ELT infill has been subject to societal debate in a number of EU countries. In recent years, questions have been raised for example in the Netherlands about the potential human health and environmental risk of hazardous substances in rubber granules on synthetic turf pitches. In 2016 and 2017 the television program 'Zembla' paid attention to the issue in their broadcasts called 'dangerous game' (gevaarlijk spel)[132]. This gave rise to societal debate and concern among many actors in the Dutch society that make use of the pitches. Debates about the (un)safety of the use of these pitches took place in media, sport clubs, municipalities and at national policy level. Football practices and matches where cancelled because of the concern. These societal concerns triggered extra research on the safety of this application of ELT-derived granules. Publications were issued by the National Institute for Public Health and the Environment RIVM (2017), and by ECHA (2017) on the risks associated with playing football on synthetic turf pitches on which ELT-derived granules are used as infill. Both ECHA and RIVM concluded that there is only a very low level of concern (virtually negligible risk) from exposure to hazardous substances currently found in granules, however, that there are uncertainties and that if the concentrations of restricted REACH-8 PAHs were as high as the general limits established in restriction entry 28 for mixtures, the level of concern would not be low. Based on the available data, both ECHA and RIVM found no reasons to advice against the use of artificial turf pitches using ELT granules.
Societal concerns are motivated by numerous factors, besides risk, for example personal norms, values and believes about the hazards. This may explain why despite the

[132] https://zembla.bnnvara.nl/nieuws/gevaarlijk-spel

conclusions of RIVM and ECHA, some societal debate is still going on. There are municipalities in the Netherlands who decided to shift from ELT-derived infill to alternative types of infill. Examples of early replacement of (very) new turf pitches have been reported by the Dutch media[133]. Companies producing ELT-derived infill also report a drop in sales (40 %) in the Netherlands because of the societal concern. Views vary whether this drop is temporary or permanent in the Netherlands (personal communication recycling sector, personal coimmunication synthetic turf sector).

Also, in other EU countries, the issue receives media attention[134]. As far as known by the Dossier Submitter, this has led to some public debate in other counties as well (e.g. in France). The Dossier Submitter does not know whether concerns raised in other countries, resulted in consequences like in the Netherlands, where actors voluntarily shifted to alternatives in the baseline situation. Introduction of a restriction can have effects on the societal concern around the use of ELT-derived infill material in artificial turf, this is discussed in the sections below.

E.8.1 Social impacts of RO1

Change in societal concern
RO1 poses a limit value of 17 mg/kg REACH-8 PAHs for all newly installed pitches and intends not to affect the existing pitches (except for refill). It is expected that in case of RO1, ELT is still used as infill material on artificial turf pitches. Societal concern may be reduced by this restriction as outliers in PAH concentrations are avoided. However, societal concern could also remain as ELT remains to be used and other hazardous substances in ELT material that are not covered in this restriction may be of concern to the public as may be environmental issues related to microplastics.

E.8.2 Social impacts of RO2

Change in societal concern
RO2 poses a limit value of 6.5 mg/kg REACH-8 PAHs for all newly installed pitches and intends not to affect the existing pitches (except for refill). Implementation of RO2 will cause a shift away of ELT for the newly installed pitches and consequently, will take away any societal concern in the EU related to the use of ELT in these pitches in 10 years time after entry into force. The restriction may not stop the societal debate about the existing pitches, as ELT remains on existing pitches for around 10 years (expected lifetime of a pitch). Actors act on the basis of numerous factors, besides on scientific risk estimates, their perception of the risk, or societal perception of the risk may play a role. As the infill currently used on the pitches does not comply with the limit value in RO2, societal concern

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[133] Note that besides human health and PAHs, other arguments (like environment, microplastics and costs) may be basis for such decisions.
[134] FR: http://sport24.lefigaro.fr/le-scan-sport/2016/10/12/27001-20161012ARTFIG00163-les-terrains-synthetiques-cancerigenes.php
SE: https://www.metro.se/artikel/larm-konstgr%C3%A4s-ger-fotbollsspelare-cancer-xr
FI: https://www.hs.fi/urheilu/art-2000002897082.html

may lead to early replacement of existing pitches in some parts of Europe. During the 24 November 2017 workshop, actors indeed indicated that they expect early replacement of pitches in case of implementation of RO2, at least in parts of the EU. Early replacement however, is not included in this impact assessment, as the Dossier Submitter does not know to what extend this may happen in practice. In 10 years' time, all pitches using ELT derived infill will be replaced by artificial pitches using other types of infill and this will make an end to the societal concern eventually. It should be noted, however, that this implies that societal concern is mainly triggered by potential health issues. Some environmental issues may remain in RO2 as majority of the alternatives are expected to be synthetic materials as well (EPDM and TPE; microplastics) and for example EPDM also contains (lower) quantities of zinc that may pose an environmental concern as well and as ELT may be used in an e-layer below artificial turf pitches using non-ELT infill material.

Perceived change in performance quality
Other types of infill or other types of artificial pitches (no infill) may have other (perceived) sport technical performance characteristics. When it comes to sporting on pitches, preferences for various types of pitches and certain type of infill differ per person. All types of infill and pitches included in this analysis, however, can comply with the FIFA Pro qualification and thus can meet this benchmark of performance quality.

E.9. Practicality and monitorability

E.9.1 Implementability and manageability

To be implementable within a reasonable timeframe, a restriction should be designed so that a supervision mechanism exists and is practically implementable for enforcement authorities. The only difference between RO1 and RO2 is the level of the concentration limit. In either case the restriction is easily understandable for affected parties which are the formulators and suppliers of granules and mulches on the EU market for use as infill in synthetic turf pitches and in loose form in sport applications and in playgrounds. The restriction targets the placing on the market (including import) of the granules and mulches as well as their use. Although the concern for human health was primarily triggered by ELT-derived rubber granules, the restriction targets all granules that are used in the same way. Thus, the restriction ascertains that with respect to risks as a consequence of PAH contaminations for all materials risk are controlled. Overall, both restriction options are considered to be implementable and manageable for all parties affected.

E.9.2 Enforceability

To be enforceable, a restriction needs to have a clear scope so that it is obvious to enforcement authorities which products are within the scope of the restriction and which are not. Moreover, the restriction needs a concentration limit value that can be subject to supervision mechanisms. The sum concentration limit for REACH-8 PAHs under RO2 and RO1 in principle is clear and unambiguous and therefore the proposed restriction is expected to be enforceable by national enforcement bodies across the EU. Furthermore, the restriction is defined for the group of REACH-8 PAHs that currently have an EU harmonized classification as carcinogen and as such provides a clear legal basis for companies and enforcement authorities that is consistent with the existing restriction on PAHs in entry 50 of REACH Annex XVII. Some generic issues however need specific attention and these are outlined below.

Product waste interface

The restriction aims to regulate PAH contaminant levels in granules and mulches used in synthetic turf, sports and playground applications. ELT derived materials that are (among others) targeted by the proposed restriction are mixtures formulated by tyre recycling companies that have a waste permit. The starting point of the restriction under REACH is the presumption that ELT derived granules and mulches placed on the market for the uses targeted by the restriction are products (mixtures) falling under the legal scope of supply and use as defined in REACH (and CLP). Hence, the assumption is that granules and mulches marketed and supplied for such uses are no longer waste. In practice however, the End-Of-Waste status of ELT derived materials may differ per EU country. This is due to the fact that the EU Waste Framework Directive (WFD; Directive 2008/98/EC) currently has not established specific End-Of-Waste criteria for tyre waste. EU Member States may therefore make their own End-Of-Waste decisions based on the framework presented by article 5 of the WFD. Uncertainties around the End-Of-Waste status of granules and mulches were acknowledged in the November 2017 stakeholder workshop as a factor that might have impact on enforceability of the proposed restriction. It was concluded not to influence the risk-based justification of the proposed EU-wide measure to ensure safe use of granules on synthetic turf pitches. In the Netherlands for granules used as infill in synthetic turf pitches that meet the criteria of Dutch quality guidelines laid down in ISA-M37 standard an End-Of-Waste decision has been taken in 2005 by the Dutch competent authorities (VROM, 2005). The ISA-M37 is a national standard prescribing technical requirements of performance infill granules used in artificial turf in conformity with the FIFA 2006 Quality Concept for Football Turf (now implemented in the 2015 FIFA quality program). Information on the status of ELT derived granules and mulches placed on the market in other EU countries is not available to the Dossier Submitter. It is noteworthy that in jurisdictions where these material applications are considered waste, REACH does not apply and the restriction will not be effective.

Definitions used in the restriction proposal

The restriction focuses on the use of granules as infill material in synthetic turf pitches. For enforcers some discussion may be needed to clarify terms used. To facilitate discussions and clarify the scope as foreseen by the Dossier Submitter, this Annex XV dossier includes a glossary of terms. Of most importance for enforcement is the intention to include all performance infill materials used in synthetic turf pitches in the scope. The scope hence includes ELT derived granules but also other recycled or virgin granules such as TPE, EPDM and cork. Water and sand are excluded from the scope as these infill materials are not regarded to fall under the definition of performance infill that is needed for long pile synthetic turf pitches to perform their function as intended. Water and sand are normally used as infill in short pile turfs such as tennis courts and hockey pitches. So-called mulches (flakes) are also covered by the restriction proposal as during the preparation of the Annex XV report the Dossier Submitter has gained information on the use of mulches in the EU in loose form in playgrounds and some sport applications. As the lifelong exposure scenarios in our risk assessment cover both sporting at all ages (focusing on football players and goalkeepers as primary users) and playing by children, we concluded such loose applications, apart from synthetic turf infill applications, should also be covered by the proposal. It is acknowledged that it may be challenging for enforcers to distinguish between loose playground and sports applications that are in the scope of the restriction and applications that are not. Non-compliant mulches for instance, may after entry into force of the restriction still be sold to consumers for landscaping purposes (i.e. for gardening). Use by consumers on playgrounds may in that case be regarded as a misuse that can reasonably be foreseen in advance. The Dossier Submitter notes that based on the limited information available, many of the uses for which mulches are placed on the market may involve exposure to humans but decided to limit the scope to playgrounds and sports applications for which the exposure scenarios are regarded to address the risk.

Mixture definition

The European Commission agreed with the majority of Member States on the legal interpretation that the rubber granules (also referred in the same document as 'rubber crumb') used in synthetic sports pitches are mixtures in the scope of REACH (European Commission, 2016). It is confirmed by ECHA experts on the guidance on substances in articles that also mulches should be regarded as mixtures (personal communication, ECHA 2018). Some alternative granule formulators present during the November 2017 workshop expressed their view that some granules used in synthetic turf pitches should be regarded as articles rather than mixtures. They claim the shape, surface and design of some of their products to be more important than the chemical composition (e.g. some of the alternative granules are designed as a hollow tube-like structure claimed to be essential for meeting the sports technical requirements). Therefore, they claim article rather than mixture rules would apply to them. As regards PAHs this would mean they claim a need to comply with REACH Annex XV entry 50.5 (individual concentration limit for each of the REACH-8 PAHs of 1 mg/kg). ELT derived granule formulators did not contest the Commission decision. The Dossier Submitter notes there may be differences in legal interpretations inherent in the fact that the various types of granules and mulches that may be placed on the market in the EU and used within the scope of the restriction proposal, are different in their shape, surface and design and chemical composition. For the current Annex XV dossier this issue was not further explored. The legal interpretation by the European Commission and the majority of EU Member States was used as a starting point for the restriction proposal. Diverging interpretations however may play a role at the level of enforcement. As regards PAH content this would mean either a need to be complaint with an article concentration limit of 1 mg/kg for each of the REACH-8 PAHs or with the limit values as proposed in RO1 or RO2.

Colored and coated granules

Granules and mulches may be placed on the market in various shapes and colors. ELT derived granules are black due to the fact that these are derived from tyres that are made from vulcanized rubbers containing carbon black for filling, reinforcement and coloring. Also, EPDM rubbers in many cases are colored black but also other colors are available. Recycled EPDM granules will be black but virgin manufactured EPDM are expected to have other colors. Coloring of EPDM and TPE can be obtained by additives used in the polymer compounding process. In addition, ELT-derived granules may be coated with polyurethane (PU) in order to achieve another color (often green). In some countries (like Italy), PU coating of ELT derived granules is used because of the national standard requirements of the non-professional league championship (ETRMA 2018). The Dossier Submitter notes that coloring of granules and mulches may introduce some challenges for enforcement. Especially as PU coated ELT derived granules may be mistaken for alternative granules. This is however not expected to hamper chemical confirmation of the composition and PAH content. Colored and coated granules (containing a thin layer of other material on the core granule) should also be regarded as mixtures. Hence, coloring and coating are not expected to hamper enforcement of the restriction.

Methodology for extraction and analyses

Currently no EU standard methodology is available for extraction and chemical analysis of PAHs contained in a rubber matrix. In the Annex XV dossier dataset various analytical methods were used to determine the PAH concentration in granules samples. Issues considering the methods applied are described in Appendix E1. Some of the methods were specifically designed to analyze PAHs in rubber granules, while other methods were originally designed to determine PAH concentrations in other matrices, such as soil, building materials with and without bitumen or tyres. Samples differed with respect to methods applied to reduce the size of granules, extraction solvent and technique applied and extraction temperature, pressure and duration. The Dossier Submitter concludes that currently, the AfPS GS 2014:01 PAH (i.e. ZEK 01.4-8) method seems to be the most rigorous and suitable standardized method for extracting and analyzing PAHs contained in rubber material. Most samples which were used to determine the REACH-8 PAH concentration were analyzed using the AfPS GS 2014:01 PAH method. During the November 2017 workshop it was claimed by some stakeholders that PAH level compliance would largely depend on the test method used as this influences the test results. Differences in PAHs concentrations reported might occur for various reasons. An important factor will be variability of PAH recoveries from ELT-derived granules as it is dependent on the methods of extraction and analysis applied. The Dossier Submitter notes that not having available a fixed and mutually accepted EU standard for extraction and analyses may hamper a harmonized enforceability of the restriction proposal. The European Commission is currently reviewing the need for standardizing analytical methods for measuring PAHs in rubber and plastic articles. Information from this review may also be helpful for determining a harmonized approach for analyzing PAHs in ELT derived granules and mulches. The Dossier Submitter recommends that efforts are made at EU level to validate and optimize extraction methods to get more confidence in the extraction efficiency of methods in general and to facilitate a harmonized enforcement of the proposed restriction.

Concentration limits
Under RO2 and RO1 concentration limits for REACH-8 PAHs of 6.5 mg/kg and 17 mg/kg respectively are set. As limits of detection and quantification are generally reported to be significantly below these values (i.e. the AfPS GS 2014:01 PAH reports a limit of quantification of 0.2 mg/kg), both concentration limits are concluded to be enforceable.

Transitional period
The restriction proposal includes a one-year transitional period. During the November 2017 workshop it was stated that the sector will not wait for action until the restriction has actually entered into force. Probably stakeholders may already start acting as soon as the decision on the actual restriction is taken in REACH Committees published. In that sense the required transition period may be short. In the other stakeholder consultations, no further arguments claiming a need for a transitional period different than one year as originally foreseen as a reasonable timeframe were brought forward. From an enforcement perspective the Dossier Submitter expects a one-year transitional period will provide no specific challenges other than the time needed to establish EU-wide harmonized methodology for extraction and analyses of PAHs in rubber matrices.

E.9.3 Monitorability

Monitoring may cover any means to follow up the effect of the proposed restriction in reducing exposure of humans. This may include the monitoring of urine PAH metabolite levels in children and adult football players to see if the exposure decreases following the restriction. A metabolite of BaP, Hydroxy-pyrene is frequently used in biomonitoring of BaP exposure through measurement in urine samples. However, human PAH exposures are the result of many different sources routes of exposure, and it will be difficult to attribute changes in urine OH-pyrene levels to this specific restriction on granules used in synthetic turf pitches. A confounding factor may also be that PAH exposure levels of humans may to a large extent depend on behavior such as smoking and food intake. Therefore, biomonitoring to assess the efficacy of the restriction through urine PAH metabolites may only be feasible in a large scale experimental set-up including many volunteers and creating sufficient knowledge on behavior and background environmental exposure.

Another means to follow up this restriction is to monitor the evolution of the fraction of granules and mulches placed on the market that have PAH levels above the proposed limit, i.e. the percentage of non-compliant granules and mulches over time. This means of monitoring is essentially identical to enforcement, but can also comprise:

- Actions undertaken by industry actors to comply with the proposed restrictions (or their voluntary national schemes, e.g. based on the extended producer responsibility principle); and
- Measurements carried out by independent test institutes, media, or green and consumer groups. Unlike the measurement of blood lead levels, this means of monitoring will be directly related to this restriction. In some countries this may become apparent due to concerns raised in the media and public awareness on the safety issues of synthetic turf pitches.

Following the above, the monitoring of the proposed restriction is expected to be done through enforcement. No additional monitoring activities are envisaged. In addition to national reporting of enforcement success, notifications of any violation of the restrictions should be reported to the RAPEX system, which in that way would support monitoring of the implementation of the proposed restriction. No additional costs for monitoring are anticipated under RO1 and RO2.

E.10 Distributional impacts

For this section is refered to the Annex XVII Restriction Dossier (Main Report) section 2.6. Only the tables from this section are provided presenting the specific outcomes of calculations to enable tracing them back. In the Restriction Dossier all estimates are rounded as they precent indications of costs (and benefits).

Table E 43: Distribution of impacts of RO1 compared to the baseline over various actors (quantified in million € over 10 years, 4 % discounted, unless stated differently)

Actors / **Impacts**	**Producers of recycled rubber mixtures**	**Artificial pitch installation**	**Maintenance companies**	**Test companies (labs)**	**Municipalities/owners of pitches**	**Athletes, children playing**	**EU citizens**	**National government**	**Impacts to society**
Cost of compliance for ELT recyclers	0-41				(x[1])		x[1]		-Max 41
Chance in costs for newly installed artificial turf system (incl. infill)				3	x[1]				-3
Compliance costs								14	-14
Wider economic impacts									No effect
Health risk and impacts reduction (carc. PAHs)		+ Risk reduction for 4 000-14 000 workers[2] Avoidance of risks of high PAH concentrations				+ Risk reduction for around 45 million individuals[2] Avoidance of risks of high PAH concentrations			+ Avoidance of <2 cancer cases Avoidance of high risk situations
Health risks reduction of other effects and other substances									No effect
Environmental risk reduction									No effect
GHG emissions									No effect
Microplastics									No effect
Social impacts						Reduction in societal concern for new pitches, concerns may remain for existing pitches			+/-?

[1] The actor that most probable has to pay for these costs

[2] due to the avoidance of high PAH concentrations that may occur between 17 and 387 mg/kg in the baseline

E.10.2 Distributional impacts of RO2 compared to the baseline

Table E 44: Distribution of impacts of RO2 compared to the baseline over various actors (quantified in million € over 10 years, 4 % discounted, unless stated differently)

Actors / Impacts	Artificial turf producers	Producers of recycled rubber mixtures	Virgin performance infill producers	Sand infill company	Artificial pitch installation	Maintenance companies	Waste managers of artificial turf	Municipalities/owners of pitches	Athletes, children playing	EU citizens	National government	Impacts to society
Alternative recycling of ELT		19								x[1]		-19
Chance in artificial turf system (incl. infill)	1028	-838	2379	172	213	150	-33	x[1]				-3072
Compliance costs											14	-14
Wider economic impacts	Potential increase in jobs	Potential job losses 400 fte	Potential increase in jobs							39		-39
Health risk and impacts reduction (carc. PAHs)					++ Risk reduction for 4 000-14 000 workers Avoidance of risks				++ Risk reduction for around 46 million individuals Avoidance of risks			++ Avoidance of <12 cancer cases Avoidance of

Actors / Impacts	Artificial turf producers	Producers of recycled rubber mixtures	Virgin performance infill producers	Sand infill company	Artificial pitch installation	Maintenance companies	Waste managers of artificial turf	Municipalities/owners of pitches	Athletes, children playing	EU citizens	National government	Impacts to society
					of high PAH concentrations				of high PAH concentrations			high risk situations
Health risks reduction of other effects and other substances					Potential risk reduction due to other hazardous effects of PAHs and other hazardous substances in ELT +?				Potential risk reduction due to other hazardous effects of PAHs and other hazardous substances in ELT +?			+?
Environmental risk reduction										Potential reduction in environmental impact from zinc, cobalt, mineral oil from ELT		+?
GHG emissions										76		-76
Microplastics										Reduction in microplastics, 30 000 ton		+ Reduction in microplastics,

Actors / **Impacts**	**Artificial turf producers**	**Producers of recycled rubber mixtures**	**Virgin performance infill producers**	**Sand infill company**	**Artificial pitch installation**	**Maintenance companies**	**Waste managers of artificial turf**	**Municipalities/owners of pitches**	**Athletes, children playing**	**EU citizens**	**National government**	**Impacts to society**
												30 000 ton
Social impacts									Reduction in societal concern for new pitches, concerns may remain for existing pitches			+/- Stop of societal concern after 10 years

[1] The actor that most probable has to pay for these costs

E.11. Comparison and conclusions (proportionality to the risk)

Table E 45: Societal costs of RO1 (€ over 10 years, discounted at 4 %, only societal costs due to market impacts included) per unit value.

	Societal costs over 10 years	Unit of input	Societal costs per unit of input
Cost per cancer case avoided	€ 41-66 million	<2 cancer cases avoided (theoretical maximum)	>€ 19-30 million per cancer case avoided
Costs per EU citizen	€ 41-66 million	500 million citizens	€ 0.08-0.13 per EU citizen
Costs per full size football pitch (2028)	€ 35-55 million	34 000 pitches	€ 1 012-1 620 per full size pitch
Costs per registered football players	€ 35-55 million	15 million football players	€ 2.25-3.59 per registered football player
Costs per registered and unregistered football players	€ 35-55 million	38 million football players	€ 0.90-1.45 per registered and unregistered football player
Costs per mini-pitch (2028)	€ 7-11 million	55 000 mini-pitches	€ 122-195 per mini-pitch
Costs per mini-pitch user	€ 7-11 million	8 million mini-pitch user	€ 0.83-1.33 per mini-pitch user

E.11.1.4 Cost-effectiveness and affordability of RO2

Table E 46: Societal costs of RO2 (€ over 10 years, discounted at 4 %, only societal costs due to market impacts included) per unit value.

	Societal costs over 10 years	Unit of input/ impact	Societal costs per unit
Cost per cancer case avoided	€ 3 100 million	<12 cancer cases avoided (theoretical maximum)	€ 268 million per cancer case avoided
Costs per EU citizen	€ 3 100 million	500 million citizens	€ 6 per EU citizen
Costs per full size football pitch (2028)	€ 2 500 million	34 000 pitches	€ 73 355 per full size pitch (football)
Costs per registered athletes	€ 2 500 million	15 million athletes	€ 163 per registered athlete
Costs per registered and unregistered athletes	€ 2 500 million	38 million athletes	€ 66 per registered and unregistered athlete
Costs per mini-pitch (2028)	€ 600 million	55 000 mini-pitches	€ 11 059 per mini-pitch
Costs per mini-pitch user	€ 600 million	8 million mini-pitch users	€ 75 per mini-pitch user

Annex F: Assumptions, uncertainties and sensitivities

In the Table F 1 below, the main sources of uncertainty are presented with an estimate of the Dossier Submitter of the potential effect on the proportionality conclusions of RO1 and RO2 compared to the baseline situation[135]. In the table, the sign '↓' is used to indicate that this uncertainty may result in an overestimation of proportionality (the proposal may be less proportional); the sign '↑' is used to indicate that this uncertainty may result in an underestimation of proportionality (the proposal may be more proportional) and the sign '**?** ' is used to indicate that the consequences on proportionality are not known. The Dossier Submitter considers that these uncertainties may have an effect on the (quantitative) estimates of costs and benefits in the impact assessment, however, the overall conclusions on proportionality are not expected to change.

Table F 1: Overview of the main uncertainties and the importance on the proportionality conclusion of RO 1 and RO2 compared to the baseline

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
Quantities of ELT infill and mulches used in sport and play applications and expected trends	There are several assumptions taken that together define the expected quantities of ELT used in the EU in the baseline situation, RO1 and in RO2: - Number of artificial turf football pitches and mini-pitches is assumed to be similar in baseline, RO1 and RO2 (*figures of individual EU countries suggest that the used total figure may be an underestimate)* - Number of artificial turf systems not for football and loose applications (*not included in the quantitative assessment, underestimate)* - Shares of various types of infill used, *other estimate used in baseline/RO1 compared to RO2, a recent source reports lower shares of ELT granules (EU association 2018, figures claimed confidential), and the estimate in the baseline situation may be overestimated.* - The (non)use of infill used in mini-pitches (*it is assumed that 50 % of*	?	Limited importance for RO1 May be important for RO2	ESTO Market Vision Report; 24 November 2017 workshop; EU association 2018, figures claimed confidential

[135] The assumptions and uncertainties related to the risk assessment are summarized in Annex B: Information on hazard and risk.

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
	mini-pitches make use of performance infill, although it is known that part of mini-pitches do not make use of performance infill, the actual share is uncertain) - Quantities of infill used on various types of pitches (*quantities differ per pitch type and type of infill used)* - Size of pitches and of mini-pitches *(various sizes have been reported both for pitches and for mini-pitches)* - Used quantities for refill - Service life of pitches (*may be an underestimate, also lifetimes of 15 years have been indicated compared to the 10 years included in the analysis*) The estimates used to derive quantities of ELT infill and mulches used in sport and play applications in the baseline situation may be overestimates and others may be underestimates. Especially the quantities used in mini-pitches are uncertain. Furthermore, there are uncertainties in the expected trends. The total figure derived in this dossier for the baseline situation is comparable with an estimate provided by an EU association (2018, figures claimed confidential). Depending on the actual and future use of ELT infill in the baseline situation, this may lead to an over or underestimate of the costs of RO1 and RO2.			
PAH concentrations in ELT and expected trends	The dossier reported on the analysis of 1 234 samples of REACH-8 PAHs concentration in ELT infill on pitches and at factory gates from 9 different EU countries. These are assumed to be representative for the EU. Whether this in fact is the case is not known. There may be various reasons why the distribution may not be representative for the EU: - Only ELT samples where included, no samples from other recycled rubber sources have been included (unless it was mixed with ELT and not noted) - Very limited information on the occurrence of high PAH concentrations in the EU is available - No estimates from eastern EU are available - No representative sample has been taken. All samples that where available to the Dossier Submitter from various sources (recycling	?	May be important both for RO1 and RO2, especially when it comes to occurrence of high PAH concentrations	See Appendix B1 and Appendix E1

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
	companies, field owners, test labs, scientific publications) have been included in the analysis. - Variability in analytical methods It is not known whether this may lead to a potential under- or overestimate. The distribution is used to estimate the expected market response of RO1 and RO2 and the expected health benefits of the restriction options and this uncertainty may thus affect both costs as benefits of the restriction.			
Temporal scope	Based on the service life of the pitches, for the impact assessment a 10 year period is chosen starting from 2019 entry into force up to 2028 as temporal scope. This may be too early as the time required for ECHAs dossier evaluation and decision making in REACH committee takes time. However, this is expected to affect benefits and costs equally and thus is not deemed relevant for the proportionality conclusion. It is however important to note that benefits of the restriction will increase over time as existing pitches will be replaced in a 10 year period, accounting for the life time of pitches. In year 10, the benefits of the restriction are expected to be at its maximum capacity. For year 10-20 benefits are expected to be substantially larger than for year 0-10. This however, is not expected to change benefit cost balance of RO1 and RO2	↑	Limited importance both for RO1 and RO2	See Annex E
Discounting	4 % has been applied as standard discounting of the cost estimates derived in the impact assessment of RO1 and RO2. Change in discount rate will have an effect on the magnitude of the quantified cost figures, especially in RO2 as costs of this scenario are more substantial compared to the costs or RO1. The effect can go in both directions depending on the alternative discount rate chosen. This however, is not expected to change the order of magnitude of costs in both scenarios.	↑ ↓	Limited importance both for RO1 and RO2	ECHA 2008
Market response to RO 1 and RO2	*RO1 – 17 mg/kg* The Dossier Submitter expects that in RO1 ELT granules and mulches can continue to be used in sport and play applications as 95 % of the infill/mulches produced currently are expected to already comply with the	↑ ↓	Limited importance both for RO1 and RO2	Appendix E2; ETRMA 2018; 24 November 2017

Assumption/ estimate	**Description/Explanation/Source**	**Over/under estimation of proportionality conclusion**[1]	**Importance for the impact assessment/ proportionality conclusion**	**Source/ basis of the estimate**
	limit value of 17 mg/kg and tyre recyclers will be able to take the needed additional measures to comply with the limit value. Although there is some uncertainty in the actual response of tyre recyclers to this RO, a fundamentally different response is not expected. *RO2 – 6.5 mg/kg* The Dossier Submitter expects that in RO2 ELT granules and mulches will not be used anymore in sport and play applications and that artificial turf systems are used using alternative types of infill. This is expected as only 14 % of the ELT infill currently complies with the limit value of 6.5 mg/kg and based on responses from industry, it is deemed infeasible for recycling companies to produce granules and mulches that comply with this limit value. They are expected to have limited influence on the characteristics of their material inflow. There may however be a chance that part of the ELT infill produced can still be used as infill/mulch as 14 % may be compliant. For the type of alternatives used, signals from artificial turf market has been used indicating that EPDM and TPE may be most promising. Besides cork may be used as performance infill and in time more innovative non-infill systems may be used as well. It is assumed that natural grass will not be used as replacement alternative, as these systems have different characteristics (mainly related to land use, weather conditions). Although there are uncertainties in the market response, these are not expected to have a major impact on the proportionality conclusion.			workshop
Costs of tyre recycling	*RO1 – 17 mg/kg* Tyre recycling companies may need to take measures to reduce PAH content for the 5 % of granules produced that currently may not comply with the proposed limit value. Or actors may choose to sell 5 % of the granules and mulches produced for other uses at a lower price. Some information is available to the Dossier Submitter on prices of other ELT applications. Depending on the actual price paid for ELT in the alternative application, cost may be higher or lower. Assumptions have been taken to derive a rough estimate of these costs. Costs may be smaller or larger depending on the actual alternative tyre recycling option. If the ELT	↑ ↓	May be important for RO1	See Annex E

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
	producer has to pay € 30 per ton to get rid of the 5 % infill, the total societal costs will increase with € 7 million (about 10 % cost increase). If the producers will receive € 100 per ton ELT granules, the societal costs will decrease with € 18 million (about 30 % cost decrease) compared to the middle estimate. Furthermore, it is expected that RO1 will result in an increase of testing for REACH-8 PAH by tyre recyclers. It is not known to the dossier submitter what share of companies is already testing PAHs in the baseline situation and what frequency of tests will be applied in RO1. Costs may be lower or higher, depending on the price of a test as well (assumed to be € 130 per test/ pitch). *RO2 – 6.5 mg/kg* As ELT granules and mulches cannot be used anymore in sport and play applications, alternatives ways of tyre recycling is required in this scenario. This will increase societal costs for recycling. In the dossier, three alternative ways of tyre recycling have been evaluated to derive an estimate of the additional costs to society, the middle estimate has been included in the quantitative costs assessment. Costs may be smaller or larger depending on the actual alternative tyre recycling option, however, this is not expected to change the order of magnitude of costs (as total costs are largely determined by the costs of alternative pitch systems).	↑ ↓ ↑ ↓	May be important for RO1 Limited importance for RO2	See Annex E See Annex E
Costs of various alternative (mini-) pitch systems	In the cost estimates of various alternative artificial turf pitches, the costs of artificial turf carpet, infill, installation, maintenance and end-of-life are included. Costs of the substructure have not been included as these are expected to be similar for the various systems. Potential clean-up costs of potential environmental pollution of artificial turf pitches e.g. due to leaching of zinc, cobalt and mineral oil from ELT granules have not been included. This may be an overestimate of the difference in price between ELT based and alternative pitches and may thus result in an overestimate if costs of the restriction. Systems that make use of alternative types of infill are currently substantially more expensive compared to systems that make	↑	May be important for RO2	See Annex E

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
	use of ELT. Increase in demand in RO2 is assumed not to affect price in the impact assessment, however, this may very well be the case in practice. Market costs for the change in artificial turf systems therefore may be overestimated in RO2. For RO1 this is not deemed relevant as ELT is expected to continue being used in that scenario.			
Distributional impacts	The Dossier Submitter assumes that municipalities are owners of pitches and mini-pitches, and that the extra costs for artificial turf pitches are expected to be passed on to all EU citizens. Passing the costs to athletes may change the effect of the RO's as participation in physical activity depends on the price of membership fees, and increase in the costs to play football (or other sports) may affect the participation rate (Anokye et al. 2014; Ward et al., 2017). In theory this could lead to a reduction in sport activities and consequently in a reduction in the number of pitches required. Furthermore it could lead to less healthy people if people sport less. This may be relevant for RO2, it is deemed less relevant for RO1 as societal costs of that scenario are expected to be limited. However, as the costs per athlete are limited in RO2 it is questionable whether this effect in practice will occur.	?	Limited importance for RO1 and RO2	See Annex E; Anokye et al. 2014; Ward et al., 2017
Enforcement costs	Estimate of enforcement costs has been made based on an ECHA study reviewing EU-wide costs of enforcement of REACH restrictions and represent an average estimate. Actual costs for enforcement largely depends on the actual enforcement effort of specific members states and enforcement costs may be substantially larger if a Member State decides to enforce the restriction over a substantial period of time, including employee costs, costs for testing and potentially costs of forced replacement in case of non-compliance both for RO1 and RO2. Often however, enforcement entities are expected to have a fixed budget within Member States and for what this is applied is a matter of choice. In that sense, enforcement of a restriction as such is not expected to increase actual enforcement costs.	↓	Limited importance both for RO1 and RO2	See Annex E; Dubourg, ECHA 2016 2016
Population that	Estimates has been included of the number of athletes, other users of	?	Limited importance	See Annex D:

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
may come into contact with PAHs in granules and mulches in sport and play applications, population potentially at risk and expected trends herein	mini-pitches, installation and maintenance workers that may come into contact with performance infill on artificial turf and infill/mulches on sport and play applications has been derived. For the football population, reliable estimates are available. The number of users of mini-pitches and installation and maintenance workers has been roughly estimated. These estimates are expected to be more uncertain. No trend estimate over time has been derived for the population that may come into contact with granules and mulches. This may lead to an underestimate of the result as the number of artificial turf pitches is expected to grow over time. It is not known what the overall effect of this estimate would be, however, having the full EU population included as an upper bound check, this uncertainty appears to be of limited importance for the conclusion. It should be noted that the included quantitative estimates of the population cover the population that <u>potentially</u> may come into contact with recycled (ELT) granules and mulches and that the population exposed and at risk are expected to be lower.		both for RO1 and RO2	UEFA 2016[44]; UEFA 2018; Dutch Cruyf Courts website[136]
Risk reduction and avoided cancer cases	Estimates of the risk levels for various life-long exposure scenarios are presented by the Dossier Submitter at various PAH concentrations to indicate the risk reduction both in RO1 and RO2 compared to the baseline. When it comes to human health gains, differentiation is made in: - Avoidance of high PAH concentrations (>21 mg/kg (P99 of the baseline) up to the current limit value for mixtures) that will result in high risk reduction levels both in RO1 and RO2. These are deemed relevant for few specific individuals rather than for the full target population as high PAH concentrations are expected to be incidents. - Reduction in risk of RO2 because of a shift in PAH concentration from 21 to 0 mg/kg. This risk reduction may be relevant for a larger share of the target population. Based on this, a theoretical upper bound	↓	Limited importance both for RO1 and RO2	See Annex E

[136] https://www.cruyff-foundation.org/activiteiten/cruyff-courts

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
	estimate of potential avoided cancer cases due to a reduction in PAH content is estimated. In this estimate it is assumed that all individuals that may come into contact with ELT (the total of sub-populations) have a risk reduction level in RO2 that is comparable to the value of the professional keeper. In practice, risk reduction of RO2 is expected to be (much) smaller for a substantial part of the population as these are expected to have lower risk levels in the baseline situation. The estimated 8 avoided cancer cases in RO2 is expected to be an overestimate of the benefits of RO2. For RO1 a similar approach has been taken to estimate the upper bound number of avoided cancer cases due to a shift from 21 mg/kg to 17 mg/kg. Although only an upper bound estimate of potential avoided cancer cases has been derived for RI1 and RO2, more refined analysis of benefits are not expected to change proportionality conclusions both for RO1 and RO2.			
Estimate of other benefits	Potential hazardous effects of the use of ELT infill and mulches in sport and play applications, to human health and the environment, other than carcinogenicity of PAHs, are out of scope of the risk assessment of this dossier and have not been considered in Annex B[137]. End-of-market of ELT in RO2 may result in additional health and environmental benefits in the impact assessment. These can be potential human health effects of other hazard characteristics of PAHs, potential human health effects or environmental effects of other hazardous substances in ELT. Furthermore, benefits are expected due to avoided emissions of microplastics in RO2 compared to the baseline situation. These potential other effects (benefits) have only been briefly considered in the impact assessment and were not further quantified (except for microplastics), or monetised. This may	↑	May be important for RO2	See Annex E

[137] ECHA has been requested by the Commission to consider the non-PAH substances in rubber granules used as infill in artificial turf systems: https://echa.europa.eu/documents/10162/13641/request_echa_cooperate_with_the_nl_and_rubber_granules_en.pdf/df803191-d222-0bb5-a838-7a936454f5b9.

Assumption/ estimate	Description/Explanation/Source	Over/under estimation of proportionality conclusion[1]	Importance for the impact assessment/ proportionality conclusion	Source/ basis of the estimate
	underestimate the actual benefits of RO2. For RO1 this is deemed irrelevant as ELT infill and mulches will continue to be used in that scenario.			
Greenhouse gas (GHG) emissions	Additional societal costs of RO2 are expected as alternative systems have higher GHG emissions compared to the ELT based artificial turf system as no recycled materials are used. Changes in GHG emissions have been quantified based upon a Swedish LCA study. This study only includes infill and does not include differences in artificial turf systems (difference in carpet and use of shockpad). It is not known what the effect of these missing elements may be on the LCA results. Differences in GHG emission has been monetized using an EU estimate of the value of GHG emissions. This estimate is relatively low compared to other available value estimates and this may result in an underestimate of these societal costs. This however, will only be a small fraction of the total estimates societal costs of RO2. For RO1 this is irrelevant as ELT will continue to be used in this scenario.	↑ ↓	Limited importance for RO2	Skenhall et al., 2012; EC 2014
Societal concern	The use of ELT infill in artificial turf pitches has resulted in societal concern in various EU countries. RO1 is expected to reduce societal concern related to human health as high PAH concentrations are avoided, however, concern may remain e.g. related to environmental issues as ELT is still used as infill material. In RO2 the risk of PAHs in infill and mulches is expected to be reduced to zero in a 10 year period as within that time frame all ELT containing pitches are expected to be replaced with alternatives. Societal concern around existing pitches may increase temporally in RO2 and may even result in early replacement of existing pitches. This potential impact has not been included in the impact assessment. However, it has the potential to increase societal costs substantially. It is deemed more likely that this effect may occur in RO2, however, it could also occur in RO1. In that case also benefits would increase.	↓	May be important both for RO1 and RO2	See Annex E

[1] Legend: ↑= overestimate of proportionality (if this appears to be the case, less proportional); ↓= underestimate of proportionality (if this appears to be the case, more proportional); ? = uncertain consequence on proportionality

Annex G: Stakeholder information

Information about the ELT derived granules and mulch market, the concentrations of PAHs in ELT derived granules used as infill material on synthetic turf pitches and about the sythetic turf market has been obtained by a series of consultations with a wide array of stakeholders. These interactions with the stakeholders happened mainly through ECHA's call for evidence procedure, workshop organised by the Dossier Submitter and ECHA and personal communication (calls, e-mails, site visits and meetings). ECHA launched a call for evidence on 28 August 2017 and ended it on 18 October 2017. During the consultation, 21 comments were received from stakeholders, including individuals, several industry associations and Member State Competent Authorities[138]. In order to augment the information received from the call for evidence, RIVM and ECHA contacted some stakeholders directly between August 2017 and May 2018. The Dossier Submitter together with ECHA organised a workshop in the Netherlands on 24 November 2017, which was attended by 42 stakeholders, representing different organizations, such as tyre recyclers, tyre manufacturers, synthetic turf manufacturers, academia and manufacturers of alternatives. The chairman summary of the stakeholder workshop is included in Appendix G1.

All stakeholders that were contacted and provided information are listed below. In addition, information from ECHA's 2017 Annex XV report on rubber granules, including a separate stakeholder consultation, has been used for this dossier.

[138] Note that not all names are included in table G 1 below as some where claimed confidential.

Table G 1: List of Stakeholders

Name	Type of organization	Response received	Mode of contact
Apollo Vredestein	Company	Yes	• Plant visit
AVE SK odpadové hospodárstvo s.r.o.	Company	Yes	• Personal communication
Berleburger Schaumstoffwerk GmbH	Company	Yes	• Workshop
Branchevereniging Sport en Cultuurtechniek (BSNC)	Association	Yes	• Call for evidence • Workshop • Meeting RIVM at BSNC
BSW Berleburger Schaumstoffwerk GmbH	Company	Yes	• Call for evidence
Celanese So.F.teR	Company	Yes	• Call for evidence • Workshop • Personal communication
City of Stockholm, Environmental and health administration	Regional or local authority	Yes	• Call for evidence
Conradi-Kaiser GmbH	Company	Yes	• Call for evidence • Workshop
CS GummiRecycling	Company	No	• Personal communication
Dywilan SA	Company	Yes	• Personal communication
Danish EPA	National authority	Yes	• Call for evidence
European Tyre Recycling Association (ETRA)	Association	Yes	• Workshop
European Tyre & Rubber Manufacturers' Association (ETRMA)	Association	Yes	• Call for evidence • Workshop • Personal communication
The European Synthetic Turf Organisation (ESTO)	Association	Yes	• Call for evidence • Workshop • Personal communication
Environment Agency Austria	National authority	Yes	• Call for evidence
Federazione Nazionale Gioco Calcio	Association	Yes	• Workshop
Flemish Authority - Policy Area Environment	Regional or local authority	Yes	• Call for evidence
Fraunhofer	Company	Yes	• Workshop
Genan Holding A/S and Genan A/S	Company	Yes	• Personal communication • Workshop • Plant visit
GEYER & HOSAJA Sp.z.o.o	Company	Yes	• Personal communication
Gezolan	Company	Yes	• Personal communication
Granuband	Company	Yes	• Personal communication • Workshop • Plant visit
HvR Speeltotaal	Company	Yes	• Personal communication
International Carbon Black Association	Association	Yes	• Workshop
Kempeneers-Milieu	Company	Yes	• Workshop
Labosport Ltd	Laboratory	Yes	• Personal communication • Workshop
Lega Nazionale Gioco Calcio	Association	Yes	• Call for evidence
Metaloidas UAB	Company	No	• Personal communication
Melos GmbH	Company	Yes	• Personal communication
MRH Muelsen GmbH	Company	Yes	• Call for evidence
Murfitts Industries Ltd	Company	No	• Personal communication

Polytan GmpH	Company	Yes	• Workshop
PVP Triptis GmBH	Company	Yes	• Workshop
Ragn-Sells AS	Company	Yes	• Personal communication • Workshop
Recipneu	Company	Yes	• Call for evidence • Personal communication
RecyBEM/Band en Milieu	Company	Yes	• Workshop • Personal communication • Involved in plant visits
Riteco AG	Company	No	• Personal communication
Rubbergreen Industrie	Company	Yes	• Personal communication
Rumal	Company	Yes	• Workshop • Plant visit
Sekisui Alveo	Company	Yes	• Workshop
SGS Intron	Company	Yes	• Workshop
STARGUM	Company	No	• Personal communication
Stirling University	Academic Institution	Yes	• Workshop
Swedish Environmental Agency	National authority	Yes	• Call for evidence
TenCate Grass Holding B.V.	Company	Yes	• Workshop • Personal communication • Plant visit
Terra Sports Technology	Company	Yes	• Workshop
Trimex Tyre & Rubber Import und Export GmbH	Company	Yes	• Personal communication
UNION sport & cycle	Association	Yes	• Personal communication
Unirubber Sp. z o.o.	Company	Yes	• Personal communication
University of Torino	Academic institution	Yes	• Call for evidence
University Twente	Academic institution	Yes	• Personal communication • Workshop • Visit
Utrecht University, Institute for Risk Assessment Sciences	Academic institution	Yes	• Call for evidence • Workshop
VSO Consulting	Company	Yes	• Personal communication
wdk - Wirtschaftsverband der deutschen Kautschukindustrie	Company	Yes	• Call for evidence
Zwartgroen	Company	Yes	• Personal communication

Appendix B1: Overview of PAH concentrations in ELT rubber granules

PAHs generally occur in complex mixtures, which may consist of hundreds of compounds. The summed concentration of a few PAHs is generally used as marker of occurrence and toxicity of a mixture. For example, EFSA uses the sum of four or eight PAHs (EFSA-PAH4, EFSA-PAH8) (EFSA, 2008) and EPA applies the sum of 16 PAHs (EPA-PAH16) (Keith, 2015) (Table B1-1). In REACH regulations the sum of 8 PAHs is used (REACH-8 PAH) (EC, 2013). In this document an overview is given of the PAH concentrations (=content) in granules of the individual eight REACH PAHs as well as the sum of these eight PAHs.

It was aimed to obtain information on as many granule samples produced from end of life tyres (ELT) as possible to obtain representative information on the PAH content in ELT granules currently in the EU. The list of PAHs (Table B1 1) was based on the previous RIVM work (RIVM, 2017) on PAHs in granules. Concentration data of PAHs in ELT granules was provided by industry and obtained from public literature. The overview is restricted to uncoated granules produced from ELT rubber. It should be noted that rubber granules in most cases originate from ELT, but may be mixed with other rubber waste streams. Concentrations are only included when sampled (from a granules production site or a sports field) in the EU in the year 2010 or later. In 2010 a REACH restriction (EC, 2005) became effective which restricted the concentration of PAHs in extender oils used for the production of tyres or parts of tyres. It is assumed that the extender oil restriction led to a reduction of the PAH concentration in tyres and ELT granules. Therefore, PAH concentrations from samples prior to 2010 are considered not representative for current granules in the EU.

When available, the following information was retrieved from the documents providing concentration data:

- Unit
- Year of sampling
- Sampling method
- Sampling location (country and community)
- Age of the sports field (not applicable when sampled from a production site)
- Year of analysis
- Analytical method
- Manufacturer

All information was entered in an Excel file and analysed using R (version 3.4.0) (R Core Team, 2017).

Table B1-1: List of PAHs

PAH	CAS	abbreviation	REACH-8 PAH	EFSA PAH4	EFSA PAH8	EPA PAH16
Benzo[a]pyrene	50-32-8	BaP	X	X	X	X
Benzo[a]anthracene	56-55-3	BaA	X	X	X	X
Benzo[b]fluoranthene	205-99-2	BbFA	X	X	X	X
Benzo[e]pyrene	192-97-2	BeP	X			
Benzo[j]fluoranthene	205-82-3	BjFA	X			X
Benzo[k]fluoranthene	207-08-9	BkFA	X		X	
Chrysene	218-01-9	CHR	X	X	X	X
Dibenz[a,h]anthracene	53-70-3	DBAhA	X		X	X
Benzo[ghi]perylene	191-24-2				X	X
Indeno[1,2,3-cd]pyrene	193-39-5				X	X
5-Methylchrysene	3697-24-3					
Acenaphthene	83-32-9					X
Acenaphthylene	208-96-8					X
Anthracene	120-12-7					X
Benzo[c]fluorene	205-12-9					
Cyclopenta[cd]pyrene	27208-37-3					
Dibenzo[a,e]pyrene	192-65-4					
Dibenzo[a,h]pyrene (Dibenzo[b,def]chrysene)	189-64-0					
Dibenzo[a,i]pyrene (Benzo[rst]pentaphene)	189-55-9					
Dibenzo[a,l]pyrene	191-30-0					
Fluoranthene	206-44-0					X
Fluorene	86-73-7					X
Naphthalene	91-20-3					X
Phenanthrene	85-01-8					X
Pyrene	129-00-0					X

Description of the concentration data

Concentration data of PAHs in rubber granules was provided by industry, authorities, other stakeholders and obtained from public literature. The obtained samples were taken in various European countries: Belgium (100), Denmark (17), Germany (143), Italy (23), the Netherlands (1035), Portugal (5), Spain (15), Sweden (4), the UK (27) and EU (4). The country of origin of four samples was not provided, but analysis was ordered by European manufacturers and therefore considered as relevant samples for the European market. From the above samples, 1234 samples measured the REACH-8 PAHs and these were further considered in the analysis.

Samples come from public literature, authorities, field owners, recycling companies and test organisations (Ruffino et al., 2013; Marsili et al., 2014; Menichini et al., 2011; Gomes et al., 2010;

Gomes et al., 2010; Fraunhofer, 2017; Depaolini et al., 2017; RIVM, 2017; ECHA, 2017[139]; Celeiro et al., 2018). Not all available sources are mentioned here as some are claimed confidential.

Samples were taken from sports pitches or from big bags at the site of the manufacturer. When samples were taken from sports pitches, each sample represents one field. Samples from sports pitches were, in most cases, pooled samples from multiple locations on one field. Samples from manufacturers were taken from one big bag or pooled from multiple big bags. The age of the sports pitches was recorded when available. However, this age does not necessarily represent the age of the rubber granules on the field as these are normally renewed and replenished through an annual maintenance scheme. Due to the unknown age of the granules on the pitches and the lack of information about field age for the majority of pitches, no attempt was made to correlate PAH concentrations to field age. In addition, PAH concentrations of old granules could have decreased over time due to aging and leaching. Therefore, granule samples from pitches do represent current PAH concentrations, but may have been higher in the past, hampering accurate time trend analysis.

For the analysis of the time trend in PAH concentrations, solely samples were used which were taken at the manufacturing sites.

Various analytical methods were used to determine the PAH concentration in granules samples. Issues considering these methods are described elsewhere (Appendix E1).

Several measurements resulted in concentrations below the limit of detection (LOD), i.e. their actual concentration is somewhere between zero and LOD. To derive sum-PAH concentrations and the various summary statistics mentioned below, two datasets were created, one by setting the concentrations below LOD to zero (<LOD=0) and one by setting the concentrations below LOD to the LOD (<LOD=LOD). These two scenarios describe the lower (LL) and upper limit (UL) concentrations. In some samples the concentration sum of benzo[j]fluoranthene (BjFA) or benzo[k]fluoranthene (BkFA), and benzo[b]fluoranthene (BbFA) were reported. This hampers an accurate analysis of the concentrations of these three PAHs. Fortunately, the information on these three PAHs was sufficient to derive the REACH-8 PAH concentration.

An overview of the concentration data is only presented for the PAHs informing the REACH-8 PAH group (Table B1-1). For each individual PAH and the sum of eight PAHs the following data and figures are derived:

- The total number of samples in which the specific PAHs were measured, or in case of the sum PAHs, in which all PAHs are measured (above or below LOD) (Table B1-2 and Table B1-3).
- The number and percentage of measured values above and below LOD (Table B1-2 and Table B1-3).
- The geometric mean (GM) and geometric standard deviation (GSD) of concentrations (without the zero concentrations when <LOD=0) (Table B1-2 and Table B1-3).
- Various percentiles of the concentration distribution (Table B1-2 and Table B1-3).

[139] Samples provided to ECHA by Murfitts Industries and the FA Group. Data provided to ECHA by DEFRA are listed separately (three rows below) because individual data was used in our overview.

- Histograms of the concentration data (without the zero concentrations when <LOD=0) (Figure B1-1, Figure B1-3, Figure B1-5, Figure B1-7, Figure B1-9, Figure B1-11 , Figure B1-13, Figure B1-15, Figure B1-17 and Figure B1-18)
- Scatter plots of the concentrations of granule samples at the manufacturer against the year of sampling (Figure B1-2, Figure B1-4, Figure B1-6, Figure B1-8, Figure B1-10,
  Figure B1-12, Figure B1-14, Figure B1-16 and Figure B1-19).
- Contribution of the individual PAH to the REACH-8 PAH concentration (Table B1-4)
- The trend in REACH-8 PAH concentration over time (2010 to 2017) (Figure B1-20).
- Comparison of REACH-8 PAH concentrations between available countries (Figure B1-21).

Observations on the data and results

Limits of detection varied between 0.01 and 2.85 mg/kg (e.g. between analytical methods, laboratories, PAHs).

LODs of 0.2 mg/kg occurred most, since this is the required LOD of the most applied analytical method (AfPS GS 2014:01 PAH) (Appendix E1)

P50, P95 and P99 concentrations obtained by setting the values below LOD at LOD are 11, 17 and 21 mg/kg respectively for the REACH-8 PAH. For a detailed overview on the number of samples, number of samples with concentrations below LOD and various percentiles of the concentration distributions, see Table B1-2 and Table B1-3.

Analysis of REACH-8 PAH concentration against year of sampling (at manufacturer) (Figure B1-20) shows that, from 2010 onwards, there is a (significant) decrease in REACH-8 PAH concentration. The decrease seems to level off in the last four years (2014-2017). Follow-up measurements are required to verify the steady concentration levels from 2014 onwards. It should be noted that the observed decrease strongly depends on the limited number of (rel. high) samples in 2010 to 2013.

The highest contribution to the REACH-8 PAH is from benzo[e]pyrene (30 %), followed by benzo[a]pyrene, benzo[a]anthracene, benzo[b]fluoranthene and chrysene, which each contribute to the REACH-8 PAH concentration between 10 % and 20 %. Benzo[j]fluoranthene, benzo[k]fluoranthene and dibenz[a,h]anthracene contribute for about 4 % to the REACH-8 PAH concentration. However, in some samples the concentration sum of benzo[j]fluoranthene or benzo[k]fluoranthene, and benzo[b]fluoranthene was reported, which hampers an accurate analysis of the contribution of these three PAHs.

REACH-8 PAH concentration ranges in Belgium, Denmark, Germany, Italy, the Netherlands and the UK overlap. The concentrations in Sweden seem lower than in the other European countries. We do not have an explanation for these lower concentrations. An adequate analytical method (AfPS GS 2014:01 PAH) was used, i.e. the low concentrations are unlikely underestimated due to the analytical method. Considering the low sample size (n=4), the low concentration could be just coincidental.

Table B1-2: Summary data of PAH concentrations in ELT granules.
Values below LOD are set to zero. GM and percentiles are in mg/kg

	BaP	**BaA**	**BbFA**	**BeP**	**BjFA**	**BkFA**	**CHR**	**DBAhA**	**REACH-8 PAH**
Total number of Samples	1,370	1,365	1,356	1,237	1,326	1,360	1,371	1,343	1,234
number ≥LOD	1,306	1,293	1,300	1,229	1,114	1,110	1,335	184	1,230
Percentage ≥LOD	95	95	96	99	84	82	97	14	100
Number <LOD	64	72	56	8	212	250	36	1,159	4
Percentage <LOD	5	5	4	1	16	18	3	86	0
GM*	1.5	1.1	1.5	3.1	0.46	0.46	1.7	0.34	9.9
GSD*	1.5	1.9	1.7	1.5	1.6	1.6	1.8	1.9	1.6
P01*	0.40	0.20	0.40	0.60	0.20	0.20	0.30	0.10	2.3
P05*	0.80	0.40	0.60	1.5	0.20	0.20	0.50	0.13	4.2
P10*	1.0	0.50	0.70	1.8	0.30	0.30	0.80	0.20	5.4
P25*	1.2	0.80	1.2	2.6	0.38	0.30	1.3	0.20	8.1
P50*	1.5	1.3	1.6	3.3	0.50	0.45	1.9	0.30	11
P75*	1.8	1.8	2.1	4.0	0.60	0.60	2.5	0.40	13
P90*	2.2	2.2	2.6	4.6	0.80	0.80	3.1	0.60	15
P95*	2.5	2.6	2.9	4.9	1.0	1.0	3.4	0.99	17
P99*	3.1	4.0	4.0	5.8	1.7	2.1	4.5	4.3	21
P01#	0	0	0	0.44	0	0	0	0	2.1
P05#	0.20	0	0.40	1.5	0	0	0.40	0	4.2
P10#	0.89	0.40	0.60	1.8	0	0	0.60	0	5.4
P25#	1.2	0.70	1.1	2.6	0.30	0.20	1.2	0	8.0
P50#	1.5	1.2	1.6	3.3	0.40	0.40	1.8	0	11
P75#	1.8	1.7	2.1	4.0	0.50	0.60	2.5	0	13
P90#	2.2	2.2	2.5	4.6	0.70	0.80	3.1	0.22	15
P95#	2.5	2.5	2.9	4.9	0.90	0.90	3.4	0.40	17
P99#	3.1	3.9	4.0	5.8	1.6	1.8	4.4	0.71	21

* Excluding zeros
\# Including zeros

Table B1-3: Summary data of PAH concentrations in ELT granules.
Values below LOD are set to LOD. Hence, all samples are at or above LOD. GM and percentiles are in mg/kg.

	BaP	**BaA**	**BbFA**	**BeP**	**BjFA**	**BkFA**	**CHR**	**DBAhA**	**REACH -8 PAH**
Total number of Samples	1,370	1,365	1,356	1,237	1,326	1,360	1,371	1,343	1,234
GM	1.4	1.1	1.4	3.0	0.42	0.41	1.6	0.35	10
GSD	1.6	1.9	1.8	1.6	1.7	1.7	1.9	1.7	1.5
P01	0.20	0.20	0.20	0.44	0.20	0.15	0.20	0.10	2.9
P05	0.76	0.30	0.50	1.5	0.20	0.20	0.50	0.20	4.8
P10	1.0	0.50	0.70	1.8	0.20	0.20	0.70	0.20	5.8
P25	1.2	0.80	1.1	2.6	0.30	0.30	1.2	0.20	8.3
P50	1.5	1.2	1.6	3.3	0.40	0.40	1.8	0.50	11
P75	1.8	1.7	2.1	4.0	0.60	0.60	2.5	0.50	14
P90	2.2	2.2	2.5	4.6	0.70	0.80	3.1	0.50	16
P95	2.5	2.5	2.9	4.9	1.0	0.90	3.4	0.50	17
P99	3.1	3.9	4.0	5.8	1.7	1.9	4.4	1.0	21

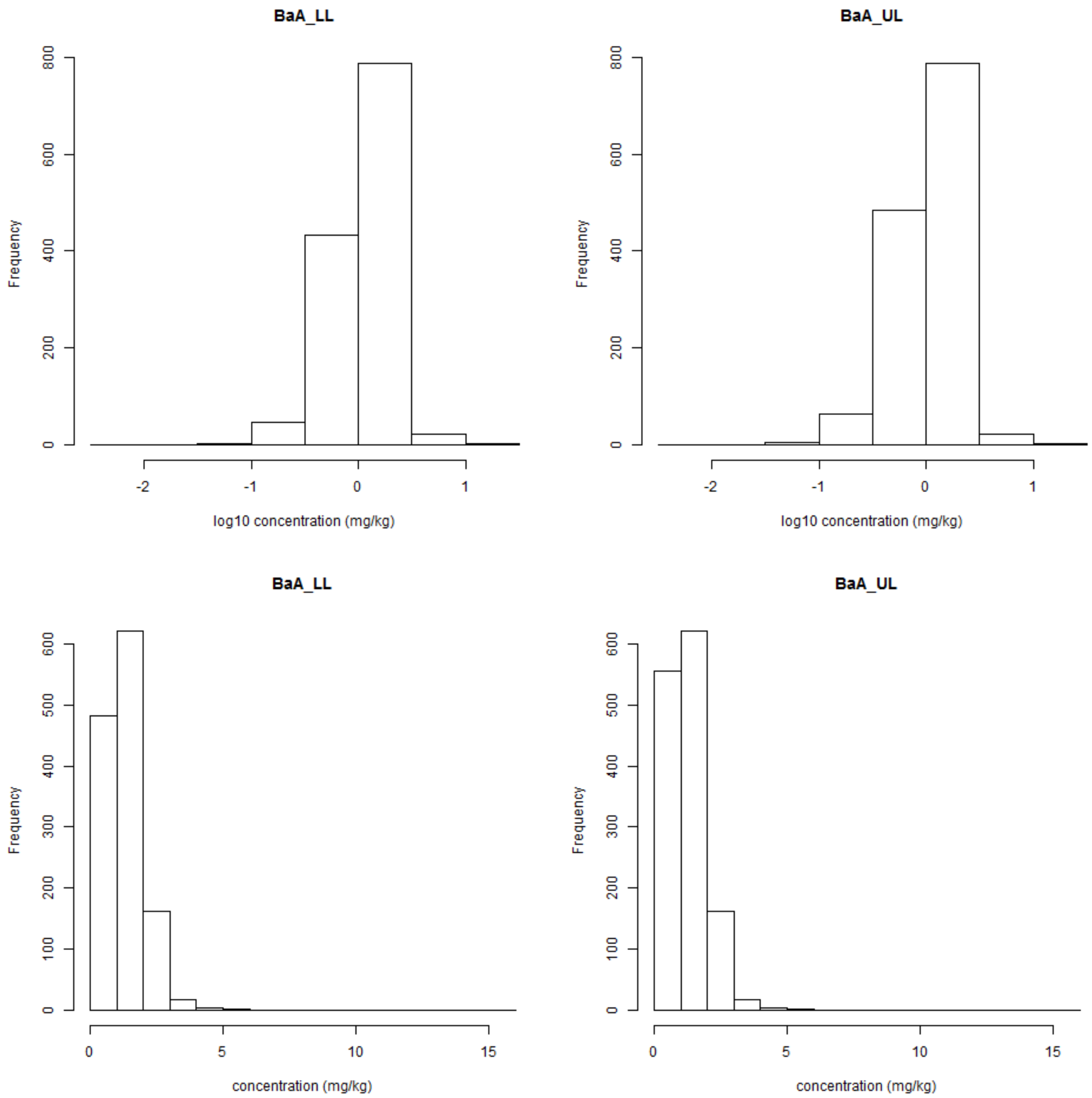

Figure B1-1 Benzo[a]anthracene.
Histograms of concentrations, upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

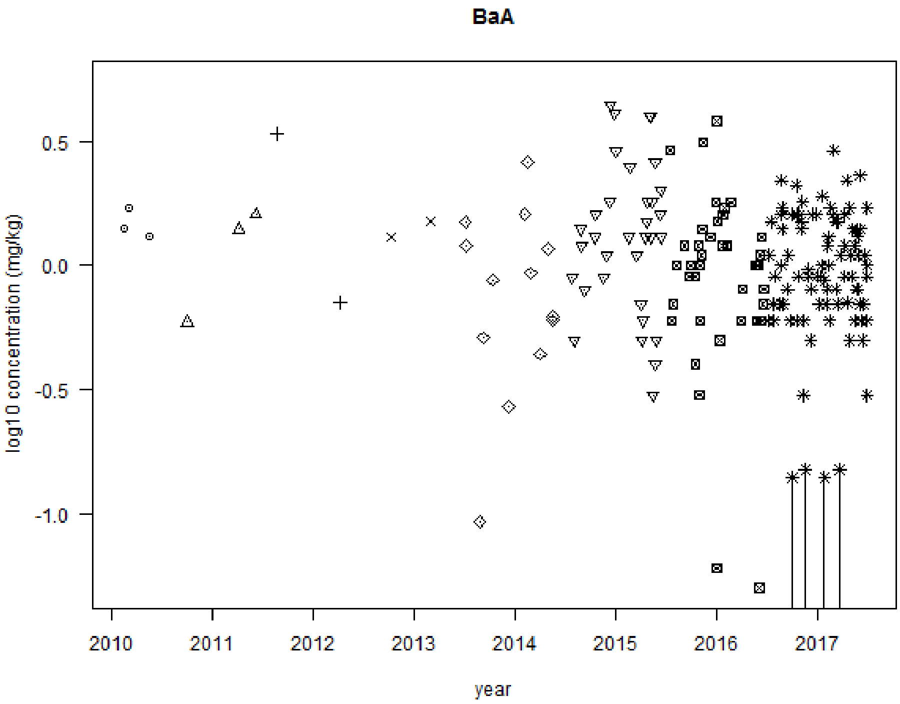

Figure B1-2: Benzo[a]anthracene. Log10 concentration against year of sampling.
Different symbols indicate different year of sampling. All samples taken at a granule production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

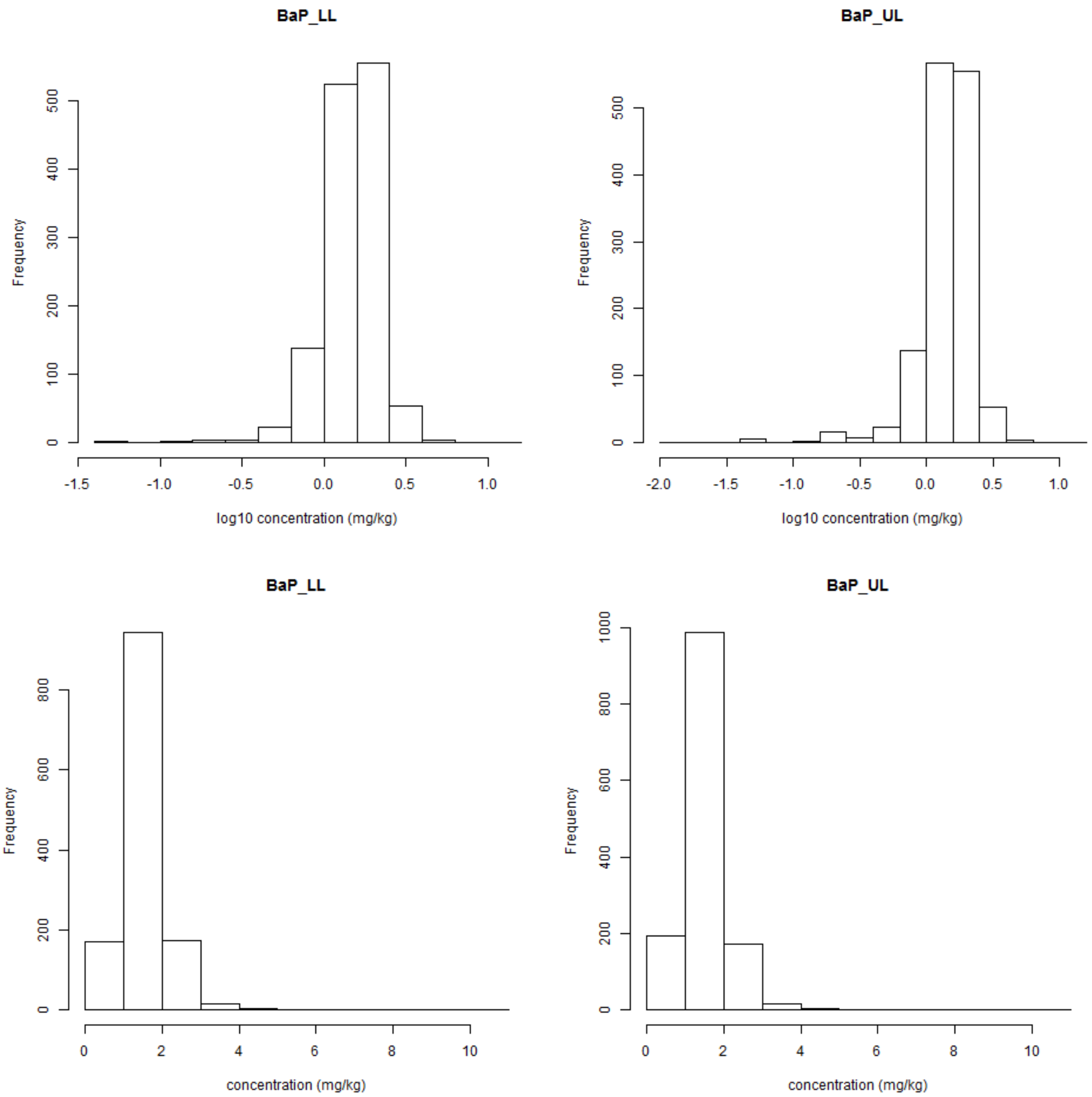

Figure B1-3: Benzo[a]pyrene. Histograms of concentrations,
upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

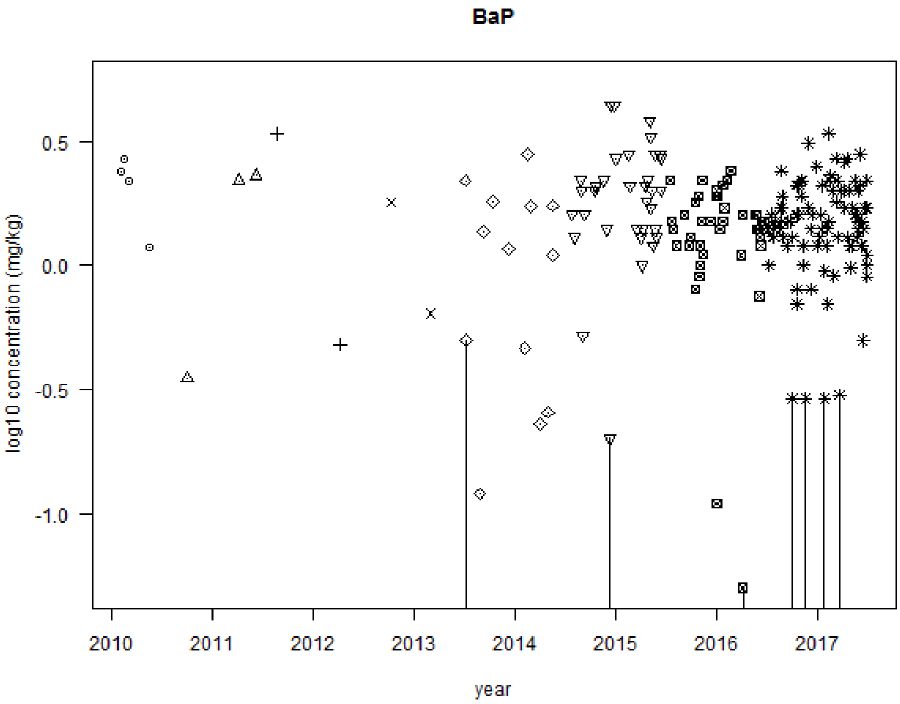

Figure B1-4: Benzo[a]pyrene. Log10 concentration against year of sampling.
Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

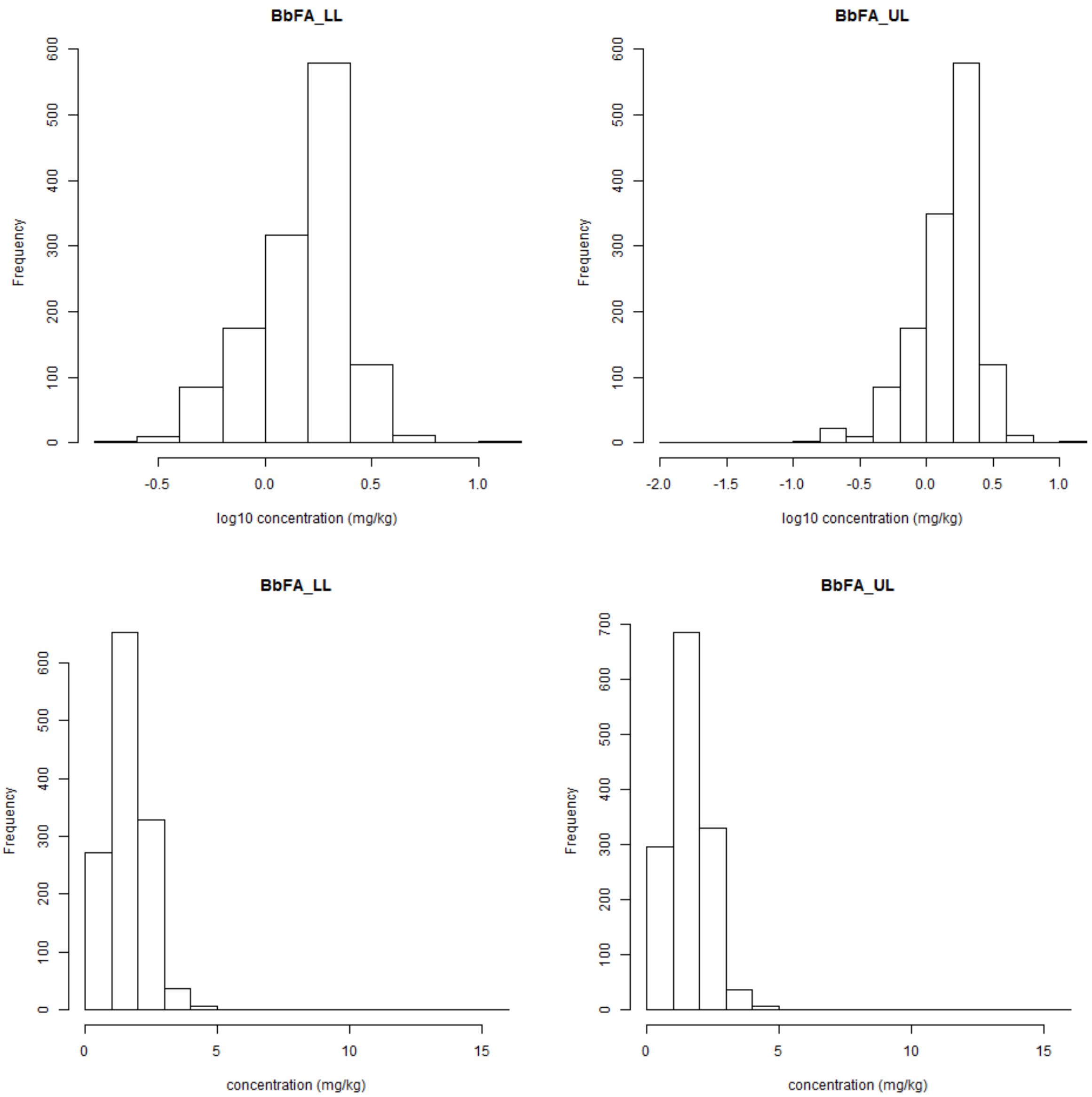

Figure B1-5: Benzo[b]fluoranthene.
Histograms of concentrations, upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

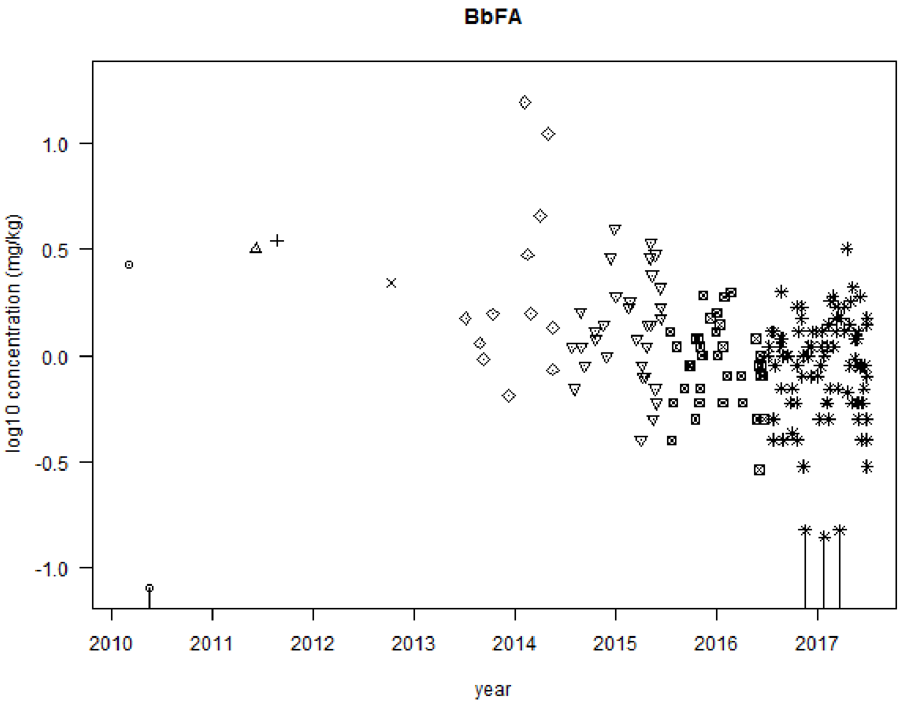

Figure B1-6: Benzo[b]fluoranthene. Log10 concentration against year of sampling.
Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

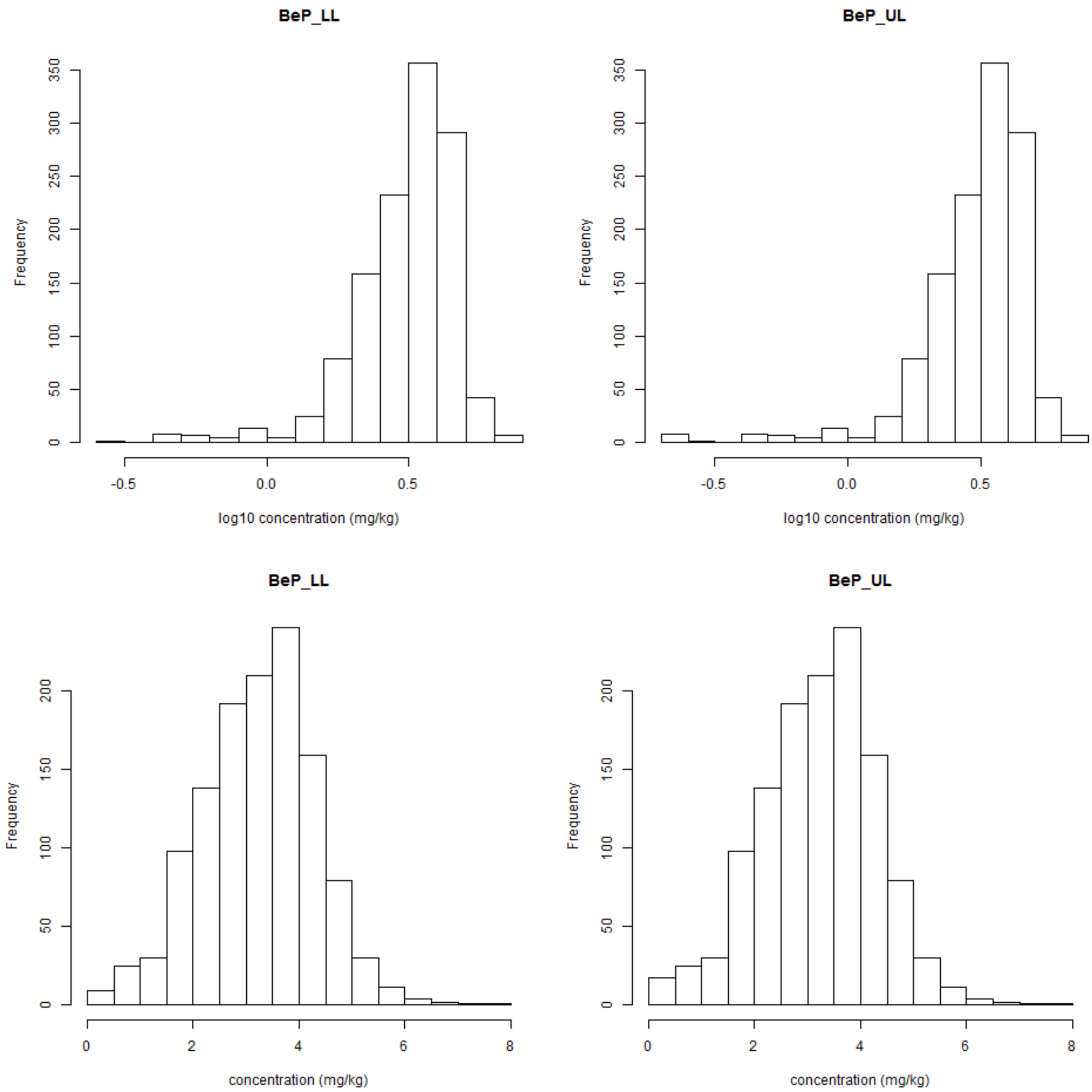

Figure B1-7: Benzo[e]pyrene.
Histograms of concentrations, upper panels on log10-scale. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

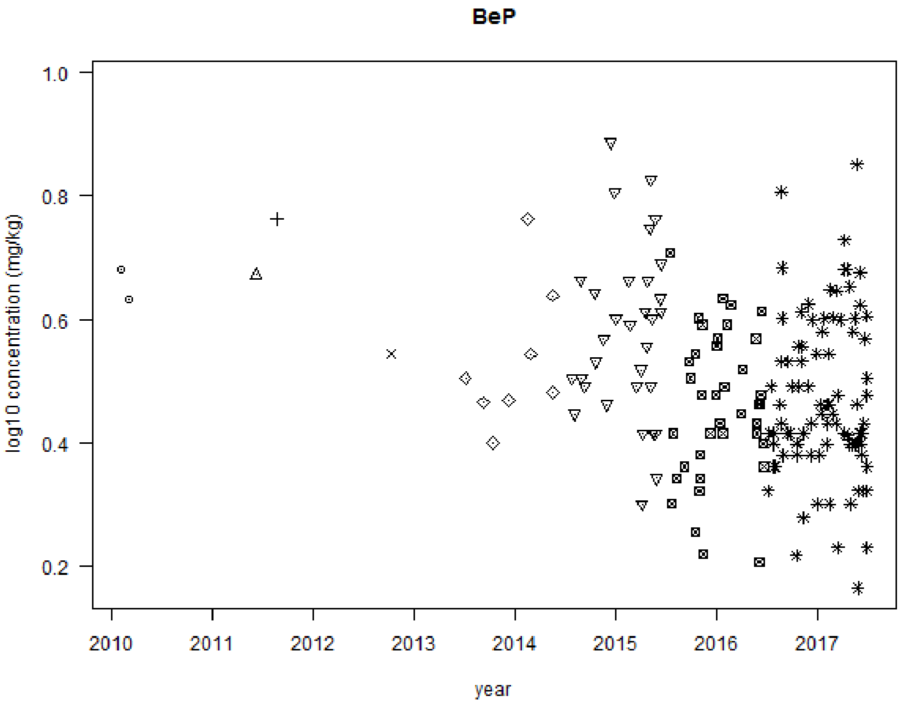

Figure B1-8: Benzo[e]pyrene. Log10 concentration against year of sampling.
Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

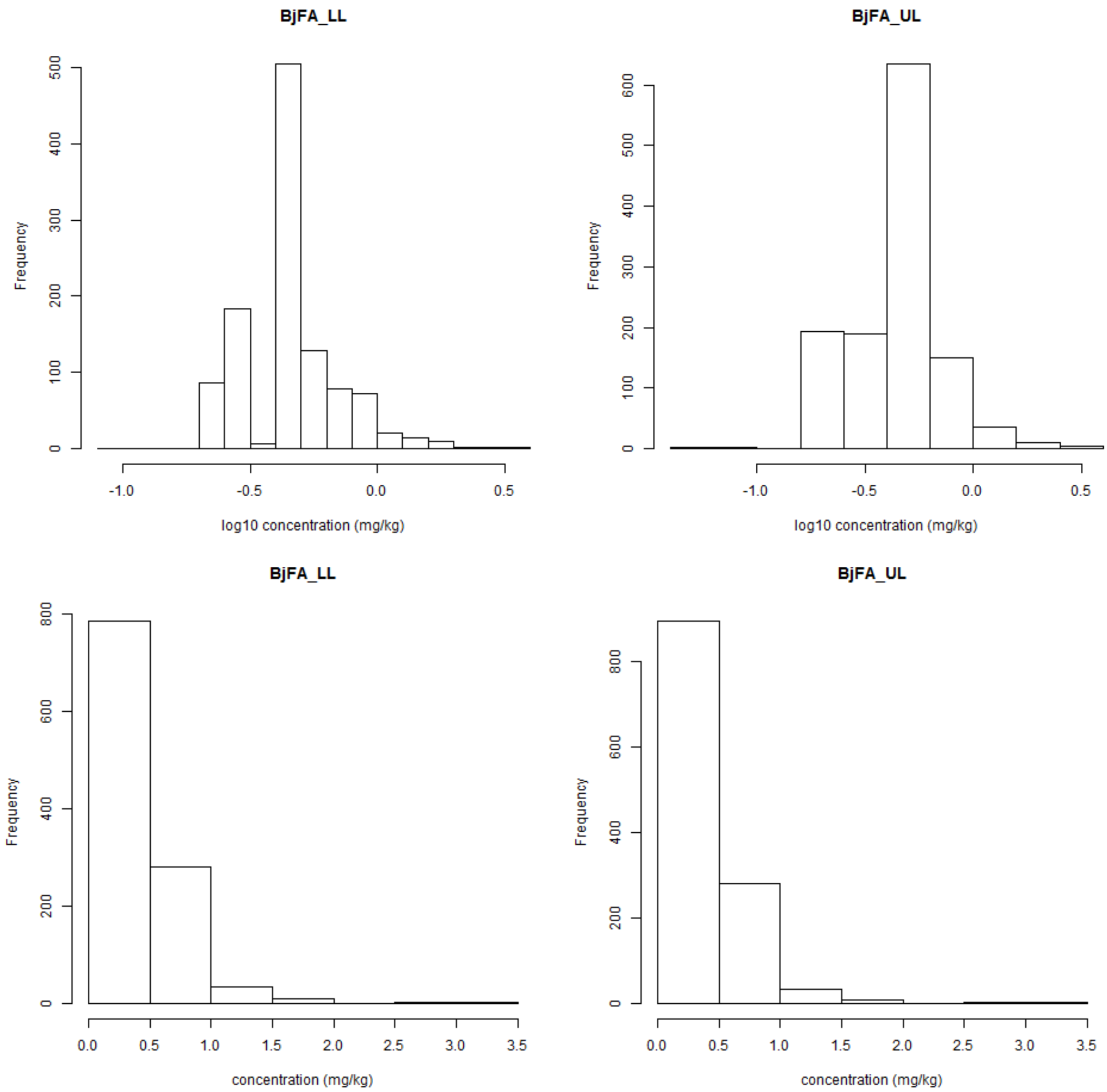

Figure B1-9: Benzo[j]fluoranthene.
Histograms of concentrations, upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

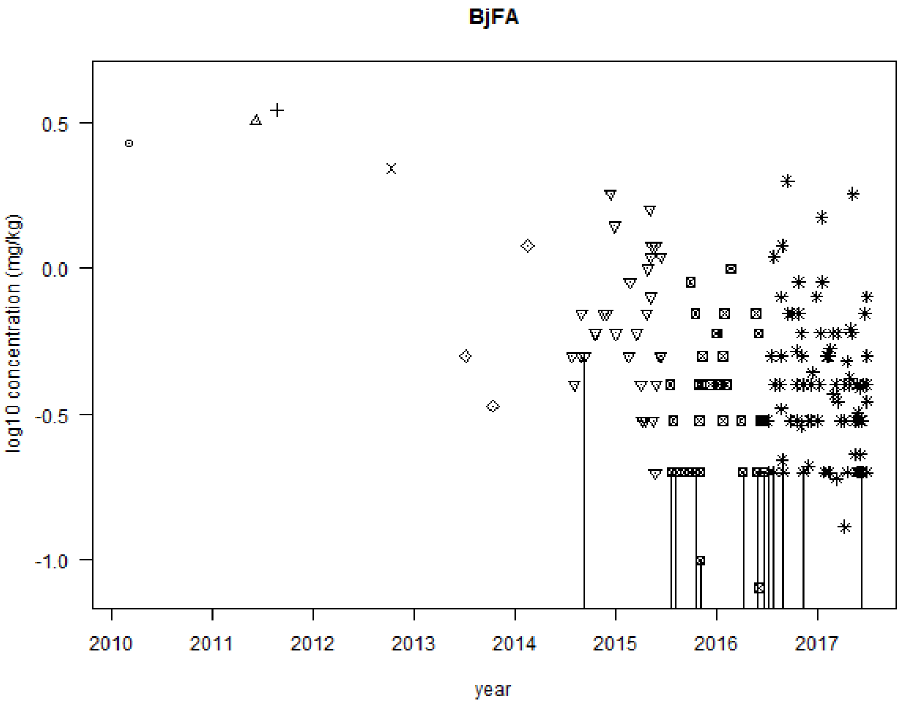

Figure B1-10: Benzo[j]fluoranthene. Log10 concentration against year of sampling. Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

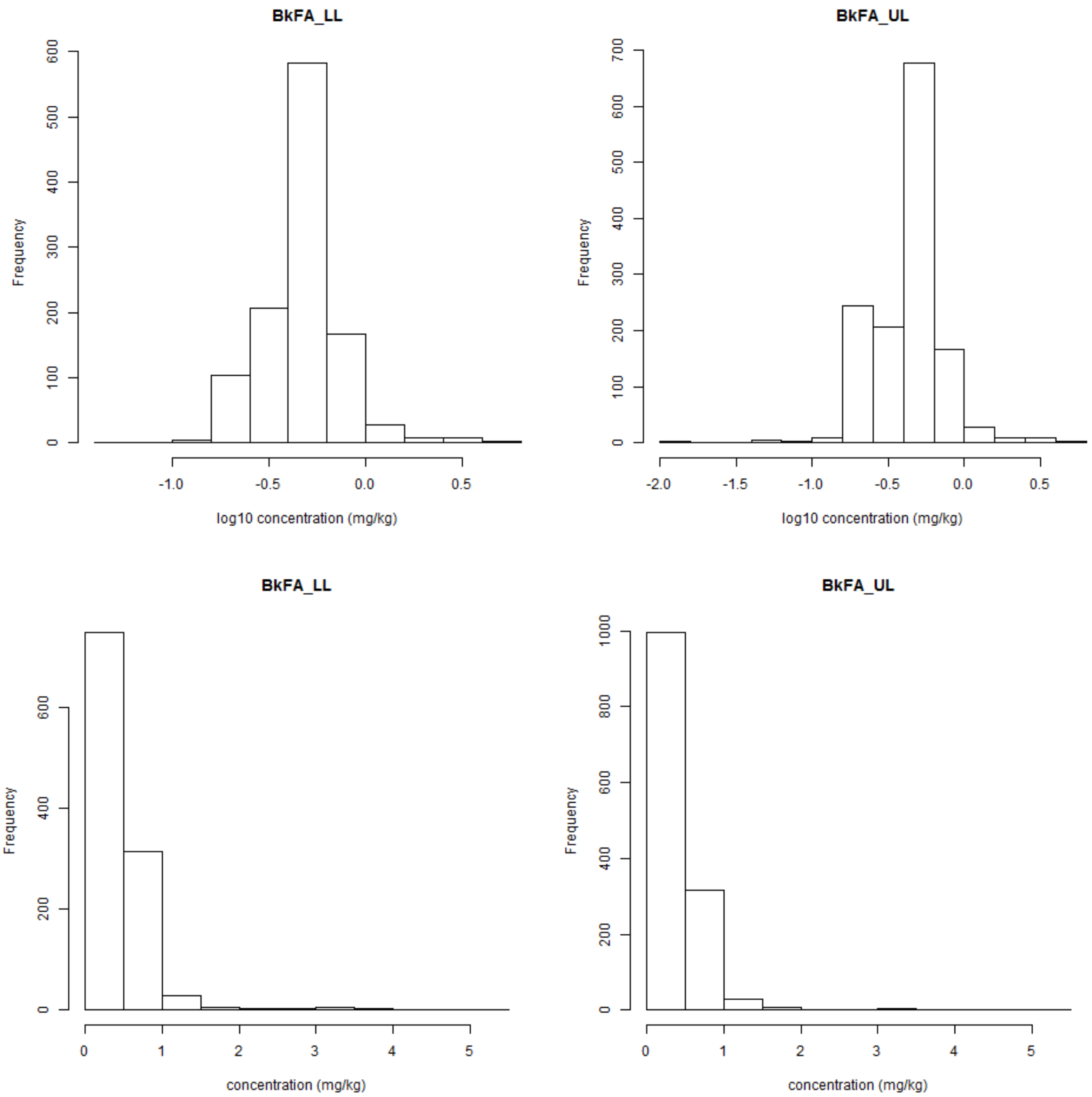

Figure B1-11: Benzo[k]fluoranthene.
Histograms of concentrations, upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

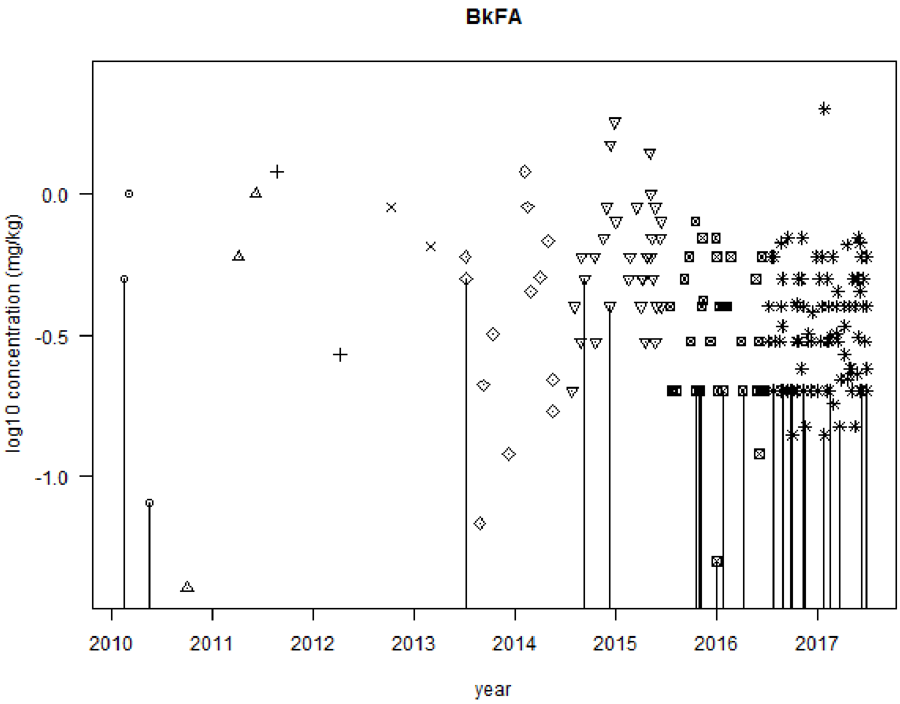

Figure B1-12: Benzo[k]fluoranthene. Log10 concentration against year of sampling. Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

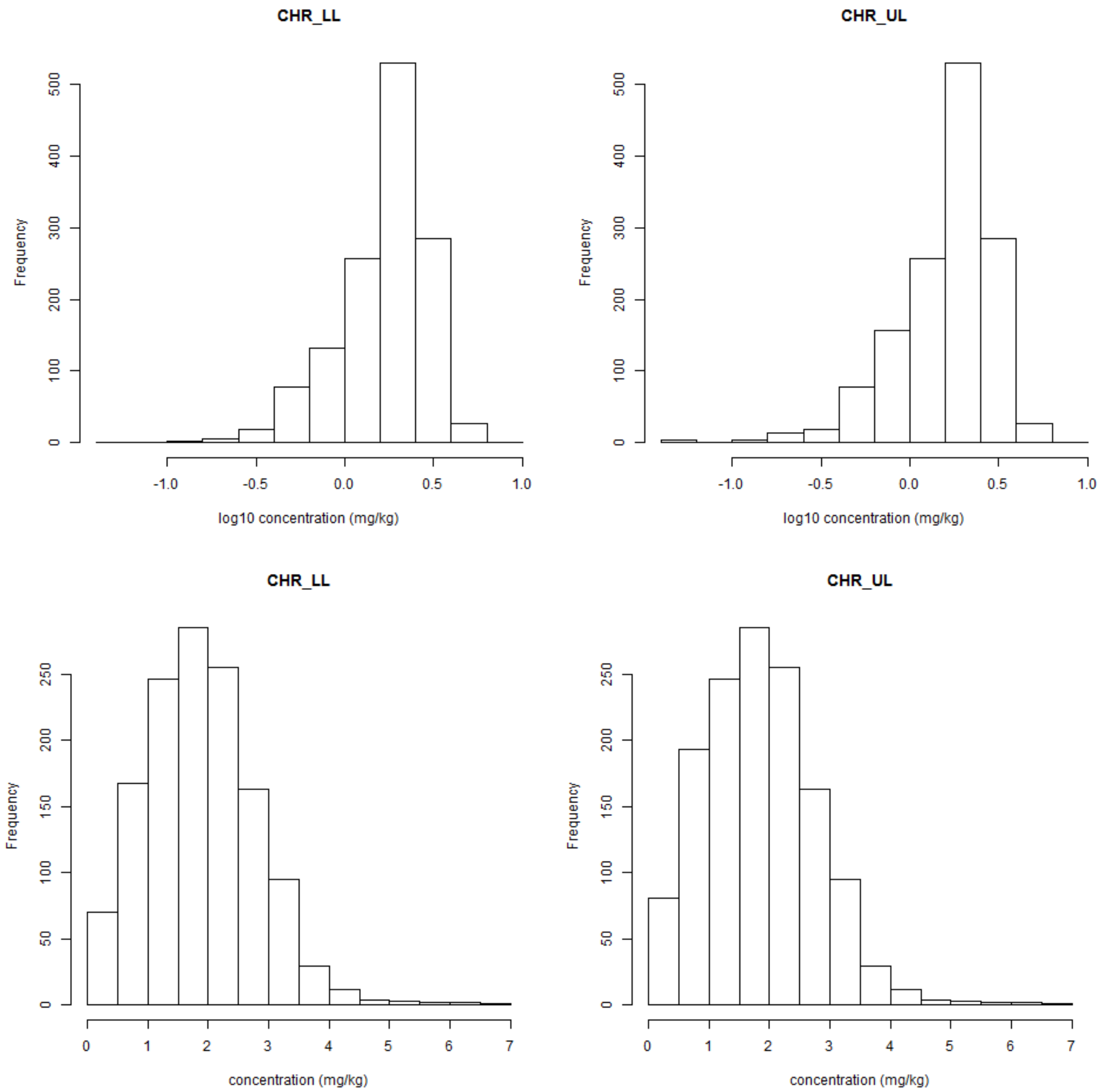

Figure B1-13: Chrysene.
Histograms of concentrations, upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

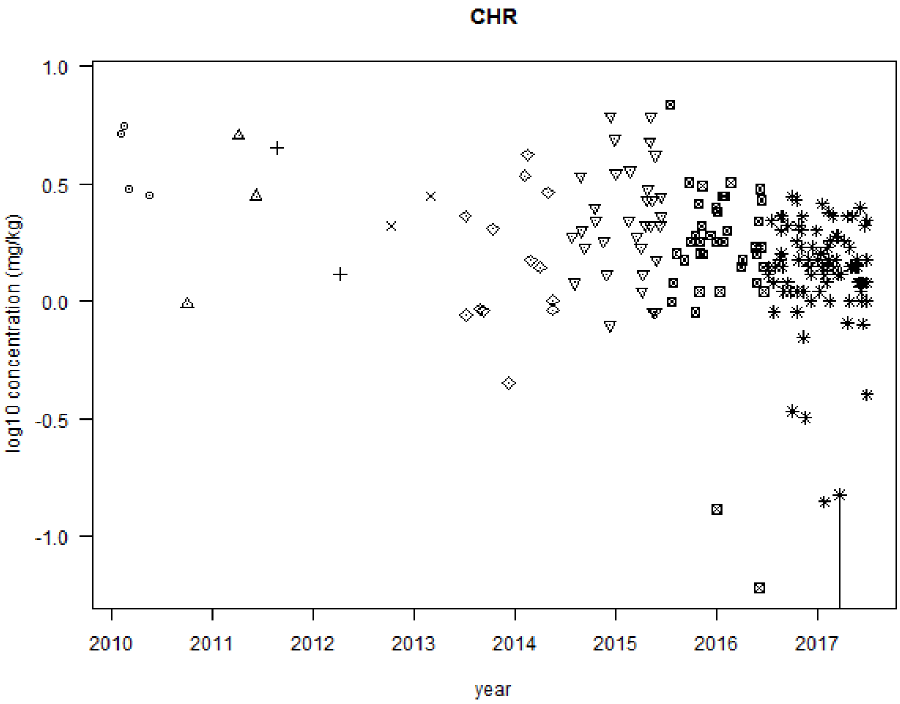

Figure B1-14: Chrysene. Log10 concentration against year of sampling.
Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

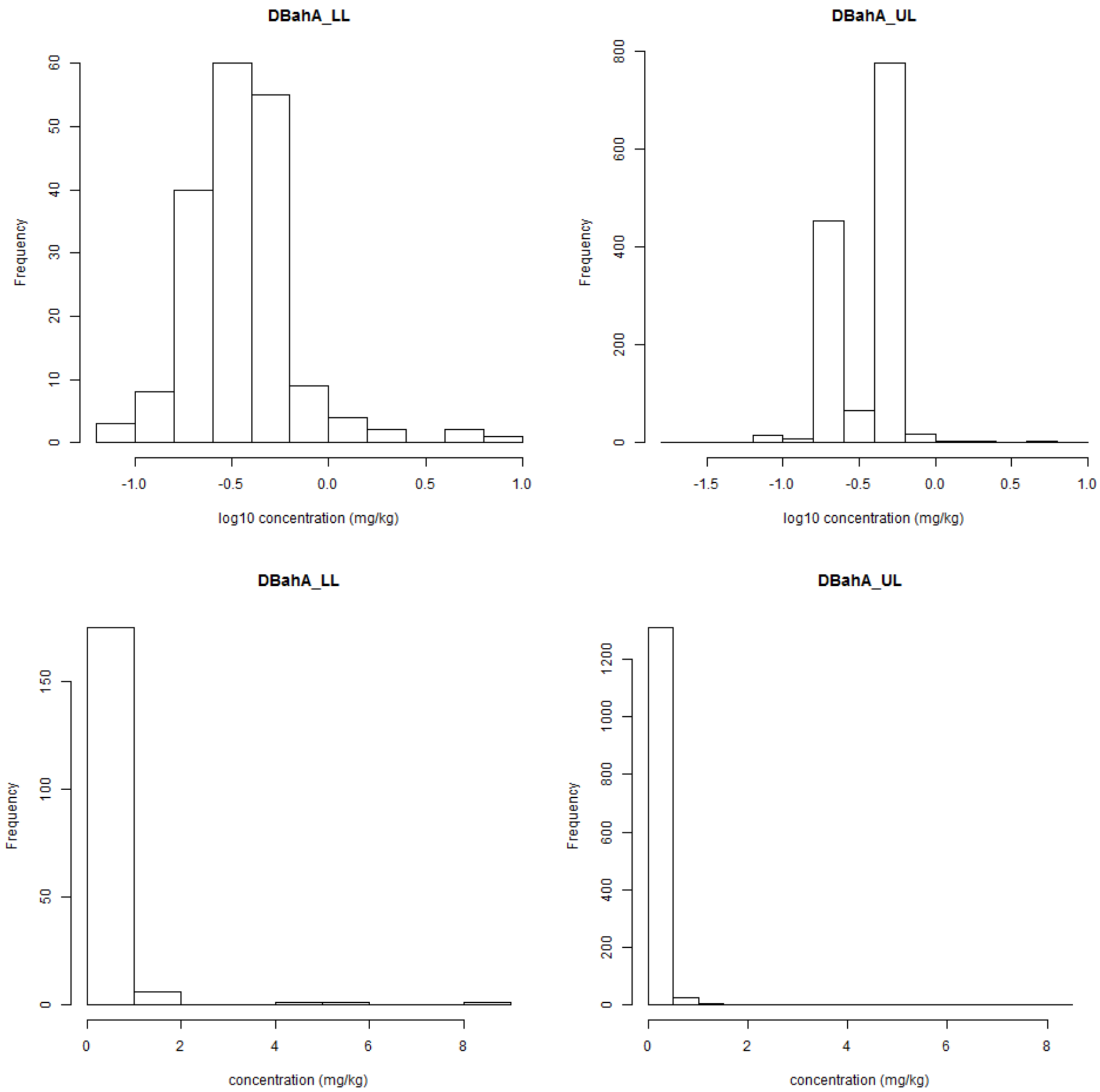

Figure B1-15: Dibenz[a,h]anthracene.
Histograms of concentrations, upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

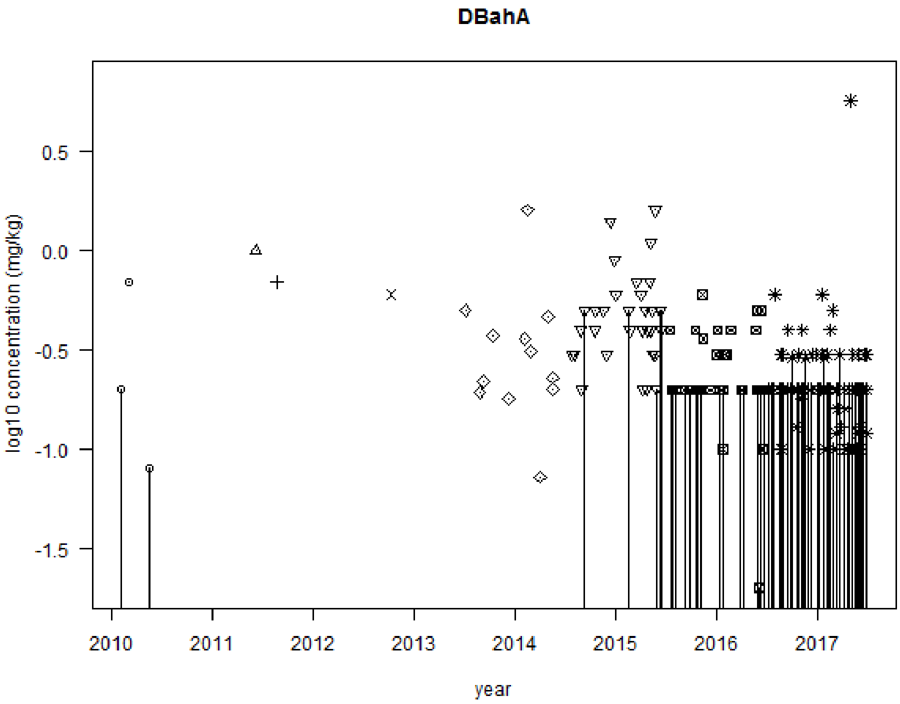

Figure B1-16: Dibenz[a,h]anthracene.
Log10 concentration against year of sampling. Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that <LOD was measured. The concentration at the upper end of the vertical line is the LOD.

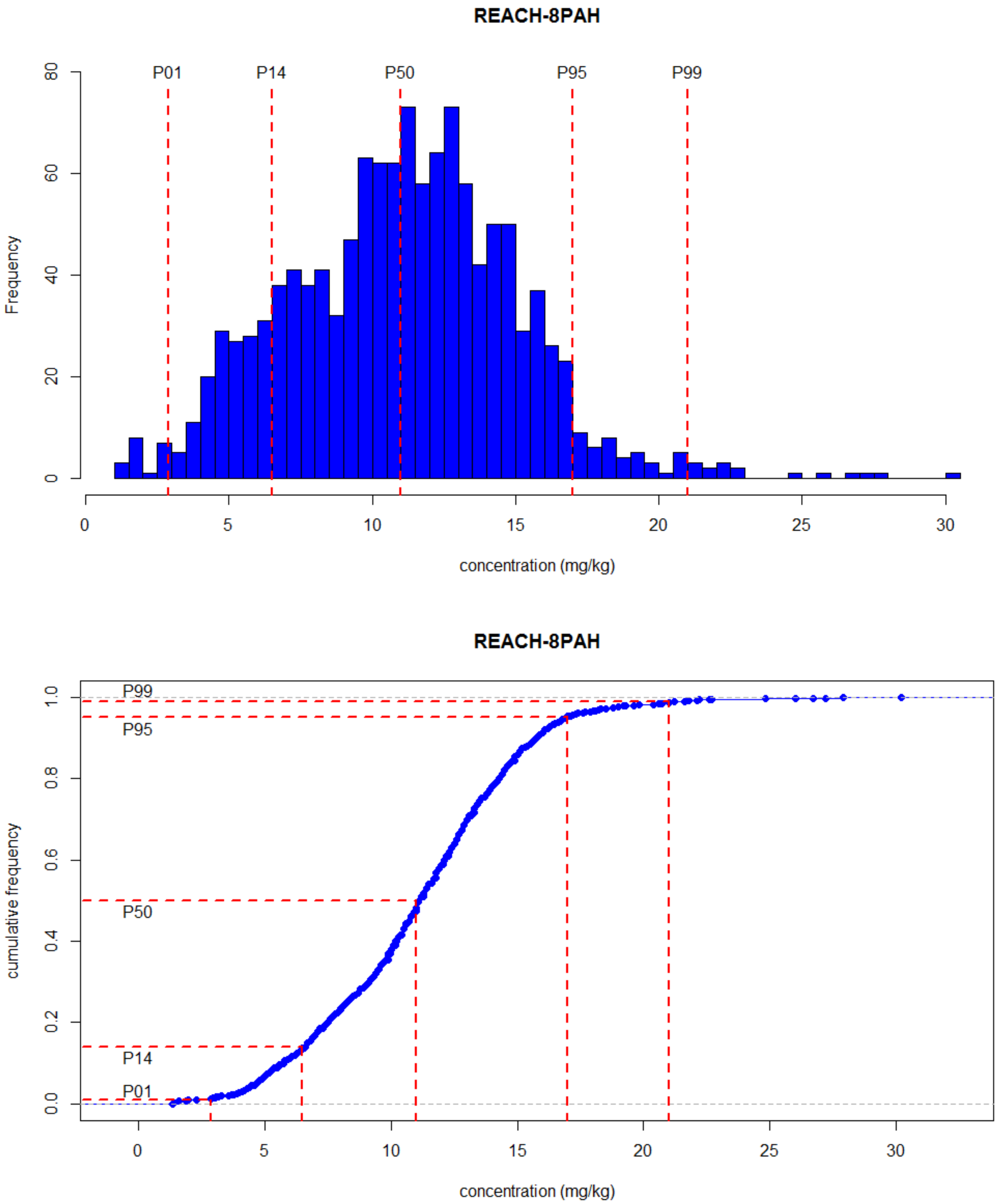

Figure B1-17: Histogram (upper panel) and cumulative plot (lower panel) of all available measured REACH-8 PAH concentrations (n=1234). Red lines indicate the 1st percentile (2.9 mg/kg), 14th percentile (6.5 mg/kg), 50th percentile (11 mg/kg), 95th percentile (17 mg/kg) and 99th percentile (21 mg/kg). In these figures concentrations of individual congeners measured below LOD are set to equal LOD. This does not influence the obtained distribution. Note that this histogram is the same as the lower right panel Figure B1-18, except for the bin sizes.

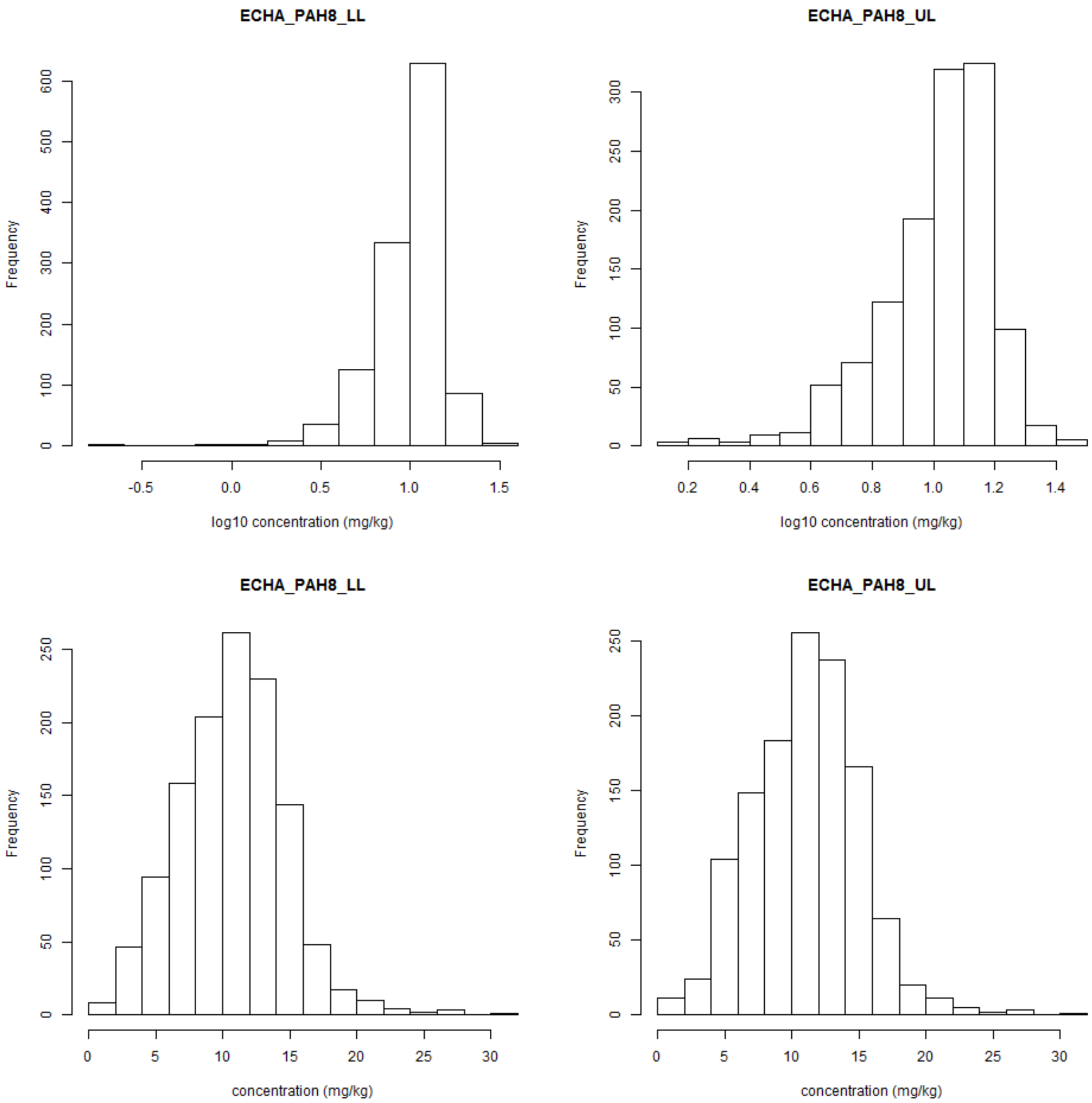

Figure B1-18: REACH-8 PAH. Histograms of concentrations,
upper panels on log10-scales and lower panels on original scales. Left panels are without concentrations <LOD. Right panels are with concentrations below LOD set to LOD.

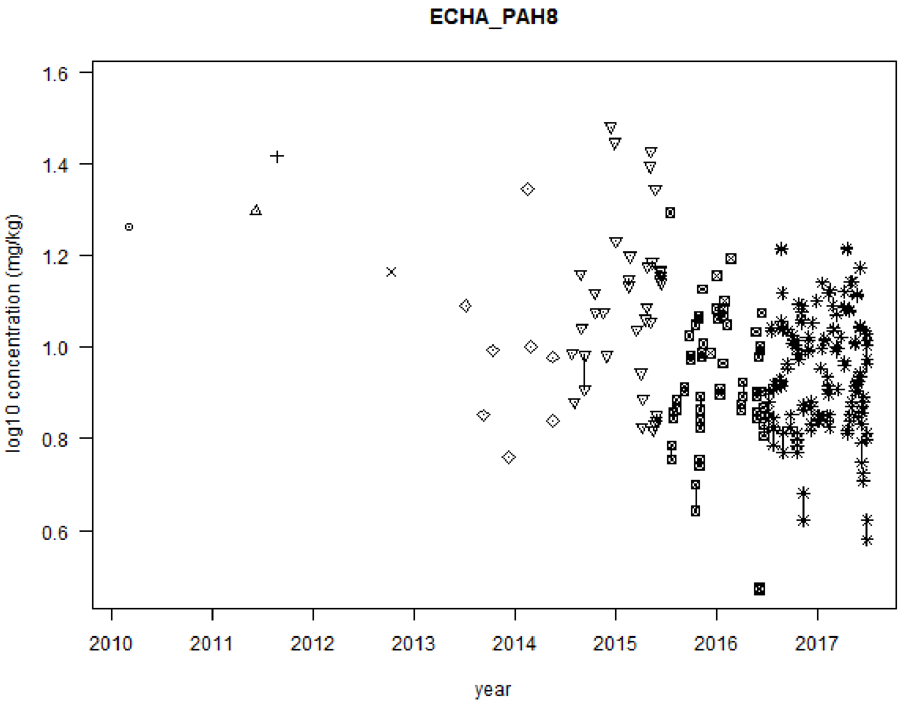

Figure B1-19: REACH-8 PAH. Log10 concentration against year of sampling.
Different symbols indicate different year of sampling. All samples taken at a granules production site. Samples taken from (aged) sports pitches are not included. Vertical lines indicate that at least for one of the 8 PAHs <LOD was measured. The concentration at the upper end of the vertical line represents the 8 PAH with concentrations below LOD set to LOD. The lower end of the vertical line indicates the 8 PAH concentration with <LOD set to zero.

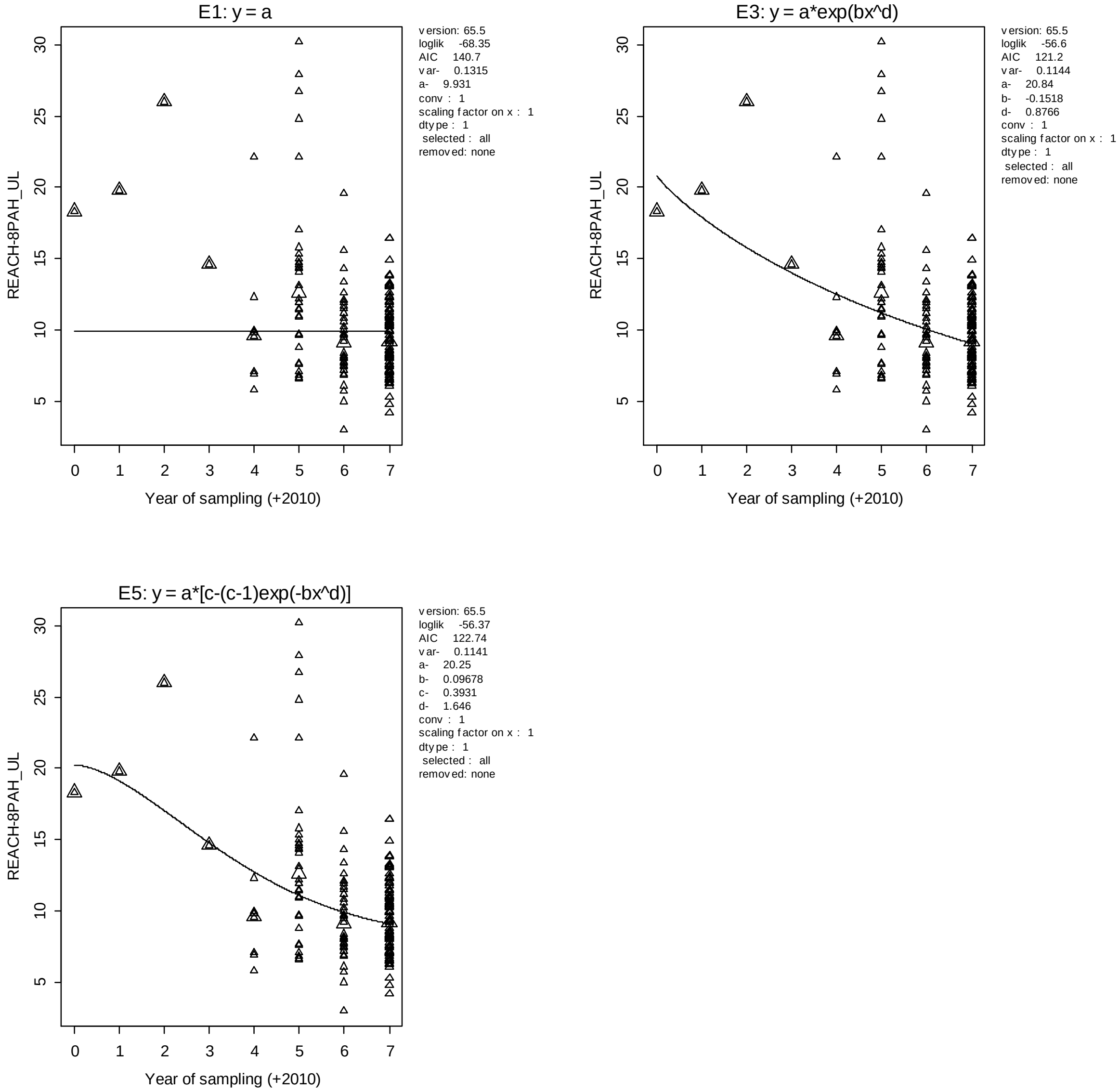

Figure B1-20: REACH-8 PAH. The trend in REACH-8 PAH concentration over time, where 0 is 2010 and 7 is 2017. Small triangles indicate the individual measurements. All samples are taken at a granules production site. Samples taken from (aged) sports pitches are not included. Large symbols indicate the mean year concentrations. In 2010 to 2013 the mean concentrations equal the individual concentrations because only one sample is available in each of these years.

The plots indicate that models E3 and E5 provide an equally good description of the data (AICs are within 2 points of eachother). E3 and E5 result in a better fit of the data (the AIC is lower) compared to model E1. Hence, from 2010 onwards, there is a (significant) decrease in REACH-8 PAH concentration. The decrease seems to level off in the last four years (2014-2017). It should be noted that the observed decrease is based on the limited number of (rel. high) samples in 2010 to 2013. For more details on the applied functions and comparison between results, see EFSA (2017).

Table B1-4: Contribution (%) of the individual PAHs to the REACH-8 PAH (n=1 234).
On average, the contributions are according to the 50th percentile (P50). However, samples do deviate from this average as can be concluded from the 5th (P05) and 95th percentiles (P95), i.e. samples may have lower (than average) contributions from one or more PAHs, which is compensated by higher contributions from other PAHs.

	<LOD set to zero			<LOD set to LOD		
	P05	**P50**	**P95**	**P05**	**P50**	**P95**
BaP	11	15	23	10	14	21
BaA	6.3	12	18	6.3	12	17
BbFA	8.9	15	20	9.0	15	19
BeP	22	31	40	21	30	38
BjFA	0.0	4.0	7.0	2.7	3.9	6.9
BkFA	0.0	3.9	6.5	2.5	3.9	6.6
CHR	11	18	23	10	17	22
DBAhA	0.0	0.0	3.0	1.5	3.5	6.3

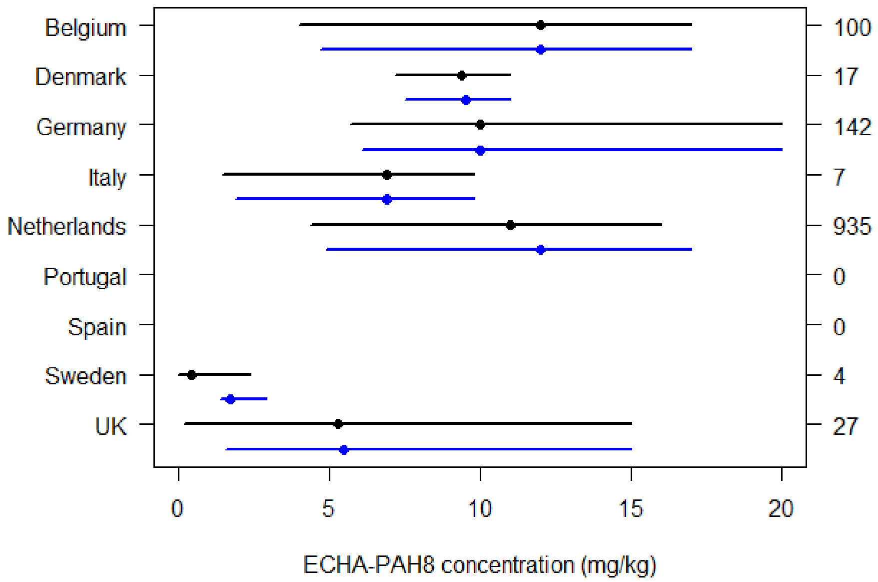

Figure B1-21: Illustrating the available REACH-8 PAH concentrations per country.
The dot indicates the 50th percentile. The line ranges from the 5th to the 95th percentile. Black lines are obtained when concentrations of individual congeners measured below LOD are set to zero. Blue lines are obtained when concentrations of individual congeners measured below LOD are set to equal LOD. Right y-axis gives the sample size in each country.

Appendix E1: Basics on extraction methods encountered in the documentation on the PAH concentration in granulate

INTRODUCTION

To determine the concentration of (semi volatile) REACH-8 PAH[140] in rubber granules generally three analytical steps are required. First, the PAHs need to be extracted from the rubber matrix, then the extract is concentrated and cleaned-up, and step three is the actual measuring of the PAHs (often performed with a GC or HPLC method). The extraction step is assumed the most critical step in determining PAH concentrations. When the extraction is not complete, the PAH concentration is underestimated.

In the following document an overview is provided on the extraction methods which were used to determine the PAH concentrations in rubber granule samples obtained from literature and industry. Furthermore, concluding remarks are made on the availability of appropriate and standardized methods, and on the influence of various parameters on the extraction efficiency of PAHs from a rubber matrix. Based on these conclusions the uncertainty in the currently obtained REACH-8 PAH concentrations is qualified.

Most samples were extracted according to standardized methods. Applied standardized methods were:

- ISO 18287
- AP04-SB-III
- AP04-SB-VII
- AP04-SG-IX
- AfPS GS 2014:01 PAH
- ZEK 01.4-8

The use of two standardized methods US EPA 8270 and ISO 21461 is mentioned in several PAH analyses. However, as will be described in more detail below, US EPA 8270 does not describe the extraction step in PAH analysis and ISO 21461is not capable to derive the concentrations of the individual PAHs.

References to all standardized methods are listed in the reference list.

STANDARDIZED EXTRACTION METHODS

ISO 18287

This International Standard specifies the quantitative determination of 16 polycyclic aromatic hydrocarbons (PAH) according to the priority list of the Environmental Protection Agency, USA. This International Standard is deemed applicable to **all types of soil** (field-

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[140] Benzo[a]pyrene, Benzo[a]anthracene, Benzo[b]fluoranthene, Benzo[e]pyrene, Benzo[j]fluoranthene, Benzo[k]fluoranthene, Chrysene, Dibenz[a,h]anthracene

moist or chemically dried samples), covering a wide range of PAH contamination levels. The method is principally based on the extraction method described in ISO 13877.

In ISO 13877, two different methods, A and B, are described. For non- or lightly polluted soils ("µg/kg range") it is of major importance that the extractant be able to break up the soil aggregates and allow an intensive contact between extractant and individual particles. This can be achieved by using a polar extractant, such as acetone, in combination with mechanical shaking (method A).

For more heavily polluted soils ("mg/kg range") a less polar extractant is needed for dissolving PAH from soot or tar particles. Although the highly toxic benzene still is the best extractant, the less toxic toluene is prescribed for this purpose in combination with exhaustive Soxhlet extraction (method B).

Both methods can be applied to all concentration ranges. However, applying acetone extraction for highly contaminated soils and toluene extraction for lightly contaminated soils can result in poor recoveries. Selection of the appropriate method should be based on concentrations of PAH and the expected type of adsorption or distribution within the soil.

In the literature a number of experiments have been reported using different solvents and/or extraction techniques. Solvents such as hexane, cyclohexane, methylene chloride, acetonitrile or tetrahydrofuran have been used. Other extraction techniques such as ultrasonic extraction or supercritical fluid extraction (SFE), accelerated solvent extraction (ASE) or microwave-assisted solvent extraction (MASE) have been applied. The results from these experiments are often comparable to those obtained by using the methods given in this International Standard. However, the use of procedures other than those described in this International Standard is not covered and their users should not refer to this International Standard.

In ISO 18287, ISO13877 is modified for the use of gas-chromatography with mass spectrometric detection and is applicable for different PAH pollution levels of soils. Two alternative extraction methods, A and B, are described in this International Standard.

Method A: Extraction of the field-moist soil sample with acetone and petroleum ether.

Method B: Extraction of the field-moist soil sample with a mixture of acetone, petroleum ether and water in the presence of sodium chloride. This method is preferred for soil samples with a high content of organic matrix.

Experience has shown that these two methods are applicable with comparable results to less as well as highly polluted soils.

AP04-SB-III, AP04-SB-VII and AP04-SG-IX

These three standardized methods are part of the (Dutch) accreditation program on testing of **soil batches, building material and granular waste** (Keuring van partijen grond, bouwstoffen en korrelvormige afvalstoffen, https://www.sikb.nl/). AP04-SB-III and VII are methods for the determination of PAHs in building materials excluding and including bituminous materials respectively. The extraction in AP04-SB-III can be performed with only acetone or acetone and an a-polar solvent with a boiling point between 40 °C and 98

°C (NEN 6972/A1 and NEN 6971/C1). In AP04-SB-VII two methods are described: a soxhlet extraction with petroleum ether for 16 hours of cryogenic grounded material (NEN 7331) and a shaking extraction with petroleum ether after reducing the size of the material to <0.4 mm (NEN-EN 15527).

AP04-SG-IX is a method for the determination of PAHs in soil. Extraction is performed using acetone and petroleum ether or heptane (NEN 6972/A1) or acetone only (NEN 6971/C1).

AfPS GS 2014:01 PAH and ZEK 01.4-8

The ZEK 01.4-8 method is the German version of the AfPS GS 2014:01 PAH method, and are essentially the same.

This method is designed specifically to determine PAHs from (extender) oils and carbon black in **rubbers, (soft) plastics and paints**. Extraction is performed by taking a representative partial sample of the material which is cut up into pieces with a maximum size of 2–3 mm using scissors, wire cutters, etc. Then, 500 mg of the sample is weighed into a container and extracted with 20 ml of toluene (to which an internal standard has been added) for 1 h at 60 °C in an ultrasonic bath. The method specifies that the limit of quantification for material samples is 0.2 mg/kg per PAH.

OTHER STANDARDIZED METHODS

US EPA 8270

Several analysis reports refer to this standardized method. However, this method describes the analytical step of PAH (GC settings), and for the extraction it refers to US EPA Method 3561 which describes a supercritical fluid extraction (SFE) procedure. It is not clear from the analysis reports whether or not the samples analysed according to US EPA 8270 have been extracted according to Method 3561 or to some other method.

ISO 21461

The hydrogen atoms in the bay region, characteristic of aromatic oils are identified. The percentage of Bay Region Hydrogens (%Hbay) is determined. This gives an indication of the aromaticity of the sample. Concentrations of individual PAHs cannot be determined using this method. According to Pan and Legg (2017) “the ISO 21461 does not produce data proportionally reflecting the concentrations of BaP or "sum of 8 PAHs" in the tyres”. This standardized method is mentioned in combination with another standardized or non-standardized method, which determines the actual concentrations.

NON-STANDARDIZED EXTRACTION METHODS

The following non-standardized extraction methods have been used to determine the PAH concentrations in rubber granulate samples obtained from literature and industry.

I. One sample was extracted by taking 5 g of the rubber infill. The sample was *extracted overnight, in hot dichloromethane.*

II. *Ruffino et al. used microwave-assisted extraction of a 2-g rubber granulate sample* with 20 mL of dichloromethane for 20 min at 600 W.

III. Marsili et al (2014) took about 1.0 g of rubber crumb and extracted with a mixture of KOH 2M/methanol (1:4) in a Soxhlet apparatus for 4 h at 75°C. However, they refer to a published method which seems to be a method for extraction from sediment (Holoubek et al 1990).

IV. Menichini et al. (2011) used a method described in ISTISAN 10/8 (2010) ultrasonically extracted PAHs with three 20-ml portions of dichloromethane and then with one 20-ml portion of n-hexane (each extraction time, 30 min).

V. At Fraunhofer (2017) a method was developed were rubber granulate was ground to a particle size of ≤ 750 micrometres using a centrifugal mill (Retsch ZM-200). For that purpose, the granules were embrittled by means of liquid nitrogen. About 0.5 g of the ground and homogenous sample material were extracted, after adding an isotope-labelled PAH standard mix (internal standard) with cyclohexane, by means of accelerated solvent extraction (Dionex/Thermo ASE 200) under the following extraction conditions: Pressure: 100 bar, temperature: 100 °C, cycles: 3 of 15 min each (static). To verify completeness of extraction, the material was re-extracted with fresh solvent.

VI. Depaolini et al. (2017) used hexane:dichloromethane (1:1) to extract PAHs in an ultrasound bath at 80°C for 30 min.

VII. Celeiro et al. (2018) extracted PAHs from rubber using ethyl acetate as a solvent in an ultrasound bath during 20 minutes at 25 ºC.

VIII. Two samples were extracted according to a method described in ISTISAN 16/13(2016). This method was developed for the analysis of PAHs in tyres. With the use of a knife and / or cutter strips of the tyre-tread are cut of about 0.1-0.3 mm in thickness, taking care that there they are foreign parts to the tyre. The strips are reduced into small pieces of about 2 mm. A tyre rubber sample of about 3.0 g is extracted with 300 mL of acetone in a Soxhlet extractor. The extraction continues for 8 hours, adjusting the heating conditions so that the distilled solvent fills the extraction cup at least 5 times per hour.

CHOICE OF EXTRACTION SOLVENT

Pan and Legg (2017) tested the PAH extraction efficiencies of 7 organic solvents.

Seven solvents were used for the extraction of a custom-made rubber slab: toluene, acetone, carbon disulphide, carbon tetrachloride, cyclohexane, 1,4-dioxane, and propionic acid. These solvents were selected for their low dielectric constants. Rubber was ground up using a Fitz mill and liquid nitrogen. Samples were taken from the size range of 0.71-1.0 mm. Each sample was weighed out to 500 mg in duplicates and was extracted in a cellulous extraction thimble (22 mm x 65 mm, Whatman, Cat# 2800-226), with a glass wool ball placed on the top of the thimble to prevent rubber slivers from floating out, using a Soxhlet extractor (125 ml) for 4 hours.

The experimental solvents extraction efficiency, based on the sum of 5-ring PAHs, were, in order: toluene (~23 ppm) > carbon disulphide (~20 ppm) > acetone = 1,4-dioxane (~14 ppm) > propionic acid (~12 ppm) > carbon tetrachloride (~9 ppm) > cyclohexane (~7 ppm). To compare with the findings of Bergmann below, acetone is an almost a factor 2 less efficient extraction solvent.

Bergmann (2011) compared the extraction efficiency of toluene and acetone. Cured rubber material (5g) was cut in lumps of about 2 x 2 x 2 mm), weighted and placed into an extraction tube in a fluidized-bed fexIKA 200 control series extractor. As extraction solvent 105 ml toluene or acetone was added. For one extraction cycle the heating temperature of 180 °C (if toluene was used) or 140 °C (if acetone was used) was set for 20 min period of time, than the system was cooled down till 60 °C (if toluene was used) or 35 °C (if acetone was used), hold one minute at this temperature and then a new cycle was started.

Acetone turns out to be much less efficient (factor 2-3 lower) than toluene to extract the 8 EU priority PAHs.

CONCLUSIONS

Various extraction methods have been used to determine PAH concentrations in rubber granules. See Table E1-1 for an overview. Some of these methods were specifically designed to analyse PAHs in rubber granules, while other methods were originally designed to determine PAH concentrations in other matrices, such as soil, building materials with and without bitumen or tyres.

The methods used various techniques to reduce the size of the granules, extraction durations, extraction temperatures or pressure, extraction techniques and extraction solvents.

In theory, reducing the size of the granules increases the surface to volume ratio of the material and hence the recovery of the PAHs from the rubber matrix. In some methods the size of the granules was not reduced at all, while in other methods it was prescribed that the size of the granules or rubber article was reduced by cutting (to at least 2 or 3 mm) or cryogenic milling.

The extraction methods covered a wide range of applied durations, temperatures/pressure and techniques, such as immersing in solvent, shaking in solvent, soxhlet extraction, ultrasonic extraction, supercritical fluid extraction (SFE), accelerated solvent extraction (ASE) or microwave-assisted solvent extraction (MASE). Solvents which were used, are acetone, petroleum ether, heptane, toluene, dichloromethane, KOH 2M/methanol (1:4), n-hexane, cyclohexane, hexane:dichloromethane (1:1), ethyl acetate and CO_2.

Depending on the combination of duration, temperature/pressure, technique and solvent a method may be more or less suitable to extract PAHs from rubber granules. In general, the method should be able to extract even the PAHs present at the core of the particle. This could be achieved by applying a sufficiently vigorous method, i.e. using a sufficiently long duration, high temperature/pressure, powerful technique and solvent which swells the rubber to get access to all PAHs inside the particle and in which the PAHs are soluble.

Currently, the AfPS GS 2014:01 PAH (i.e. ZEK 01.4-8) 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 the AfPS GS 2014:01 PAH method. When assuming this method to be a sufficiently efficient method to extract PAHs from rubber, it can be concluded that the obtained REACH-8 PAH concentrations correctly describe the current REACH-8 PAH concentrations in granules. It should be noted that the validation reports of all mentioned methods were not available. Efforts to validate and optimize extraction methods are recommended to get more confidence in the extraction efficiency of methods in general.

Table E1-1: Overview of methods used to determine PAH concentrations in rubber granulate. Of these samples, all eight ECHA PAHs were measured in 1234 samples.

Standard / reference	Number of samples
Standardised methods	
ISO 18287	25
AP04-SB-III	2
AP04-SB-VII	91
AP04-SG-IX	4
AfPS GS 2014:01 PAH	1203
ZEK 01.4-8	3
Non-standardized methods	
I	1
II / Ruffino	4
III / Marsili	8
IV / Menichini	4
V / Fraunhofer	1
VI / Re Depaolini	5
VII / Celeiro	15
VIII	2
Other standardized methods	
US EPA 8270(1)	1
ISO 21461	Not relevant
Unknown method	4
TOTAL	1373

Appendix E2: Overview of substances in EPDM, TPE and ELT infill

Table E2-1 below gives an overview of the substances found in EPDM, TPE and ELT infill samples.
In appendix to Annex 1, Table I.5, I.6, I.9 & I.12 from ECHA 2017, an overview is presented on measured concentrations of compounds other than PAHs. Data from Marsili et al. (2014), Aliapur (2015), Murfitts Industried (2016), Bocca et al. (2009), Menichini et al (2011, excl. recycled scrap rubber and gaskets), Ruffino et al. (2013), Schiliro et al (2013), Simcox, Salonen et al. (2015), Norwegian Building Research Institute (2006) are copied from the ECHA report. Data from Norwegian Building Research Institute (Plesser and Lund 2004), Nilsson 2008 and RIVM (2016) are incorporated from the original studies. Data on PAHs (appendix to Annex 1, Table I.7 & I.8) are not copied from the ECHA report because they are already included in the dataset of the current restriction proposal (see Appendix B1). Note that the table intends to give a general impression of the substances found and in what concentrations and does not intend to be extensive or complete. Only the sources that were readily available to the Dossier Submitter have been included in the table. Especially for ELT, no further search for information was performed. Available information is included as reported by the various sources and was not further processed. The table only includes content information and some air measurements. Information on leaching to the environment is not included.

Table E2-1: Overview of substance in EPDM, TPE and ELT infill
<value means below detection limit, values separated by a "±" sign indicate a mean and standard deviation, values separated by a "-" sign indicate a minimum-maximum range.

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
PAHs				
PAH (16)	1		51, 74, 76	Plesser and Lund, 2004
EPA PAHs 16	1.6, individual PAHs <0.1			TURI, 2017 (Gezofill)
EPA PAHs 16	11	<0.8, <0.8	56, 52, 62, 63	Bauer et al., 2017
EPA PAH 16	Except fluoranthene and pyrene (see below) individual PAHs all <0.5 [141]		P50: 18.3 P90: 42.0	RIVM, 2017
10 PAHs		<4, individual PAHs <0.51		Celanese (environmental assesment of

[141] Unpublished data, based on 2 samples. Note that this may be a mix of EPDM and other infill materials, see further explanation E 2.5. Chemicals within the material.

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
				Holo SP(-D))
REACH-8 PAHs		<0.5		Celanese (SO.F.TER group, 25/09/2015)
REACH-8 PAHs			P50: 11 P95: 17	Appendix B1 current proposal)
Sum 38 PAHs in air (indoor, gas phase)		121 ng/m^3	174, 364 ng/m^3	Dye et al., 2006
Sum 38 PAHs in air (indoor, airborne dust, PM10)		4.89 ng/m^3	10.84, 6.46 ng/m^3	Dye et al., 2006
Fluoranthene	2.5, 2.9 [141]		P50: 3.4 Max: 20.3	RIVM, 2017
Fluoranthene	1.4			TURI, 2017 (TTII)
Pyrene	9.6, 11.2 [141]		P50: 7.5 Max: 28.7	RIVM, 2017
Pyrene	8.3			TURI, 2017 (TTII)
Phthalates				
Total phthalate in air (indoor, airborne dust)		PM10: 117.1 ng/m^3 PM2.5: 84.9 ng/m^3	PM10: 131.4, 134.4 ng/m^3 PM2.5: 37.3, 81.2 ng/m^3	Dye et al., 2006
BBP (Benzylbutylphthalate)	<1.0		1.3, 2.8, 1.9	Plesser and Lund, 2004
BBP	<0.80	<2.0 <2.0	<0.80, <0.80, <0.80, <0.80	Bauer et al., 2017
BBP	<0.5 [141]		Max: 0.99	RIVM, 2017
BBP in indoor air (particle phase)			5.2, 4.3 ng/m^3	ECHA (Norwegian Inst. Air Res., 2006)
DEHP (di-2-ethylhexyl phthalate)	383, 490 [141]		P50: 7.6 Max: 27.2	RIVM, 2017
DEHP	3.9		21, 21, 29	Plesser and Lund, 2004
DEHP		62	52	Nilsson et al., 2008
DEHP	<0.80	34±12, 149±52	6.4 ± 2.2, 6.8 ± 2.4, 14±5, 11±4	Bauer et al., 2017
DEHP			<LOD-0.052	ECHA (Ruffino et al. 2013)
DEHP in indoor air (particle phase)			31.3, 17.7 ng/m^3	ECHA (Norwegian Inst. Air Res., 2006)
DBP (di-n-butylphthalate)	<0.5, 2.3 [141]		Max: 0.86	RIVM, 2017
DBP	1.6		3.4, 2.6, 3.9	Plesser and Lund, 2004
DBP	17 ± 6	<2.0, <2.0	0.97 ±0.34, 0.86 ± 0.3, 1.2 ±0.4, 1.4±0.5	Bauer et al., 2017
DBP in indoor air (gas phase)		0.06, 0.18 ng/m^3	0.20, 0.20, 0.38, 0.07, 0.07 ng/m^3	Dye et al., 2006
DBP in indoor air			Gas phase: 0.07-0.38 µg/m^3 Particle phase: 31.4-51.7 ng/m^3	ECHA (Norwegian Inst. Air Res., 2006)
DIDP (diisodecyl phthalate)	133 [141]		Max: <10	RIVM, 2017

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
DIDP			<1.0, <1.0	Plesser and Lund, 2004
DINP (diisononyl phthalate)	35.1 [141]		P50: 35 Max: 61	RIVM, 2017
DINP			57, 78	Plesser and Lund, 2004
DEHA (bis (2-ethylhexyl) adipate)	7.9 [141]		P50: 0.3 Max: 1.1	RIVM, 2017
DNNP (di-n-nonyl phthalate)	6.5 [141]		P50: 0.5 Max: 0.8	RIVM, 2017
DIBP (diisobutyl phthalate)		175	77	Nilsson et al., 2008
DIBP	<0.5 [141]		P50: <0.5 Max: 2.3	RIVM, 2017
DIBP	<0.80	<2.0 <2.0	2.6 ± 0.9, 2.3 ± 0.8, 2.8±1.0, 3.0±1.0	Bauer et al., 2017
DIBP			<LOD-0.077	ECHA (Ruffino et al. 2013)
DIBP in indoor air (gas phase)		0.03, 0.05 ng/m^3	0.07, 0.10, 0.13, 0.02, 0.01 ng/m^3	Dye et al., 2006
DIBP in indoor air (gas phase)			0.01-0.13 µg/m^3	ECHA (Norwegian Inst. Air Res., 2006)
DMP (dimetylphthalate)	3.4		<1.0, <1.0, <1.0	Plesser and Lund, 2004
DMP	<0.80	<2.0, <2.0	<0.80, <0.80, <0.80, <0.80	Bauer et al., 2017
DMP	<0.5 [141]		Max: <0.5	RIVM, 2017
DMP in indoor air (particle phase)			39.1, 50.3 ng/m^3	ECHA (Norwegian Inst. Air Res., 2006)
DEP (dietylphthalate)	1.5		<1.0, <1.0, <1.0	Plesser and Lund, 2004
DEP	<0.80	<2.0, <2.0	<0.80, <0.80, <0.80, <0.80	Bauer et al., 2017
DEP	<0.5 [141]		Max: 2.92	RIVM, 2017
DEP in indoor air (gas phase)		0.06, 0.09 ng/m^3	0.04, 0.06, 0.03, 0.01, 0.02 ng/m^3	Dye et al., 2006
DEP in indoor air			Gas phase: 0.01-0.06 µg/m^3 Particle phase: 24.4-10.4 ng/m^3	ECHA (Norwegian Inst. Air Res., 2006)
DOP or DNOP (di-n-octylphthalate)	3.2		<1.0, <1.0, <1.0	Plesser and Lund, 2004
DOP or DNOP	<0.80	<2.0 <2.0	<0.80, <0.80, <0.80, <0.80	Bauer et al., 2017
DOP or DNOP	<0.1		Max: <0.1	RIVM, 2017
DOP or DNOP in indoor air (particle phase)			<0.01, <0.01 ng/m^3	ECHA (Norwegian Inst. Air Res., 2006)
DPrP (di-n-propyl phtalate)	<0.80	<2.0, <2.0	<0.80, <0.80, <0.80, <0.80	Bauer et al., 2017

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
DPP (di-pentyl phthalate)	<0.80	<2.0 <2.0	<0.80, <0.80, <0.80, <0.80	Bauer et al., 2017
DPP			P50: <0.1 Max: 0.1	RIVM, 2017
DCHP (dicyclohexyl phthalate)	<0.80	<2.0 <2.0	<0.80, <0.80, <0.80, <0.80	Bauer et al., 2017
DCHP	<0.1		P50: 0.1 Max: 0.2	RIVM, 2017
DHP (dihexylphtalate)	<0.5 [141]		<0.5	RIVM, 2017
DFP (difenylphthalate)	<0.1		Max: 0.11	RIVM, 2017
Metals				
Aluminium			603-876	ECHA (Aliapur, 2015)
Aluminium			25.7	ECHA (Murfitts Industries, 2016)
Aluminium			1.2- 6680	ECHA (Bocca et al. 2009)
Aluminium			164-1028	ECHA (Menichini et al. 2009)
Aluminium			68-94	ECHA (Ruffino et al. 2013)
Antimony	<0.039 [141]			RIVM, 2017
Antimony			<0.05	ECHA (Murfitts Industries, 2016)
Antimony			0.3-7.7	ECHA (Bocca et al. 2009)
Antimony			0.46-6.4	ECHA (Menichini et al. 2009)
Arsenic	< 2		<3, <3, <2	Plesser and Lund, 2004
Arsenic	<0.8	<0.7, >0.6	0.27, 0.22, 0.33, 0.19	Bauer et al., 2017
Arsenic	<0.05 [141]			RIVM, 2017
Arsenic			<3	ECHA (Aliapur, 2015)
Arsenic			<0.05	ECHA (Murfitts Industries, 2016)
Arsenic			0.10-1.21	ECHA (Bocca et al. 2009)
Arsenic			0.10-0.42	ECHA (Menichini et al. 2009)
Arsenic			<5.3	ECHA (Ruffino et al. 2013)
Barium	<0.05 [141]			RIVM, 2017
Barium		1.21		TURI, 2017 (TTII)
Barium			5-12	ECHA (Aliapur, 2015)
Barium			2.6	ECHA (Murfitts Industries, 2016)
Barium			2.4-4778	ECHA (Bocca et al. 2009)
Barium			2.4-741	ECHA (Menichini et al. 2009)
Barium			10.7-167	ECHA (Ruffino et al. 2013)
Beryllium			<3	ECHA (Aliapur, 2015)
Beryllium			0.001-0.37	ECHA (Bocca et al. 2009)
Beryllium			0.007-0.04	ECHA (Menichini et al. 2009)
Boron			11.5	ECHA (Murfitts Industries, 2016)
Cadmium	<0.5		1,1,2	Plesser and Lund, 2004

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
Cadmium	0.07 ± 0.05	0.31±0.08, 0.13±0.05	1.7, 1.6, 0.93, 1	Bauer et al., 2017
Cadmium	<0.004 [141]			RIVM, 2017
Cadmium			0.47-2.05	ECHA (Marsili et al 2014)
Cadmium			<3	ECHA (Aliapur, 2015)
Cadmium			<0.5	ECHA (Murfitts Industries, 2016)
Cadmium			0.11-1.89	ECHA (Bocca et al. 2009)
Cadmium			0.12-1.9	ECHA (Menichini et al. 2009)
Cadmium			<0.25	ECHA (Ruffino et al. 2013)
Cadmium			0.47-2.38	ECHA (Marsili et al. 2014)
Chromium	0.43 ± 0.11	0.97±0.20, 427±80	0.97, 1.0, 1.3, 1.0	Bauer et al., 2017
Chromium	5200		<2, <2, <2	Plesser and Lund, 2004
Chromium	0.43			Bauer et al., 2017
Chromium	<0.01 [141]			RIVM, 2017
Chromium	0.75			TURI, 2017 (FieldTurf)
Chromium		13.2		TURI, 2017 (TTII)
Chromium			3.34-17.52	ECHA (Marsili et al 2014)
Chromium			0.4-56	ECHA (Bocca et al. 2009)
Chromium			<0.3-6.2	ECHA (Menichini et al. 2009)
Chromium			<0.71	ECHA (Ruffino et al. 2013)
Chromium			1.91-5.37	ECHA (Marsili et al. 2014)
Chromium III			<0.5	ECHA (Murfitts Industries, 2016)
Chromium VI			<0.004	ECHA (Murfitts Industries, 2016)
Cobalt	0.06 ± 0.21	0.25±0.21, 0.27±0.18	212, 178, 101, 128	Bauer et al., 2017
Cobalt	<0.03 [141]			RIVM, 2017
Cobalt			99-268	ECHA (Aliapur, 2015)
Cobalt			0.7	ECHA (Murfitts Industries, 2016)
Cobalt			3.5-234	ECHA (Bocca et al. 2009)
Cobalt			5.0-234	ECHA (Menichini et al. 2009)
Cobalt			97-125	ECHA (Ruffino et al. 2013)
Copper	<3		35, 20, 70	Plesser and Lund, 2004
Copper	11 ± 2	<0.9, 15±3	105, 97, 49, 45	Bauer et al., 2017
Copper	<0.05 [141]			RIVM, 2017
Copper			5.59-84.49	ECHA (Marsili et al 2014)
Copper			39-111	ECHA (Aliapur, 2015)
Copper			39.2	ECHA (Murfitts Industries, 2016)
Copper			0.8-60	ECHA (Bocca et al. 2009)
Copper			8.7-60	ECHA (Menichini et al. 2009)
Copper			29-60.5	ECHA (Ruffino et al. 2013)
Copper			5.49-65.11	ECHA (Marsili et al. 2014)
Iron			129.12-7256	ECHA (Marsili et al 2014)

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
Iron			451-2310	ECHA (Aliapur, 2015)
Iron			15-4318	ECHA (Bocca et al. 2009)
Iron			199-620	ECHA (Menichini et al. 2009)
Iron			37-105	ECHA (Ruffino et al. 2013)
Iron			262.2-1577.4	ECHA (Marsili et al. 2014)
Lead	<0.1 [141]			RIVM, 2017
Lead	8		20, 15, 17	Plesser and Lund, 2004
Lead	17.3	0.5, <0.5		TURI, 2017 (FieldTurf)
Lead	<0.4	7.6±1.5, <0.3	23, 24, 21, 18	Bauer et al., 2017
Lead	Average 2.4-3.0 (highest value 15)			Kim et al., 2012
Lead			13.97-33.58	ECHA (Marsili et al 2014)
Lead			11-25	ECHA (Aliapur, 2015)
Lead			<0.5	ECHA (Murfitts Industries, 2016)
Lead			12-46	ECHA (Bocca et al. 2009)
Lead			<0.7-28	ECHA (Menichini et al. 2009)
Lead			19.7-308	ECHA (Ruffino et al. 2013)
Lead			10.76-38.99	ECHA (Marsili et al. 2014)
Lithium			0.6-11	ECHA (Bocca et al. 2009)
Lithium			0.60-7.4	ECHA (Menichini et al. 2009)
Lithium				
Lithium				
Magnesium			288-507	ECHA (Aliapur, 2015)
Magnesium			123-966	ECHA (Bocca et al. 2009)
Magnesium			235-966	ECHA (Menichini et al. 2009)
Magnesium			36-53	ECHA (Ruffino et al. 2013)
Manganese			4-19	ECHA (Aliapur, 2015)
Manganese			2.6	ECHA (Murfitts Industries, 2016)
Manganese			3.0-30	ECHA (Bocca et al. 2009)
Manganese			3.0-5.2	ECHA (Menichini et al. 2009)
Manganese			4-5.5	ECHA (Ruffino et al. 2013)
Mercury	<0.03		0.04, 0.04, <0.03	Plesser and Lund, 2004
Mercury	<0.1	<0.09, <0.08	<0.04, 0.042, <0.04, <0.04	Bauer et al., 2017
Mercury	<0.0005 [141]			RIVM, 2017
Mercury			<3	ECHA (Aliapur, 2015)
Mercury			<0.5	ECHA (Murfitts Industries, 2016)
Mercury			0.03-0.16	ECHA (Bocca et al. 2009)
Mercury			0.05-0.16	ECHA (Menichini et al. 2009)
Molybdenum	<0.05 [141]			RIVM, 2017

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
Molybdenum			<3	
Molybdenum			0.04-6.6	ECHA (Bocca et al. 2009)
Molybdenum			0.09-0.29	ECHA (Menichini et al. 2009)
Nickel	<5		<2, <1, <5	Plesser and Lund, 2004
Nickel	<0.4	4.0±1.2, 3.7±1.1	2.9, 2.5, 2.3, 2.7	Bauer et al., 2017
Nickel	<0.1 [141]			RIVM, 2017
Nickel		68.2, <0.5		TURI, 2017 (FieldTurf)
Nickel			4.11-26.12	ECHA (Marsili et al 2014)
Nickel			3-8	ECHA (Aliapur, 2015)
Nickel			<0.5	ECHA (Murfitts Industries, 2016)
Nickel			0.6-5.8	ECHA (Bocca et al. 2009)
Nickel			0.67-5.8	ECHA (Menichini et al. 2009)
Nickel			<1.5	ECHA (Ruffino et al. 2013)
Nickel			3.9-5.75	ECHA (Marsili et al. 2014)
Selenium	<0.039 [1]			RIVM, 2017
Selenium			<3	ECHA (Aliapur, 2015)
Selenium			<0.5	ECHA (Murfitts Industries, 2016)
Selenium			<0.3-<0.3	ECHA (Bocca et al. 2009)
Selenium			<0.3-<0.3	ECHA (Menichini et al. 2009)
Strontium			0.6	ECHA (Murfitts Industries, 2016)
Strontium			3.2-90	ECHA (Bocca et al. 2009)
Strontium			3.2-19	ECHA (Menichini et al. 2009)
Tin	<0.1 [1]			RIVM, 2017
Tin			<0.5	ECHA (Murfitts Industries, 2016)
Tin	<0.5			TURI, 2017 (FieldTurf)
Tin			0.1-3.0	ECHA (Bocca et al. 2009)
Tin			0.58-2.4	ECHA (Menichini et al. 2009)
Tin			13-39	ECHA (Ruffino et al. 2013)
Titanium	<0.05 [1]			RIVM, 2017
Titanium			32-72	ECHA (Aliapur, 2015)
Titanium			0.01-0.21	ECHA (Bocca et al. 2009)
Titanium			0.03-0.14	ECHA (Menichini et al. 2009)
Titanium			36-48.5	ECHA (Ruffino et al. 2013)
Vanadium	0.26	5.8, 1.5	0.70, 0.67, 0.90, 0.93	Bauer et al., 2017
Vanadium	<0.05 [1]			RIVM, 2017
Vanadium			<3	ECHA (Aliapur, 2015)
Vanadium			0.4-22	ECHA (Bocca et al. 2009)
Vanadium			1.3-3.5	ECHA (Menichini et al. 2009)
Wolfram			0.02-2.0	ECHA (Bocca et al. 2009)

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
Wolfram			0.06-0.36	ECHA (Menichini et al. 2009)
Zinc	16		16200, 18500, 16800, 21000	Nilsson et al., 2008
Zinc	9500		7500, 7300, 17000	Plesser and Lund, 2004
Zinc	6610	196		TURI, 2017 (TTII)
Zinc	3.5 ± 1.6	7640±200, 2.2±1.2	20220, 19100, 17500, 16500	Bauer et al., 2017
Zinc			3474-13202	ECHA (Marsili et al 2014)
Zinc			15000-20000	ECHA (Aliapur, 2015)
Zinc			491	ECHA (Murfitts Industries, 2016)
Zinc			118-19375	ECHA (Bocca et al. 2009)
Zinc			1063-19375	ECHA (Menichini et al. 2009)
Zinc			1220-1530	ECHA (Ruffino et al. 2013)
Zinc			4168-6006	ECHA (Marsili et al. 2014)
Alkylphenols				
Sum octylphenol	<5.0	<5.0, <5.0		Bauer et al., 2017
Sum nonylphenol	5.0 +/- 1.0	<5.0, <5.0		Bauer et al., 2017
Iso-nonylphenol	1.120		21.2, 21.6, 9.12	Plesser and Lund, 2004
4-iso-Nonylphenol			5.3 ± 0.8, 4.8 ± 0.7, 5.3 ± 0.8, 5.5 ± 0.8	Bauer et al., 2017
4-n-nonylphenol	<0.005		<0.005, <0.005, <0.005	Plesser and Lund, 2004
4-n-nonylphenol			<0.001, <0.001, <0.001, <0.001	Bauer et al., 2017
4-t-octylphenol	0.0498		33.7, 27.8, 19.6	Plesser and Lund, 2004
4-t-octylphenol			16 ± 2, 12 ± 2, 12 ± 2, 19 ± 3	Bauer et al., 2017
4-t-octylphenol			P50: 4.8 Max: 22.4	RIVM, 2017
Bisphenol A			P50: 0.5 Max: 2.5	RIVM, 2017
Others				

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
Total selected[142] vulcanisation and preservative compounds in airborne dust (indoor)		PM10 & P 2.5: <LOD, which range from 0.003 to 5 ng/m^3	PM10: 2185, 1691 ng/m^3 PM2.5: 2068, 1268 ng/m^3	Dye et al., 2006
N-(1,3-dimethylbutyl)-N'-phenyl-1,4-Benzenediamine (6PPD)			1039, 649, 727	Nilsson et al., 2008
N,N dimethyl-1-dodecanamine			125	Nilsson et al., 2008
N,N-dimethyl-1-tetradecanamine			77	Nilsson et al., 2008
2-(2H-benzotriazol-2-yl)-5-methylphenol		962		Nilsson et al., 2008
2-(5-chloro-2-benzotriazolyl)-6-tertbutyl-p-cresol		1260		Nilsson et al., 2008
2,2,6,6-Tetramethyl-4-piperidylic compound		485		Nilsson et al., 2008
1-methyl-2-pyrrolidinon			80	Nilsson et al., 2008
à,à'-Dihydroxy-m-di-isopropylbenzene	84			Nilsson et al., 2008
Benzothiazole			13, 60, 78	Nilsson et al., 2008
Benzothiazole			P50: 2.7 Max: 6.3	RIVM, 2017
Benzothiazole in indoor air (gas phase)			4.5-31.7 µg/m^3	ECHA (Norwegian Inst. Air Res., 2006)
Benzothiazole in indoor air			1-13	ECHA (Salonen et al., 2015)
2-hydroxybenzothiazole			P50: 1.6 Max: 13.8	RIVM, 2017
2-hydroxybenzothiazole in indoor air (particle phase)			346, 566 pg/m^3	ECHA (Norwegian Inst. Air Res., 2006)
2-mercaptobenzothiazole			P50: 2.6 Max: 7.6	RIVM, 2017
2-mercaptobenzothiazole in indoor air (particle phase)			287, 352 pg/m^3	ECHA (Norwegian Inst. Air Res., 2006)
2-methoxybenzothiazole			P50: 2.6 Max: 10.2	RIVM, 2017

[142] 2-aminobenzothiazole, 2-methylthiobenzothiazole, N-isopropyl-N’-phenyl-p-phenylendiamine, N-cyclohexyl-2-benzothiazole sulphonamide, 2-(4-morpholinyl)benzothiazole, 2-morpholinothiobenzothiazole, N-phenyl-1,4-phenylenediamine, 2-mercapto benzothiazyl disulphide, N-cyclohexyl-2-benzothiazolamine (NCBA), 2-mercaptobenzothiazole, 2-hydroxybenzothiazole

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
2-aminobenzothiazole			P50: 0.1 Max: 0.4	RIVM, 2017
2-aminobenzothiazole in indoor air (particle phase)			54, 28 pg/m^3	ECHA (Norwegian Inst. Air Res., 2006)
N-cyclohexyl-1,3-benzothiazole-2-amine			P50: 1.5 Max: 3.9	RIVM, 2017
2,2-dithiobis-(benzothiazole)			P50: 0.2 Max: 0.3	RIVM, 2017
N-cyclohexyl-2-benzothiazole sulphenamide			P50: <0.02 Max: 0.04	RIVM, 2017
N-cyclohexyl-2-benzothiazole sulphenamide in indoor air (particle phase)			23.3 pg/m^3	ECHA (Norwegian Inst. Air Res., 2006)
Butylised hydroxytoluene (BHT)			10	Nilsson et al., 2008
D-limonene			10	Nilsson et al., 2008
Ethanone, 1,1'-(1,3-phenylen)bis-	112			Nilsson et al., 2008
Ethanone, 1,1'-(1,4-phenylene)bis-	265			Nilsson et al., 2008
Ethanone, 1-[3-(1-hydroxy-1-methylethyl)phenyl]-	118			Nilsson et al., 2008
Ethanone, 1-[4-(1-methylethenyl)phenyl]-	155			Nilsson et al., 2008
N-phenyl-1-naftalenamine			106	Nilsson et al., 2008
Phenol, 2,4-bis(1,1-dimethylethyl)-		101, 64		Nilsson et al., 2008
Phosphoric acid, tris(2-ethylhexyl)ester			64	Nilsson et al., 2008
Phenol, 2-(5-chloro-2Hbenzotriazol-2-yl)-4,6-bis(1,1-dimethylethyl)- or similar.		2391		Nilsson et al., 2008
5-Methyl-2-hexanone				Nilsson et al., 2008
Cyclohexanone				Nilsson et al., 2008
Octabenzone		1526		Nilsson et al., 2008
Drometrizol		921		Nilsson et al., 2008
Phenol		<0.75		Celanese (environmental assesment of Holo SP(-D))
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol		2.4 mg/L		Nilsson et al., 2008
PCB (sum PCB 28, 52, 101, 118, 138, 153, 180	<0.004		<0.175, <0.175, 0.202	Plesser and Lund, 2004
PCB (sum PCB 28, 52, 101, 118, 138, 153, 180	<0.14	<0.14, <0.14	0.05, <0.14, <0.14, <0.14	Bauer et al., 2017
PCB (sum PCB 28, 52, 101, 118,			P50: <0.035	RIVM, 2017

Substances	Concentrations (mg/kg, unless stated otherwise)			References
	EPDM	TPE	ELT	
138, 153, 180			Max: 0.074	
Sum 7 PCBs		<0.1		Celanese (environmental assesment of Holo SP(-D))
Benzene	<0.05 [1]		<0.05	RIVM, 2017
Benzene		<0.05		Celanese (environmental assesment of Holo SP(-D))
Benzene			0.00037-0.00064	ECHA (Ruffino et al. 2013)
Benzene (in air)			1.3-2.2 μg/m^3	ECHA (Ruffino et al. 2013)
Benzene (in air)			1.3-60 ng/m^3	ECHA (Schiliro et al. 2013)
Benzene (in air)			0.5-7.0 μg/m^3	ECHA (Salonen et al. 2015)
Ethylbenzene	<0.05 [1]			RIVM, 2017
Ethylbenzene		<0.05		Celanese (environmental assesment of Holo SP(-D))
Xylenes	<0.1 [1]		Max: 0.103	RIVM, 2017
Xylenes		<0.2		Celanese (environmental assesment of Holo SP(-D))
Xylenes			0.682-0.975	ECHA (Ruffino et al. 2013)
Xylenes (in air)			7.6-20.9 μg/m^3	ECHA (Ruffino et al. 2013)
Xylenes (in air)			7.2-33.7 ng/m^3	ECHA (Schiliro et al. 2013)
Xylenes (in air)			12.13 μg/m^3	ECHA (Simcox)
Xylenes (in air)			0.7-69 μg/m^3	ECHA (Salonen et al., 2015)
Styrene	<0.05 [1]		Max: 0.053	RIVM, 2017
Toluene	<0.05 [1]		Max: 0.057	RIVM, 2017
Toluene		<0.05		Celanese (environmental assesment of Holo SP(-D))
Toluene			0.272-0.449	ECHA (Ruffino et al. 2013)
Toluene (in air)			15-85 ng/m^3	ECHA (Norwegian Inst. Air Res., 2006)
Toluene (in air)			4.2-10.2 μg/m^3	ECHA (Ruffino et al. 2013)
Toluene (in air)			4.2-31.2 ng/m^3	ECHA (Schiliro et al. 2013)
Toluene (in air)			135.4 μg/m^3	ECHA (Simcox)
Toluene (in air)			1.5-84 μg/m^3	ECHA (Salonen et al., 2015)
Total VOC after 28 days (indoor)	490 μg/m^3 at 28 days	118 μg/m^3 at 28 days	134 μg/m^3 at 28 days	Moretto, 2007
Total VOC in air (indoor)		136, 161 μg/m^3	716, 234, 151, 255, 234, 290 μg/m^3	Dye et al., 2006
Total VOC in air			10-70 μg/m^3	ECHA (Salonen et al., 2015)
Methyl-isobutyl-ketone (MIBK) in indoor air (gas phase)			3.4-12.7 μg/m^3	ECHA (Norwegian Inst. Air Res., 2006)
Methyl-isobutyl-ketone (MIBK) in indoor air			0.8-14.5 μg/m^3	ECHA (Salonen et al., 2015)
Formaldehyde in air			1.7-4.2 μg/m^3	ECHA (Salonen et al., 2015)

Appendix G1: Workshop report

Workshop for the purpose of the REACH Annex XV dossier for a restriction on plastic and rubber granules used as infill material in synthetic turf pitches

24 November 2017, Ministry of Infrastructure and Water Management, The Hague (Netherlands).

Chairman summary

The workshop was organized by RIVM and ECHA for the purpose of collecting relevant information for the preparation of a REACH Annex XV Restriction dossier on plastic and rubber granules used as infill material on synthetic turf pitches and to ensure that information received in response of the call for evidence organized by ECHA (23 August-18 October 2017) is interpreted correctly. 42 Stakeholders attended the workshop, coming from a variation of organizations such as tyre recyclers, tyre manufacturers, synthetic turf manufacturers, academia and alternative manufacturers.

The workshop was chaired by Joke Herremans, head of the department on Consumer Product Safety within RIVMs Centre for Safety of Substances and Products (VSP). Joke welcomed the attendees and explained the purpose and conditions of the workshop which was held under the Chatham House Rule: *When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.*

At the start the attendees were given the opportunity to introduce themselves and their organisation and give a position statement regarding the use of granules as infill material on artificial turf pitches. Position statements received on paper were distributed to all attendees after the workshop together with this Chairman summary, list of attendees and the PowerPoint presentation used to introduce the discussions.

RIVM started with giving an explanation of the process of developing this Annex XV dossier and the restriction proposal, the steps that yet are to come and the possibilities for interested parties to contribute to the process. The introductory presentation is available as an Annex to the Chairman summary.

The workshop discussions were held by 4 themes. The chairman summary of the main issues discussed is presented below.

Theme 1: Risk of granules used on synthetic turf pitches

The scientific basis for the Annex XV dossier initiative and drafting a restriction proposal is the finding of both RIVM[143] and ECHA[144] that the current limit for PAHs in mixtures[145] supplied to the general public seems not to ensure adequate protection of human health if the PAH-levels in granules used on synthetic turf pitches would be as high as currently allowed. The restriction proposal will aim to limit the PAH content in granules to a level of control of risks. The RIVM risk assessment will be used as a basis for the risk assessment section of the Annex XV dossier. Additional information obtained from the ECHA report, submitted by stakeholders during the consultation and from other sources, will be used to update and improve the assessment where deemed appropriate.

A key question scheduled for discussion was whether the yet available data on actual PAH content in infill material are representative for the EU. The workshop did not provide a clear answer to that question. However, it was said that PAHs concentrations in tyres and end-of-life tyre (ELT) granules appear to be relatively stable and have gradually been reduced over time due to the extender oil restriction that entered into force in in the EU January 2010. The PAH restriction in extender oils used in tyres placed on the EU market was said to have taken effect already before the 2010 legal deadline. Differences in PAHs concentrations reported might occur for various reasons: 1. Variability of PAH recovery dependent on the analytical methods applied to determine PAH content; 2. Use of non-tyre rubber materials and articles for manufacture of granules; 3. Use of older car or truck tyres or non-automotive tyres to manufacture granules. 4. Use of imported tyres that do not comply with the EU extender oil restriction to manufacture granules and; 5 Import of waste tyres or granules from non-EU regions. Several studies looking at PAHs content in infill are ongoing and relevant information will be provided once available. Various attendees stated that there is not expected to be a difference in PAH content between ELT infill produced using a cryogenic process compared to the manufacture process at ambient temperature. Furthermore it can be questioned whether ELT infill is imported from outside Europe as this is not expected to be cost effective (transport costs).

The discussion continued by exploring relevant exposure scenarios for the risk assessment. It was explained that the exposure scenarios used in the reports from RIVM and ECHA will be used as a starting point for the restriction dossier. In these reports the focus on football field players and goalkeepers age 4-50 years that are orally (incidental ingestion) and dermally exposed to granules. The ECHA report also covered inhalation exposure. Some comments were made related to assumptions made in the exposure scenarios in the earlier studies of RIVM and ECHA (e.g. related to the amount of oral ingestion of granules as a consequence of playing on the pitch). Some attendees stated that all relevant exposure

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[143] Evaluation of health risks of playing sports on synthetic turf pitches with rubber granulate: Scientific background document. DOI 10.21945/RIVM-2017-0017

[144] Annex XV Report: An evaluation of the possible health risks of recycled rubber granules used as infill in synthetic turf sports pitches, ECHA, 28 February 2017.

[145] Entry 28 of REACH Annex XVII prohibits the placing on the market for supply to the general public of substances or mixtures containing equal to or more than 0.1 weight percent (1000 mg/kg) of the PAH that are in the scope of entry 50 of Annex XVII. For two PAHs (Benzo[a]pyrene (BaP) and Dibenzo[a,h]anthracene (DBAhA) the limit is 0.01% (100 mg/kg).

scenarios should be included in the risk assessment and an exposure scenario specifically for very young children (0-4 years of age) needs to be included in addition to the earlier work. Such scenario would account for little children playing on mini-pitches where granules may also be used. No clear preference was given to include a scenario looking to exposure via wounds. However, it was proposed to consider if some inspiration from the nickel REACH restriction can be taken (separate migration rates for post assemblies (in contact with blood) compared to other articles). It was mentioned that FIFA and UEFA have surveys of abrasion. Preference was expressed to account for migration rate in the exposure assessment and the fact that migration is related to surface size of the granules and the type of material. Furthermore it was said that the dossier should somehow account for other sources of PAHs as well that are said to be of importance for total human exposure to PAHs. However, the attendees did not provide details on how such background PAH exposure should be addressed. It was announced that additional information will be provided to evaluate the need for an extra assessment factor in the hazard assessment for children (age 4-10).

Theme 2: Scope of the restriction and restriction options

Taking into account the existing REACH restriction, entry 50 on PAHs in articles[146], we are considering to propose an additional REACH restriction on eight carcinogenic PAHs in plastic and rubber granules used as infill material in synthetic turf pitches. It is asked whether extension of the scope to other (carcinogenic) PAHs would have an added value. The general impression from the workshop is that this has no added value, as the 8 PAHs are expected to be representative (markers) for other PAHs as well and contribution from various PAHs are more or less constant. Broadening the scope is said to overcomplicate the issue with little or no added value for the risk assessment and the final restriction proposal. It however, is stated that it is important to also consider hazardous effects, other than carcinogenicity and that this might require broadening of the scope. This could for example include hazardous effects of lower molecular weight PAHs. Additional information related to these other hazardous effects was welcomed by the chair.

Related to the scoping of the restriction proposal, it was asked what infill materials should be included. The general idea among attendees is that the scope should not only embrace infill made of ELT, but also infill made out of other materials, regardless whether these are made from recycled or virgin materials as the aim is to ensure safe use of artificial sport grounds, independent on the material they are made of. It was even questioned whether also infill made of natural resources (like cork) and 'non-performance' infill like sand, should be included in the scope. Defining the scope by covering all 'performance infill layer' following the FIFA definition might be a solution to find a relevant scope. The

[146] The placing on the market for supply to the general public of articles containing polycyclic aromatic hydrocarbons (PAHs) is restricted by entry 50 of Annex XVII to REACH Regulation (EC) No 1907/2006, paragraphs 5 and 6. Articles placed on the market for supply to the general public will contravene the restriction if any of their rubber or plastic components that come into direct as well as prolonged contact or short-term repetitive contact with human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0.0001% by weight of this component) of any of the eight PAHs that are identified in Column 1 of the entry. Toys, including activity toys, and childcare articles, should not contain more than 0,5 mg/kg (0,00005 % by weight of this component) of any of the listed PAHs. Guidance for the interpretation of entry 50.5 and 6 is under development.

discussion further clarified that the use of definitions in the restriction text requires further attention when setting the scope. E.g. the term 'plastics' was said to be not a clearly defined term and it is better to use the work thermoplastic and rubber if that scope is chosen for the proposal.

Some attention was given to the question whether infill is defined as mixture or as article and whether there is a difference between infill made from ELT and infill from other (virgin) resources. There is no clarity on this issue voiced by various attendees and a request/hope to clarify the issue through this new restriction proposal. Some infill materials (not being ELT granules) were by some of the attendees said to meet the definition of an article. Various actors in the field prefer infill to be articles instead of mixtures, however, at a limit value that accounts for risk. Furthermore, the issue of potentially having various limit values for various parts of the artificial grass system is flagged, as the restriction proposal is on PAHs in infill only and the current limit values for PAHs in articles already applies to the artificial turf itself (and other articles supplied to the general public).

The starting point in setting the limit value is to choose a value that will ensure protection of human health. Hence, the human health risk assessment will form the basis for the proposed limit value. As RIVM and ECHA are still working on the risk assessment of PAHs in granules, it is currently not known at what the proposed limit value will be. It should be noted that as a result of the evaluation by the scientific committees of ECHA (Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC)) that follows after submission of the restriction proposal by the Netherlands, changes in the dossier may be considered necessary. This might include changes to the limit value that is proposed in the dossier. In the discussion, various actors stated to prefer a sum limit for 8 PAHs instead of limits for all individual PAHs as this is more practical for companies and enforcement. It was however questioned whether such sum limit value would account for the risk posed by PAHs with higher potency like Benzo(a)pyrene as well. Furthermore, various actors plead for a migration limit instead of a content limit as this according to them better relates to actual exposure. Concerns were raised related to the extraction and test method used as no standard test method is available and available test methods show significant analytical uncertainty. The wish was expressed to ensure that the limit value is protective for all hazard endpoints, not only the carcinogenicity risk.

<u>Theme 3: Alternatives</u>

Information on alternatives is requested for the restriction dossier because implementation of the restriction measure could result in a shift to alternative infill materials used in artificial turf pitches or in alternative turf pitches to be installed. Three groups of alternatives are defined: 1. Various infill materials; 2. Various grass systems and 3. Techniques to reduce PAH content in infill material.

The term 'alternative' appears to be somewhat confusing as the earlier discussion stated that all infill materials used on artificial turf systems should be included in the scope of the restriction proposal. In that sense, it might be better to talk about various infill options and various grass systems instead of alternatives. There was some discussion on correct use of terminology to make sure all infill options and grass systems are properly defined. Furthermore, it was questioned by some actors whether natural grass in group 2 is a real alternative for reason of performance. It was also questioned whether measures to reduce PAHs content in ELT derived rubber granules are in fact an alternative as this might not be possible in practice.

For the dossier it is important to obtain information of potential human health and environmental hazards of 'alternatives', as we want to avoid that a shift to alternatives would give rise to other concerns to human health or the environment. Some information comparing impacts of alternatives was said to be available and will be provided to RIVM, including a life cycle analysis. It is stated that this analysis should not only pay attention to hazardous chemicals, but also to other environmental problems (like climate change and use of resources). It was said that the variety in quality in alternative infill material is much larger compared to infill made from ELT and that there may be or in future come alternatives on the market form Asia that are of low quality and including chemicals that can give risks. Chemicals can also be used during use and maintenance of different types of pitches, e.g. to protect the artificial grass or the infill material from bacterial or plant growth. Not much information on this seems to be available, also not on differences between various types of pitches and types of infill. It however, was said to be more likely to use chemical treatment in case of natural infill, as e.g. cork is more susceptible to algae.

Also other characteristics of alternatives were discussed. Sports technical performance, intensity of use, characteristics in extreme climates (high temperatures), maintenance needs, life-time, availability and costs were mentioned. It was stated that the aspects length of infill service life (durability) and maintenance are important issues. Also costs were stated to be very important as the choice for new pitches is mostly based upon a tendering procedure having costs as the most important factor in the decision what field to choose.

The question is raised what alternatives are promising. In response to this it was said to look at those systems that have already proven themselves. EPDM and TPE are alternatives that are used. PE is an upcoming infill material. Also mixed infill can be used in practice. Alternative systems are developed to require less infill material for reasons of costs (the virgin infill material is more expensive than ELT rubber infill). Alternative systems often use shorter grass piles compared to ELT based system and often make use of a shockpad/elastic layer below the artificial grass that can for example be made out of ELT and PU.
Artificial turf systems without infill are currently not complying FIFA criteria. Various views exist whether such non-infill systems will be able to comply with the criteria in the future. Main issues here are wounds by slidings and rotation characteristics of the system. However these non-infill systems may be in use for mini-pitches or playgrounds.

Currently, not many alternative producers are active on the market, because the market for alternatives is small. If the market requests for alternatives, this will become a growing market. However, time and investments are needed adapt to such a change. In some states in the US already shifted to alternatives and can provide indications of the required time for industry to adapt to that.
In Europe a shift to alternatives is observed in The Netherlands and Sweden. It was said that at current capacity, full replacement of ELT infill by alternatives is not yet possible, but within some years this could be feasible.

Theme 4: Socio-economic effects of a restriction

The Annex XV dossier will contain a socio-economic analysis (SEA) in which the costs and benefits of the restriction options are analysed and compared to the business as usual scenario (baseline). The SEA aims to provide information to conclude upon the proportionality of the proposed restriction by comparing societal benefits and societal costs of the measure(s). In the discussion, first the baseline situation is discussed. This is the current situation without introduction of the restriction proposal.

Some information was shared related to the estimated number of artificial turf football fields in the EU and the market share of various types of infill that are currently used. Expected trends were discussed. The number of artificial turf pitches is expected to grow. The number of mini-pitches may be growing faster than the number of football fields, as this market appears to be less saturated. However, it is not very clear whether this is an EU wide trend or whether this is the situation for some specific EU countries. Furthermore, currently, ELT infill is dominant on the EU market (estimated around 90 % of all infill used), however, there are said to be differences among EU countries. (Non-ELT) alternative infills are expected to grow in the baseline situation. Mini-pitches are smaller compared to football fields (estimated around $1/10^{th}$), however, these may become large in numbers and are used for various purposes by both adults as children. Mini-pitches may both be situated outside and indoors. They are often expected to be owned by local governments but may also be private owned.

There was some discussion on the recycling of used infill material. Recycling may be possible for various infills and could become a growing market as the first artificial turf pitches are currently renewed.

Related to the number of people that come into contact with artificial turf pitches (and hence with infill material), an estimate can be made from EU residents involved in football. In some EU countries other sports also use the artificial turf pitches and these needs to be included as well. However, other users of example mini-pitches are more difficult to make. It was suggested to make an estimate based on the expected number of fields in the EU. Furthermore it was raised not to forget schools using the fields for their sport activities.

The potential consequences of various limit values of PAHs were discussed, as currently it is not known what limit value will be proposed as it will be based on the risk assessment that is currently ongoing. What is expected to happen of course largely depends on the value of the limit value. There was agreement among actors that a limit value similar to the current PAH restriction on articles would stop the use of infill made of ELT as current PAHs concentrations are higher and are not expected to significantly reduce in the future. There are different views on what values can be met currently. What limit value can be met largely depends on the test method used, and attendees request for clarity on this in the restriction proposal.

Tyre recyclers state to get problems when the limit value is too low. Infill is said to account for around 30 % of their market and that market would then be lost, resulting in job losses and losses in revenues. In addition they state that recycling targets will not anymore be met. However, a strict limit value would increase the market of alternative manufacturers. Some actors also expect wider effects of a strict limit value as social unrest might result in pressure replacing existing fields if they appear to contain higher PAH values. This may be an imported secondary effect of a restriction proposal that normally only is aimed towards supply and use of new materials. Such secondary effect might increase market impacts significantly and will put financial burden on sport clubs and local municipalities that own the pitches as well. It was stated that the sector will not wait for action until the restriction is actually entering into force. Probably stakeholders may already start acting as soon as the (draft) restriction proposal is published. In that sense the required transition period may be short. However, this of course also depends on the limit value that is proposed.

Programme workshop 24-11-2017

Chair: Joke Herremans (RIVM)

9.00 Welcome and purpose of the workshop

9.15 Tour de table

9.45 Introduction on the Annex XV dossier and the discussion of today

10.00 Theme 1. Risk of granules used on synthetic turf pitches

11.15 Theme 2. Scope of the restriction and restriction options

12.30 Lunch break

13.30 Theme 3. Alternatives

14.45 Theme 4. Socio-economic effects of a restriction

16.00 Summary of discussions

17.00 Closure, drinks

17.30 End of the meeting

List of participants

Berleburger Schaumstoffwerk GmbH	Hans Ulf Poeppel
BIR, Recybem	Barend ten Bruggencate
BSNC/Sekisui Alveo	Frenk Stoop
Celanese	Gesine Fickel
Conradi+Kaiser GmbH	Michael Winkelmüller
Conradi+Kaiser GmbH	Klaus Kaiser
ECHA	Kirsi Sihvonen
ESTO	Alastair Cox
ETRA	Ettore Musacchi
ETRMA	Laia Perez Simbor
ETRMA	Marco Nahmias
ETRMA	Daniele Formai
ETRMA/NVR	Alex van Gelderen
European Commission	Enrique Garcia John
Federazione Nazionale Gioco Calcio	Manuela Cortese
Fraunhofer	Ludwig Gruber
Genan	Daniel Schokmann
Granuband	Jan Aufenacker
International Carbon Black Association	Gerrit Höhfeld
Kempeneers-Milieu	Frank Kempeneers
Labosport	Pascal Haxaire
Ministry of Health, Welfare and Sport	Jurgen van Belle
Ministry of Infrastructure and Water Management	Cees Luttikhuizen
Ministry of Infrastructure and Water Management	Carsten Wentink
Polytan GmpH	Rutger Schuijffel
PVP Triptis GmbH	Susanne Madelung
Ragn-Sells	Sara Stiernström
RecyBEM/Band en Milieu	Frank Hopstaken
RIVM	Richard Luit
RIVM	Martijn Beekman
RIVM	Joke Herrremans
RIVM	Julia Verhoeven
RIVM	Anja Verschoor
RIVM	Arianne de Blaeij
Rumal	Jan van den Brand
Sekisui Alveo	Klim Geraedts
SGS Intron	Ulbert Hofstra
Stirling University	Andrew Watterson
Ten Cate grass holding	Bart Wijers
Terra Sports Technology	Mario Smit
University Twente	Jacques Noordermeer
University Utrecht, IRAS	Majorie van Duursen

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