

ANNEX XV REPORT

AN EVALUATION OF THE POSSIBLE HEALTH RISKS OF RECYCLED RUBBER GRANULES USED AS INFILL IN SYNTHETIC TURF SPORTS FIELDS

Substance Names: Substances in recycled rubber granules used as infill material in synthetic turf

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Contents

| | |
|---|----|
| SUMMARY..... | 5 |
| REPORT..... | 8 |
| 1 INTRODUCTION..... | 8 |
| 2 INFORMATION ON HAZARD AND RISK..... | 8 |
| 2.1 Identity of the substances..... | 8 |
| 2.1.1 Substances present in recycled rubber granules..... | 8 |
| 2.2 Information on uses of recycled rubber granules used as infill material... | 12 |
| 2.3 Overview of uses | 12 |
| 2.3.1 Applications of recycled rubber granules | 12 |
| 2.3.2 Amount of fields with synthetic turf in the EU | 14 |
| 2.3.3 Description of synthetic turf | 18 |
| 2.3.4 Recycled rubber granules used as infill material | 19 |
| 2.3.5 Overview of tyre market and end-of-life management schemes in the EU | 21 |
| 2.3.6 Overview of the rubber granules manufacturing process | 23 |
| 2.3.7 Overview of technical standards applicable to rubber granules used in sports and recreational area flooring | 24 |
| 2.3.8 Imports of rubber material under HS codes 4003.00, 4004.00, 4012.20 | 26 |
| 3 HAZARD INFORMATION | 28 |
| 3.1 Classification and limit values applicable to recycled rubber granules..... | 28 |
| 3.1.1 Harmonised classification in Annex VI to CLP..... | 29 |
| 3.2 Additional hazard information..... | 32 |
| 3.2.1 Substance specific information..... | 32 |
| 3.2.2 General discussion on carcinogenicity in the rubber industry..... | 37 |
| 3.3 Exposure information | 38 |
| 3.3.1 Human exposure – literature review | 38 |
| 3.3.2 Exposure scenarios..... | 44 |
| 3.4 Risk characterisation | 52 |
| 3.5 Preliminary risk evaluation | 57 |
| 4 SUMMARY OF EXISTING LEGAL REQUIREMENTS | 59 |
| 5 INFORMATION ON ALTERNATIVE INFILL MATERIALS | 60 |
| 6 UNCERTAINTIES IN THE ASSESSMENT | 62 |
| 7 CONCLUSIONS | 64 |
| 8 STAKEHOLDER CONSULTATION | 67 |
| 9 REFERENCES..... | 68 |

| | |
|--|----|
| ANNEX I – COMPOSITION OF RECYCLED RUBBER GRANULES | 71 |
| ANNEX II – SCREENING OF SUBSTANCES – CMRS CATEGORIES 1A OR 1B | 71 |
| ANNEX III - RECYCLED TYRES (OR OTHER RECYCLED RUBBER PRODUCTS) USED AS INFILL MATERIAL – WASTE STATUS IN SOME EU MEMBER STATES, INCLUDING INFORMATION FROM STAKEHOLDERS..... | 71 |
| ANNEX IV - SELECTED SUBSTANCES AND SOME METALS – LIMIT VALUES | 71 |
| ANNEX V – OVERVIEW OF TYRE MARKET IN THE EU | 71 |
| ANNEX VI - EXPOSURE ASSESMENT STUDIES - LITERATURE REVIEW | 71 |
| ANNEX VII – RISK CHARACTERISATION AND EXCESS LIFETIME CANCER RISK ESTIMATIONS | 71 |
| ANNEX VIII – INFORMATION FROM ALTERNATIVE INFILL MATERIALS | 71 |
| ANNEX IX – CONFIDENTIAL INFORMATION | 71 |

Table of Tables

| | |
|---|----|
| Table 2.1 Infill demand for artificial turf in the world in 2015 (thousand tonnes per year) | 13 |
| Table 2.2 Markets for ELT granules and powder in 2011 and 2014 | 14 |
| Table 2.3 Estimates of the number of synthetic turf fields in some Member States..... | 16 |
| Table 2.4 Total imports of rubber material into the EU-28 and EEA in 2006-2015 | 27 |
| Table 3.1 Harmonised classification including information on limit values applicable for recycled rubber granules | 29 |
| Table 3.2 - Maximum air concentration from the exposure assessment studies from the literature and for comparison the reference limit values used..... | 42 |
| Table 3.3 Parameters used in exposure scenarios - players..... | 48 |
| Table 3.4 Parameters used in exposure scenarios - workers..... | 52 |
| Table 3.5 Risk characterisation ratios of selected substances via oral, dermal and inhalation | 55 |
| Table 3.6 Lifetime excess risk of cancer related to polycyclic aromatic hydrocarbons (EU 8) | 56 |

Table of Figures

| | |
|--|----|
| Figure 2.1 Number of artificial football fields installed annually | 15 |
| Figure 2.2 Two types of synthetic turf systems..... | 18 |
| Figure 3.1 Mechanised application of infill (photo submitted by ESTO)..... | 49 |
| Figure 3.2 Semi-mechanised application of infill | 50 |

SUMMARY

ECHA has found no reason to advise people against playing sports on synthetic turf containing recycled rubber granules as infill material. This advice is based on ECHA's evaluation that there is a very low level of concern from exposure to substances found in the granules. This is based on the current evidence available. However, due to the uncertainties, ECHA makes several recommendations to ensure that any remaining concerns are eliminated.

ECHA has evaluated the human health risks from substances found in recycled rubber granules that are used as an infill material in synthetic turf, such as that used in outdoor and indoor football fields.

By 2020, it is estimated that 21 000 full size pitches and about 72 000 minipitches will exist in the EU.

In the EU, rubber granules used as an infill material are mainly produced from end-of-life tyres (ELT). Industry has informed ECHA that most of this infill material is made from EU-produced tyres. The quantity of tyres and recycled rubber granules imported into the EU is reported to be small. However, ECHA cannot verify this information from an independent source.

ECHA has identified a number of hazardous substances in recycled rubber granules from the literature and from the results of several recent studies. Substances commonly present in recycled rubber granules are polycyclic aromatic hydrocarbons (PAHs), metals, phthalates, volatile organic hydrocarbons (VOCs) and semi-volatile organic hydrocarbons (SVOCs).

ECHA has investigated the risks to children playing football and other sports on synthetic sports fields (including goalkeepers), adults playing professional sports and workers installing or maintaining the fields.

ECHA has considered exposure to rubber granules by skin contact, ingestion and inhalation of substances evaporating from the granules, as well as dust formed by the granules themselves.

ECHA concludes that there is at most a very low level of concern from exposure to recycled rubber granules:

- 1) In the studies that ECHA has evaluated the concentrations of PAHs in recycled rubber granules have normally been well below the limit values set in the REACH restriction relevant for such mixtures. The studies covered approximately 50 samples from new recycled rubber granules and several hundreds of samples taken from more than 100 fields. The samples were from different Member States, e.g. from Finland, Italy, the Netherlands, Portugal and the United Kingdom. In addition, ECHA received studies from industry, which investigated PAHs from different fractions of tyres. It is important to note, however, that if the concentration of PAHs would be as high as the generic limit for mixtures supplied to the general public defined in REACH, the level of concern would not be low.

The concern for lifetime cancer risk for players and workers is very low given the concentrations of PAHs typically measured in recycled rubber granules in the EU.

- 2) The concern to players and workers is negligible given the available, although limited, migration data for metals, which are below the limits allowed in the current toys legislation¹.
- 3) No concerns to players and workers were identified from the concentrations of phthalates, benzothiazole and methyl isobutyl ketone in rubber granules as these are below the concentrations that would lead to health problems.
- 4) It has been reported that VOCs emitted from rubber granules in indoor halls might cause irritation to the respiratory track, eyes and skin.

The conclusions in this evaluation are consistent with the results of several other recent studies, such as the investigations of RIVM in the Netherlands and those of the State of Washington in the US.

ECHA identified the following uncertainties in its evaluation:

- The conclusions are based on available studies from almost 10 Member States covering more than 100 fields (infill material already in use) and around 50 samples of new recycled rubber granules. While ECHA was unable to find any particular bias in the studies, it is uncertain to what extent they are representative for recycled rubber granules used in the sports fields in the whole of the EU.
- There are still some knowledge gaps as regards to the substances present and their concentrations in the recycled rubber granules typically used as infill material in sport fields.
- Some imported tyres entering the EU or other rubber material with unknown composition can be converted at the end of their life cycle into rubber granules and may have different concentrations of substances than those in the above mentioned studies. Indeed rubber granules themselves may be imported, and the composition of such granules is not known.
- The combined effects of all the substances in rubber granules are not known and very difficult to assess. However, this uncertainty is not considered to affect the main conclusions of this evaluation.
- Some of the input values used in the risk assessment are assumptions. In this evaluation, the assumed values were conservative (for example such as how many granules children would swallow when playing). This approach reduced the uncertainty of this evaluation.

Rubber granules used in artificial turf continue to be investigated in the EU and elsewhere. For example, the US EPA is expected to produce its report on 'Recycled Tire Crumb Used on Playing Fields' in late 2017. The conclusions of ECHA's evaluation will need to be reviewed when this report becomes available.

¹ Comparison with limit values for dry powder like or pliable toy material as example.

Based on its evaluation, ECHA recommends the following:

1. Consider changes to the REACH Regulation to ensure that rubber granules are only supplied with very low concentrations of PAHs and other relevant hazardous substances.
2. Owners and operators of existing (outdoor and indoor) fields should measure the concentrations of PAHs and other substances in the rubber granules used in their fields and make this information available to interested parties in an understandable manner.
3. Producers of rubber granules and their interest organisations should develop guidance to help all manufacturers and importers of (recycled) rubber infill test their material.
4. European sports and football associations and clubs should work with the relevant producers to ensure that information related to the safety of rubber granules in synthetic turfs is communicated in a manner understandable to the players and the general public.
5. Owners and operators of existing indoor fields with rubber granule infills should ensure adequate ventilation.

In addition, ECHA recommends that players using the synthetic pitches should take basic hygiene measures after playing on artificial turf containing recycled rubber granules. For example, they should always wash their hands after playing on the field and before eating, quickly clean any cuts or scrapes, take off their shoes/cleats, sports equipment and soiled uniforms outside to prevent tracking crumb rubber into the house, and any players who accidentally get crumb rubber in their mouths should not swallow it.

REPORT

1 INTRODUCTION

Concerns have been raised by the Member States and the Commission on whether substances in recycled rubber granules used as infill material in synthetic turf in (sport) fields are causing health risks.

On 1 June 2016, the Commission requested ECHA to advise them in its consideration of whether there is a risk to human health that is not adequately controlled and needs to be addressed at a European Union (EU) level². Based on its consideration, the Commission may request ECHA to prepare a REACH Annex XV dossier for restriction.

ECHA has evaluated the risks to human health from substances found in recycled rubber granules that are used as an infill material in synthetic turf (e.g. used on football fields). No evaluation was made of any risks to the environment as this was not part of the remit of the request.

ECHA has investigated the risks to the general population, such as children playing on synthetic sports fields (football players as an example group, including goalkeepers), adults playing professional sports, and workers installing or maintaining the fields.

ECHA has considered exposure to rubber granules by skin contact, ingestion and inhalation of substances evaporating from the granules, as well as of dust formed by granules themselves.

2 INFORMATION ON HAZARD AND RISK

2.1 Identity of the substances

2.1.1 Substances present in recycled rubber granules

ECHA has investigated the available information³ on substances found in recycled rubber granules used as infill material in synthetic turf. In this report, information from both publicly available studies, and unpublished information is used.

Recycled rubber granules are regarded as mixtures⁴. These rubber granules contain a wide variety of substances depending on the material from which the granules are produced (recycled). The most commonly used material for

² See:

https://echa.europa.eu/documents/10162/13641/echa_rest_proposals_rubber_granules_en.pdf/1a8a254c-bd4a-47b1-a091-99ae4a94a8c2

³ Information that is available in the scientific literature or available in studies carried out and reported until January 2017.

⁴ As agreed by the Commission with Member States in the Meeting of Competent Authorities for REACH and CLP (outcome communicated at CARACAL-21, 29 June-1 July 2016).

manufacturing granules are vehicle tyres (ETRMA, 2016) while a small proportion of granules comes from other sources.

Vehicle tyres are typically made using styrene butadiene rubber⁵, which is why recycled granules from tyres are often called SBR (Styrene Butadiene Rubber) granules.

Determining which substances are in rubber granules is complicated because of the vulcanisation process of rubber used to make tyres. Vulcanisation may cause reaction products to be found in tyres.

Other materials are recycled in a much smaller proportion e.g. from ground rubber components of gaskets (Menichini et al., 2011; Unirubber, 2016). In addition, products made of ethylene propylene diene monomer (EPDM) and thermoplastic elastomers (TPE) are also used. However, rubber granules are not often made from these substances as far as we are aware.

Manufacturers of rubber granules, research institutes and other stakeholders have analysed the composition of rubber granules. In addition, there are a number of reports giving information on substances found in rubber granules that evaporate or leach from the material.

Annex I provides more detailed information on the substances and the concentrations present in rubber granules. The annex also has more information on substances used in the production of tyres and those that can be found after vulcanisation. Some information about rubber granules as a source for microplastics in the environment is also provided although the Commission did not request ECHA to evaluate the risk of rubber granules to the environment.

The information in the literature and in studies has been divided in the following way:

- Substances analysed in rubber granules:
 - o information related to new material from the manufacturer or from stocks; and
 - o information related to material gathered from the field studies.
- Substances that evaporate from rubber granules.
- Substances that leach from rubber granules.

Substances that are most often measured from recycled rubber granules are polycyclic aromatic hydrocarbons (PAHs)⁶, metals, phthalates, volatile organic

⁵ This is a simplification. Truck, tractor (off the road) and airplane tyres are primarily based on Natural Rubber (NR) and passenger tyres on a mix of Styrene Butadiene Rubber (SBR), NR and Butadiene Rubber (BR) in varying ratios, per type of tyre and per producer. Specific formulations are commonly proprietary.

⁶ PAHs have been in extender oils used to make tyres. The level of eight carcinogenic PAHs in extender oils decreased in the EU from 2010 due to the implementation of restriction entry 50 in Annex XVII to REACH.

compounds (VOCs)⁷ and semivolatile organic compounds (SVOCs)⁸. In this report, the information from EU studies is mainly used even though there is information from non-EU studies e.g. from USA and Canada.

Many substances have been found in rubber granules produced from recycled tyres (see Annexes I and VI). To focus the risk evaluation in this report on the substances that matter, a screening of substances has been carried out.

The starting point for the list of substances to be screened was the list of substances in rubber granules identified in a recent US research initiative. In 2016, the US Environment Protection Agency (EPA), together with other relevant agencies, launched a Federal Research Action Plan to investigate the risks to human health from recycled granules manufactured from tyres. The research protocol for the study was published in August 2016.

In this protocol, the EPA listed substances for target analysis based on information from research studies, information from potential tyre manufacturing chemicals and analytical laboratories; in addition, the availability of methods to measure these substances during the study was taken into account. There are more than 200 substances on the EPA list.

The substances on the EPA list were then compared to Annex VI to the Classification, Labelling and Packaging Regulation (CLP). Of the screened substances, 20 had harmonised classification as carcinogenic, mutagenic or toxic to reproduction (CMRs, categories 1A or 1B), such as some PAHs and phthalates. These substances are listed in Annex II.

In addition, 17 of the screened substances were skin sensitisers (e.g. formaldehyde and benzothiazole-2-thiol (2-mercaptobenzothiazole)) and one of the 17 was also a respiratory sensitiser (cobalt).

Substances selected for a more detailed investigation in this report are:

- Polycyclic aromatic hydrocarbons: benzo(a)pyrene, benzo(e)pyrene, benzo(a)anthracene, chrysene, benzo(b)fluoranthene, benzo(j)fluoranthene, benzo(k)fluoranthene and dibenz(a,h)anthracene (total PAHs (these are collectively called the EU-8 carcinogenic PAHs)).
- Phthalates: di-2-ethylhexylphthalate (DEHP), di-isobutylphthalate (DIBP), dibutylphthalate (DBP), benzylbutyl phthalate (BBP).
- Other: formaldehyde, benzothiazole, benzothiazole-2-thiol, methyl iso butylketone, benzene.

Some metals and several other substances that have been found in recycled rubber granules are also discussed briefly in this report as well.

⁷ Volatile organic compound (VOC) shall mean any organic compound having at 293,15 K a vapour pressure of 0,01 kPa or more, or having a corresponding volatility under the particular conditions of use. For the purpose of this Directive, the fraction of creosote which exceeds this value of vapour pressure at 293,15 K shall be considered as a VOC. See: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0013&from=EN>.

⁸ Semivolatile organic compounds (SVOCs): boiling point range 240-260 °C to 380-400 °C

Based on the literature review and information provided by stakeholders, an overview of the concentrations of the selected substances in recycled rubber granules was obtained. This overview was the basis for the subsequent risk assessment (see section 5.2.1. Exposure information). The studies covered approximately 50 samples from new recycled rubber granules and several hundreds of samples taken from more than 100 fields. The samples were from different Member States, e.g. from Finland, Italy, the Netherlands, Portugal and United Kingdom. In addition, ECHA received studies from industry, which investigated PAHs from different fractions of tyres.

It should be noted that the information obtained by ECHA is based on the studies evaluated. This does not mean the information represents the exact composition of the rubber granules (it only represents the substances extracted and there may have been other substances not detected). Whether all relevant substances have been accounted for is an uncertainty in the evaluation.

In new rubber granules manufactured from recycled tyres (i.e. not yet installed as infill), the total PAH content typically varies between 9.12-58.21 mg/kg⁹. For the EU-8 carcinogenic PAHs the total PAH content varies between 2.12-22.78 mg/kg. Benzo(a)pyrene (BaP) concentrations have been found between the detection limit (<0.08) and 1.19 mg/kg.¹⁰

The samples taken from the fields in the EU contain PAHs between 1.90-72.94 mg/kg in rubber granules from recycled tyres/SBR¹¹. The BaP concentration is found between below the detection limit (0.01 mg/kg) and 2.38 mg/kg. The corresponding values for EU-8 carcinogenic PAHs are 0.98-42.88 mg/kg. The corresponding concentrations for rubber granules from other recycled material (recycled scrap of vulcanised rubber and ground gaskets) have been between 1.59-22.9 mg/kg (total PAHs), 0.07-4.12 mg/kg (EU-8 carcinogenic PAHs) and 0.02-2.83 mg/kg (BaP).

The rubber granules made from recycled tyres collected from outdoor fields seem to have somewhat higher levels of PAHs rubber granules made from than recycled tyres collected from indoor fields.

In addition to the PAHs, the content of some metals in recycled rubber granules was investigated. As examples cadmium was found between 0.11 mg/kg and 2.38 mg/kg, cobalt was found in recycled rubber granules with varying concentrations (3.5 - 268 mg/kg) and lead was found between the detection limit (<0.5 mg/kg) and 308 mg/kg.

⁹ Note that in the following concentrations, 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.

¹⁰ In one reported case, a sample originating from Asia was tested. Very high concentrations of chrysene and benzo(a)pyrene were seen and the concentrations were higher than the limit value set in entry 28 of Annex XVII to REACH. The rubber granules, in this case, did not comply with the restriction in entry 28 of Annex XVII. The infill material was from Asia, but it was not known which type of material the granules were produced from or if it was recycled material. The material was thus not used as infill material.

¹¹ The highest concentration is from a study of recycled SBR, however, the study does not define if this material is from tyres or from other SBR material.

In relation to the metals found in rubber granules, only those whose elemental metal is itself classified were selected for preliminary evaluation. This is because it is not possible to say in which form the metals are in the recycled rubber granules. Therefore, it is possible that some of the compounds of the metals, which might be classified as CMR, Cat 1A or 1B, are not considered. This is an uncertainty in the report.

2.2 Information on uses of recycled rubber granules used as infill material

2.3 Overview of uses

2.3.1 Applications of recycled rubber granules

According to the European Tyre and Rubber Manufacturers Association (ETRMA, 2016)¹², the most commonly used elastomeric material in infill in sports fields is rubber derived from end-of-life tyres (ELTs).

Other materials can be used as well, such as ethylene propylene diene monomer (EPDM) and thermoplastic elastomer (TPE), both of these can be used as virgin or as recycled material. Table 2.1 describes the global demand for infill for artificial turf in 2015. Compared to the level of demand in 2009 (total demand 5 993 000 tonnes) there is a clear increase.

¹² ETRMA (2016), replies to questions posed by ECHA.

Table 2.1 Infill demand for artificial turf in the world in 2015 (thousand tonnes per year)

| | SBR* | EPDM | TPE | Coated sand/SBR | Other | Total |
|-------------------|----------------|------------|-------------|-----------------|------------|----------------|
| Contact sport | 1 265.0 | 4.7 | 12.9 | 3.4 | 9.1 | 1 286.0 |
| Non-contact sport | 2.0 | 0.0 | 0.0 | 0.0 | 0.0 | 2.0 |
| Leisure/DIY | 3.6 | 0.0 | 0.0 | 0.1 | 0.2 | 3.7 |
| Landscaping | 0.8 | 0.0 | 0.0 | 0.0 | 0.0 | 0.8 |
| Total | 1 271.4 | 4.7 | 13.0 | 3.5 | 9.3 | 1 292.5 |

* SBR: tyre recycled rubber is often referred to as styrene butadiene rubber (SBR) in the artificial turf market

Source: AMI consulting – 2010 & 2016 Annual report on Artificial turf market – Received from ETRMA’s response, 2016

ELT-derived rubber granules are used in many applications. According to ETRMA, ELT-derived rubber granules and powders are currently used for:

- Synthetic turf: ELT-derived rubber granules are used as an infill material that provides proper resilience and shock absorbance to the artificial turf playing fields.
- Sport surfaces/athletic tracks: ELT-derived rubber (non-granules) is used in many outdoor sport areas (primarily for athletics, multi-use sports) to dissipate the vibrations and impacts that otherwise would lead to muscular-skeletal effects in athletes. ELT-derived rubber is also used in indoor surfaces (e.g. for volleyball and basketball courts), generally with a polyurethane (PU) top coating but this represents a small volume compared to outdoor surfaces. These surfaces are regarded as articles (tiles, rolls etc.).
- Shock-absorbing pavements: ELT-derived rubber is typically used to produce shock-absorbing floorings (*in-situ* floors or mats) that are durable in outdoor conditions, weather-resistant, permeable to water, etc.
- Moulded rubber goods: ELT rubber granules and powders can be mixed with polyurethane binders to produce re-moulded rubber articles such as wheels for trolleys (e.g. caddies, dustbins wheelbarrows, etc.), urban furniture, safety corners, rail filler block systems, etc.
- Other applications: Asphalt rubber, equestrian floor, etc.

Based on the consolidated data from four ELT management companies in Portugal, France, Italy and Spain, an overview of the ELT granules/powder market is described in Table 2.2:

Table 2.2 Markets for ELT granules and powder in 2011 and 2014

| Use | Percentage in 2011 | Percentage in 2014 |
|-----------------------------------|--------------------|--------------------|
| Asphalt and road paving | 4 % | 1 % |
| Sports and children playgrounds | 23 % | 24 % |
| Moulded objects | 21 % | 24 % |
| Synthetic turf (including infill) | 43 % | 30 % |
| Other uses | 2 % | 5 % |
| Undetermined (export, trader) | 7 % | 16 % |

Source: ETRMA

Based on this information it appears that the share of ELT granules/powder used in synthetic turf (including infill) is decreasing. The decrease has not been explained, but it might be due to the use of other rubber infill than ELT in these four countries, or because the number of fields has stabilised the demand, when less new fields are installed per year and ELT granules are used more as refill material.

According to ETRMA (2016), infill material is not used in synthetic turf that is installed in recreation areas e.g. next to swimming pools.

In this report, the focus is on synthetic turf and especially where recycled rubber is used as infill material. It is to be noted that sports fields could have shock-absorbing pavements in addition to infill material, which is made of recycled rubber tyres.

2.3.2 Amount of fields with synthetic turf in the EU

The European Synthetic Turf Organisation (ESTO, 2016)¹³ states in its Market Report Vision 2020, that there are over 13 000 synthetic turf football fields within the EU and over 47 000 minipitches used for football.

Data from the major synthetic turf manufacturers and the ELT granulators operating in the EU indicate that around 1 200–1 400 new football fields are nowadays installed every year in the EU (see Figure 2.1). This includes the replacement of old fields. According to ESTO, the number of fields is expected to continue to grow, e.g. by 2020 the number of football fields with synthetic turf is expected to be about 21 000 and the number of minipitches around 72 000.

¹³ ESTO (2016), replies to questions posed by ECHA.

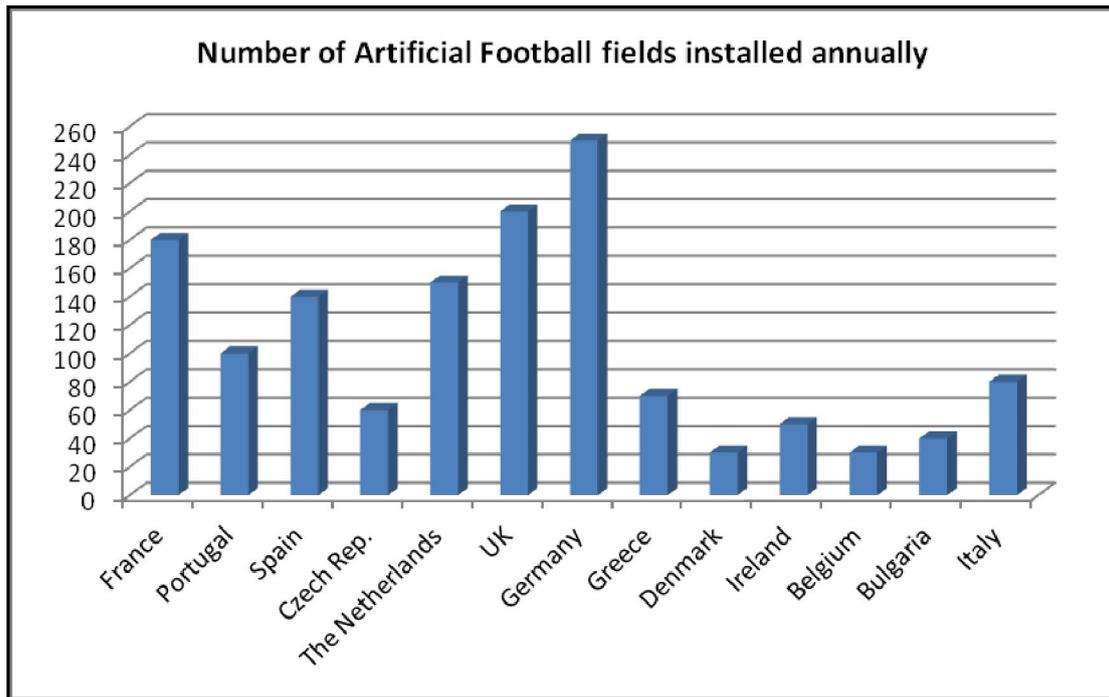


Figure 2.1 Number of artificial football fields installed annually

Source: ETRMA

According to ESTO, football is by far the largest sports' user of long pile synthetic turf fields¹⁴. Examples of other sports using this type of surface are:

- rugby;
- Gaelic sports;
- lacrosse; and
- American football.

Based on industry estimates (ETRMA, 2016), the quantity of ELT rubber infill that is used on European sport fields is about 80 000 to 130 000 tonnes per year. In the EU, ELT is by far the most common form of infill used. Other materials used are: ethylene propylene diene monomer (EPDM), thermoplastic polymer (TPE), thermoplastic olefins (TPO), thermoplastic vulcanisates (TPV), cork and coconut fibre. Of these, EPDM and TPE rubber infill can be from the recovery process.

It is estimated that around 10 %-15 % of total sales each year of synthetic turf sports surfaces are for short pile synthetic turf fields (non-ELT infill surfaces). These are used for a range of sports such as hockey, tennis, cricket and multi-sport activities.

ESTO estimates that over 95 % of all synthetic turf installations are currently located outdoors. The number of fields, type of fields and the tonnages of rubber infill used per year on the field are described in Table 2.3 (based on information received from some Member States and football associations).

¹⁴ See more information in Section 5.1.3.

Table 2.3 Estimates of the number of synthetic turf fields in some Member States

| Member State | Amount of fields with synthetic turf | Infill material | Amount of rubber granules per year or field | Remarks |
|-----------------|---|--|--|--|
| Finland | 39 (indoors/ football) Around 250 (outdoors/ football) | Commonly made from styrene butadiene rubber (SBR) | 45-113 tonnes per field (average size of field is 7 500 sqm) (note amount depends on the layer thickness) | 2013 |
| France | 2 497 fields with synthetic turf | 85 % from black rubbers from recycled tyres. Also encapsulated, encapsulates SBR rubber from tyres, EPDM or polyurethane are used. | | First field with infill rubber was installed in 1998. All material used in France are approved by Labosport. |
| The Netherlands | 1 800 full size synthetic pitches for football (all outdoors) | 95 % filled with SBR rubber | | |
| Norway | Around 800 football pitches Outdoor fields/sport/ running tracks: 125 large and 256 smaller pitches based on rubber granules | 90 % of football pitches, 80 % of outdoor fields (etc.) | Outdoor fields/sport/ running tracks: around 5 900 tonnes are in use. Football pitches: 85 000 tonnes in use. Around 5 tonnes used as refill. | |
| Sweden | 1 191 football fields (676 for teams of 11 players, 210 for 5, 7 or 9 players and 350 small football fields) | Estimation that 90 % of the infill material consists of SBR rubber. | New fields: estimation of 2 550 tonnes (SBR). Old fields: estimation of 1 520 tonnes (SBR) by Sweco and 2070-3510 tonnes (SBR) by IVL | 2015. Total area estimated to be 6 117 600 m ² . Every year, around 100 fields with synthetic turf built. |

| Member State | Amount of fields with synthetic turf | Infill material | Amount of rubber granules per year or field | Remarks |
|--------------------|--|-----------------|---|---------|
| The United Kingdom | Over 5 000 artificial grass pitches (AGPs ¹⁵). Around 2 750 3G pitches (3 rd generation pitches, latest development of AGPs). | | | |

Source: Member States and Football Associations

In addition, ESTO (2016) provided information that around 30 Gaelic sports fields are built each year in Ireland.

¹⁵ Artificial grass pitches.

2.3.3 Description of synthetic turf

Several different types of synthetic turf 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. Sand and rubber granulate are used to fill the spaces between the artificial grass. The sand provides weight and holds the plastic web in place, while the rubber provides elasticity. Other infill materials than rubber crumb are available (see Annex VIII for some information on these substances). 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.

The quality of infill used in a long pile synthetic turf surface will depend on the height of the pile and performance required. 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. If the system incorporates a shockpad, the pile height may be lower and the infill quantity could be as low as 40 tonnes. Figure 2.2 (source ETRMA and ESTO (2016)) illustrates these two types of artificial turf systems.

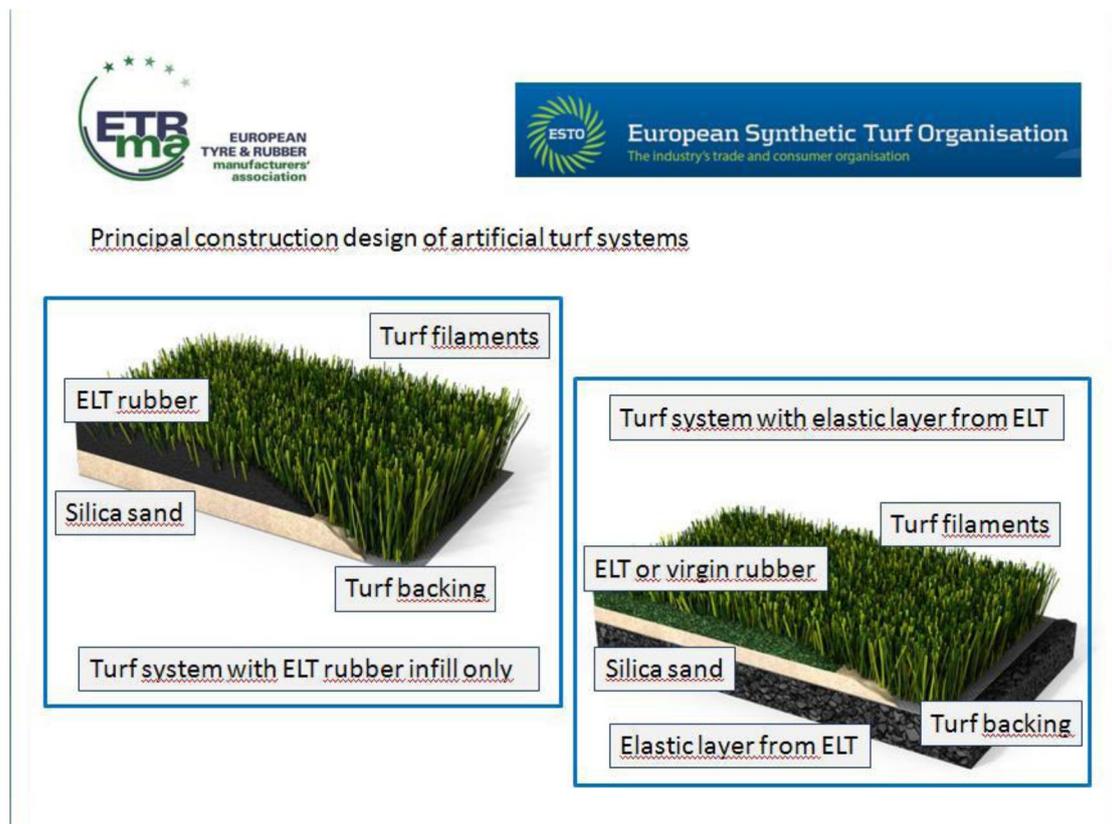


Figure 2.2 Two types of synthetic turf systems

Source: ETRMA and ESTO

As rugby and gaelic sports fields are larger than football fields, they use proportionally more infill.

The new generation of 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 tyre granulate. 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 FIFA¹⁶ provides some criteria for hazards of the material i.e. '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 that no such substances will be released as a vapour or dust during normal use.'

FIFA has established the FIFA Quality Programme for Football Turf, which certifies final installations are subject to the testing procedure.¹⁷ On its website, FIFA lists providers that fulfil their quality programme. The number of fields in the EU that fulfil the FIFA quality programme is not known.

Some Member States have specific control systems in place. For example, the French Football Association (FFF, 2017)¹⁸ notes that the owners of the fields are municipalities, who require laboratory reports to prove the filler 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 fields. FFF control the quality of fields every five years. According to FFF, the main driver to choose the infill material is the price.

According to the DEFRA, UK¹⁹ (2017), the samples are typically collected as part of the field test verification of the artificial grass pitches. The process involves the collection of circa 5 kg of the 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)²⁰, Tony Atherton, the relevant sports standards which are used are FIFA Quality Program, World Rugby Reg 22 and more recently BS EN 15330-1.

2.3.4 Recycled rubber granules used as infill material

In the EU, there are many manufacturers of rubber granules from recycled rubber. The exact number of manufacturers of rubber granules, used as infill material in synthetic turfs, is not known. However, ETRA (2017)²¹, the European

¹⁶ <http://quality.fifa.com/globalassets/fqp-handbook-of-test-methods-2015.pdf> and <http://quality.fifa.com/globalassets/fqp-handbook-of-requirements-2015.pdf>

¹⁷ <http://quality.fifa.com/en/Football-Turf/About-Football-Turf/Quality-Assurance/>

¹⁸ Berly, Jean-Michel (FFF), personal communication

¹⁹ Carmichael, Penny (DEFRA), personal communication

²⁰ Atherton Tony (Sport England), personal communication

²¹ ETRA (2016, 2017), replies to questions posed by ECHA

Tyre Recycling Association, has confirmed that manufacturers of rubber granules are present in 21 countries in the EU²².

2.3.4.1 Rubber granules derived from recycled tyres (and SBR infill)

As previously stated, rubber granules from recycled end-of-life (ELT) tyres (SBR granules²³) that originate from tyres are by far the most common form of infill used in synthetic turfs in the EU according to industry. In some countries, ELT is used in over 95 % of all fields, e.g. in the UK, Ireland and France (ESTO, 2016). SBR rubber granules can also be coated with polyurethane-based coatings (ETRMA, 2016).

The share of SBR rubber granules used as infill material that are from non-ELT rubber and not from EU sourced tyres is unclear.

As in some studies SBR rubber is only mentioned as infill material, the following list provides other uses of SBR rubber: houseware mats, drain board trays, shoe soles and heels, food container sealants, tyres, conveyor belts, sponges, adhesives and caulks, automobile mats, brake and clutch pads, hoses, flooring, military tank pads, hard rubber battery box cases, extruded gaskets, rubber toys, moulded rubber goods, shoe soling, cable insulation and jacketing, pharmaceutical, surgical, sanitary products and food packaging.²⁴

2.3.4.2 Recycled rubber granules derived from other materials

According to industry (ETRMA, 2016), recycled rubber made of ethylene propylene diene monomer (EPDM) or thermoplastic polymers can be used as infill material in addition to virgin materials. For example, Unirubber Sp, a Polish company produces infill material from recycled EPDM and virgin EPDM infill material (UniRubber, 2016).

In 2015, EPDM represented 0.3 % of the infill material used in synthetic turf globally, while TPE represented 1 %. According to ESTO, in Germany, it is estimated that 50 % of all fields use EPDM or TPE and that similar infills have significant usage in Scandinavia (whether these are recycled or virgin material is not known). It is to be noted that competent authorities from Finland and Sweden stated that rubber infill material used in their countries is mainly SBR rubber.

Based on the available information, EPDM is used in various applications such as windows and door seals in the automobile industry, waterproofing of flat roofs, garden roofs, ponds or basins and other waterproofing applications (Source: Hertalan website²⁵).

²² Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, The Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden, The UK.

²³ This is a simplification. Truck, tractor (off the road) and airplane tyres are primarily based on natural rubber (NR) and passenger tyres on a mix of styrene butadiene rubber (SBR), NR and butadiene rubber (BR) in varying ratios, per type of tyre and per producer. Specific formulations are commonly proprietary.

²⁴ See: <http://iisrp.com/WebPolymers/09E-SBRPolymerSummaryJuly16.pdf>

²⁵ See: http://www.hertalan.co.uk/about_us.aspx

According to a manufacturer of TPE goods²⁶ 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).

Unirubber Sp (2016) provided information that infill materials can also be produced using SBR, EPDM and TPE rubber from mats, belts, sleeves, spouts and gaskets. The infill material that they produce does not contain recycled tyres. According to Unirubber Sp they sell infill materials mainly to Poland, Lithuania, Estonia and Latvia. Some EPDM and TPE-derived rubber granules are sold as refill material to Finland²⁷.

2.3.5 Overview of tyre market and end-of-life management schemes in the EU

In the EU, tyre production in 2014 by European Tyre Rubber Manufacturers Association (ETRMA) members (source ETRMA) was estimated to account for 20 % of the world tyre production, i.e. 4.8 million tonnes. The total production, including also non-ETRMA members, is currently not known.

In the EU, landfilling end-of-life tyres (ELTs) has been prohibited since 2006 following the European Directive 1999/31/EC. Under the Extended Producer Responsibility, ELTs have to be managed by their manufacturers and importers.

According to ETRMA²⁸, the Extended Producer Responsibility, where implemented, 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 or Sweden), through multiple ELT management companies or consortia (such as in Italy, France or Spain) or through individual producer responsibility (in Hungary). Free market²⁹ systems operate in Austria, Switzerland, Germany and the UK.

²⁶ See: <http://www.hexpoltpe.com/en/index.htm>

²⁷ NH-Koneet Oy, personal communication (2016)

²⁸ End of Life Tyre Report 2015, ETRMA:
<http://www.etrma.org/uploads/Modules/Documentsmanager/elt-report-v9a---final.pdf>

²⁹ 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.

More details on ELT management schemes and ELT recycling figures in the EU are available in Annex V. 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 deriving from irregular sales/imports, as described in Annex V.

Imported tyres

Regarding the imports, in the last decade imports from China are dominating the market, especially in the passenger and truck tyres segments (source ETRMA Statistics Report 2014). More details on imports are available in Annex V. Information on imported used tyres are in Section 4.2.8³⁰ and in the confidential Annex IX.

The main possible differences in the composition of tyres produced in the EU versus tyres produced outside the EU are related to the³¹:

- Type of extender oils used³²; and
- Type of reinforcement used.

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 method³³.

The concentrations of PAHs in different types of imported tyres³⁴ is not available to ECHA.

The use of silica reinforcement instead of carbon black for passenger car tyre treads (introduced in the EU in the early 90s) is another possible difference in the concentrations of PAHs in tyres. The silica-reinforced tyres contain about 1.5 times more oil than the carbon black-reinforced ones³⁵. Most non-EU producers have adopted this silica reinforcement technology (at least for the EU market).

³⁰ 4.2.8 Imports of rubber material under HS codes 4003.00, 4004.00, 4012.20

³¹ Based on information exchanged with Jacques W.M. Noordermeer, em. Professor of Elastomer Technology and Engineering (University of Twente, the Netherlands).

³² Oils used in tyre production may belong to the class of substances known as TDAE (Treated Distillate Aromatic Extract) or to DAE (Distillate Aromatic Extract). Aromatic oils belonging to the DAE class of substances have been replaced in the EU market by oils belonging to the TDAE class, due to the concerns related to the content of polycyclic aromatic hydrocarbons (PAHPAHs) in DAE. Restriction entry 50 of Annex XVII to REACH forbids the production or import into the EU of tyres produced since January 1, 2010 with non-complying oils.

³³ 1H-NMR bay-proton analysis is a relatively complex technique (both expensive and requiring high skills) and furthermore a destructive test.

³⁴ Including imported used tyres.

³⁵ Based on information exchanged with Jacques W.M. Noordermeer, em. Professor of Elastomer Technology and Engineering (University of Twente, the Netherlands).

In relation to tyres produced before 2010 and imports, the European Tyre Recycling Association (ETRA, 2017)³⁶ has recently stated, following its own analysis that:

'Based on the results of the research, we should consider producing infill material for artificial turf pitches exclusively from tires manufactured in Europe since 2010, when the PAH in the rubber was radically reduced. Tires 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.'

2.3.6 Overview of the rubber granules manufacturing process

Rubber crumb is the name given to 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. Rubber granules are mainly manufactured from ELT rubber³⁷. Scrap tyre rubber comes from different types of tyres (ETRMA, 2016):

- 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 16–20 % of the total weight of EU-28 scrap tyres;
- other tyres, which account for less than 10 % of the total weight of EU-28 scrap tyres

A typical scrap tyre contains (by weight): 70 % recoverable rubber, 15 % steel, 3 % fibre and 12 % extraneous material (e.g. inert fillers).

The largest scrap tyre recycler in the world is Genan Holding A/S ("Genan"), with its headquarters in Denmark. It operates four large plants in the EU that recycle exclusively European-sourced tyres and one plant in the US (Houston, Texas).

There are several processes for manufacturing rubber granules. Two of the most common are ambient grinding and cryogenic processing:

- Ambient grinding can produce any particle size. It 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 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

³⁶ See: <http://www.etra-eu.org/libraries/articles/Chemicals%20in%20artificial%20turf%20SBR%20Infill%20Committee.pdf>

³⁷ Tyre buffings, a byproduct of tyre retreading, is not used to produce infill materials, according to ETRA (2017).

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 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. 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.

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 characteristics of all size-reduced tyre materials are described (for example) in the UK publicly available specification (PAS 107:2012)³⁸ for the manufacture and storage of size-reduced tyre materials.

2.3.7 Overview of technical standards applicable to rubber granules used in sports and recreational area flooring

There are a number of different technical standards applicable to rubber granules. Some producers of sports and recreational area flooring describe the standards they use to test the quality and properties of their granules in the technical data sheets of their product.

This information can be used by customers to check the overall quality and characteristics of the granules. The most common technical standards described in technical data sheets are listed, as found on the web³⁹:

- EN 15330-1 (2013): Surfaces for sports areas. Synthetic turf and needle-punched surfaces primarily designed for outdoor use.
- EN 933-1 (2012): tests for geometrical properties of aggregates part 1: determination of particle size distribution – sieving method.
- EN 14955 (2005): surfaces for sport areas – determination of composition and particle shape of unbound mineral surfaces for outdoor sport areas.
- EN 1097-3 (1998): tests for mechanical and physical properties of aggregates – part 3: determination of loose bulk density and voids.

³⁸ See: <http://tyrerecovery.org.uk/wp-content/uploads/2012/11/pas-107-2012-88.pdf>

³⁹ FIFA quality documents are described in Section 4.2.3.

- EN 14836 (2005): synthetic surfaces for outdoor sport areas. Exposure to artificial weathering.
- DIN 18035-7:2002-06: Sports Grounds Part 7: Synthetic Turf Areas, Determination of Environmental Compatibility
- NF P90-112: Sports grounds - Unbound mineral surfaces for outdoor sport areas - Specifications for construction.

The following parameters are usually tested according to DIN 18035-7:2002-06 and NF P90-112:

- DOC (Dissolved Organic Carbon)
 - EOX (extractable organic halides)
 - lead (Pb)
 - cadmium (Cd)
 - chromium total (Cr)
 - chromium VI
 - mercury (Hg)
 - zinc (Zn)
 - tin (Sn)
- PAS 107:2012: publicly available specification, for the manufacture and storage of size-reduced tyre materials.

In general, the quantitative determination of heavy metals and other chemicals in the rubber granules can be carried out according to the analytical methods described in the specific standards.

The previous list is not intended to be exhaustive. In addition, 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 end-of-life tyres. The documents which are currently under preparation are:

- *"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"*.

The documents are expected to be published by the end of 2017. 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.

Among the rubber samples tested, at least one sample of uncoated rubber granules, from end-of-life tyres, used as infill material in synthetic turf and one sample of coated rubber granules will be studied.

2.3.8 Imports of rubber material under HS codes 4003.00, 4004.00, 4012.20

In this section, information related to the imports of rubber material for HS⁴⁰ codes 4003.00, 4004.00, 4012.20 in the EU 31 (including Norway, Liechtenstein and Iceland) from extra-EU countries, is reported. These codes indicate:

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

Some of this material (e.g. used pneumatic tyres), at the end of its life cycle, might be potentially transformed into rubber granules or used (when already in the form of rubber granules) as infill material, for different purposes. However, there is no accurate information available on the use of this material and on its life cycle in the EU territory. It is not possible to exclude that other rubber material entering the EU under HS codes other than the ones mentioned, might be transformed, at the end of their life cycle, into rubber granules.

In addition, there is no information available on the quality of this material and whether quality may be related to the country of origin or not. Parts of this rubber material, may also enter the EU having the status of waste⁴¹.

According to ETRMA (2016), imported tyre-related rubber goods (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.

European sports fields use around 80 000 to 130 000 tonnes per year of ELT rubber infill. If all of the 35 000 tonnes would be used as infill material, this would represent 19–43 % of the used infill material. However, this is unlikely as according to ESTO (2016), most ELT that is recycled to produce rubber infill is sourced locally (or certainly regionally) due to the need to minimise transportation costs. ESTO assumes that some ELT is imported from the Ukraine and Russia and that it may be used in some eastern EU Member States.

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 2.4. in 10 years (2006-2015).

⁴⁰ Harmonised system (HS) is one of the two most important international trade classification systems (HS and SITC) to classify and define internationally traded goods:

See: <http://www.foreign-trade.com/reference/hscod.htm>

See: <http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=14>

⁴¹ 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.

Table 2.4 Total imports of rubber material into the EU-28 and EEA in 2006-2015

| Product code | Total imports 2006-2015 (tonnes) |
|--------------|----------------------------------|
| 4003.00 | 202 985 |
| 4004.00 | 509 923 |
| 4012.20 | 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 IX. TARIC 4012200090⁴² 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 legislation⁴³.

⁴² 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.

⁴³ 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.*"

3 HAZARD INFORMATION

3.1 Classification and limit values applicable to recycled rubber granules

REACH Annex XVII entry 28 requires substances listed as carcinogens category 1A or 1B, such as the PAHs EU-8, not to be placed on the market, or used as substances, as constituents of other substances, or in mixtures, for supply to the general public.

Entry 28 of Annex XVII sets concentration limits for application of the restriction. These limits are the relevant specific concentration limit specified in Annex VI to the CLP Regulation (Regulation (EC) No 1272/2008). This means that for benzo[a]pyrene and dibenz[a,h]anthracene the concentration limit is 0.01 % by weight (100 mg/kg) and for the other six carcinogenic PAHs with harmonised classification, the limit is 0.1 % by weight (1 000 mg/kg).

Articles placed on the market for the general public that contain one or more PAHs are restricted by entry 50 of Annex XVII to REACH if the concentration of each PAH is greater than or equal to 0.0001% (1 mg/kg) by weight of the rubber or plastic components of certain articles (when other criteria specified in the entry are met). This limit is much lower than that in entry 28 of Annex XVII.

In addition, according to entry 50, extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain:

- a) more than 1 mg/kg (0.0001% by weight) benzo[a]pyrene, BaP; or
- b) more than 10 mg/kg (0.001% by weight) of the sum of all 8 listed PAHs.

Table 3.1 provides information on limit values for selected substances relevant to recycled rubber granules. Annex IV provides information on other limit values established for other purposes. In addition, Annex IV provides limit values for some other substances than the selected ones.

3.1.1 Harmonised classification in Annex VI to CLP

The harmonised classification has been provided for selected substances in Table 3.1. In addition, the limit values as set in restriction entries 5 and 28-30 (applicable for recycled rubber granules) are provided in the table.

Table 3.1 Harmonised classification including information on limit values applicable for recycled rubber granules

| Substance | CAS number | Registered? | Classification and labelling | Limit value if restricted under REACH entries 28-30. Limit value is the same when the mixture need to be classified | |
|----------------------|------------|----------------|---|---|-------------------------|
| | | | | % | mg/kg |
| Benz[a]anthracene | 56-55-3 | Not registered | Carc. 1B Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Generic 0.1 | Carc. 1B: Generic 1 000 |
| Chrysene | 218-01-9 | Not registered | Carc. 1B Muta. 2 Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Generic 0.1 | Carc. 1B: Generic 1 000 |
| Benz[b]fluoranthene | 205-99-2 | Not registered | Carc. 1B Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Generic 0.1 | Carc. 1B: Generic 1 000 |
| Benz[j]fluoranthene | 205-82-3 | Not registered | Carc. 1B Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Generic 0.1 | Carc. 1B: Generic 1 000 |
| Benzo[k]fluoranthene | 207-08-9 | Not registered | Carc. 1B Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Generic 0.1 | Carc. 1B: Generic 1 000 |

| Substance | CAS number | Registered? | Classification and labelling | Limit value if restricted under REACH entries 28-30. Limit value is the same when the mixture need to be classified | |
|--------------------------|------------|----------------|--|---|-------------------------|
| | | | | % | mg/kg |
| Benzo[a]pyrene | 50-32-8 | Not registered | Carc. 1B Muta. 1B Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Specific: 0.01 | Carc. 1B: Specific: 100 |
| Benzo[e]pyrene | 192-97-2 | Not registered | Carc. 1B Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Generic 0.1 | Carc. 1B: Generic 1 000 |
| Dibenz[a,h]anthracene | 53-70-3 | Not registered | Carc. 1B Aquatic Acute 1 Aquatic Chronic 1 | Carc. 1B: Specific 0.01 | Carc. 1B: Specific: 100 |
| di-2-ethylhexylphthalate | 117-81-7 | Registered | Repr. 1B | Repr. 1B: Generic 0.3 | Repr. 1B: Generic 3 000 |
| di-isobutylphthalate | 84-69-5 | Registered | Repr. 1B | Repr. 1B: Generic 0.3 | Repr. 1B: Generic 3 000 |
| dibutylphthalate | 84-74-2 | Registered | Aquatic Acute 1 Repr. 1B | Repr. 1B: Generic 0.3 | Repr. 1B: Generic 3 000 |
| benzyl butyl phthalate | 85-68-7 | Registered | Aquatic Acute 1 Aquatic Chronic 1 Repr. 1B | Repr. 1B: Generic 0.3 | Repr. 1B: Generic 3 000 |
| Benzene* | 71-43-2 | Registered | Flam. Liq. 2 Carc. 1A Muta. 1B Asp. Tox. 1 STOT RE 1 | Carc. 1A: Generic 0.1 (same limit as in entry 5) | Carc. 1A: Generic 1 000 |

| Substance | CAS number | Registered? | Classification and labelling | Limit value if restricted under REACH entries 28-30. Limit value is the same when the mixture need to be classified | |
|------------------------|------------|-------------|--|---|-------|
| | | | | % | mg/kg |
| | | | Skin Irrit. 2 Eye Irrit. 2 | | |
| Benzothiazol | 95-16-9 | Registered | No harmonised classification | | |
| benzothiazole-2-thiol | 149-30-4 | Registered | Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1 | | |
| Methyl-isobutyl-ketone | 108-10-1 | Registered | No harmonised classification | | |
| Formaldehyde | 50-00-0 | Registered | Carc. 1B Muta. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1 | Carc. 1B: Generic 0.1, but not restricted with entry 28 | |

* REACH Annex XVII entry 5 (benzene): a) in mixture 0.1 % by weight.

3.2 Additional hazard information

3.2.1 Substance specific information

Polycyclic aromatic hydrocarbons (PAH)

Polycyclic aromatic hydrocarbons (PAHs) constitute a large class of organic compounds that are composed of two or more fused aromatic rings. They are primarily formed by incomplete combustion or pyrolysis of organic matter and during various industrial processes.

PAHs generally occur in complex mixtures, which may consist of hundreds of compounds. Humans are exposed to PAHs by various pathways. While for non-smokers the major route of exposure is consumption of food, for smokers the contribution from smoking may be significant.

Many PAHs have shown clear evidence of mutagenicity/genotoxicity in somatic cells in experimental animals *in vivo*. These compounds may be regarded as potentially genotoxic and carcinogenic to humans.

Because it is not possible to analyse all PAHs, instead it is normal to measure certain benchmark substances. These benchmark substances are for example EUEU-8 PAHs⁴⁴ and EPA-16 PAHs⁴⁵. Naphthalene and BaP are often used as indicators for the presence of PAHs. These substances have reference values, which can be used in exposure and risk assessment.

According to IARC Monographs on "The Evaluation of Carcinogenic Risks to Humans VOLUME 92 Some Non-heterocyclic Polycyclic Aromatic Hydrocarbons and Some Related Exposures (2010)", a number of PAH compounds have been classified as carcinogens:

- Benzo[a]pyrene is *carcinogenic to humans* (Group 1);
- Cyclopenta[cd]pyrene, dibenz[a,h]anthracene and dibenzo[a,l]pyrene are *probably carcinogenic to humans* (Group 2A); and
- Benz[j]aceanthrylene, benz[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[c]phenanthrene, chrysene, dibenzo[a,h]pyrene, dibenzo[a,i]pyrene, indeno[1,2,3-cd]pyrene and 5-methylchrysene are *possibly carcinogenic to humans* (Group 2B).

Phthalates

⁴⁴ Eight PAH substances (EU-8 PAHs for the purpose of this report) are specified in entry 50 of Annex XVII to REACH: 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) and dibenzo[a,h]anthracene (DBAhA). See: <https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach>

⁴⁵ See e.g.: https://ec.europa.eu/jrc/sites/jrcsh/files/Factsheet%20PAH_0.pdf

The four phthalates (diisobutyl phthalate, dibutyl phthalate, benzyl butyl phthalate and bis(2-ethylhexyl)phthalate) are all classified as toxic to reproduction in category 1B (may damage the unborn child and are suspected of damaging fertility), and BBP and DBP also as toxic to the aquatic environment.

In addition, ECHA's Member State Committee (MSC) has unanimously confirmed that these four phthalates are endocrine disruptors related to human health, although they did not agree unanimously that they were of equivalent concern, and that DEHP is an endocrine disruptor in the environment. The REACH Committee recently voted positively on a Commission proposal to identify the 4 phthalates as substances of equivalent concern (EDs related to human health).

Following oral administration, phthalates are generally rapidly absorbed from the gastrointestinal tract (probably in monofrom). Phthalates can also be absorbed through the lungs, whereas absorption through the skin appears to be limited.

The DNELs are based on reprotoxicity and they are most relevant for protecting pregnant women (and foetuses) and very small children. Other groups of the population would, however, also be protected as, based on current knowledge, reprotoxicity is the most sensitive endpoint for phthalates although there are some uncertainties related to this.

All four substances described below are substances of very high concern (SVHCs) and included in the Candidate List⁴⁶ for authorisation. These require authorisation before being used⁴⁷.

Diethylhexyl phthalate (DEHP): DNELs for the adult (general) population, children and workers have been derived for the oral, dermal and inhalation routes. DNELs for workers are 0.88 mg/m³ for inhalation and 1.882 mg/kg/d for the dermal route. DNELs for the general population (adult) are 0.034 mg/kg/d for the oral route, 0.672 mg/kg/d for dermal route and 0.16 mg/m³ for inhalation. DNELs for children are the same for the oral and the dermal route, but 0.12 mg/m³ is derived for inhalation.

Absorption percentages for humans used in RAC's opinion are 100 % for oral, 5 % for dermal and 75 % for adults and 100 % for children through inhalation (RAC Opinion, Authorisation, establishing reference DNELs for DEHP, 2013)⁴⁸.

Dibutyl phthalate (DBP): DNELs for the adult (general) population, children and workers have been derived for the oral, dermal and inhalation routes. DNELs for workers are 0.13 mg/m³ for inhalation and 0.19 mg/kg/d for the dermal route. DNELs for the general population are 0.007 mg/kg/d for oral route, 0.07 mg/kg/d for the dermal route and 0.02 mg/m³ for inhalation. DNELs for adults and children are the same. Absorption percentages for humans used in the RAC opinion are

⁴⁶ See: <https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d82a7>

⁴⁷ See Annex XIV to REACH: <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list/-/dislist/details/0b0236e1807e09fa>

⁴⁸ See: https://echa.europa.eu/documents/10162/21961120/rac_24_dnel_dehp_comments_en.pdf/e0506f6b-35f7-433e-99da-35464a26e2df

100 % for inhalation and the oral route, and 10 % for dermal exposure (RAC Opinion, Authorisation, establishing reference DNELs for DBP, 2013)⁴⁹.

Benzyl butyl phthalate (BBP): DNELs for the adult (general) population, children and workers have been derived for the oral, dermal and inhalation routes. DNELs for workers are 9.9 mg/m³ for inhalation and 28 mg/kg/d for the dermal route. DNELs for the general population are 0.5 mg/kg/d for the oral route, 10 mg/kg/d for the dermal route and 1.7 mg/m³ for inhalation. DNELs for adults and children are same. Absorption percentages for humans used in the RAC opinion are 100 % for inhalation and oral exposure, and 5 % for dermal exposure. (RAC Opinion, Authorisation, establishing reference DNELs for BBP, 2013)⁵⁰.

Diisobutyl phthalate (DIBP): DNELs for workers are 2.94 mg/m³ for inhalation (long-term) and 830 µg/kg bw/day (long-term). DNELs for the general population are 720 µg/m³ for inhalation, no hazard identified for dermal exposure and 83 µg/kg bw/day (read-across from DBP) for the oral exposure route.

Formaldehyde

The classification of formaldehyde, amended by Regulation (EU) No 605/2014 of 5 June 2014, is Carc. 1B, Muta. 2, Acute Tox. 3 (oral), Acute Tox. 3 (dermal), Acute Tox. 3 (inhalation), Skin Corr. 1B and Skin Sens. 1.

According to the Committee for Risk Assessment (RAC opinion on harmonised classification, 2012⁵¹) the route(s) for exposure should not be stated in the hazard statement of carcinogenicity as it is not proven that other routes besides inhalation can be excluded. According to RAC, formaldehyde is a local acting genotoxic carcinogen. In addition, RAC noted that the database for low-dose effects is limited and that the data does not allow a firm conclusion on a threshold mode of action or the identification of threshold.

In its opinion proposing a harmonised classification and labelling, RAC states that there is limited evidence of carcinogenicity in humans mainly from the positive association of nasopharyngeal tumours in industrial cohorts, but that there is sufficient evidence of carcinogenicity from animal studies.

France (draft RMOA, 2016⁵²) is using the following DNELs in its risk characterisation:

- the worker long-term DNEL for inhalation is 0.3 ppm (0.37 mg/m³); and
- the worker short-term DNEL for inhalation is 0.6 ppm (0.75 mg/m³).

⁴⁹ See: https://echa.europa.eu/documents/10162/21961120/rac_24_dnel_dbp_comments_en.pdf/44ab77fd-d6fa-4d73-b0ed-9317fd6c0422

⁵⁰ See: https://echa.europa.eu/documents/10162/21961120/rac_26_reference_dnels_bbp_en.pdf/f7e55089-a402-4eb1-b79d-a93e2387db5d

⁵¹ See: <https://echa.europa.eu/documents/10162/254a73cf-ff8d-4bf4-95d1-109f13ef0f5a>

⁵² See: <http://www.consultations-publiques.developpement-durable.gouv.fr/consultation-publique-sur-le-rapport-de-l-anses-a1421.html>

The RMOA states that prevention of irritant effects of formaldehyde is considered protective of its carcinogenic effects through inhalation.

No DNELs for effects on the consumer have been derived, however, if a DNEL is appropriate it could be expected to be lower than the DNEL for workers. An indoor air quality guideline value of 0.1 mg/m³ is available.

Benzene

According to the harmonised classification and labelling in Annex VI to CLP, this substance may be fatal if swallowed and it enters airways, may cause genetic defects, may cause cancer, causes damage to organs through prolonged or repeated exposure, is a highly flammable liquid and vapour, causes serious eye irritation and causes skin irritation.

No DNELs have been derived. Based on Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, the exposure of workers must not exceed the prescribed limit value. For benzene, the limit value in the directive (Annex III) is 3.25 mg/m³ (1 ppm) (reference period of eight hours).

Health concerns of benzene are due to repeated dose toxicity, mutagenicity and carcinogenicity. Indirect exposure of humans through the environment occurs predominantly through the air. There are industrial sources for benzene exposure and also other sources like commercial and residential heating, traffic exhaust, petrol distribution, environmental tobacco smoke. Due to the genotoxic and carcinogenic effects of benzene, no safe level of exposure can be recommended.

Benzothiazole (BTZ)

There is no harmonised classification for benzothiazole in Annex VI to CLP.

According to notifications submitted to ECHA, the substance has been classified as Acute Toxicity category 3 H301 (Toxic if swallowed), Acute Toxicity category 3 H311 (Toxic in contact with skin), Eye Irritation category 2 (H319 Causes serious eye irritation) and Acute Toxicity category 4 H332 (Harmful if inhaled). In addition, according to the classification provided by companies to ECHA in REACH registrations, it may cause damage to organs through prolonged or repeated exposure.

No DNELs have been derived.

Ginsberg *et al* (2011) have concluded that BTZ may volatilise from crumb rubber and result in inhalation exposure. The boiling point of BTZ is 235 °C and vapour pressure is 13 kPa (20 °C). BTZ has been identified to exert acute toxicity, respiratory irritation and skin sensitisation. The substance has shown positive effects in salmonella assays with metabolic activation. A structural analogue 2-mercaptobenzothiazole, also called benzothiazole-2-thiol (2-MBT) has been more widely tested.

Benzothiazole-2-thiol (2-MBT)

According to the harmonised classification and labelling in Annex VI to CLP, 2-MBT is very toxic to aquatic life, is very toxic to aquatic life with long-lasting

effects and may cause an allergic skin reaction (Skin Sens. 1). The substance has been included in the CoRAP list (concerning skin sensitisation and consumer uses).

The conclusion document of the relevant Substance Evaluation (2014), clarified that there is no need for a proposal for harmonised classification and labelling of 2-MBT regarding carcinogenicity or genotoxicity⁵³. The substance evaluation was targeted to consumer use and risks, so only DNELs for the general population were derived in the document, but not for workers. The long-term systemic effect DNELs for the general population were 0.31 mg/kg bw/day for the oral route, 0.94 mg/kg bw/day for the dermal route and 1.09 mg/m³ for inhalation. Because of the lack of data, it was not possible to derive DNELs for the sensitising effects.

Methyl isobutyl ketone (MIBK), 4-methylpentan-2-one

MIBK is a liquid and its boiling point is 116-118 °C. Its vapour pressure is 21-26 hPa.

According to the harmonised classification and labelling in Annex VI to CLP, this substance is a highly flammable liquid and vapour, causes serious eye irritation, is harmful if inhaled and may cause respiratory irritation.

Harmonised classification: Flam. Liquid 2 H225, Eye Irritation category 2 (H319 causes serious eye irritation), STOT SE 3 (H335 May cause respiratory irritation), Acute Toxicity category 4 (H332 Harmful if inhaled).

The following DNELs have been derived in the registration dossier:

- Worker DNEL inhalation, long-term 83 mg/m³; dermal 11.8 mg/kg bw/day;
- General population DNEL inhalation 14.7 mg/m³, dermal 4.2 mg/kg bw/day, oral 4.2 mg/kg bw/day.

Metals

A number of metals have been identified in recycled rubber granules, however, the information available to ECHA only refers to the results of elemental analysis. Therefore the information does not refer to the specific metal compounds found. Annex I provides information on elemental metals detected.

Many of the compounds of the elemental metals identified have harmonised classifications (not given here). Some of harmonised classifications are for CMR effects.

No DNELs have been derived for the threshold effects of the metals.

⁵³ However, IARC has recently evaluated 2-MBT and classified it to a Group 2A (*Probably carcinogenic to humans*). The IARC Monographs Volume 115 is still under preparation and when available the issue will need to be reassessed. This is an uncertainty in the evaluation.

3.2.2 General discussion on carcinogenicity in the rubber industry

The International Agency for Research on Cancer (IARC) has updated its review on occupational exposures in the rubber-manufacturing industry (IARC Monographs 100F, 2012). The conclusion on the evaluation is that there is sufficient evidence in humans for the carcinogenicity of occupational exposures in the rubber-manufacturing industry.

Occupational exposures in the rubber-manufacturing industry cause leukaemia, lymphoma and cancers of the urinary bladder, lung and stomach. In addition, positive association has been observed between exposure and some other cancers. The overall conclusion by IARC is that occupational exposure in the rubber-manufacturing industry is carcinogenic to humans (Group 1).

IARC stated that the complexity of occupational exposure in the rubber-manufacturing industry had so far precluded a clear conclusion about an association between increased cancer mortality and incidence, and exposure to particular chemicals (except historically well-known associations between 2-naphthyleamine and bladder cancer, and benzene and leukaemia).

Concern has been raised about whether rubber granules, especially those recycled from tyres, may cause cancer⁵⁴. The concern may be due to the fact that the manufacturing of tyres and rubber-manufacturing industry have been under scrutiny for many years and due to the chemicals used in the production of tyres, the IARC has categorised the rubber-manufacturing industry as carcinogenic to humans (see below).

However, the most recent investigation on reported cancer among soccer players in Washington State did not show increased rates of cancer among players considered in the study, and the available research does not suggest that playing soccer on artificial turf causes cancer (Washington State Department of Health, 2017)⁵⁵. The same was observed by (RIVM, 2016). Since the 1980s, a slight rise has been observed in the Netherlands in the number of people aged between 10 and 29 who get leukaemia. However, this trend has not changed since fields made of synthetic turf were first used in the Netherlands in 2001.

It should be noted that concentrations at the workplace are much higher compared to those in the playing fields⁵⁶. Workers may also be exposed to dust from rubber processing, to fumes from rubber curing (heating and curing of rubber compounds generates visible fumes) and substances that are formed during the vulcanising process.

IARC Monographs 93 (2010) has also evaluated carbon black. The conclusion is that there is inadequate evidence in humans for the carcinogenicity of carbon

⁵⁴ On 21 February 2016, the Irish Times published an article 'Synthetic pitches: Are health fears totally groundless?' In this article they refer to Amy Griffin, a 1991 FIFA World Cup winner with the USA and goalkeeping coach for the US under-20 soccer team, who became aware of the number of cancer cases amongst goalkeepers.

⁵⁵ See: <http://www.doh.wa.gov/CommunityandEnvironment/Schools/EnvironmentalHealth/syntheticTurf>

⁵⁶ IARC Monographs 28 1982: e.g. for benzene: 1.5 mg/m³ (8 plants; median) and 0.6-24 mg/m³ (23 samples); for benzo(a)pyrene 0-32.3 µg/m³ (7 plants)

black. The evidence in experimental animals for the carcinogenicity of carbon black is sufficient (incidences of lung tumour increases) as well as sufficient evidence in experimental animals for the carcinogenicity of carbon black extracts (skin tumours and sarcomas after subcutaneous injection, the last one when carbon black contained high levels of PAHs). The overall conclusion is that carbon black is possibly carcinogenic to humans (Group 2B).

3.3 Exposure information

3.3.1 Human exposure – literature review

Exposure of synthetic turf installation and maintenance workers (IndusTox 2009, Ecopneus 2016), coaches (Castellano, 2008) and athletes (VanRooij 2010, Menichini 2011, Simcox 2011, Ecopneus 2016) has been investigated in several studies.

Exposure assessment has been performed by measuring airborne impurities in the breathing zone of the workers or at the waist height of the players. The waist height sampling shows the worst-case scenario and also the exposure of children.

The air or the airborne dust on the synthetic turf fields in outdoor (ETRA, Ecopneus 2016, Schiliro 2013, Vidair 2010, Shalat 2011, Broderick 2007, Lim 2009, Vetrano 2009) or indoor (NILU 2006, Moretto 2009, Salonen 2015, Simcox 2011) air arenas has been studied. The sampling has been performed using stationary sampling or a robotic sampler. The main air impurities that have been monitored in all these studies are inhalable and respirable dust, PM10 and PM2.5 particulates⁵⁷, PAHs, volatile organic compounds (VOCs) as separate substances or as a total VOC and some metals.

According to the studies, exposure to the inhalable and respirable dust can be moderate during the installation and maintenance work. The highest measured value for inhalable dust has been 3.1 mg/m³. The exposure to the inhalable dust during work can be controlled if the high exposure has been identified as it was performed in the study of Industox and Kempeneers Milieu (2009).

Implementation of relevant risk management measures reduces the maximum exposure level to dust to below 1 mg/m³. Respirable dust in the breathing zone of the workers during the installation of football fields has been seen in the range of 0.02 to 1.43 mg/m³ in an Italian study (Ecopneus & Waste and chemicals 2016).

Generally, the PM10 concentrations have been comparable to urban outdoor levels and have been in a range of 10-40 µg/m³ in indoor air arenas. The portion of rubber in PM10 dust was 23-28% in the Norwegian study (NILU 2006).

The exposure to VOC has some variation in indoor and outdoor arenas. The concentration of VOCs that were sampled with passive monitors from the breathing zone of workers, were below the detection limit. The concentrations of

⁵⁷ It can be said roughly that PM10 reflects thoracic fraction and PM2.5 alveolic fraction.

VOC (sampled into the sorbent tube) have been higher in indoor air arenas than in outdoor arenas.

The maximum concentration of VOC has been 716 $\mu\text{g}/\text{m}^3$ measured from an indoor arena with SBR infilling and without ventilation. The portion of ketones and aldehydes can be relatively high (111 $\mu\text{g}/\text{m}^3$) in the air of indoor arenas.

Measured VOC compounds have included compounds that are skin sensitizers e.g. formaldehyde and benzothiazole-2-thiol. There is some evidence that chemical substances used in rubber processing e.g. thiourams and benzothiazole-2-thiol, are causing sensitisation in athletes (Ventura, 2001). This information is not specifically linked to the rubber granules used in sports field, but generally to many different sports activities. However, both of these substances (group of substances) may be present in rubber granules.

Indoor VOCs may also cause irritation in eyes, skin and upper respiratory tract. In a Finnish study (Salonen 2015), the football players reported symptoms of sore throat, running nose and eye and skin irritation, and the VOCs were assumed to be the reason for these symptoms. The substances that have been identified and detected from air samples are e.g. 4-methyl-2-pentanone (MIBK) in a maximum range of 14.5-36 $\mu\text{g}/\text{m}^3$, formaldehyde (5-6 $\mu\text{g}/\text{m}^3$) and acetone (6-11 $\mu\text{g}/\text{m}^3$).

A typical rubber component is benzothiazole in a maximum range from 14-32 $\mu\text{g}/\text{m}^3$. Alkyl benzenes (e.g. styrene, xylene) have been analysed from the air of the indoor arenas. Also, 2-butanone, chloroform and hexane have been found to be unique to the synthetic turf fields, but not at a level that they would cause health effects.

Dimethylphthalate (DMP, max 50 ng/m^3), diethylphthalate (DEP, max 28 ng/m^3), dibutylphthalate (DBP, max 45 ng/m^3) and diethylhexylphthalate (DEHP, 31 ng/m^3) have been identified and analysed from airborne dust.

Diethylphthalate (DEP, 0.06 $\mu\text{g}/\text{m}^3$), diisobutylphthalate (DiBP, 0.10 $\mu\text{g}/\text{m}^3$) and dibutylphthalate (DBP, 0.38 $\mu\text{g}/\text{m}^3$) have been identified and analysed from air samples.

Many other organic compounds from the airborne dust with pg/m^3 level have been analysed e.g. different kind of benzothiazoles, aromatic amines. The level of nitrosoamines has been below the detection limit. Benzene concentrations on the synthetic turf field have been at the same level as urban air, except in one measurement in an indoor arena where the concentration was 7 $\mu\text{g}/\text{m}^3$ and outside the concentration was 0.5 $\mu\text{g}/\text{m}^3$. In the same indoor arena, the concentrations of other VOCs like toluene and xylene were also elevated. In this indoor arena, the ventilation was not working properly.

The measured airborne PAH concentrations are comparable with urban levels. In many studies, the airborne PAH levels have been greater in winter than in summer. This can be explained with external PAH sources such as heating and traffic exhaust which causes higher emissions during winter than in summer. Naphthalene (113 ng/m^3), methylated naphthalenes, fluorene (53 ng/m^3), fluoranthene, phenanthrene (32 ng/m^3) and pyrene are the main PAH compounds when the vapour phase PAH compounds have been analysed.

Particle-bound PAHs (containing more than four aromatic rings) exist in much lower concentrations in the air above the synthetic fields and the concentrations are often below the detection limit.

In an unpublished study (provided by ETRA), particle-bound PAHs were measured during playing and without playing. The goal was to clarify if the playing resulted higher emissions of dust and PAHs. The highest PAH concentrations were measured in December 2006 in Porto, Portugal. The total EPA PAH concentrations were 66 ng/m³ during playing and 47 ng/m³ without playing. The highest measured BaP values were 2.6 µg/m³ during playing and 7.5 µg/m² without playing. In other studies, the measured BaP concentrations have been in a range of 1.2 (indoor) – 0.4-2 ng/m³ (outdoor) on a synthetic turf field.

Ecopneus (2016) and partners have analysed higher BaP levels from the breathing zone of the workers and football players in Italy. The measured BaP concentrations have varied from 0.0 to 26.7 ng/m³ during installation of the football field. In this study, dermal exposure was studied by placing pads on the skin of the workers and players. BaP was analysed from the pads, and the concentrations ranged from 0.0 to 0.19 ng/cm².

The high concentration in the air did not correlate to the dermal contamination on pads. In the same study, the airborne BaP was measured during the match from the breathing zone of the players, levels being 7.2-13.7 ng/m³. At the same time, BaP was measured in ambient air, and the concentration was 7.4 ng/m³ before the match and 12.3 ng/m³ during the match. Since the BaP levels in the breathing zone of the players were consistent with the levels in ambient air, the PAH exposure of players is presumably not related to the crumb rubber granules, but more to the external sources from background ambient air.

There are four studies where biomonitoring has also been used to estimate the exposure to PAHs among workers and football players on synthetic sports fields with tyre crumb infill (VanRooij and Jongeneelen 2010, Castellano 2008, IndusTox 2009 and Ecopneus 2016). The benefit of using biomonitoring in exposure assessment is that it takes into account both inhalation and dermal exposure.

Urinary 1-hydroxypyrene is a useful and widely used quantitative biological indicator of exposure to PAHs. However, there are also many external PAH sources e.g. diet, smoking and traffic, which may alter the results by increasing the background value. The concentration of 1-hydroxypyrene after the exposure to crumb rubber infill was mainly below the reference value that the American Conference of Industrial Governmental Hygienists (ACGIH⁵⁸) has set for non-occupationally exposed workers (both non-smokers and smokers), 1 µg/l urine (0.49 µmol/mol creatine). In some cases, there were increases in concentrations after the exposure compared to the concentration before the exposure, but the difference was not high and it could be explained by the external PAH source such as diet or smoking. *These studies provide evidence that the uptake of PAH by workers and football players is minimal and it is in the range of uptake of PAH from other sources in the environment and food.*

⁵⁸ See: <http://www.acgih.org/>

In a study by Castellano (2008), the metabolite of benzene was also analysed from the urine samples of coaches and maintenance personnel. The levels of t,t-MA benzene metabolite were low (average 21 µg/g of creatinine) when considering that the limit value recommended by ACGIH is 500 µg/g creatinine. The average value detected on 53 non-smokers residing in the same city was 46.9 µg/g of creatinine. *The study shows that the exposure level of benzene among coaches and maintenance workers is minimal.*

Chromium, lead and zinc have been detected in the air measurements performed on the synthetic turf field (Vetrano 2009 and EPA 2009). However, the concentrations have been very low and it has been concluded that these metals don't cause health effects or they have been at the same level with the background samples. In one study (Shalat 2011), it was concluded that it is possible that inhalable lead is present on the synthetic turf fields. The inhalable lead was measured from the breathing zone of a 12-year old boy who was playing on the field. The concentration was 8 ng/m³.

Table 3.2 - Maximum air concentration from the exposure assessment studies from the literature and for comparison the reference limit values used.

| Substance | Max. conc. in the literature | DNEL | Limit value for indoor air | Occupational exposure limit value | Other |
|---|------------------------------|--|---|---|---|
| Inhalable dust, mg/m ³ | 3.1 | - | | 10 for inorganic dust; 5 for organic dust (Sweden, Finland), 4 (Germany) | |
| Respirable dust, mg/m ³ | 1.4 | - | | 0.3 (Germany) | 3 (ACGIH) |
| PM10, µg/m ³ | 40 | - | | | 50 for 1 day; 40 calendar year (EU air quality limit value) |
| TVOC, µg/m ³ | 715 | - | 100 (Finland) | | |
| Benzene, µg/m ³ | 7 | - | | 3 250 (= 1 ppm, EU, the UK, France, Finland), 1 900 (tolerable cancer risk) or 200 (acceptable cancer risk) (Germany) | 5 annual (EU air quality limit value) |
| Benzothiazole, µg/m ³ | 32 | No DNELs | | 20 000 (Poland) | |
| 2-mercapto-benzothiazole, µg/m ³ | 0.000352 | 1 090 (general population) | | 4 000 (inhalable aerosol, Germany) | |
| MIBK, µg/m ³ | 36 | 83 000 (worker), 14 700 (general population) | | | |
| Formaldehyde, µg/m ³ | 6 | | 10 (France); 15 (Finland) 100; 30 min (WHO Guidelines for Indoor Air) | 150 (The Netherlands), 370 (Germany) | ¹⁾ |
| Naphthalene, ng/m ³ | 122 | | 10 000; (WHO Guidelines for Indoor Air) | 500 000 (inhalable aerosol, Germany), | ²⁾ |

| Substance | Max. conc. in the literature | DNEL | Limit value for indoor air | Occupational exposure limit value | Other |
|-------------------------|------------------------------|--|----------------------------------|--|---|
| | | | | 5 000 000 (Finland), 50 000 000 (EU) | |
| BaP, ng/m ³ | 2 or 13.7 ³ | | | 70 (Germany); 551 (The Netherlands); 2000 (Sweden); 10 000 (Finland; | 1 (EU Air quality target value), 4). 5) |
| DEHP, µg/m ³ | 0.031 | 880 (worker), 160 (adult, general population) and 120 (children, general population) | | | |
| DBP, µg/m ³ | 0.43 | 130 (worker), 20 (general population) | | | |
| BBP, µg/m ³ | | 9 900 (worker), 1 700 (general population) | 3 000 (Austria, Denmark, Sweden) | | |
| DiBP, µg/m ³ | 0.10 | 2 940 (worker), 720 (general population) | 1 000 (Latvia), 3 000 (Denmark) | | |
| Lead, µg/m ³ | 0.008 | | | | 0.5 annual (EU air quality limit value) |

1. In the EXPOLIS study in Helsinki, the average air concentration of formaldehyde in homes was 41.4 $\mu\text{g}/\text{m}^3$ (range 8.1–77.8 $\mu\text{g}/\text{m}^3$) and at the workplace 15 $\mu\text{g}/\text{m}^3$, whereas average personal exposure was 26.8 $\mu\text{g}/\text{m}^3$ ²⁰.
2. WHO Guidelines for Indoor Air Quality: naphthalene 0.01 $\text{mg}/\text{m}^3 = 10\ 000\ \text{ng}/\text{m}^3$ (annual average concentration). In the EU, indoor concentrations and personal exposures to naphthalene are usually low, typically below 1–2 $\mu\text{g}/\text{m}^3$
3. The value 2 $\mu\text{g}/\text{m}^3$ or less is a typically measured concentration for BaP. The value 13.7 $\mu\text{g}/\text{m}^3$ has been measured on the outdoor field in winter, and the BaP concentration in ambient air was at the same level at the same time.
4. BaP: WHO Guidelines for Indoor Air Quality: 0.1 mg/m^3 (30-minute average concentration); Germany: TRK Limit value (Technische Richtkonzentration) 8 h and weekly 2 $\mu\text{g}/\text{m}^3 = 2000\ \text{ng}/\text{m}^3$; Germany AGS: 0.00007 $\text{mg}/\text{m}^3 = 70\ \text{ng}/\text{m}^3$ (inhalable fraction) workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk; Sweden 0.002 mg/m^3 ; Finland 0.01 mg/m^3 ; The Netherlands 0.0005507 mg/m^3 .
5. BaP levels 0.01–0.65 ng/m^3 in European homes and 1.42 ng/m^3 in Italian homes and the BaP concentration was 0.2 ng/m^3 (0.05 – 0.5 ng/m^3) in Helsinki, 2005.

More information is available in Annex VI.

3.3.2 Exposure scenarios

Relevant exposure routes

Inhalation

Players and workers may be exposed to substances in rubber granules through inhalation. Substances that can be inhaled are those that are volatile (or semi volatile) or those that are bound to airborne dust. In the case of polycyclic aromatic hydrocarbons, many studies have measured PAHs bound to airborne dust and from the gas phase (e.g. NILU, 2006). NILU, 2006 also investigated what proportion of the dust was coming from rubber granules. Airborne dust is typically considered as inhalable and respirable dust, PM10 fraction (particulate material with an equivalent aerodynamic diameter < 10 μm) and PM 2.5 fraction (particulate material with an equivalent aerodynamic diameter < 2.5 μm). In this report, exposure due to inhalation has been analysed for workers and players.

In our exposure estimation due to inhalation, we have used the maximum measured air concentration on the synthetic turf fields with crumb rubber infilling or/and the maximum measured concentration in rubber granules and estimated the air concentration by using measured PM10 concentration in air (NILU, 2006). This is assumed to be a reasonable worst case based on the available information.

The latter approach was used in the recent report from the Netherlands (RIVM, 2016). However, ECHA did not take into account the rubber content in the dust,

which will overestimate the concentration of substances in the airborne dust. The measured maximum concentration values are from the literature. For the risk estimation of PAHs, the total amount of EU 8 PAHs, 20 mg/kg, in recycled rubber granules was used. This was regarded to represent the values found in the studies; especially in the recent RIVM study (2016). In the literature, a few higher concentrations were found, however, these were not used in lifetime cancer risk estimations, because it would heavily overestimate the risk and a more realistic value was preferred.

Dermal

Substances in rubber granules may come into contact with the skin when the synthetic turf is used, installed and maintained. Both rubber granules and airborne rubber dust contributes to the skin exposure. The dermal exposure may happen as contact to the rubber granules occurs e.g. touching granules with hands, sitting or laying on the turf or sliding on the turf. Deposition of airborne dust, which include substances on the skin may also contribute to the dermal exposure.

In addition, skin abrasions may occur during play increasing the likelihood of dermal absorption. The dermal route of exposure is considered both for workers and players.

Rubber granules contain a great number of different substances. The migration of the substances from rubber to artificial sweat have been studied (RIVM 2016, Ecopneus, 2016). The migration factors of PAHs to the artificial sweat have been detected from 0.007 to 0.02%.

In our exposure estimation through the dermal route, we used the same approach used in the recent report from the Netherlands (RIVM, 2016). In this report, the dermal exposure level was estimated by using the migration factor into the artificial sweat. The content of the substance was multiplied with the migration factor to estimate the total external amount on the skin. Absorption of 100 % is used in risk characterisation, which can be regarded as an overestimate, but this takes into account the effects of any abrasion of the skin.

Oral

According to NILU (2006), many users have stated that they sometimes accidentally swallow rubber granulate. In the same study, the average weight of 10 granules was between 10-15 mg for SBR rubber and 7 mg for TPE.

In the recent RIVM (2016) report, it was estimated that children would swallow 0.2 g rubber granules in one event and adults 0.05 g granules. The authors, however, state that it is difficult to imagine, that during the whole football playing life and for every training or game the amount of 0.2 g would be swallowed. ECHA agrees with this statement, and thus this oral exposure estimation needs to be regarded as a worst-case exposure. In our evaluation, more realistic amounts have been used, 0.05 g for children and 0.01 g for adults. In addition, the oral route of exposure is not considered a relevant exposure route for workers as it is expected that workers do not accidentally swallow the granules due to good hygiene practices.

Targets of exposure

Professional and non-professional players and other consumer groups

Exposure to rubber granules used as infill material may occur through inhalation, dermal contact and ingestion (accidental ingestion of granules). Sport participants (both professionals and non-professionals) training and those otherwise playing on the fields as well as non-sport playing children, e.g. school classes having different types of exercise on the fields may be exposed.

It has been taken into account that other less frequent exposures may occur. Small children may also be exposed, for example, while being with their parents who are following their older sisters or brothers playing. Some day-care groups and children in general might also use the fields for different types of play/sport activities. Spectators are also a potential exposed consumer group as they watch the games by the fields. However, it is assumed that these exposures are taken into account in the other reasonable worst case scenarios presented.

Different types of sports, like football, rugby, American football, Gaelic sports can take place on sports fields made of synthetic turf. In this report, football has been chosen as an example sport, for which exposure scenarios have been developed.

Football is typically played in all EU Member States and it is assumed that there are millions of players in the EU. For instance, in the Netherlands there are around 1 200 000 players that are registered in the Dutch football association (RIVM, (2017)⁵⁹), 141 000 players registered in the Finnish football association, of which 12 000 – 15 000 are goalkeepers (Finnish Football Association, (2017)⁶⁰). In Sweden, there were 332 000 registered players who were over 15 years and 240 000 younger than 15 (information from 2014, Sweco (2016)). Players are also using natural grass fields. In Finland, it is estimated that 75 % of time is played on the synthetic turf and 25 % on the natural grass fields.

In this report, several exposure scenarios are considered. Children typically start to play football at the age of 5 to 6 (sometimes even at 3 to 4 years old, but they start with training courses and not regular training or playing). When children grow older, the frequency and the duration of the training and playing time increases. A small number of players will become a professional player in the end, but the number of professional players in the EU is still high.

Some of the exposure scenarios in this report are close to the scenarios used in the report prepared by RIVM (2016). The differences include that children from 3-6 years and professional players have been taken into account in this ECHA report. In addition, different exposure times have been used and e.g. from 6 years we assume that playing can happen 10 months per year (more months compared to the scenarios in the RIVM (2016) report). For goalkeepers, who are more frequently in contact with the ground, there is a separate scenario, as in the RIVM study.

⁵⁹ Martin Beekman, personal communication.

⁶⁰ Tero Auvinen, personal communication.

The following exposure scenarios for children and adults training and playing on the fields are considered in this report:

1. Children from 3 to 6 years.
2. Children from 6 to 11 years
3. Children from 6 to 11 years – goalkeepers.
4. Children from 11 to 18 years, active players, but non-professionals.
5. Adults, professionals.
6. Adults, professional goalkeepers.

In Table 3.3, the parameters used in the exposure scenarios are described. Information in the RIVM (2016) report and information received from the Finnish Football Association (2017) has been used to estimate the duration and frequency of the exposure⁶¹. For bodyweight, the default parameters have been taken from the report prepared by RIVM (2014), representing worst-case default values. It is assumed that goalkeepers starting from 6 years old are using gloves. The exposure scenarios cover both females and males.

It is assumed that these scenarios are worst-case scenarios, but only for a small group of people. We assume that not all players are exercising and playing with such a heavy frequency on synthetic turf fields. Fields with other infill material and natural fields are used as well.

⁶¹ These assumptions will need to be cross checked with the US EPA study (when available) and any information submitted after January 2017.

Table 3.3 Parameters used in exposure scenarios - players

| | 1 – Children from 3 to 6 years (heavy exercise) | 2 – Children from 6 to 11 years (heavy exercise) | 3 – Children from 6-11 goalkeeper (heavy exercise) | 4 – Children from 11 to 18 years (heavy exercise) | 5 – Adults, professionals (heavy exercise) | 6 – Adults, professional goalkeepers (heavy exercise) |
|---|---|--|--|---|--|---|
| Bodyweight (kg) | 15.7 | 24.3 | 24.3 | 44.8 (default for 11-16 years) | 68.8 | 68.8 |
| Duration of the exposure (training/playing) (hours per event) | 1 | 1.5 | 1.5 | 1.5 | 2 x 2 | 2 x 2 |
| Frequency of exposure (frequency per week) | 1 | 4 | 4 | 6 | 5 | 5 |
| Months per year | 6 | 10 | 10 | 10 | 10 | 10 |
| Skin contact area (cm ²) | 1260 (1/4 legs, 1/2 arms and hand) | 1750 (1/4 legs, 1/2 arms and hand) | 1290 (1/4 legs, 1/2 arms) | 2680 (1/4 legs, 1/2 arms and hand) | 3680 (1/4 legs, 1/2 arms and hand) | 2780 (1/4 legs, 1/2 arms) |
| Amount of granules (g) in contact with skin | 1 | 10 | 3.3 | 3.3 | 6 | 10 |
| Inhalation rates (m ³ /hour) | 1.58 | 1.92 | 1.92 | 2.53 | 3.07 | 3.07 |
| PM10 (µg/m ³) | 40 | 40 | 40 | 40 | 40 | 40 |
| Direct ingestion (g/event) | 0.05 | 0.05 | 0.05 | 0.01 | 0.01 | 0.01 |

An exposure scenario to cover where small children are exposed by being with their parents following the training or games of an older brother or sister, is not considered further. This exposure is considered to be very infrequent compared to the exposure of the older children who are playing regularly. This is despite the fact that they are normally very close to the synthetic turf and take the granules in their hands and even might swallow some. The assumption is that this type of exposure is not happening that often. Spectators are also not considered here as their exposure is regarded to be much lower compared to the players.

Workers

In this section, only the workers installing the synthetic turf and workers doing the maintenance are considered. Other workers in the fields such as coaches, referees, and professional players etc. are discussed in the previous section together with other players.

Installation of synthetic fields with rubber infill

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 have between 110 and 120 tonnes of infill on a full size football field (approximately 15 kg/m²). With a shorter high pile, 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 fields (ca. 10 kg/m²).

According to the ESTO (2016), 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 3.1).



Figure 3.1 Mechanised application of infill (photo submitted by ESTO)

Source: ESTO

For smaller areas, small companies typically load one tonne or 1.5 m³ big-bags into a small tractor unit (open driving space), which distributes the infill across on the pitch (see Figure 3.2).

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.



Figure 3.2 Semi-mechanised application of infill

Source: ESTO

ETRMA (2016) has stated that the outdoor and indoor installation procedures are similar.

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. Workers use protective masks to prevent inhalation of dust and protective clothing. 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).

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. If the same workers are installing the new field, it is assumed that, taking into account that installation typically occurs during warm periods (6 months), as a worst-case workers do the infill procedure approximately 120 days 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).

Fields are normally built during the summer months (6 warmer months of the year). The synthetic turf carpet and infill need to be dry to allow the infill to flow into the carpet pile. According to ESTO (2016), the temperature of the synthetic turf field with ELT rubber can reach in excess of 80 °C during very warm and sunny periods and that it would be unusual for work to proceed in such hot conditions.

Maintenance

Different types of maintenance activities occur on the fields.

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 winter service (rubber infill removed with 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.

Other types of maintenance work include workers sometimes 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. Shoveling of the rubber granules from the sacks occurs as well. Nilsson *et al.* (2008) refers to a maintenance guide 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.

One maintenance guidance⁶² 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); and
- Sweeping: as needed (same for indoors).

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

⁶²

<http://www.fieldturf.com/media/W1siZiIsIjIwMTYvMDcvMjAvMTcvMTkvNTYvMzY1L0Jyb2NodXJlX01haW50ZW5hbmNIX0d1aWRlbgIuZXNfRmlbGRUdXJmXzIwMTZFRW1haWwucGRmIl1d/Brochure%20-%20Maintenance%20Guidelines%20-%20FieldTurf%20-%202016%20-%20Email.pdf>

Table 3.4 Parameters used in exposure scenarios - workers

| | Workers doing the installation, infilling (light exercise) | Workers doing the maintenance work/refilling (light exercise) | Workers doing the other type of maintenance work/brushing (light exercise) |
|--|--|---|--|
| Bodyweight (kg) | 77.2 | 77.2 | 77.2 |
| Duration of the exposure (hours per day) | 6 | 6 | 2 |
| Frequency of exposure (days per week) | 3 | 1 | 1 |
| Months per year | 6 | 1 | 10 |
| Skin contact area (cm ²) | 1 500 ½ arms | 1 500 ½ arms | 1 500 ½ arms |
| Inhalation (m ³ /hour) | 1.61 | 1.61 | 1.61 |

In the workers' scenarios, it is assumed that men are mainly doing the job, thus some parameters are different compared to the exposure scenarios for players. Other assumptions are that gloves are used during the work, but not respiratory equipment. For these scenarios, it is assumed that t-shirts are used with long trousers.

3.4 Risk characterisation

A number of substances have been identified for risk characterisation. Substances have been prioritised according to their hazardous properties (classification and labelling) and their existence in the rubber granules and in the exposure studies.

Some of the substances have been recognised to be unique when the rubber granule infilling has been used. The substances that were selected for risk characterisation were:

- polycyclic aromatic hydrocarbons (EU8-PAHs)
- phthalates
- methyl isobutyl ketone
- benzothiazole and benzothiazole-2-thiol (i.e. 2-mercaptobenzothiazole, 2-MBT)
- formaldehyde and benzene

Exposure and risk assessment to four phthalates through all three exposure routes (oral, dermal and inhalation) was considered. From the exposure scenarios, the most concerned ones are shown in Annex VII.

Exposure estimates were compared to the DNELs which have been derived under various RAC opinions. Combined risk characterisation shows that risk characterisation ratios (RCR) are well below 1 in all exposure scenarios.

The same procedure was also performed for benzothiazole-2-thiol (2-MBT), benzothiazole and methyl isobutyl ketone. These three substances are typically contained in rubber granules. The potential exposure estimates and also measured values from air on the synthetic field show low exposure levels for 2-MBT. In addition, the RCRs are well below 1 in all exposure scenarios.

Benzothiazole and MIBK contribute remarkably to the concentration of measured VOC, especially in samples collected from indoor halls. In the case of benzothiazole for which there are no available DNELs, we applied the DNEL of 2-MBT which belongs to the same group of substances, but is much more hazardous and also has different physicochemical properties. However, it was considered that with this assumption risks would be overestimated. However, when exposure estimates were compared to DNELs, the RCRs are well below 1.

Formaldehyde and benzene were assessed qualitatively. Both substances are carcinogens and they exist both in indoor and outdoor air. The measured concentrations found in the literature (2-7 µg/m³) were at the same level as background samples and urban air. For example, the concentration levels of formaldehyde are normally much higher in homes and workplaces than measured on synthetic fields. The WHO Guideline for Indoor Air Quality is 0.1 mg/m³ (30-minute average concentration).

The exposure to PAHs as was evaluated for lifetime cancer risk. Lifetime cancer risk was calculated separately for players, goalkeepers and workers. For players and goalkeepers, the childhood playing time was also taken into account because cancer risk caused by exposure to PAHs belongs to the lifelong excess risks. We assumed in our estimations that the playing happens all the time on the synthetic fields with crumb rubber granules. This will overestimate the exposure.

Benchmark dose (BMD) methodology according to EFSA was used in lifetime cancer risk calculations (EFSA 2008). The BMD10 value is the dose where the change in response is 10% (10% of the test animals get cancer as a result of exposure), and the lower bound of the benchmark dose 95% confidence interval is the BMDL10. The BMDL10 is considered an appropriate reference point for compounds that are both genotoxic and carcinogenic. EFSA (2008) derived BMDL10 values from a 2-year dietary carcinogenicity study in female mice with coal tar mixtures by Culp *et al.* (1998). EFSA (2008) used the lowest BMDL10 value from the different statistical models that still had an acceptable fit which provides for further margin of safety (additional to the use of the BMDL10 over the BMD10). The lowest BMDL10 was 0.49 mg/kg bw/day for the mixture of EFSA

8 PAHs⁶³. EFSA 8 PAHs differs with two PAHs from the EU 8 PAHs. EFSA 8 PAHs has replaced BeP and BbFa with BghiPer and Ind123-cdP. However, we are assuming the toxicological potency of the 8 PAHs doesn't change remarkable with this difference. The BMDL10 was converted to a human BMDL10 by applying an allometric scaling factor of 7 for mice in accordance with ECHA guidance. It was assumed that oral absorption in humans is equal to oral absorption in the mouse. No other assessment factors were applied⁶⁴. Since the BMDL10 is the dose (in µg/kg bw/day) where the change in response is 10%, the percentage (excess risk) can be calculated for 1 µg/kg bw/day. Dermal BMDL10 value was derived from the oral value by taking into account of oral (rat) and dermal (human) absorption fractions. An oral absorption fraction 0.5 was assumed and for dermal absorption a fraction 0.2 was used. The oral absorption fraction is based on bioavailability values (35-99%, 75-87%, 10% and 40%) from rat studies (Ramesh *et al* 2004, as cited by RIVM Report 2016-0184). The used dermal absorption fraction value follows the judgement in the RIVM Report 2016-0184 where the value was selected based on human skin studies and expert judgement.

The oral route affects the lifetime cancer risk most. Exposure through skin or inhalation contributes less than oral exposure. The oral route estimations have a high uncertainty because of the difficulty in estimating the number of granules that children or adults will swallow while they play. In our estimations, we assumed that children may swallow 50 mg granules in one event which is around 50 granules. For adults, we estimated the amount to be 10 mg. These estimations are lower than that was used in the recent report (RIVM, 2016) where it was concluded that the oral route estimations were highly conservative because of the unrealistic ingestion amounts.

The excess lifetime cancer risk for EU-8 PAHs was calculated and was below one in a million (10^{-6}) for players, goalkeepers and workers. Calculations are in Annex VII.

Table 3.5 provides risk characterisation ratios for selected substances and Table 3.6 provides the excess lifetime cancer risk for polycyclic aromatic hydrocarbons.

⁶³ EFSA 8 PAH substances are: benzo[a]pyrene (BaP), benzo[a]anthracene (BaA), chrysen (CHR), benzo[b]fluoranthene (BbFA), benzo[k]fluoranthene (BkFA) and dibenzo[a,h]anthracene (DBAhA), benzo[ghi]perylene (BghiPer) and indeno(123-cd)pyrene (Ind(123-cd)P).

⁶⁴ This is in accordance with the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.8. The study by Culp *et al.* (1998) started exposure when the mice were 5 weeks of age. This corresponds to roughly to 1400 human days or 3.8 years (40 human days = 1 mice day according to Dutta and Sengupta (2016)). This age roughly corresponds to the time that children may start playing regularly on artificial turf and thus the exposure of children is fully considered.

Table 3.5 Risk characterisation ratios of selected substances via oral, dermal and inhalation

| Substance | Max concentration in rubber granules mg/kg | Max measured air concentrations on the fields µg/m ³ | Combined Risk Characterisation Ratios* | | | | |
|----------------|---|--|--|--------------------------|----------------------|----------------|--------------------------|
| | | | Children 6-11 years | Professional goalkeepers | Professional players | Workers (PM10) | Workers (inhalable dust) |
| MIBK | Na | 36 | 2.45E-03 | 2.45E-03 | 2.45E-03 | 4.34E-04 | 4.34E-04 |
| Benzothiazole | 6.3 | 32 | 3.22E-02 | 3.13E-02 | 3.05E-02 | 2.94E-02 | 2.94E-02 |
| 2-MBT | 7.6 | 0.000352 | 3.38E-03 | 2.36E-03 | 1.42E-03 | 3.23E-07 | 3.23E-07 |
| DEHP | 52 | 0.031 | 8.91E-04 | 2.85E-04 | 2.84E-04 | 3.55E-05 | 3.55E-05 |
| DBP | 3.9 | 0.43 | 2.17E-02 | 2.15E-02 | 2.15E-02 | 3.31E-03 | 3.31E-03 |
| BBP | 2.8 | na | 2.38E-06 | 4.00E-07 | 3.96E-07 | 9.56E-09 | 6.59E-07 |
| DIBP | 77 | 0.1 | 3.96E-03 | 6.78E-04 | 6.78E-04 | 3.51E-05 | 3.51E-05 |
| Formaldehyde** | Na | 6 | 6.00E-02 | 6.00E-02 | 6.00E-02 | 1.62E-02 | 1.62E-02 |

* for inhalation measured concentration used instead of calculated values, except for BBP. ** Risk characterisation for formaldehyde was performed only via inhalation. See more information parameters and DNELs used on Annex VII.

Table 3.6 Lifetime excess risk of cancer related to polycyclic aromatic hydrocarbons (EU 8)

| | Max concentration in rubber granules | Excess risk for the exposure scenarios* and combined lifetime excess risk | | | | | | | | |
|----------------|--------------------------------------|---|------------------------------------|----------------|------------------|----------------------|----------|------------|-------------------------------|---------------------------|
| | | Childhood players 3-11 years | Childhood – goalkeepers 3-11 years | Children 11-18 | Players - adults | Goalkeepers - adults | Veterans | Workers | Combined lifetime goalkeepers | Combined lifetime players |
| Oral | 20 | 2.88E-07 | 2.88E-07 | 4.10E-08 | 1.14E-07 | 1.14E-07 | 1.81E-08 | - | | |
| Dermal | 20 | 5.12E-08 | 1.69E-08 | 1.20E-08 | 5.12E-08 | 1.02E-07 | 9.67E-09 | 3.26E-08 | | |
| Inhalation | 20 | 1.31E-08 | 1.31E-08 | 2.00E-8 | 9.80E-08 | 9.80E-08 | 1.74E-08 | 3.98E-08 | | |
| Light activity | | | | | | | | 7.24E-08** | 6.39E-07 | 6.62E-07 |
| High intensity | | | | | | | | | 7.50E-07 | 7.73E-07 |

*High intensity activity for players

**Combined dermal and inhalation

Concerning the metals a qualitative assessment was carried out evaluating only a comparison of measured concentrations in recycled rubber granules to different limit values in addition to reviewing the studies from literature.

In one study, the metal migration has been measured using standard EN 71-3 (applicable to toys), and the migration of metals from recycled rubber granules were below the limit values set in the Toy Safety Directive (Directive 2009/48/EC).

Cadmium concentrations in new rubber granules and rubber granules taken from the field were below the limit values for plastic material and jewellery articles as set in entry 23 to Annex XVII to REACH.

The concentrations of cobalt in the rubber granules were higher than expected. However, some cobalt compounds are not classified, thus it would be useful to have more information on this matter.

The lead concentrations detected in recycled rubber granules were below the limit value as set in entry 63 for jewellery articles and articles supplied to the general public.

In addition, it has been reported that the concentrations of metals in the air have been low, and at the same level as ambient air.

Therefore, although limited information is available on both the compounds of metals present in recycled rubber granules and the migration of metals from recycled rubber granules, the concern appears to be negligible. However, there is some uncertainty in this evaluation raised by the lack of available data.

3.5 Preliminary risk evaluation

It can be concluded that based on the available information, with the concentrations of polycyclic aromatic hydrocarbons (PAHs) found to be typically present in rubber crumb recycled from ELTs used as infill in synthetic sports fields), the concern for excess lifetime cancer risk for players and workers is very low.

According to the ECHA Guidance⁶⁵ concerning dose (concentration) response to human health, the cancer risk decision points used for lifetime exposure of the general population are generally in the range of 10^{-5} to 10^{-6} . There is no formal maximum limit but an excess cancer risk of 10^{-6} was seen as an acceptable level of risk.

The concentrations of phthalates, benzothiazole and methyl isobutyl ketone measured in rubber granules are below the concentrations that would lead to systemic health problems. However, the fraction of volatile organic compounds contains low concentrations of irritating and sensitising compounds like formaldehyde and other aldehydes, methyl isobutyl ketone and other ketones,

⁶⁵ See: https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/e153243a-03f0-44c5-8808-88af66223258

benzothiazole and benzothiazole-2-thiol and xylenes, which might cause irritation to respiratory track and eye and skin irritation. The VOC concentrations are often elevated in indoor halls compared to the levels in outdoor fields. It is important to make sure that the air ventilation in indoor halls is working properly.

Although limited information is available on the migration of metals from recycled rubber granules, the migration appears to be low. In one study, the migration of metals was conducted by using the specific standard for toys and the metal concentrations were below the limit values in the Toy Safety Directive.

The following overall conclusions have been drawn:

- 1) The concern for lifetime cancer risk for players and workers is very low given the concentrations of PAHs typically measured in recycled rubber granules.
- 2) In studies ECHA has evaluated the concentrations of PAHs in recycled rubber granules have normally been well below the limit values set in the REACH restriction relevant for such mixtures. The studies covered approximately 50 samples from new recycled rubber granules and several hundreds of samples taken from more than 100 fields. The samples were from different Member States, e.g. from Finland, Italy, the Netherlands, Portugal and United Kingdom. In addition, ECHA received studies from industry, which investigated PAHs from different fractions of tyres. It is important to note, however, that if the concentration of PAHs would be as high as the generic limit for mixtures supplied to the general public defined in REACH, the level of concern would not be low.
- 3) The concern to players and workers is negligible given the available, although limited, migration data for metals, which are below the limits allowed in the current toys legislation⁶⁶.
- 4) No concerns to players and workers were identified from the concentrations of phthalates, benzothiazole and methyl isobutyl ketone in rubber granules as these are below the concentrations that would lead to health problems.
- 5) It has been reported that volatile organic compounds emitted from rubber granules in indoor halls might cause irritation to the respiratory track, eyes and skin.

In this preliminary evaluation, several uncertainties related to the information on substances in recycled rubber granules and in the assessment are described in Section 6.

⁶⁶ Comparison with limit values for dry powder like or pliable toy material as example.

4 SUMMARY OF EXISTING LEGAL REQUIREMENTS

Regulation (EC) No 1907/2006 (REACH)

Recycled rubber granules are regarded as mixtures. 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 (concentration limit values defined, see Table 3.1 for selected substances).

Waste Framework Directive (2008/98/EC)

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. ECHA received information from some Member States and from some stakeholders about the waste status of recycled tyres (see Annex III).⁶⁷

Workers 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 (see table 8 for the most relevant). In addition, each Member State may have limit values for other substances or higher limit values compared to the EU OELs. Substances in recycled rubber granules are numerous, some of them are released to the air or in the airborne dust. The relevant OELs (or biological limit values) need to be followed.

Waste shipment Regulation (EC) No 1013/2006

⁶⁷ Note the recent Danish Order on fees and subsidies for recovery of tires / Bekendtgørelse om gebyr og tilskud til nyttiggørelse af dæk (See: <https://www.retsinformation.dk/Forms/R0710.aspx?id=184728>), which provides limit values for certain substances as precondition for receiving financial support from the public for the recycling business.

To address the problem of uncontrolled transport of waste, Regulation (EC) No 1013/2006 of 14 June 2006 on shipments of waste lays down procedures for the transboundary shipments (i.e. transport) of waste. This regulation implements the provisions of the "Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal" into EU law, as well as the OECD decision. The regulation includes a ban on the export of hazardous wastes to non-OECD countries ("Basel ban") as well as a ban on the export of waste for disposal.

Different regimes apply to shipments of waste for disposal and for recovery, as well as to hazardous and "green-listed" non-hazardous wastes. The shipment of hazardous waste and of waste destined for disposal is generally subject to notification procedures with the prior written consent of all relevant authorities of dispatch, transit and destination. However, as a rule, the shipment of "green-listed" waste for recovery within the EU and OECD does not require the consent of the authorities.

Despite the regulation, illegal shipments of waste are still a significant problem (some estimates suggest that the overall non-compliance rate with the regulation could be around 25 %). To strengthen the Member States' inspection systems, the regulation was amended in 2014 through Regulation (EU) No 660/2014 of 15 May 2014. Member States are required to apply the new changes in 2016/17.⁶⁸

5 INFORMATION ON ALTERNATIVE INFILL MATERIALS

There are different types of alternatives other than ambient and cryogenic-processed SBR (styrene butadiene rubber) from passenger cars⁶⁹, available on the market to produce infill material. The main ones are:

- cork, coconut fibre or a combination of both;
- thermoplastic elastomers: TPE and TPV;
- ethylene propylene diene monomer (EPDM); and
- Nike grind^{®70}(recycled athletic shoes and Nike manufacturing scrap which are ground up and turned into infill crumb)

In addition, a natural grass field is also an alternative to synthetic turf.

All of these materials, compared to SBR (styrene butadiene rubber) have their specific strengths and weaknesses when used to build infill material suitable for sport surfaces. It is not in the remit of this report to analyse technical strengths and weaknesses for each type of infill in relation to their specific (athletic) uses.

⁶⁸ See: <http://ec.europa.eu/environment/waste/shipments/>

⁶⁹This is a simplification. Truck, tractor (off the road) and airplane tyres are primarily based on Natural Rubber (NR) and passenger tyres on a mix of Styrene Butadiene Rubber (SBR), NR and Butadiene Rubber (BR) in varying ratios, per type of tyre and per producer. Specific formulations are commonly proprietary.

⁷⁰ <http://www.nikegrind.com/>

A few general technical observations are provided in relation to EPDM and TPE/TPV. Regarding EPDM, it is usually reported to be used as a virgin non-recycled material to produce granules for infill material. However, it seems that recycled EPDM material (e.g. old window-seals, motor compartment parts, etc.) may also be used by some producers⁷¹. TPE is produced by using prime raw material and can be recycled after its use as infill (see section 2.3.4.2).

Based on an exchange of information with an expert on Elastomer Technology and Engineering⁷², it is possible to briefly report that in general:

- the type of oils commonly used for EPDM formulations are paraffinic oils, which are practically free of PAHs. EPDM will contain 1-2 wt % ZnO for the vulcanisation process. However, EPDM requires the use of ultra-accelerators (contrary to SBR and natural rubber (NR)). The benefit of EPDM over SBR and NR is that it ages much better (under all conditions of sun, rain, heat and cold) and ozone resistance. A disadvantage of EPDM versus SBR or NR is that it is a somewhat less resistant material against wearing.
- TPE/TPV are blends of polypropylene and EPDM, most commonly not vulcanised: TPE, or vulcanised: TPV (with another system than sulphur, which does not require ZnO). If oils are used in the formulation, these are paraffinic, practically free of PAHs. The overall lifetime of these materials may be expected to be between SBR/NR and pure EPDM (polypropylene being the weak link). A disadvantage versus SBR or NR is that it is a less resistant material against wearing.

Information from studies concerning the substances measured from alternative infill materials is provided in Annex VIII. As a summary, the limited data available shows that concentrations of PAHs in TPE and in EPDM are lower compared to the concentrations measured from recycled rubber granules from tyres, even though in one case higher PAHs were seen in one TPE sample (Menichini E. *et al.* (2011)).

One study showed higher concentrations of some PAHs in virgin natural rubber material, which are not regarded as carcinogenic (Marsili L. *et al.* (2014)). To find PAHs in TPE and EPDM granules, contradicts the information received from the expert (see above). The reasons could be contamination from external sources if the samples are collected from outside fields, or that granules based on EPDM may only contain a limited amount of EPDM rubber⁷³.

⁷¹ Source: Terra Sports Technology (Differences between EPDM based and TPE/TPV based infill systems for artificial turf); http://www.wellesleyma.gov/pages/WellesleyMA_SpragueResources/TPE%20vs%20EPDM%20vs%20SBR%20and%20quality.pdf

⁷² Jacques W.M. Noordermeer, em. Professor of Elastomer Technology and Engineering, University of Twente, the Netherlands.

⁷³ E.g: about 20 to 25 % (weight), according to Terra Sports Technology. Source: Differences between EPDM based and TPE/TPV based infill systems for artificial turf. http://www.wellesleyma.gov/pages/WellesleyMA_SpragueResources/TPE%20vs%20EPDM%20vs%20SBR%20and%20quality.pdf

Concentrations of metals in one study showed lower levels in TPE sample and higher (Al, Ba, Cu, Mo) in the other sample, which had similar levels of some metals (Cd, Co, Cr, Li, Mg, Ni and Pb) compared to recycled rubber.

A lower total content of benzene, toluene and xylene was seen in TPE compared to the samples from SBR. Evaporation of VOCs from EPDM was lower compared to the recycled rubber granules (Norwegian Building Research Institute (2004), as was the case with TPE infill material (NILU, 2006). High aliphatic and alicyclic compounds were measured from TPO infill (Salonen R. *et al.* (2015)).

There are some uncertainties related to alternatives and their composition. There were only a few studies available concerning the composition of EPDM and TPE. Based on expert information, PAHs should not be present in materials made of EPDM and TPE only. However, these were measured from samples containing EPDM and TPE granules. The origin of the PAHs is unknown.

According to the Finnish Football Association (2017)⁷⁴, the prices of the alternative infill materials compared to the recycled rubber granules originated from tyres (EUR 500/tonne, i.e. cost per field EUR 22 500 – EUR 50 000) are the following:

- EPDM-TPO-TPE-granules approximately EUR 2 000/tonne, i.e. per field EUR 90 000 – EUR 200 000
- Granulated cork approximately EUR 1 500/tonne, i.e. per field EUR 67 500 – EUR 150 000.

6 UNCERTAINTIES IN THE ASSESSMENT

The main uncertainties identified in the assessment are summarised in this section and are related to:

Imports of rubber material, which may be potentially transformed at the end of its life cycle into infill material

The enactment of restriction entry 50 of Annex XVII to REACH forbids the production or import into the EU of tyres produced with non-complying oils since 1 January 2010. However, in relation to imports, it might be complicated to check whether imported tyres contain oils belonging to the class of substances known as DAE or TDAE⁷⁵ using the ISO 21461:2006 method⁷⁶.

This issue might be especially relevant for imported used pneumatic tyres, which may enter the EU with the status of waste material (e.g. TARIC 4012200090). The use of a complex technique for compliance checks may not be very functional in the case of waste material. The quality of this material is unclear.

⁷⁴ Tero Auvinen, personal communication

⁷⁵ DAE:Distillate Aromatic Extract; TDAE:Treated Distillate Aromatic Extract. Content of PAHs in DAE and TDAE differs significantly.

⁷⁶ The ¹H-NMR bay-proton analysis is a relatively complex and costly technique and furthermore a destructive test.

Overall, the quantity of imports of rubber material into the EU, which is used as infill material, is not known. There is no verified information available on the use and quality of this material and on its life cycle, especially when entering the EU territory, with the status of waste.

ELT management schemes

The ELT management schemes can differ significantly in different Member States and each country may face quite unique situations varying from historical stockpiling to extra quantity of ELT deriving from irregular sales and/or imports, as described in Annex V. ELTs arising from old stockpiles or imports (e.g. used tyres) may have higher PAHs levels.

Composition of recycled rubber granules

The substances selected for detailed analysis were already those identified as the most hazardous. There may be other substances that have not been identified in this evaluation. Also in this evaluation it has not been possible to evaluate the combined health effects. It is difficult to do such analysis.

In addition, it is not possible to say in which form (species) metals are found in the recycled rubber granules and thus it is possible that some compounds of the metals that might be classified as CMR, Cat 1A or 1B are present.

Impact of uncertainties to risk assessment

The uncertainty assessment suggests that the hazards and risks from the four phthalates may be underestimated. Some studies indicate that reproductive toxicity may not be the most sensitive endpoint and that the selected DNELs may not be sufficiently protective.

Moreover, the Member State Committee (MSC) has confirmed that these four phthalates are endocrine disruptors related to human health and the REACH Committee recently voted to agree they were substances of equivalent concern under Article 57(f) of REACH. This raises additional uncertainties with the risk of these substances. Specifically, this uncertainty pertains to risk assessment of all phthalates, not only those related to rubber granules.

Exposure scenarios are based on worst-case scenarios. Oral ingestion of rubber granules was estimated to be 50 milligrams per event (event being a match or a training session) for children between 6 and 11 years. This is still considered to be an overestimation as it seems very unlikely that a child would swallow as is the dermal absorption factor of 100 % which is used.

Concerning workers exposure, the scenarios were generic stemming from a lack of more detailed information, especially in relation to maintenance work.

Concerning metals, there is some uncertainty in this evaluation raised by the lack of available data. The limited information on migration of metals showed that migration is lower than the limit values set for toys.

Ongoing studies

There are ongoing studies concerning the possible risks of recycled rubber granules to human health. The US Environmental Protection Agency together with

other relevant agencies launched a Federal Research Action Plan on recycled tire crumb used on playing fields and playgrounds in 2016. A status report was published in December 2016 and the results of the research are expected to be published in 2017.

In addition, California's Office of Environmental Health Hazard Assessment has several scientific studies ongoing in partnership with the US EPA and other federal agencies.

The EU industry in a joint initiative from tyre manufacturers, End of Life Tyre (ELT) management companies, tyre recyclers and synthetic turf manufacturers and field installers is launching an extensive and independent study throughout the EU: "Rubber derived from End of Life Tyres: Assessment of the health risks associated with the use of tyre granulates in sport surfaces"

A scientific advisory board will accompany and supervise the study. This is a two years project which will start in Q1/2017.

7 CONCLUSIONS

ECHA has found no reason to advise people against playing sports on synthetic turf containing recycled rubber granules as infill material. This advice is based on ECHA's evaluation that there is a very low level of concern from exposure to substances found in the granules. This is based on the current evidence available. However, due to the uncertainties, ECHA makes several recommendations to ensure that any remaining concerns are eliminated.

ECHA has evaluated the risks to human health from substances found in recycled rubber granules that are used as an infill material in synthetic turf (e.g. used on football fields). This preliminary evaluation was carried out at the request of the Commission⁷⁷. No evaluation was made of any risks to the environment as this was not part of our remit.

In the EU, granules produced from end-of-life tyres (ELT) are the most common form of infill used in synthetic turf. According to industry estimates, ELT sourced rubber granules are used on European sports fields in quantities of about 80 000 to 130 000 tonnes per year. It is estimated that by 2020 there will be 21 000 full size pitches and about 72 000 minipitches in the EU.

According to ESTO and ETRMA most ELT rubber granules used as infill material are sourced from EU-produced tyres. Industry has also stated that the quantity of tyres and recycled rubber granules imported into the EU from third countries is relatively small. New tyres and used tyres are imported into the EU. These imported tyres might be used for the production of granules in the EU. In addition, there is some evidence that rubber granules are also imported into the EU. ECHA has not been able to verify all the information above.

ECHA has identified a number of hazardous substances in recycled rubber granules based on literature and from the results of several recent field measurement studies. Substances that are commonly present in recycled rubber

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https://echa.europa.eu/documents/10162/13641/echa_rest_proposals_rubber_granules_en.pdf/1a8a254c-bd4a-47b1-a091-99ae4a94a8c2

granules are polycyclic aromatic hydrocarbons (PAHs), metals, phthalates, volatile organic compounds (VOCs) and semi-volatile organic compounds (SVOCs).

ECHA has investigated the risks to the general population, such as children playing football on synthetic sports fields (including goalkeepers) and adults playing professional sports, and workers installing or maintaining the fields. ECHA has considered exposure to rubber granules by skin contact, ingestion and inhalation of substances evaporating from the granules, as well as dust formed by the granules themselves.

ECHA concludes that given the available concentrations of substances found in granules there is at most a very low level of concern:

- 1) With the concentrations of PAHs typically measured from recycled rubber granules (around 20 mg/kg), the concern for lifetime cancer risk for players and workers is very low⁷⁸.
- 2) The available migration data for metals are below the limits allowed in the current toys legislation⁷⁹. The concern to players and workers is negligible based on this limited information.
- 3) The concentration in rubber granules of phthalates, benzothiazole and methyl isobutyl ketone is below the concentrations that would lead to health problems. No concerns to players and workers were identified.
- 4) It has been reported that volatile organic compounds emitted from rubber granules in indoor halls might cause irritation to eyes and skin.

These conclusions are consistent with the results of several other recent studies, such as the investigations of the Netherlands and of the State of Washington in the US.

Recycled rubber granules are mixtures under REACH unless they are considered as waste in a Member State; different rules would then apply as waste is out of the scope of REACH. REACH already regulates mixtures (such as recycled rubber granules) made available to the general public in Annex XVII entries 28-30 when they contain carcinogenic, mutagenic or reproductively toxic (CMR) substances.

The list of restricted substances includes many that have been found in recycled rubber granules, such as a number of PAHs. The restriction applies to these PAHs (i.e. the mixture cannot be made available or sold to the general public) when their concentration in the mixture is above their set concentrations limits; either 0.1% or 0.01% depending on the specific PAH.

PAHs occurring in recycled rubber used in articles, however, have a concentration limit of 0.0001% (entry 50 of Annex XVII to REACH). In addition, certain oils used in EU tyres from 2010 have had a limitation on PAHs. This means that tyres placed on the EU market after that date will have low amounts of PAHs in them. In the studies ECHA has evaluated, the concentrations of polycyclic aromatic

⁷⁸ In this evaluation, very low is considered to be a lifetime risk of getting cancer due to the exposure of PAHs being less than one in a million (10^{-6}).

⁷⁹ Some of the concentrations of metals in recycled rubber granules are higher than the migration limits but the migration tests done show migration lower than the limits. Not all the content will migrate out of the granules and be available to players and workers. Toys legislation does not have limit values for all metals, but provides such for many hazardous ones.

hydrocarbons in recycled rubber granules have been well below the limit values set in entry 28 in Annex XVII to REACH. The studies covered approximately 50 samples from new recycled rubber granules and several hundreds of samples taken from more than 100 fields. The samples were from different Member States, e.g. from Finland, Italy, the Netherlands, Portugal and the United Kingdom. In addition, ECHA received studies from industry, which investigated PAHs from different fractions of tyres. It should be noted, however, if the concentration of PAHs would be as high as allowed under restriction entry 28, the level of concern would not be low.

ECHA identified the following uncertainties:

- The conclusions are based on available studies from nearly 10 Member States covering more than 100 fields (infill material already in use) and around 50 samples from new recycled rubber granules. While ECHA was unable to find any particular bias in them, it is uncertain to what extent they are representative for recycled rubber granules used in football and other sports fields in the EU.
- Some imported tyres entering the EU or other rubber material with unknown composition can be converted at the end of their life cycle into rubber granules with different concentrations of substances. Indeed rubber granules themselves may be imported, and the composition of such granules is not known.
- There are still some knowledge gaps as regards to substances and their concentrations in the recycled rubber granules typically used as infill material in sport fields.
- The combined effects of all the substances in rubber granules are not known and very difficult to estimate. However, this uncertainty is not considered to affect the main conclusions of this evaluation.
- Some of the input values used in the risk assessment are assumptions. In this evaluation, the assumed values were conservative (for example such as how many granules children would swallow when playing). This approach reduced the uncertainty of this evaluation.

Finally it should be noted that some studies on rubber granules used in artificial turf are still ongoing. For example, the US EPA is expected to produce its report on Recycled Tire Crumb Used on Playing Fields towards the end of 2017. In addition, other studies on the effects of rubber granules on health and the environment are currently being carried out and when this new information is available the conclusions in this report will need to be reviewed to see if anything in our assessment should be changed. This review could be carried out at the same time as any further work we are requested to do by the Commission, such as implement the recommendations.

Recommendations

To take into account the uncertainties already mentioned, ECHA recommends the following legislative and non-legislative measures:

1. Consider changes to the REACH Regulation to ensure that rubber granules are only supplied with very low concentrations of PAHs and other relevant hazardous substances. This is supported because:

- In the studies ECHA has evaluated, the concentrations of PAHs in recycled rubber granules have been well below (normally under 20 mg/kg) the limit values set in entry 28 in Annex XVII to REACH. However, if the concentrations of restricted PAHs (EU-8) were as high as the general limits established in restriction entry 28, the level of concern would not be very low. It would be important to ensure that the concentrations of PAHs remain low in the future in the EU.
2. Owners and operators of existing indoor fields with rubber granule infills should ensure adequate ventilation.
 3. Owners and operators of existing (outdoor and indoor) fields should measure the concentrations of PAHs and other substances in the rubber granules used in their fields and make this information available to interested parties in an understandable manner.
 4. Producers of rubber granules and their interest organisations should develop guidance to help all manufacturers and importers of (recycled) rubber infill test their material.
 5. European sports and football associations and clubs should work with the relevant producers to ensure that information related to the safety of rubber granules in synthetic turfs is communicated in a manner understandable to the players and the general public.

In addition, ECHA recommends that players using the synthetic pitches should take basic hygiene measures after playing on artificial turf containing recycled rubber granules. For example, they should always wash hands after playing on the field and before eating and quickly clean any cuts or scrapes, take off shoes/cleats, sports equipment and soiled uniforms outside to prevent tracking crumb rubber into the house, and any players who accidentally get rubber granule in their mouths should not swallow it.

Moreover, some Member States regard recycled rubber granules as waste thus being outside the scope of REACH (see Annex III). It would be useful to clarify the waste or non-waste status of rubber granules in different Member States.

8 STAKEHOLDER CONSULTATION

During the preparation of the report, stakeholders were consulted, especially the European Tyre and Rubber Manufacturers Association (ETRMA) (including member companies), the European Synthetic Turf Organisation (ESTO) and the European Tyre Recycling Association (ETRA). ECHA received information from several Member State competent authorities. Some information was received from certain national football associations.

ECHA has been in contact with US authorities (US EPA and other relevant authorities) investigating the risks of rubber granules.

ECHA launched a call for comments and evidence on 9 November 2016, which ended on 9 January 2017. Six comments were submitted during the call.

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ANNEX I – COMPOSITION OF RECYCLED RUBBER GRANULES

ANNEX II – SCREENING OF SUBSTANCES – CMRS CATEGORIES 1A OR 1B

ANNEX III - RECYCLED TYRES (OR OTHER RECYCLED RUBBER PRODUCTS) USED AS INFILL MATERIAL – WASTE STATUS IN SOME EU MEMBER STATES, INCLUDING INFORMATION FROM STAKEHOLDERS

ANNEX IV - SELECTED SUBSTANCES AND SOME METALS – LIMIT VALUES

ANNEX V – OVERVIEW OF TYRE MARKET IN THE EU

ANNEX VI - EXPOSURE ASSESMENT STUDIES - LITERATURE REVIEW

ANNEX VII – RISK CHARACTERISATION AND EXCESS LIFETIME CANCER RISK ESTIMATIONS

ANNEX VIII – INFORMATION FROM ALTERNATIVE INFILL MATERIALS

ANNEX IX – CONFIDENTIAL INFORMATION

This annex is for the provision of confidential information, where it is considered necessary to include it.