ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

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

IUPAC NAME(S): -

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

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

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[1] Benzo[a]pyrene (BaP), Benzo[e]pyrene (BeP), Benzo[a]anthracene (BaA), Chrysene (CHR), Benzo[b]fluoranthene (BbFA), Benzo[j]fluoranthene (BjFA),Benzo[k]fluoranthene (BkFA), Dibenzo[a,h]anthracene (DBAhA): further referred to as REACH-8 PAHs

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Preface

The basis for this restriction proposal by the Netherlands is a concern for human health resulting from current concentration limits for polycyclic aromatic hydrocarbons (PAHs) in End-of-Life Tyre (further referred to as ELT) derived rubber infill granules used in synthetic turf pitches. The legal interpretation by the European Commission and supported by a majority of EU Member Sates (European Commission, 2016) is that these rubber granules and ELT mulches (also referred to as 'rubber crumbs' and flakes respectively) are mixtures in the scope of REACH. Concentration limits for mixtures supplied to the general public are currently set at either 100 or 1 000 mg/kg for each of the eight individual PAHs of concern (REACH Annex XVII, entry 28).

In recent evaluations, RIVM (2017) and ECHA (2017) concluded that the mixture concentration limits are too high to guarantee safe supply and use of these granules on synthetic turf pitches even though PAH levels found in granules on synthetic turf pitches currently in use are assessed to result in a relatively low excess cancer risk in highly exposed individuals (professional football players). ECHA (2017) recommended lowering the limit value for granules through a restriction under REACH as this would address the concern identified above and would impose concentration limits that are closer to the much lower limit values for individual PAHs in articles supplied to the general public (1 mg/kg) and in toys (0.5 mg/kg) laid down in REACH Annex XVII, entry 50.5 and 50.6.

To address these concerns and ensure acceptable risk levels for use of infill granules and mulches, the Netherlands in cooperation with ECHA, has prepared this Annex XV dossier and restriction proposal in the framework of REACH Regulation article 69, paragraph 4. The Dossier Submitter took into consideration various exposure scenarios related to the use of granules on synthetic turf pitches, such as for installation and maintenance workers and individuals playing sports. Furthermore, the Dossier also accounts for the use of rubber granules or mulches in loose applications on playgrounds and in sport applications where especially children may be exposed. During the Annex XV Dossier development the possibility of other chemical risks (both to human health and the environment) related to the use of rubber infill granules was acknowledged but not further considered in this Dossier. On request of the European Commission, ECHA is currently gathering information on the possible risks associated with other chemicals in ELT granules with the aim to evaluate the need for additional risk management measures.

The restriction proposal consists of a summary of the proposal (5 pages), a report setting out the main evidence justifying the proposed restriction (65 pages) and a number of Annexes containing detailed information, analysis and references underpinning the report (341 pages).

The Dossier Submitter would like to thank the many stakeholders that contributed to the call for evidence and in subsequent discussions during the development of this report.

This report is non confidential. Some confidential information is included in a confidential Annex available to the Scientific Committees.

Summary

The conclusion of the Dossier Submitter's assessment is that due to the currently allowed levels of eight carcinogenic Polycyclic Aromatic Hydrocarbons (REACH-8 PAHs), control of the human health risks following use of rubber granules as infill material in synthetic turf pitches and use of granules or mulches in loose form on playgrounds and sport applications is not guaranteed. Human health risks are assessed for football players (including goalkeepers), playing children and for workers involved in installation and maintenance of pitches and playgrounds. Exposure estimates are combined in a range of lifelong exposure scenarios. The current limit values for the eight carcinogenic PAHs in mixtures supplied to the general public are not protective as the excess cancer risk following lifelong exposure of the general public to the granules and mulches containing REACH-8 PAHs up to the currently allowed limit value is 5.9×10^{-5} (professional goalkeeper scenario). The lifetime exposure is based on the worst case assumptions; i) individuals play at playgrounds from the age of 1 to 13 years and ii) play sports from 4 to 50 years of age. The exposure assessment was drawn up in a way that the lifetime exposure estimate covers the majority of the target population. It is noted that the exposure scenarios and contributing scenarios together will describe a target population that is a relatively small part of the EU population. In the baseline scenario, assuming exposure at the level of the 99th percentile of the PAH distribution the excess lifetime cancer risk for the professional goalkeeper is $3.2.10^{-6}$.

Granules used as infill material are considered mixtures in the scope of the REACH Regulation and therefore, PAH content limits are up to a factor of 100 to 1 000 higher than those applicable to articles covered by REACH Annex XVII entry 50. To indentify the most appropriate measure to address these risks, an analysis of risk management options (RMOs) was conducted, including other restriction options under REACH, other existing EU legislation and other possible Union-wide RMOs (See section 2.2). Two restriction options were taken forward in the impact assessment:

- Restriction option 1 (RO1) covering the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 17 mg/kg (0.0017 %) of the sum of REACH-8 PAHs. The specific limit value reflects the 95th percentile of the REACH-8 PAH sum concentration in measurements taken from synthetic turf pitches.
- Restriction option 2 (RO2) covering the placing on the market of granules and mulches as infill material for synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 6.5 mg/kg (0.00065 %) of the sum of REACH-8 PAHs. The specific limit value reflects the REACH-8 PAHs sum concentration below which the lifetime excess cancer risk of all individuals exposed is below $1x10^{-6}$.

On the basis of an analysis of the effectiveness, proportionality, practicality and monitorability of the RMOs, and the impact assessment performed for RO1 and RO2 the following restriction is proposed:

Proposed Restriction: RO1

Brief title: Restriction on PAHs in synthetic turf infill granules/mulches and loose uses on playgrounds and in sport applications

Polycyclic-aromatic hydrocarbons (PAH) (a) Benzo[a]pyrene (BaP) CAS No 50-32-8 (b) Benzo[e]pyrene (BeP) CAS No 192-97-2 (c) Benzo[a]anthracene (BaA) CAS No 56-55-3 (d) Chrysen (CHR) CAS No 218-01-9 (e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2 (f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3 (g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9 (h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3	1. Granules or mulches shall not be placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications if these materials contain more than 17 mg/kg (0.0017 % by weight of this component) of the sum of the listed PAHs. 2. The restriction shall apply 12 months after its entry into force

The proposal restricts the placing on the market and use of granules or mulches containing >17 mg/kg (0.0017 % by weight) of eight carcinogenic polycyclic aromatic hydrocarbons (REACH-8 PAHs) as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications.

In recent years, questions have been raised in the Netherlands and other EU countries about the potential human health risks of hazardous substances in rubber granules on synthetic turf pitches. This is due to the fact that the rubber granules applied originate predominantly from ELT and other rubber articles, the production of which may have included hazardous substances, such as PAHs (as contaminants) in the rubber matrix. The existing REACH restriction entry 50 on PAHs covers the use of extender oils for the manufacture of tyres (including PAHs in tyres placed on the market) and the placing on the market for the general public of articles that come into direct contact with the skin or the oral cavity. Granules and mulches are mixtures under REACH and hence are not covered by the existing entry 50. The eight PAHs in the scope of Annex XVII entry 50 (REACH-8 PAHs) have a harmonized classification in Annex VI of the CLP Regulation as Carc. Cat. 1B. Based on this classification REACH Annex XVII entry 28 limits supply of granules and mulches (mixtures) to the general public containing PAHs at individual concentrations equal to or above 0,01 % by weight (100 mg/kg) for BaP and DBAhA or 0,1 % by weight (1 000 mg/kg) for the other six PAHs. An allowable sum limit value for REACH-8 PAHs in mixtures is not prescribed in the entry but it follows applying the additivity calculation rules in the CLP guidance taking into account differences in potency per PAH and the ratio between the

PAHs found in the material. Maximum concentrations of individual PAHs allowed in articles and toys placed on the market to which the general public may be exposed[2] are 0.0001 % by weight (1 mg/kg) and 0.00005 % (0.5 mg/kg) respectively. The risk assessment shows that the excess cancer risk following lifetime exposure to the granules and mulches containing PAHs up to the current limit value in Annex XVII entry 28 for mixtures is 5.9 x 10^{-5} (professional football player scenario). At a level of 17 mg/kg (0.0017 % by weight) calculated as the sum of REACH-8 PAHs, the human health risks are at the level of $2.6.10^{-6}$. This is consistent with earlier findings by ECHA (2017) and RIVM (2017). The risks for children aged 1-13 playing on playgrounds and (mini-)pitches containing infill or loose granules or mulches have been included as contributing scenarios in the lifelong overall exposure assessment. Hence, due to the high permitted levels of PAHs in mixtures, control of the human health risks following use of rubber granules as infill material on synthetic turf pitches and granules and mulches in loose form on playgrounds and in sport applications is not guaranteed. Therefore, it is proposed to restrict the concentration of PAHs in these granules and mulches. In the scope of the risk assessment the Dossier Submitter uses an acceptable risk level of one additional cancer case per million exposed individuals during lifelong exposure.

Risks to individuals playing and performing sports activities (e.g. football) on artificial turf pitches with rubber granules (rubber crumb) made of recycled tyres, are the primary concern addressed by this restriction proposal. For the ease of analysis the Dossier Submitter focussed on football as the predominant use of synthetic turf pitches requiring performance infill granules in the EU. Information on other sports was analysed but not accounted for in detail in the risk- and impact assessment. In 2018 the Dossier Submitter estimated 19 000 full size synthetic turf football pitches and 63 000 mini-pitches are in use in the EU. It is expected that new pitches are continued to be installed resulting in 34 000 pitches and 109 000 mini-pitches in 2028. The Dossier Submitter considers that in principle all individuals in the EU may come into contact with ELT granules and mulches. Sub-populations of individuals in the EU that are most likely to come into contact with ELT granules are workers for installation and maintenance, professional athletes, amateur athletes and children playing at playgrounds.

The dossier focusses only on the risks related to exposure to PAHs as these substances are the main concern due to their carcinogenic properties and their presence in tyres and granules and mulches made from ELT. Furthermore, the presence of these carcinogenic PAHs are restricted for articles supplied to the general public that come into direct contact with the skin and the oral cavity, whilst for mixtures the permissible level is a factor of 100 to 1 000 higher. Possible human health- and environmental risks related to other chemicals (such as zinc and cobalt) present in the granules and mulches are outside the scope of this dossier. It is acknowledged that information gathered in the Annex XV proposal development may form an incentive for further exploring the need for regulatory measures

[2] REACH Annex XVII, entry 50, paragraph 5 and 6 applies to articles that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reason- ably foreseeable conditions of use.

beyond the current proposal to restrict the PAHs content. Moreover, in August 2017 the European Commission requested ECHA to investigate if other substances than PAHs may cause risk to human health or to the environment that may warrant a development of a restriction proposal.

Summary of the justifications

Identified hazard and risk

ELT derived granules and mulches contain carcinogenic PAHs as a consequence of the tyre manufacture process. These materials are considered mixtures in the scope of REACH and its supply to the general public is restricted above CLP-based specific concentration limits in Annex XVII entry 28 for REACH-8 PAHs that are however too high to ensure risks for athletes, playing children and workers due to use as infill material in synthetic turf pitches and as loose material are controlled. The Dossier Submitter concludes the risk of these uses are unacceptable and therefore proposes to set a lower sum concentration limit for REACH-8 PAHs that is also closer to the lower concentration limits applicable to articles and toys made from rubber and plastic material in REACH Annex XVII, entry 50.5 and 50.6.

Justification that action is required on a Union-wide basis

The risk associated with use of ELT-derived granules or mulches as infill material on synthetic turf pitches or in loose form on playgrounds needs to be addressed on a Union-wide basis because the Dossier Submitter identified an unacceptable risk as a consequence of an EU-wide use of granules as infill in synthetic turf pitches. Synthetic turf pitches requiring performance infill materials have been developed and the number of pitches in use in recent years has been growing across the EU. The Dossier Submitter also obtained information on an EU-wide market of granules and mulches used in loose form in playgrounds and a range of sport applications. To address the identified unacceptable risks arising from these uses, only an EU-wide measure is considered an appropriate risk management option.

Effectiveness in reducing the identified risks

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

Proportionality to the risk

The societal costs of proposed restriction are estimated to be limited and bearable for the actors at stake. With the proposed restiction (very) high PAH concentrations and consequent risk levels are avoided for the population that comes into contact with granules or mulches in sport and play applications and the residual cancer risk from PAH exposure will be at an acceptable level. Furthermore, social concern related to human health effects will be reduced as high PAH concentrations are avoided. Considering this, the Dossier Submitter concludes that the proposed restriction is proportional.

Practicality

The proposed restriction is practical because it is implementable, manageable and enforceable:

Implementability and manageability

The restriction targets the placing on the market (including import) of the granules and mulches as well as their use as infill in synthetic turf pitches and in loose form on playgrounds and sport applications. Although the concern for human health was primarily triggered by use of ELT-derived rubber granules, the restriction targets all granules and mulches that are used in the same way. Thus, the restriction ascertains that with respect to risks as a consequence of PAH contaminations for all materials risk are controlled. A sum concentration limit for REACH-8 PAHs in mixtures placed on the market and used for the applications in the scope of the restriction can be readily implemented and managed by stakeholders involved. PAHs controls are already common practice for ELT derived granules formulators.

Enforceability

The sum concentration limit for REACH-8 PAHs in principle is clear and unambiguous and therefore the proposed restriction is expected to be enforceable by national enforcement bodies across the EU. Furthermore, the restriction is defined for the group of REACH-8 PAHs that currently have a EU harmonized classification as carcinogen, and as such provides a clear legal basis for companies and enforcement authorities consistent with the existing restriction on PAHs in entry 50 of REACH Annex XVII. The Dossier Submitter notes that some factors may negatively impact EU-wide enforceability of the proposed measure however limited information is on the extent to which these factors may be of influence currently and how these will develop in the future. Such factors are: 1) the possible differences between Member Sates in the interpretation of the product or waste status of ELT derived granules or mulches marketed for uses in the scope of the restriction 2) a proper common understanding across stakeholders in the EU of the terminology used (e.g. performance infill, mulches, loose form, sport applications etc.) and 3) current absence of EU harmonised methodology for PAH extraction and analyses from rubber and other matrices. These issues are discussed in section 2.5 and Annex E.1 (including appendix E1) and Annex E.9.2.

Monitorability

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

Report

1. The problem identified

1.1. Introduction

The Dossier Submitter identifies an unacceptable risk to human health as a consequence of the use of PAH-containing granules and mulches as infill material in synthetic turf pitches and in loose form in other sport applications. Such granules and mulches are regarded as mixtures in the scope of REACH and the limit values for PAHs applicable for supply to the general public do not ascertain risks are controlled. The concern was raised based on the finding that granules and mulches derived from ELT can contain high concentrations of PAHs but also other types of granules used for the same purpose may contain PAHs. Therefore the Dossier Submitter proposes to restrict the PAHs concentrations in all granules and mulches used as performance infill material in synthetic turf pitches and in loose applications in playground and sport facilities other then synthetic turf pitches.

The use of ELT-derived rubber granules as performance infill in synthetic turf pitches has greatly increased in the last 10-15 years due to several factors including the EU landfilling prohibition for scrap tyres, EU recycling goals and technical limitations of other waste handling options such as incineration in regular municipal solid waste incinerators. Therefore, waste rubber is increasingly used for making granules of varying grain sizes which are used for various purposes such as the manufacture of recycled rubber articles or infill material to be used in synthetic turf pitches. The use of granules as performance infill in long pile synthetic turf pitches (3rd generation) started in the mid-1990s when synthetic turf pitches were developed to better suit the needs of football (See Annex A.2.3). Since then, the use of ELT-derived granules as infill in synthetic turf has increased steadily. The total annual EU tonnage of ELT-derived infill material is estimated by the Dossier Submitter at 390 000 tonnes in 2018 (new installations, maintenance and re-surfacing of old pitches). In addition, other alternative substances are also used to formulate granules e.g. TPE, EPDM, cork and other organic materials, and their use is also increasing.

The use of ELT-derived granules on synthetic turf pitches has recently gained public attention in some EU countries (e.g. the Netherlands and France) because of concerns raised due to the presence of hazardous chemicals and the possible human health and environmental risks associated with the use of these pitches. One of the concerns on the use of ELT granules focuses on the PAHs that are found in the material matrix. Carcinogenic PAHs are known to be constituents of extender oils and carbon black used in the manufacture of rubber tyres and as such they end up in the rubber matrix possibly posing a risk to human health. The societal concerns triggered research on the safety of this application of ELT-derived granules. PAHs are genotoxic carcinogens for which in principle no safe level of exposure can be derived. However, a policy-based, acceptable risk level is often applied, for example for enforcement purposes. Based on current policy-based acceptable risk levels (also referred in ECHA guidance R8 as indicative tolerable risk levels), the Dossier Submitter considers that an excess lifetime cancer risk of one in a million (1 x 10^{-6}, i.e. one additional case of cancer per one million lifelong exposed individuals) is an acceptable risk to be borne by the general population in exchange for the benefits of using

the recycled infill material. The Dossier Submitter considers that the acceptable risk level for workers involved in the process of installation and maintenance of pitches is higher; this consideration is based on the REACH Guidance on information requirements and chemical safety assessment; Chapter R.8: Characterisation of dose (concentration)-response for human health which states that an excess lifetime cancer risk of 1×10^{-5} could be seen as an indicative tolerable risk level when setting DMELs for workers for a working life of 40 years (ECHA 2012).

Publications are available from ECHA (2017) and by the Dutch National Institute for Public Health and the Environment RIVM (2017) on the risks associated with playing football on synthetic turf pitches on which ELT-derived granules are used as infill. Both ECHA and RIVM concluded that the presence of carcinogenic PAHs in granules at the concentration *currently allowed* in these mixtures poses an unacceptable risk for athletes playing on synthetic turf pitches. According to ECHA, excess cancer risk levels for athletes exposed to PAH concentrations *actually found* in granules on EU pitches were assessed to be mostly of low level of concern but some players could surpass the acceptable risk level of 1×10^{-6} under specific exposure conditions. Based on a realistic worst case risk assessment concluded the risk to be virtually negligible (between 2×10^{-6} and 3×10^{-6}).

It was recommended by ECHA to initiate a restriction to lower the *currently allowed* concentration limit for PAHs in these granules to ascertain safe future use of synthetic turf pitches. Furthermore, it was noted by RIVM (2017) that there is a lacking scientific basis for the large difference between the concentration limit for PAHs in mixtures supplied to the general public being some orders of magnitude higher than those applicable for articles, toys and childcare articles through REACH Annex XVII entry 50 paragraphs 5 and 6. RIVM (2017) recommended adjusting the concentration limit for rubber granules to one that is closer to the concentration limit applicable to consumer articles regulated by entry 50 of REACH Annex XVII. It was considered that '*better supported and more stringent limits for rubber granulate may contribute over time towards reducing current concerns on health risks due to playing sports on synthetic turf*' (RIVM, 2017). Based on the conclusions and recommendations in the RIVM and ECHA reports, the Netherlands decided to prepare a restriction proposal that would limit the PAH concentration limit value in granules used on synthetic turf pitches.

During the development of this Annex XV dossier, the Dossier Submitter was aware that additional research into PAHs and other chemicals, including possible environmental risks has been on-going (e.g. research program by ETRMA, research by US-EPA and other US institutions). In the Netherlands, RIVM recently published a study on the long-term environmental risks of the use of ELT-derived granules in synthetic turf pitches (RIVM, 2018). In addition, at the request of the European Commission, ECHA is investigating the potential human health or environmental risks of other chemicals in ELT-derived granules.

1.2. Scope of the proposed restriction

1.2.1. Substance and risk coverage

The scope of this Annex XV dossier underpinning the restriction proposal is limited to the eight PAHs[3] (REACH-8) that are in the scope of REACH Annex XVII entry 50 and that have a EU-harmonised classification in Annex VI of the CLP Regulation as a carcinogen (Carc. Cat. 1B). The group of polycyclic aromatic hydrocarbons is much larger and it is expected that more PAHs will in the future be classified as carcinogenic compounds. The classification of two other PAHs as carcinogens was concluded by the Risk Assessment Committee (RAC)[4] during writing of this Annex XV report. These two PAHs are however not included in the scope of this proposal. The justification to confine the Annex XV dossier and restriction proposal to the REACH-8 PAHs is as follows:

- Targeting only the REACH-8 PAHs that currently have an EU-harmonised classification as a carcinogen provides a clear legal basis for companies and enforcement authorities that is also consistent with entry 50 of REACH Annex XVII;

- PAHs are generally present in aromatic extender oils and carbon black in the form of mixtures (combination of a range of PAHs), and hence these combinations of PAHs may also be found in rubber materials in which these products are used to perform a function. Limiting the permissible content of the REACH-8 PAHs will in practice limit the use of all PAHs as these are contained in aromatic oils or carbon black as complex mixtures. Hence, the REACH-8 PAHs are used as marker PAHs limiting the content of a larger group of potentially carcinogenic PAHs that may be contained in recycled rubber granules. Consequently, from a risk management perspective, adding other carcinogenic PAHs to the marker group has no added value;

- Extending the marker group of REACH-8 PAHs will increase the administrative burden for companies and enforcement agencies as they will have to extend their PAHs analyses window. Additional costs may be relatively limited though;

- Information on carcinogenicity of the REACH-8 PAHs is expected to be sufficient to underpin the need for a restriction and can be prepared in a relatively short period of time. Data on other effects of the REACH-8 PAHs and of other hazardous substances in recycled rubber is expected to be more limited and would require further research to assess the potential need for risk management options and would take more time.

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[3] Benzo[a]pyrene (BaP) CAS No 50-32-8, Benzo[e]pyrene (BeP) CAS No 192-97-2, Benzo[a]anthracene (BaA) CAS No 56-55-3, Chrysene (CHR) CAS No 218-01-9, Benzo[b]fluoranthene (BbFA) CAS No 205-99-2, Benzo[j]fluoranthene (BjFA) CAS No 205-82-3, Benzo[k]fluoranthene (BkFA) CAS No 207-08-9, Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3

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

It is acknowledged that due to the lack of information and knowledge about possible carcinogenic properties of all PAHs that are contained in PAHs mixtures (such as in aromatic oils or carbon black), targeting the focus of the risk assessment on the REACH-8 PAHs may possibly underestimate risks.

Carcinogenicity is taken forward as primary human health concern of the REACH-8 PAHs for this Annex XV dossier as this is generally known to be the most critical long term human health effect associated with PAHs exposure. Cancer was also used as the endpoint of concern in RIVM (2017) and ECHA (2017a) for their respective risk assessments of the use of rubber granules on synthetic turf pitches. It is acknowledged that some PAHs may be associated with other human health hazards such as mutagenicity, skin sensitisation and reproduction toxicity effects. However, the scientific knowledge on these other hazardous properties for humans is limited to only a few of the substances such as BaP and chrysene. Therefore, other possible human health hazards and possible risks of PAHs are not further discussed in this dossier (see annex B).

There is evidence that other hazardous chemicals may also be present in recycled rubber granules, such as other PAHs, phthalates and bisphenol-A, and metals such as cobalt, lead and zinc (ECHA 2017a, RIVM 2017, see table E2-1 in Appendix E2). Possible additional human health risks and/or environmental risks due to the presence of such other hazardous chemicals are not included in the scope of the Annex XV dossier. This is due to the fact that exposure to carcinogenic PAHs has been the primary concern that formed the basis for the reports that triggered the preparation of this dossier. Possible risks due to other hazardous chemicals contained in granules are acknowledged as a possible concern but research on these issues is still in a preliminary phase. On request of the European Commission, ECHA is currently gathering information on possible risks of other chemicals in ELT with the aim to evaluate the need for further additional risk management measures.

1.2.2. Use

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

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

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

In our exposure assessment we covered all relevant processes involving possible human exposure to the granules and mulches, which are installation and maintenance by workers and all sports and leisure activities by the general public on synthetic turf pitches, on playgrounds and on other sports facilities in which loose granules or mulches are applied. Uses of granules or mulches in non-sporting facilities such as landscaping uses in

recreational areas and parks, use for gardening and residential uses are considered outside of the scope of the restriction proposal.

Football is by far the largest sport that is taking place on synthetic turf in the European Union. Therefore, the exposure and risk scenarios are focussed on football players and in particular on goalkeepers. Other sports such as rugby, Gaelic sports, baseball, lacrosse and American football also use long-pile synthetic turf pitches. These sports are included in the assessment through analogy with the football exposure scenarios. Field hockey takes place on short pile synthetic turf not requiring infill other than sand or water and hence is not covered by the dossier.

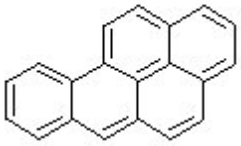
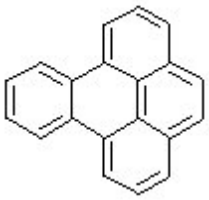
1.3. Hazard, exposure/emissions and risk

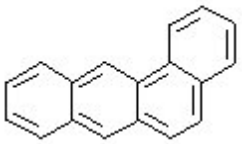
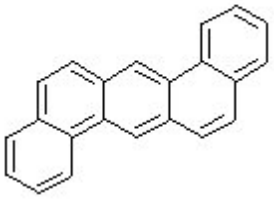
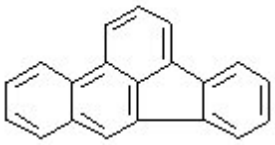
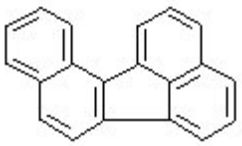
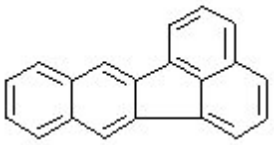
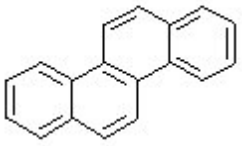
1.3.1. Identity of the substance(s), and physical and chemical properties

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

The textbox below includes some information on the composition of the REACH-8 PAHs. The concentration data of PAHs in ELT granules are provided by industry, authorities, other stakeholders and obtained from public literature sampled (from a granules production site or a synthetic turf pitch) in the EU in the year 2010 or later (values below limit of detection (LOD) are set to LOD). See Appendix B1 for further details on these concentration data.

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

Chemical Name: **Benzo[a]pyrene** EC Number: 200-028-5 CAS Number: 50-32-8 IUPAC Name: Benzo[d,e,f]chrysene Concentration range (P01-P99): 0.20 – 3.1 mg/kg	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Benzo[e]pyrene** EC Number: 205-892-7 CAS Number: 192-97-2 IUPAC Name: 1,2-Benzopyrene Concentration range (P01-P99): 0.44 – 5.8 mg/kg	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Benzo[a]anthracene** EC Number: 200-280-6 CAS Number: 56-55-3	Molecular weight: 228.3 g/mol Molecular formula: $C_{18}H_{12}$ Structural formula:

IUPAC Name: 1,2-Benzanthracene Concentration range (P01-P99): 0.20 – 3.9 mg/kg	
Chemical Name: **Dibenzo[a,h]anthracene** EC Number: 200-181-8 CAS Number: 53-70-3 IUPAC Name: 1,2:5,6-Dibenzanthracene Concentration range (P01-P99): 0.10 – 1.0 mg/kg	Molecular weight: 278.3 g/mol Molecular formula: $C_{22}H_{14}$ Structural formula: 
Chemical Name: **Benzo[b]fluoranthene** EC Number: 205-911-9 CAS Number: 205-99-2 IUPAC Name: 2,3-Benzfluoranthene Concentration range (P01-P99): 0.20 – 4.0 mg/kg	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Benzo[j]fluoranthene** EC Number: 205-910-3 CAS Number: 205-82-3 IUPAC Name: 10,11-Benzofluoranthene Concentration range (P01-P99): 0.20 -1.7 mg/kg	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Benzo[k]fluoranthene** EC Number: 205-916-6 CAS Number: 207-08-9 IUPAC Name: 11,12-Benzofluoranthene Concentration range (P01-P99): 0.15 – 1.9 mg/kg	Molecular weight: 252.3 g/mol Molecular formula: $C_{20}H_{12}$ Structural formula: 
Chemical Name: **Chrysene** EC Number: 205-923-4 CAS Number: 218-01-9 IUPAC Name: 1,2-Benzophenanthrene Concentration range (P01-P99): 0.20 – 4.4 mg/kg	Molecular weight: 228.3 g/mol Molecular formula: $C_{18}H_{12}$ Structural formula: 

The table below presents the physicochemical properties of the eight PAHs under current evaluation.

Table 1: Physicochemical properties of the REACH-8 PAHs

Property	Substance	Value	Reference
Physical state	Benzo[a]pyrene	yellowish	WHO (1998)
	Benzo[e]pyrene	pale yellow	WHO (1998)
	Benzo[a]anthracene	colourless	WHO (1998)
	Dibenzo[a,h]anthracene	colourless	WHO (1998)
	Benzo[b]fluoranthene	colourless	WHO (1998)
	Benzo[j]fluoranthene	yellow	WHO (1998)
	Benzo[k]fluoranthene	pale yellow	WHO (1998)
	Chrysene	colourless	WHO (1998)
Melting point	Benzo[a]pyrene	178.1 °C	WHO (1998)
	Benzo[e]pyrene	178.7 °C	WHO (1998)
	Benzo[a]anthracene	160.7 °C	WHO (1998)
	Dibenzo[a,h]anthracene	266.6 °C	WHO (1998)
	Benzo[b]fluoranthene	168.3 °C	WHO (1998)
	Benzo[j]fluoranthene	165.4 °C	WHO (1998)
	Benzo[k]fluoranthene	215.7 °C	WHO (1998)
	Chrysene	253.8 °C	WHO (1998)
Boiling point	Benzo[a]pyrene	496 °C	WHO (1998)
	Benzo[e]pyrene	493 °C	WHO (1998)
	Benzo[a]anthracene	400 °C	WHO (1998)
	Dibenzo[a,h]anthracene	524 °C	WHO (1998)
	Benzo[b]fluoranthene	481 °C	WHO (1998)
	Benzo[j]fluoranthene	480 °C	WHO (1998)
	Benzo[k]fluoranthene	480 °C	WHO (1998)
	Chrysene	448 °C	WHO (1998)
Relative density	Benzo[a]pyrene	1.351	WHO (1998)
	Benzo[e]pyrene	Not available	
	Benzo[a]anthracene	1.226	WHO (1998)
	Dibenzo[a,h]anthracene	1.282	WHO (1998)
	Benzo[b]fluoranthene	Not available	
	Benzo[j]fluoranthene	Not available	
	Benzo[k]fluoranthene	Not available	
	Chrysene	1.274	WHO (1998)
Vapour pressure	Benzo[a]pyrene	7.3×10^{-7} Pa at 25 °C	WHO (1998)
	Benzo[e]pyrene	7.4×10^{-7} Pa at 25 °C	WHO (1998)
	Benzo[a]anthracene	2.8×10^{-5} Pa at 25 °C	WHO (1998)
	Dibenzo[a,h]anthracene	1.3×10^{-8} Pa at 20 °C	WHO (1998)
	Benzo[b]fluoranthene	6.7×10^{-5} Pa at 20 °C	WHO (1998)
	Benzo[j]fluoranthene	2.0×10^{-6} Pa at 25 °C	WHO (1998)
	Benzo[k]fluoranthene	1.3×10^{-8} Pa at 20 °C	WHO (1998)
	Chrysene	8.4×10^{-5} Pa at 20 °C	WHO (1998)
Partition coefficient n-octanol/water (log value)	Benzo[a]pyrene	6.50	WHO (1998)
	Benzo[e]pyrene	6.44	WHO (1998)
	Benzo[a]anthracene	5.61	WHO (1998)
	Dibenzo[a,h]anthracene	6.50	WHO (1998)
	Benzo[b]fluoranthene	6.12	WHO (1998)
	Benzo[j]fluoranthene	6.12	WHO (1998)
	Benzo[k]fluoranthene	6.84	WHO (1998)
	Chrysene	5.91	WHO (1998)
Water solubility	Benzo[a]pyrene	0.0038 mg/L at 25 °C	WHO (1998)
	Benzo[e]pyrene	0.0051 mg/L at 23 °C	WHO (1998)
	Benzo[a]anthracene	0.014 mg/L at 25 °C	WHO (1998)
	Dibenzo[a,h]anthracene	0.0005 mg/L at 27 °C	WHO (1998)
	Benzo[b]fluoranthene	0.0012 mg/L at 20 °C	WHO (1998)
	Benzo[j]fluoranthene	0.0025 mg/L at 25 °C	WHO (1998)
	Benzo[k]fluoranthene	0.00076 mg/L at 25 °C	WHO (1998)
	Chrysene	0.0020 mg/L at 25 °C	WHO (1998)

1.3.2. Justification for grouping

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

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

In addition to the REACH-8 PAHs addressed in this dossier, clearly many more of the PAHs possibly contained in rubber granules may be genotoxic carcinogens (while others may not) and the reason for them not being included as carcinogen in Annex VI to the CLP regulation may simply be that they have up to now not been evaluated. In section 1.2.1 a justification is given for using the REACH-8 PAHs as a marker for all carcinogenic PAHs.

1.3.3. Classification and labelling

The table below presents the harmonised classification according to Annex VI of CLP Regulation EC 1272/2008 and the self-classification as notified by industry included in ECHA's C&L inventory. The self-classifications written in *italics* in this table are additional when compared to the harmonised classifications according to EC Regulation 1272/2008.

Table 2: Harmonised classification according to Annex VI of CLP Regulation EC 1272/2008 and the self-classification as notified by industry in ECHAs C&L inventory of REACH-8 PAHs.

Name	**CAS**	**CLH according 1272/2008 (including possible SCLs and M-factors)**	**Self-classification by notifiers**
Benzo[a]pyrene	50-32-8	Skin Sens. 1 (H317) Muta. 1B (H340) Carc. 1B (H350) (SCL: C ≥ 0.01 %) Repro. 1B (H360FD) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Skin Sens. 1 (H317) Muta. 1B (H340) Carc. 1B (H350) Repro. 1B (H360FD) *Repro. 2 (H360)** Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) *Aquatic Chronic 4 (H413)*
Benzo[e]pyrene	192-97-2	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[a]anthracene	56-55-3	Carc. 1B (H350) Aquatic Acute 1 (H400) (M=100) Aquatic Chronic 1 (H410)	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Dibenzo[a,h]anthracene	53-70-3	Carc. 1B (H350) (SCL: C ≥ 0.01 %) Aquatic Acute 1 (H400) (M=100) Aquatic Chronic 1 (H410)	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[b]fluoranthene	205-99-2	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[j]fluoranthene	205-82-3	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Benzo[k]fluoranthene	207-08-9	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Chrysene	218-01-9	Muta. 2 (H341) Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Muta. 2 (H341) *Carc. 1A (H350)* Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

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

1.3.4. Hazard assessment

1.3.4.1. Mutagenicity/carcinogenicity

Given the targeting of this dossier, only mutagenicity and carcinogenicity will be addressed (see section 1.3.2. for the individual classification of the substances included).

Animal data

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

Human data

No data are available on the carcinogenic effects of single PAHs in humans. In contrast, most of the human studies have addressed the carcinogenicity of PAH mixtures with BaP as marker compound. A considerable number of epidemiological studies have demonstrated that occupational exposure to soot, coal tar, and other PAH-containing mixtures is carcinogenic to humans. However, interpretation and comparison of these data is partly hampered due to differences in study design (case control versus cohort); differences in exposure measurements; not taking into account lifestyle factors; unawareness of co-exposure; and, incomplete data presentation. Nevertheless, despite these confounding factors, the majority of the epidemiological data associated airborne PAH exposures with increased lung cancer risk.

In addition, exposed workers, particularly at coke ovens and aluminium smelters, have shown excess bladder cancer for which a relationship to PAH exposure was highly suggestive. From the most robust meta-analysis by Armstrong (2003, 2004) which included 39 different cohorts for lung cancer and 27 cohort for bladder cancer, unit relative risk[5]

[5] The unit relative risk describes the ratio of the probability of events occurring (in this case developing lung or bladder cancer) after being exposed to the probability of events occurring when not being exposed (background occurrence) within the respective populations exposed vs. non-exposed.

(URRs) values of 1.20 (95 % CI, 1.11-1.29, p<0.001; log-linear model) for lung cancer and 1.33 (95 % CI: 1.16-1.52, no significant heterogeneity) for bladder cancer could be derived at inhalation exposure of 100 µg BaP /m^3-year. By using the Armstrong et al. (2003, 2004) inhalation exposure data, it is implicitly assumed that the dermal exposure will be as in the occupational settings that were covered by Armstrong et al. (2003, 2004). Although this assumption inevitably introduces some uncertainties, systemic exposure via the dermal route is taken to be reflected in these URRs. Locally, skin cancer has been reported to be positively associated with dermal PAH exposure, but not with inhalation exposure.

1.3.4.2. Derivation of DNELs/DMELs

Oral

The mouse oral carcinogenicity study of Culp et al. (1998) (see Annex B.5.8.1.2 for a detailed summary of this study) was selected as key study, taking the benchmark dose lower confidence limit where 10 % increase in effect occurs ($BMDL_{10}$) for the REACH 8 PAHs of 0.49 mg/kg bw/day (as derived by EFSA (2008), see Annex B.5.8.1.2) as point of departure.

Linear extrapolation was subsequently used to express the estimated exposure in terms of excess lifetime cancer risk[6]. This was done in accordance with the REACH Guidance (ECHA 2012). The $BMDL_{10}$ was converted into a 'human' $BMDL_{10}$ (by adjusting for allometric scaling and applying a factor of 7 for mouse-to-human extrapolation). To determine the dosage at which the excess lifetime cancer risk is one in a million (i.e. 10^{-6}) the 'human' $BMDL_{10}$ was divided by a high-to-low dosage factor (i.e. dividing 10 % = 0.1 by 100 000 to obtain 10^{-6}). The excess cancer risk from REACH 8 PAH at 1 in 10^6 corresponds to (0.49/ 7)/ 100 000 = 0.0007 µg/kg bw/day. In other words, the excess cancer risk per 1 µg/kg bw/d is 1.43×10^{-3}. This dose-response relationship will be used for the risk characterisation when calculating the excess lifetime cancer risk from oral PAH-exposure via contact with or ingestion of rubber granules for the general population assuming 70 years of exposure (see Annex B.10).

Dermal

For the purpose of assessing dermal (systemic) exposure to PAHs, the oral $BMDL_{10}$ value for REACH-8 PAHs was converted to a dermal $BMDL_{10}$ value using route-to-route extrapolations. The route-to-route extrapolation was done by using absorption fractions for the oral route of 0.3 and for the dermal route of 0.2 (see Annex B.5.1.1 for details), resulting in a dermal $BMDL_{10}$ of 0.74 mg/kg bw/d. Following the same extrapolation as described for the oral route, the excess lifetime cancer risk is estimated at 9.46×10^{-4} per 1

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

µg/kg bw/d for the dermal route. This dose-response relationship has been used for the risk characterisation for calculating the excess cancer risk from dermal PAH-exposure via contact with rubber granules for the general population (as described in Annex B.10). For the workers (i.e. involved in installation and maintenance of the pitches), an adjustment factor of 0.38 to account for differences in exposure calculated in days, weeks and years (*i.e.* 5/7 × 48/52 × 40/70) is applied to correct for difference in exposure conditions between workers and the general population.

Inhalation

For the inhalation route, the meta-analysis of Armstrong et al. (2003, 2004) is considered to provide a robust, appropriate and reliable basis for assessment of the inhalation exposure, and is therefore selected as key study (see Annex B.5.8.4). It is noted that dose-response relations for lung (and bladder) cancer for workers exposed to PAHs were recently developed by ECHA (2017c), using the URR from this meta-analysis in combination with a more recent value for reference lifetime risk based on the latest data of incidence of lung and bladder cancer from the year 2012 being available for most of the EU28 countries. In short, relative risk predictions for lung cancer at given cumulative exposure values can be made using the formulae:

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

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

$ELCR = P_{ref} \times (RR_x - 1)$

where P_{ref} is the cancer risk in the reference group (background risk in the unexposed target population), *i.e.* 0.07 for lung cancer (ECHA, 2017c).

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

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

1.3.5. Exposure assessment

The exposure assessment of PAHs contained in ELT granules is based on the use of these rubber granules or mulches on artificial turf. The formulation of rubber granules (recycling of scrap tyres into ELT-derived granules) is outside of the scope of the exposure assessment.

The use is subdivided into four exposure scenarios (ES):

- ES1: Installation of synthetic turf pitches with ELT infill – worker
- ES2: Maintenance of synthetic turf pitches with ELT infill – worker
- ES3: Playing sports on synthetic turf pitches with ELT infill – worker[7]
- ES4: Playing at playgrounds and playing sports on synthetic turf pitches with rubber infill – consumer

Information on exposure to PAHs from rubber granules during installation and maintenance of pitches as well as for sports and playing activities on artificial turf with rubber granules is rather limited. As a result, the exposure assessments for workers exposure in this report relied predominantly on two studies dealing with installation of artificial turf by IndusTox (2009) and Ecopneus (2016). With respect to exposure during playing at playgrounds the assessment as performed by RIVM (2016) is the basis for the exposure assessment and for playing sports the assessments done by ECHA (2017a) and RIVM (2017) are the primary sources for this dossier.

In the sections below a brief description of each ES is provided. Please note that the exposure assessments were performed for a theoretical case where the concentration of the mixture of REACH-8 PAHs is a high as the concentration limit currently applicable to the PAHs according to Annex VI of the CLP Regulation, and for the 95th percentile of the PAH content in samples of ELT granules taken by RIVM (for more details, the reader is referred to Annex B, chapter B9).

ES1: Installation of synthetic turf pitches with rubber infill – worker

The way of installing rubber granules on synthetic turf pitches can vary depending on the size and pile height of the turf and where the pitches are installed (location indoor and outdoor, country, and contractor). According to ETRMA (2016), the installation of a new pitch takes a total of 30-35 working days. The duration of the infill procedure is 6 hours per day and lasts 2-3 days per week. It is assumed that, taking into account that installation typically occurs during warm periods, workers do the infill procedure approximately 6 months per year. The exposure during installation and maintenance are most likely related to dust formations and via direct dermal contact when emptying the big-bags containing granules and the manual distribution of the granules over the synthetic turf pitches. In the worker exposure assessment, personal protective equipment is not considered.

ES2: Maintenance of synthetic turf pitches with rubber infill – worker

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

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

Large maintenance is done once per year and normally involves large scale infilling of material. Large maintenance resembles the installation process of infilling, where similar machines are used. Small maintenance includes the brushing or raking the infill granules after the games. Brushing can be done with dedicated machines designed for this purpose, but manual brushing also occurs when a smaller area needs to be fixed.

Since no information is available on exposure to PAHs from ELT granules during maintenance, the exposure assessment for maintenance was based on data on installation and corrected for differences in durations and frequency. Therefore, below ES1 and ES2 are described together with respect to input parameters and calculations as to how the exposure estimate was derived.

ES1 and ES2 Installation and maintenance – workers - Input parameters

The Ecopneus (2016) study provided data for both the inhalation and dermal route of exposure that could be used in the exposure assessment of the workers. The Ecopneus study included in total around eight workers (exact number unclear based on the information provided, but this number can be lower for specific measurements) that were monitored during installation of synthetic turf pitches with rubber granules. The monitoring study included respirable dust, BaP in the breathing zone of the workers, and BaP concentrations on pads to assess dermal exposure.

Dermal

In the Ecopneus study the dermal load on the skin is estimated by summing up the BaP concentration on the four pads on shoulder, wrist, calf and chest. The maximum sum of four measured values was 0.19 ng BaP/cm^2. Based on the available information, it is difficult to assess whether the method used by Ecopneus (2016) is adequate to measure the exposure to the skin. For example, exposure via dermal contact with the hands was not assessed (but was approximated by the wrist pad), whereas one would expect for workers to have dermal contact mainly through their hands and lower arms. As gloves are not typically worn the exposure to the hands may be highest. Also, the pads only allow a relatively small area for contact and thus may not catch a representative portion of the exposure.

For the reasons above, the approach taken for current evaluation is to use the highest measured dermal concentration of the cumulative dermal load (0.19 ng BaP/cm^2) and to extrapolate this to a total amount of REACH-8 PAHs and rubber granules in contact with the skin over six hours of work, i.e. 3.6 grams (see below Table 3; for details see Annex B, chapter B.9). This amount is corrected based on duration for small maintenance activities.

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

Inhalation

Ecopneus (2016) measured BaP in the breathing zone of the worker during installation. Based on their data a 90th percentile of 23.24 ng BaP/m^3 could be calculated. These measurements seem to represent the exposure to PAH from rubber infill installation most reliably even though the sample size is rather limited and only BaP was measured as a

marker for PAH. The measurement data can be used directly in the equation to derive the cumulative exposure over 40 years of working life. To derive the year average inhalation exposure, the amount of BaP/m^3 (i.e. 23.24 ng BaP/m^3) is multiplied by the frequency, duration per day and by the number of months per 12 months.

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

To obtain the inhalation exposure for the worker over a 40 years working life, the year average exposure was multiplied by 40 years which in fact provides an exposure in terms of µg/m^3-years. The remaining parameters for exposure are given in the table below.

Table 3: Input parameters for the worker exposure of installation and maintenance workers

Exposure parameters	Worker - installation	Worker – Large maintenance	Worker – Small maintenance
General			
Duration of exposure (hours/day)	6	6	2
Frequency of exposure (days/week)	3	1	1
Months per year	6	1	10
Body weight (kg)[a]	68.8	68.8	68.8
Dermal			
Dermal load BaP (ng/cm^2)*	0.19	0.19	0.19
Skin contact area (cm^2)[a,*]	5 150	5 150	5 150
Extrapolation factors (for size and duration)*	6	6	2
Fraction BaP in REACH-8 PAH[b,*]	0.15	0.15	0.15
Assumed content in Ecopneus study (mg/kg)[b,*]	11	11	11
Amount rubber granules on skin (g)	3.6	3.6	1.2
Inhalation			
BaP in breathing zone (ng/m^3)	23.24	23.24	23.24

[a] from RIVM 2014; [b] from annex D; * Required parameters to calculate the amount on skin, i.e. 0.19/1 x 10^{-3} x 5 150 x (100/15) x (1/11) x 3 x 2 = 3.6 gram.

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

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

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

The exposure estimates for the dermal and inhalation route for the workers are presented in the table below. It shows that the highest exposure can be expected during installation, followed by small but regular maintenance. Lowest exposures are expected as a result of large maintenance which probably is caused by the low frequency.

Table 4: Exposure estimates for the dermal and inhalation route for workers in ES1 and ES2, based on REACH-8 PAH content of 17 mg/kg; P95).

Worker scenario	**Dermal exposure estimate (µg/kg bw/day)**	**Inhalation exposure estimate (µg/m^3-year BaP)**
Installation	0.00013	0.21
Large maintenance	7.3×10^{-6}	0.012
Small maintenance	2.4×10^{-5}	0.039

ES3: Playing sports on synthetic turf pitches with rubber infill – worker

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

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

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

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

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

The following contributing scenarios (CS) have been created:

1. Child, 2 year old playing on playground
2. Child, 3 to 6 year old playing on playground
3. Child, 6 to 11 year old playing on playground
4. Child, 11 to 13 year old playing on playground
5. Children aged 4 to 11 years playing sports (outfield player)
6. Goalkeepers starting at 7 years of age

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

In the sections below the CS1-4 together (playground scenarios), CS5-9 together (playing sports scenarios) and CS10 (lifelong scenario) will be described. In the exposure assessment drawn up by the Dossier Submitter, the assessment aims at a 95th percentile of the exposed population, which is the typically used percentile for determining the reasonable worst-case consumer exposure. Underlying conservative assumption is that it is assumed that all contact events are with artificial turf containing ELT infill. This assumption is most conservative for those players whose sports club is not using artificial turf with ELT infill.

CS1-4 playground scenarios

In the reasonable worst-case scenario used for the exposure assessment (aiming at a 95th percentile of the exposure, typically used percentile for determining the reasonable worst-case consumer exposure), a child is assumed to visit a playground with ELT-derived granules or mulches containing PAHs for a few hours per day, on a number of days per year, from the age of two up to and including 12. This age range was selected since children in this age range start walking, visit playgrounds, and spend time at daycare centres or elementary school where playground equipped with ELT-derived granules or mulches can be present. During these visits, inhalation, dermal and oral exposure is possible, respectively, from inhaling particles, having dermal contact with granules especially to hands, legs and feet, and by ingestion of the granules or via hand-to-mouth contact. Below the input parameters are provided for the calculations for the exposure to PAHs at playgrounds (see Table 5 and 6). The scenario descriptions were adopted from the RIVM evaluation of PAH exposure from shock absorbing rubber tiles that are used at playgrounds (RIVM 2016), but now including oral exposure and inhalation exposure to rubber dust. With respect to the dermal exposure, most input parameters were adopted from RIVM (2016), but calculations were performed differently as the exposure from tiles was based on a diffusion model assuming a slab like surface, which in the Dossier Submitters view is not applicable to PAH exposure from ELT granules. Therefore, the exposure estimation method was brought in line with the dermal exposure assessment as done for playing sports on artificial turf (CS5-9) based on RIVM 2017.

Table 5: Anthropometric data for scenarios 1 to 4 based on RIVM 2014 and 2016.

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

Table 6: Input parameters for the dermal and oral exposure calculation (taken from RIVM (2016) with slight adjustments).

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

See for the exposure estimates of the contributing scenarios 1-4 the Table 8 and 9.

CS5-9 playing sports scenarios

The playing sports scenarios are based on the popular sport football, which the Dossier Submitter assumes to represent other sports as well, e.g. rugby, Gaelic sports and other. The contributing scenarios CS5-9 are predominantly based on the exposure assessment as described in RIVM (2017), with some minor adjustments for some of the input parameters based on new information. Playing sports can already start at the age of four and can continue as long as people feel capable of playing. Here, it is assumed that 'veterans' play up to the age of 50. The age categories considered in the exposure assessment are 'under six', children aged 11 to 18, adults aged 18 to 35 and veterans. Goalkeepers are introduced to the game from seven-years old and for that reason an 'under eight' category was introduced as well and considered separately from the outfield player in the exposure assessment. In each scenario, exposure to PAHs from granules can occur via three routes: the dermal route via skin contact, the inhalation route via inhaling of rubber dust (airborne particles), and/or the oral route via ingestion or hand-to-mouth contact. Marsilli et al. (2014) looked at possible PAH vapour exposure resulting from rubber granules under laboratory conditions. The granules were heated to 60°C representing hot summer days and analysed the vapours released from the rubber granules for PAHs. In a subsequent worst case exposure and risk assessment, assuming that the PAH released remain directly above the pitch and are available for inhalation, resulted in excess lifetime risk estimates of $1x10^{-6}$ for carcinogenic effects. The worst case approach and conditions that are unlikely to take place the entire year and the low vapour pressures of the PAHs have led to the conclusion of the Dossier Submitter to disregard the possible very low contribution of PAHs in vapour phase to the inhalation exposure.

The main difference between the outfield players and goalkeepers is the higher estimated dermal exposure across all age categories and higher oral exposure during adulthood for the goalkeepers (oral exposure between goalkeeper and outfield player is up until adulthood assumed the same). The main drivers for exposure are the frequency and durations of contact to the amount of rubber granules contacted (dermal exposure), ingested (oral exposure), or inhaled as rubber dust and the migration of PAHs from the rubber granule matrix.

Durations and frequencies were based on training schedules at arbitrarily selected football clubs in the Netherlands. The frequency and duration may differ per club, because the clubs themselves decide how the activities are structured. The age categories including 11-years up to 35 years (contributing scenarios CS7 and CS8) are based on performance-oriented teams with higher frequency and duration than typical recreational teams. According to the Dutch Football Association KNVB they represent a top-amateur level. Frequency over the year (months per year) are set differently for the dermal route since during the winter period, players will train in suitable outfits that fully cover arms and legs. The Dossier Submitter notes that this assumption may not hold for all regions across the EU.

The input parameters for the exposure assessment are given in Table 7. For more detail on the contributing scenarios, see Annex B, chapter B.9.

Table 7: Input parameters for contributing scenarios 5 to 9

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

* See Annex D.

See for the exposure estimates of the contributing scenarios 5-9 the Table 8 and Table 9.

CS10 life-long scenario

The lifelong exposure is determined by multiplying the year average exposure by the number of years that the average annual exposure can take place per contributing scenario, compared to a lifespan of 70 years (the toxicological reference value is based on 70 years exposure). In other words, the 4-year-old scenario for sports lasts for seven years (covering the years up to the age of 10, in what is a worst-case approach as lower body weights are

used to derive the exposure), while the year average exposure for the 4-year-old scenario is multiplied by a factor of 0.1 (=7/70).

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

The lifelong exposure for professional players is obtained by replacing the year average exposure of scenario 8 by scenarios W1 for the outfield player or W2 for the goalkeeper.

The Table 8 and 9 below provide the exposure estimates per route of exposure for each of the scenarios for the consumers and professional players and their combined lifelong exposure. The dominant route of exposure is the oral exposure, followed by the dermal route. The relevance of the exposure in terms of risks is presented in Section 1.3.6.

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

Contributing scenario	**Oral exposure estimate (µg/kg bw/d)**	**Dermal exposure estimate (µg/kg bw/d)**	**Inhalation exposure estimate (µg/m³-year BaP)**
1	0.00011	2.1×10^{-6}	1.8×10^{-6}
2	0.00038	6.2×10^{-6}	5.5×10^{-6}
3	0.00040	1.4×10^{-5}	9.1×10^{-6}
4	0	4.7×10^{-6}	3.6×10^{-6}
5	0*	9.0×10^{-6}	2.2×10^{-6}
7	0.00010	2.6×10^{-5}	8.0×10^{-6}
8	0.00017	7.9×10^{-5}	2.7×10^{-5}
9	5.7×10^{-5}	2.6×10^{-5}	9.1×10^{-6}
W1	0.00020	9.5×10^{-5}	6.6×10^{-5}
Total			
Lifelong prof. player	0.0013	0.00018	1.1×10^{-4}
Lifelong consumer	0.0012	0.00017	6.7×10^{-5}

*Oral exposure covered by playground scenario
W= worker

Table 9: Exposure estimates per route for the playground scenarios and the goalkeeper (based on REACH-8 PAH content of 17 mg/kg; P95).

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

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

1.3.6. Risk characterisation

The REACH 8 PAHs are genotoxic carcinogens. Given the ability to induce genotoxic effects there is no threshold value below which no health risk exist for these PAHs.

Risk characterisation ratios are summarised in Table 10. The risk characterisation showed that at the 95th percentile of the distribution of actual PAH levels measured in rubber granules used in the EU sampled after 2009 (17 mg/kg), the excess lifetime cancer risks for workers are close to the 10^{-5} risk level that is considered acceptable (from a policy point of view) for 40 years of work life exposure (*i.e.* 2.9×10^{-5} for installation of synthetic turf pitches, 1.6×10^{-6} for large maintenance, and 5.4×10^{-6} for small maintenance). The professional players have similar exposures thoughout their lifes compared to the amateur players, where only the exposure differs during their professional career. Therefore, it is considered more appropriate to compare their lifelong exposure to the acceptable risk level for the general population. For professional football players, excess lifetime cancer risks are slightly above the 10^{-6} risk level that is considered acceptable for the general population for lifelong exposure (*i.e.* 2.0×10^{-6} and 2.6×10^{-6} for the outfield player and goalkeeper, respectively). Finally, the excess cancer risk for lifelong exposure of the amateur football player is slightly above the risk level that is considered acceptable for lifelong consumer exposure (*i.e.* 1.9×10^{-6} for the amateur outfield player and 2.5×10^{-6} for the goalkeeper).

This risk characterisation includes a number of assumptions and uncertainties. Most important uncertainties on the hazard side are the fact that PAH 'mixture' composition in toxicological or epidemiological studies that were used for the risk assessment may be different between studies and differ from typical PAH composition in ELT granules. Furthermore, other PAHs not included in the group of REACH-8 PAHs may be gentoxic carcinogens as well which could point towars possible underestimation of risks. Finally, we have applied summation of risk levels from the different exposure routes as a conservative

approach covering for uncertainties that may result from differences in modes of action of tumour formation per route. On the exposure side some crucial assumptions on contacted amounts, frequency, and duration needed to be made, e.g. on the oral ingestion by players that overall aim for a worst-case lifelong exposure estimate. Taken together, the Dossier Submitter considers that these uncertainties on hazard and exposure point to an overestimation of the risks, which is mainly driven by the conservatism in the assumption that people play 100 % of their playing and playing sports time on artificial turf with ELT-derived infill for the majority of their life.

Table 10: Results of the risk assessment for workers, professional players and consumers according to the linear extrapolation; based on current REACH-8 PAH content in ELT-derived granules in the EU (P95; 17 mg/kg for the sum of REACH-8 PAHs)

Workers		**Excess cancer risk**
ES1: Installation		
	Total	2.9×10^{-5}
ES2: Maintenance – large		
	Total	1.6×10^{-6}
ES2: Maintenance - small		
	Total	5.4×10^{-6}
Professional player		**Excess cancer risk**
ES3: Outfield player		
	Total	2.0×10^{-6}
ES3: Goalkeeper		
	Total	2.6×10^{-6}
Consumer		**Excess cancer risk**
ES4: Outfield player		
	Total	1.9×10^{-6}
ES4: Goalkeeper		
	Total	2.5×10^{-6}

Calculations based on the assumption that the PAH content in rubber granules would correspond to current concentration limits for mixtures in Annex XVII of REACH (*i.e.* 387 mg/kg for the sum of REACH-8 PAHs, taking into account the additivity rule in conformity with the CLP-Guidance[8] (ECHA 2017b)) suggested that the excess lifetime cancer risks would not be acceptable, both for the professional and amateur football player (outfield player and goalkeeper). This indicates that the current concentration limit for mixtures does not provide an adequate level of protection against the risk of developing lung or bladder cancer, and this strongly supports the proposal for reducing the PAH concentration limit for rubber granules.

Based on the evaluation of the hazard of PAHs and the assessment of the relevant exposure scenarios for worker and consumer, and taking into account policy-based acceptable risk levels of 10^{-5} for workers and 10^{-6} for the general population, a maximum permissible

[8] Briefly, the additivity rule prescribes that the sum of similar acting substances must not exceed the content limit of one of the substances within that group, taking into account potency differences.

concentration for PAHs in rubber granules of 6.5 mg/kg for the sum of the REACH 8 PAHs was derived. This value reflects the idea that even the most exposed player or worker should not be exposed to PAH concentrations that could result in them exceeding the policy-based acceptable risk levels.

1.4. Justification for an EU wide restriction measure

The Dossier Submitter has analysed the risks for football players using synthetic turf pitches on which ELT-derived granules containing PAHs are used. Furthermore, the risks were assessed for workers involved in installation and maintenance of these pitches, for children playing on playgrounds and for the general public where loose granules or mulches are used in sport facilities other than synthetic turf. The Dossier Submitter concluded that the existing concentration limits for eight polycyclic aromatic hydrocarbons (REACH-8 PAHs) in mixtures do not ascertain that the risks associated with these uses are controlled. In addition, the Dossier Submitter concluded that a scientific basis is lacking for the large difference between the concentration limit for PAHs in mixtures supplied to the general public (Annex XVII, entry 28) and the limit values applicable for articles, toys and childcare articles falling under the scope of REACH Annex XVII entry 50, paragraph 5 and 6. The Dossier Submitter takes account of the recommendations provided by RIVM (2017) and ECHA (2017a) to adjust the concentration limit for rubber granules to one that is closer to the concentration limit applicable to consumer articles regulated by entry 50 of Annex XVII.

A Union-wide restriction is needed to ensure that the concentration of REACH-8 PAHs in granules or mulches used as infill on synthetic turf pitches or in loose form on playgrounds is sufficiently low, ensuring safety for workers, safe sporting activities on synthetic turf pitches and other sporting facilities using loose granules or mulches and safe playing on playgrounds throughout the EU.

EU-wide use of infill material in synthetic turf pitches and loose applications

The use of synthetic turf pitches for football and other sports such as rugby takes place on the global scale. Figure 1 shows the number of pitches per county that in 2017 had been certified in accordance with the FIFA quality programme. From this figure it can be deduced that in 2017 in most European countries between 10 and 100 synthetic turf pitches had been FIFA certified. In the Netherlands and the UK over 300 pitches were certified in 2017. Noting that the number of certified synthetic turf pitches is probably significantly lower than the total number of synthetic turf pitches, these FIFA data show that synthetic turf pitches are used for football on EU-wide scale. Based on information provided by the European Synthetic Turf Organisation (ESTO) in Europe in 2016 around 13 000 synthetic turf pitches were maintained for football and 47 000 smaller so-called mini-pitches (approximately half of these used for football) were in use. The Dossier Submitter estimates between 2018 and 2028 approximately 4 200 new pitches (including resurfacing of existing pitches) and 6 600 mini-pitches are installed per year. The long pile 3rd generation synthetic turf systems developed and used in Europe since the mid-1990s require so-called performance infill granules to meet the FIFA sports technical performance requirements. ELT derived recycled rubber granules are the main source of infill material used on these football pitches and

these granules are used on EU-wide scale, also for other sports such as rugby, baseball, Gaelic sports and lacrosse. Other types of performance infill materials are TPE, EPDM and natural materials such as cork. These alternatives currently have a small share of the EU market but this is expected to grow. ELT derived and other types of granules and mulches (flakes) are also used in loose form on playgrounds and in several sports applications. Such materials are also mixtures in the scope of REACH and such uses are reported in various EU countries based on limited information available.

Because ELT-derived granules and mulches and alternative materials such as EPDM, TPE and cork are marketed and used throughout the EU, legal measures taken by individual Member Sates are not considered effective in addressing the risks of humans exposed to PAHs.

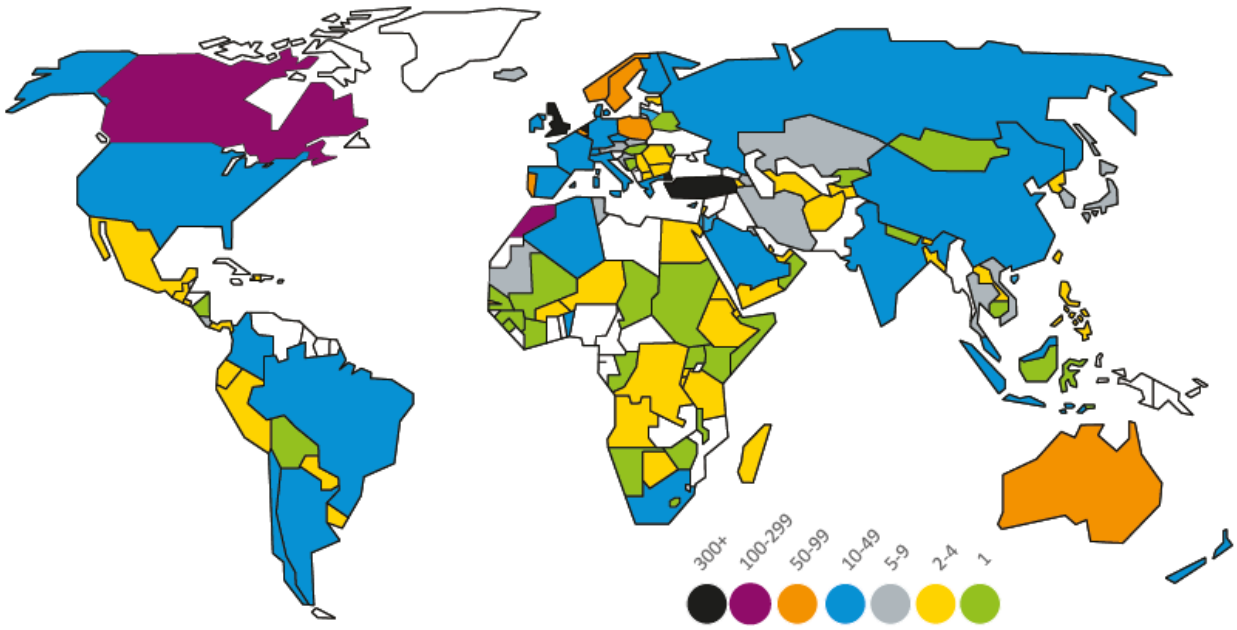


Figure 1: Number of certified synthetic turf pitches per country on a global scale (from: Environmental impact study on artificial football turf (FIFA 2017).

1.5. Baseline

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

The baseline, the "business as usual" scenario, is defined as the current and predicted future use of performance infill granules in synthetic turf pitches without the proposed restriction options. No pending legislative changes of relevance have been identified, except the uncertainty associated with the status of the UK within the European Union (EU28) and

the European Economic Area (EEA31) following their activation of article 50 of the Lisbon Treaty.

The geographical boundaries for the assessment are the territories of Member Sates of EEA31.

The study period – entry into effect (assumed for analytical purposes to be 2019) plus 10 years – is selected on the basis of the life-span of a pitch, the time anticipated for the costs and benefits[9] (in particularly those quantified and monetised) of the proposed restriction options to fully develop. The selection was also influenced by best practices for similar assessments.

To describe the baseline for this restriction proposal the following elements are discussed below:

1. The number of artificial turf pitches and sport/play areas with loose infill/mulch installed across the EU that make use of performance infill and the expected trends in the number of pitches installed over the next decade;
2. The share of various types of infill used on artificial turf pitches, the quantities infill used and the expected trends related to the application of the different types of infill over the next decade;
3. The current PAHs concentration levels in ELT-derived infill material and other infill materials and the expected trends therein;
4. The number of people potentially at risk due to PAH concentrations above the proposed limit value.

For further information describing the tyre life cycle, recycling of tyres, the formulation of granules, installation and maintenance of synthetic turf pitches and sport and leisure activities on the pitches, see Annex A.

1.5.1. Number of artificial sport pitches in Europe

Football is a very popular sport in the EU. In 2012, there were over 13 000 synthetic turf football pitches and over 45 000 mini-pitches in the EU (ESTO Market Report Vision 2020). The number of pitches is expected to reach 21 000 by 2020, and the number of mini-pitches around 70 000. This equals annual growth rates of 6.2 % and 5.6 % for football pitches and mini-pitches, respectively. Based on this information, the Dossier Submitter estimates the number of full size synthetic turf pitches to be around 34 000 in 2028, and

[9] Note that the risk assessment (section 1.3) is performed for lifelong exposure over a 70 year period for consumers (or 40 years for workers). In the impact assessment lifelong risk reduction are estimated for consumers. To quantify the theoretical maximum number of avoided cancer cases, this lifelong risk reduction is converted into annual risk reduction dividing over the 70 years.

the number of mini-pitches around 110 000 [10]. These estimates are based on newly installed pitches only. Assuming an average 10 year service life of synthetic turf pitches, the Dossier Submitter assumes that 10 % of the existing pitches are reinstalled yearly. Hence, the total number of full pitch (re-)installations between 2018 and 2028 will be on average 4 200 and the total number of mini-pitch (re-)installations will be on average around 6 600 annually.

Examples of other types of sports that are using synthetic turf pitches are rugby, American football, lacrosse and Gaelic sports. The number of pitches exclusively dedicated to other sports is considerably smaller. Rugby Europe reported the total number of installed rugby synthetic rugby pitches to be 558 in 2016. The number of pitches on which Gaelic sports are played is even smaller as the sport is largely played on grass pitches. For Lacrosse, the exact number of installed artificial turf pitches in the EU is unknown, yet estimated to be less than that for rugby. As most artificial turf pitches are football pitches and as football is by far the largest sport in the EU, the baseline focusses on football pitches and mini-pitches.

1.5.2. Types and quantities of performance infill used on artificial turf pitches in the Europe

The types of infill used throughout Europe differ by country. Overall, the infill which is manufactured from recycled ELT is by far the most common form of performance infill used in the EU (currently estimated at approximately 90 %). Other materials used are infill material manufactured from ethylene propylene diene rubbers (EPDM) (approximately 4 %), thermoplastic elastomers/thermoplastic rubbers (TPE) (approximately 4 %), poly ethylene (PE), organic material (cork, approximately 2 %). The majority of these alternative infills are expected to be virgin material; however, some of it may be from recycled materials as well. These alternatives vary greatly in terms of price, properties, maintenance and recycling costs, and other key attributes.

Alternative infill materials have been gaining in popularity e.g. in countries where there is societal concern related to the use of ELT granules. The Dossier Submitter assumes that for the newly installed pitches (new installations + re-installations) the market share of ELT infill used will be gradually reduced from 90 % 2018 to 70 % in 2028 in the baseline situation. This estimate is based upon signals received from stakeholders during the workshop held on 24 November 2017 for the preparation of this restriction proposal. Without a restriction, in 2028 70 % of the newly installed pitches would use ELT-derived infill material, 12 % TPE, 12 % EPDM and 6 % cork and other organic materials. This would mean that the share of ELT-derived granules on all synthetic turf pitches in operation in 2028 would be 78 % and 9 % for EPDM, 9 % for TPE and 4 % for cork.

Quantities of infill material used

[10] The Dossier Submitter assumes that 50 % of these pitches make use of performance infill

The amount of infill material used on synthetic turf pitches depends on the height of the pile and the performance required. The parameters applied in this Dossier are given in Table 11. In general, mini-pitches have a lower quantity of performance infill per square meter as most mini-pitches have a shorter pile height. If the system incorporates a shockpad (foam layer underneath the turf) the pile height may be lower and the required quantity of performance infill will be lower (ESTO 2017 as reported in ECHA 2017a). Systems with shockpads, shorter pile length and lower quantities of infill are especially used for non-ELT infill to compensate for the increase in price of the infill material.

Sizes of football pitches vary somewhat from 100-120 meters by 64-75 meters. The assumed standard surface area of a full-size football pitch is 7 600 m^2. Sizes of mini-pitches vary largely in size. The Dossier Submitter assumes that the area of a mini-pitch is 1 400 m^2.

Table 11: Parameters applied for estimation of the amounts per infill type use on full size football pitches and mini-pitches in the baseline scenario

Infill type	**ELT-derived rubber**	**EPDM**	**TPE**	**Cork**
Amount used on full size, 7 600 m^2 pitch (kg/m^2)	15	6	7	1.3
Amount used on a 1 400 m^2 mini-pitch (kg/m^2)	10	4	4.7	0.9
Share of use (% of the total number of long pile synthetic turf pitches) 2018	90 %	4 %	4 %	2 %
Share of use (% of the total number of long pile synthetic turf pitches) 2028	70 %	12 %	12 %	6 %
Tonnage for maintenance (kg per year) full size pitch	1 000	500	500	90
Tonnage for maintenance (kg per year) mini-pitch	100	50	50	5

Sources: ESTO 2017 as reported in ECHA 2017a, ETRMA response to ECHA and workshop 24 November 2017, personal consultation synthetic turf sector.

The total annual use tonnage of ELT-derived infill material is estimated to grow from 350 000 tonnes in 2016, 390 000 tonnes in 2018 to 550 000 tonnes in 2028 in the baseline situation[11].

[11] VACO estimates that the annual volume of infill material used in the European Union (EU) is in the range of 80 000 – 200 000 tonnes, see Annex A. The total production volume of rubber granules in the EU, on the other hand, is significantly higher, namely in the excess of 900 000 tonnes per year (VACO, 2015). The Dossier Submitter made calculations on infill required based on the available information on number of pitches and required amounts of performance infill per type of artificial pitch. The results of these calculations differ from the estimate by VACO. The difference may be caused by a difference in scope of the two sources. The estimate of the Dossier Submitter covers use of performance infill for newly installed pitches, reinstalled pitches and maintenance. It is not clear whether the estimate of VACO also includes reinstallations and maintenance.

1.5.2.1. Formulation and imports

There are about 140 formulators of rubber granules operating in the EU, most of which formulate and supply infill material throughout the EU, although up to 100 000 tonnes are exported outside the EU annually (VACO 2015 as reported in ECHA 2017a). The market is characterised by the presence of a few large players whose annual production output exceeds 50 000 tonnes and a number of smaller ones, whose annual production volumes are below 10 000 tonnes. Import of ELT-derived rubber granules or rubber mulch as end-products from outside of the EU is minimal, if non-existent. However, the import of alternative infill materials – primarily EPDM and TPE granules – into the EU is observed. This seems to be largely fuelled by the noticeable price variations between the EU and other major markets (e.g. China, India, and the ASEAN[12]). It is also noteworthy that there is a sizeable annual import volume of tyres and a variety of rubber materials into the EU, which, at the end of their life-cycle may end up in granules or mulch, and subsequently on European artificial pitches and playgrounds.

1.5.2.2. Information on mulch

In addition to granules, the proposed restriction also includes mulch given that its properties and composition, and hence the ensuing concerns, are comparable with those of recycled rubber granules. Rubber mulch is predominantly produced from recycled tyre buffings or nuggets and has a wide range of uses in the EU. It has been estimated that about 60 % of rubber mulch ends up being used in playgrounds, whereas it also has other applications including landscaping, gardens, golf courses, horse arena footings and athletic arenas. Although most of the rubber mulch produced in the EU is derived from ELT, it can also be formulated from virgin material, namely EPDM. Compared to rubber granules, the volume of rubber mulch formulated in the EU is quite low. No exact figure is currently available. No quantitative estimate on the use of mulch in the EU could be provided in the quantitative estimate of the baseline (and impact assessment). However, the volume is expected to be minimal compared to the use of infill in synthetic turf (football) pitches and mini-pitches.

1.5.3. PAH concentrations in performance infill

The eight polycyclic aromatic hydrocarbons (PAHs) – all carcinogens – that are the main target of this restriction proposal, are present in ELT derived infill material. PAHs commonly are impurities arising from the extender oil and carbon black used in the production of tyres. Following the restriction entry 50 of Annex XVII of REACH, the content of PAHs in extender oil, and therefore in tyres, has been reduced, but not eliminated from 2010 onwards[13]. At the end of the life-cycle, these tyres can be transformed into granules or

[12] Association of Southeast Asian Nations

[13] Tyre industry already started reducing PAHs in extender oil before entry in to force of the restriction in 2010.

mulch, which can then be used as infill material on synthetic turf, as well as on loose granules and mulch used in playgrounds and sport applications.

For this dossier, the data of 1 234 samples were collected for which all REACH-8 carcinogenic PAHs could be determined. Most samples were taken in the Netherlands (1 035), other samples were taken in various European countries: Belgium, Denmark, Germany, Italy, Portugal, Spain, Sweden, and the UK. Overall, the tyre market acts on an EU-wide scale and the extender oil restriction applies in all EU countries. Therefore scrap tyres across the EU are expected to have similar PAH content. Differences in PAH concentrations in manufactured granules may appear e.g. due to differences in scrap tyre selection and analytical method used to test REACH-8 PAH content. The 1 234 samples are deemed to be representative for ELT turfs in the EU. The REACH-8 PAHs concentration in ELT infill samples available varied from 2.9 (1th percentile) to 21 mg/kg (99th percentile) with a 50th percentile of 11 mg/kg. Figure 2 presents a histogram of all available measured REACH-8 PAH concentrations.

In addition to ELT, also non-tyre rubber materials and waste articles may be used for the formulation of granules. This non-tyre waste may have other PAH content due to other composition of the rubber and due to the fact that the EU extender oils restriction does not apply to such materials. Only limited information about PAHs concentrations in rubber granules from other recycled material is available. In the ECHA report (2017) two samples were tested that contained around 3 000 mg/kg of the REACH-8 PAHs. This rubber infill material was reported to originate from Asia and was not used in the reporting Member Sate.[14] It is not known whether or not this infill material is used in other EU Member Sates.

[14] Notably the concentrations of chrysene and benzo(a)pyrene were higher than the limit value set in entry 28 of Annex XVII to REACH, thus not complying with the existing restriction on PAHs for mixtures supplied to the general public.

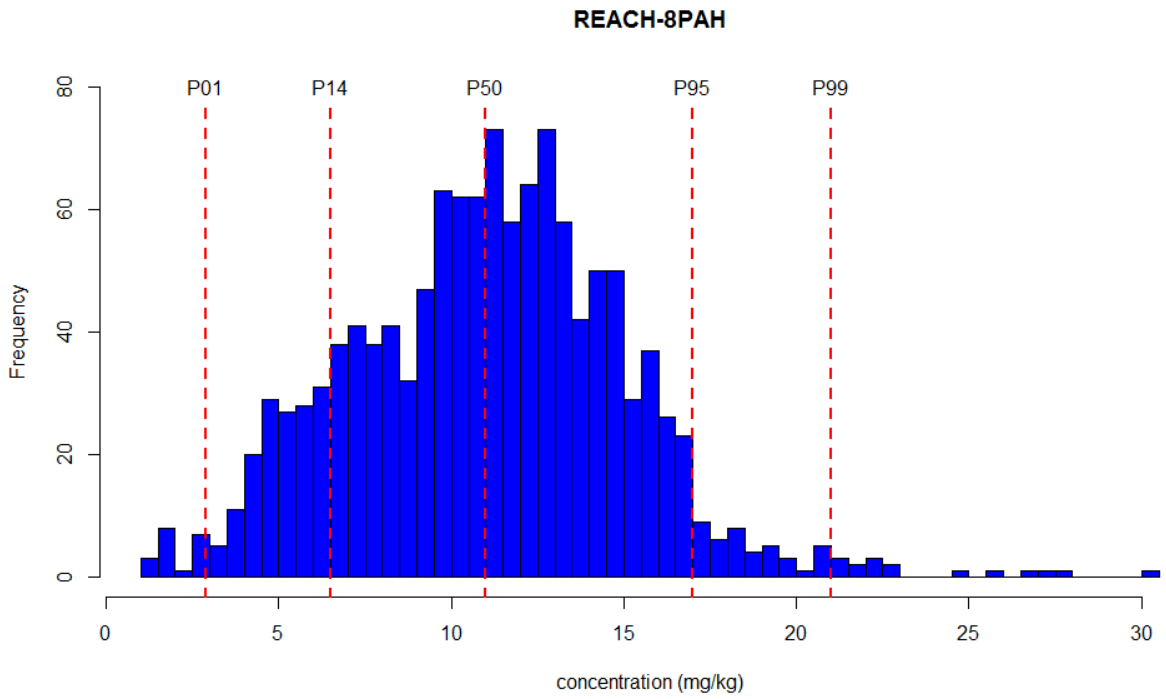


Figure 2: Histogram of all available measured REACH-8 PAH concentrations (n=1 234). Vertical red lines indicate the 1st percentile (2.9 mg/kg), 14th percentile (6.5 mg/kg), 50th percentile (11 mg/kg), 95th percentile (17 mg/kg) and 99th percentile (21 mg/kg). In this figure, concentrations of individual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

Assuming that the available samples are representative for the EU, the Dossier Submitter concludes that concentrations of 15-21 mg/kg are expected to be technically feasible for the vast majority of actors producing ELT infill.

Little more information is available to the Dossier Submitter on PAH concentrations in oils and tyres several years before the extender oil restriction became effective. CSTEE (2003) reports a total PAHs content in extender oils used in tyre manufacture in the range 300-700 mg/kg and estimates total PAH concentrations between 13 and 112 mg/kg in ELT particles due to the oils. Other sources referred to in the CSTEE opinion show ranges of 1-230 mg/kg, 30-360 mg/kg and a single reported value of 226 mg/kg in tyre material. These figures provide some indication of much higher PAH levels in oils and tyres on the EU market almost ten years prior to the EU extender oil restriction. There is some indication for a generally lower amount of PAHs in EU recycled rubber samples compared to recycled rubber samples from non-EU tyres (Depaolini et al., 2017). Moreover, this study found a difference in PAHs content in samples taken before and after 2010 for the non-EU material, while this difference was less evident for the EU samples.

Some ELT from before 2010 appears still to be placed on the EU recycling market.[15] Gradual reduction in PAHs content from before 2010 to 2017 is observed in the PAH measurements available to the Dossier Submitter. The decrease seems to level off in the last four years (2014-2017), see figure B1-10 in Appendix B1. Depaolini et al., 2017 did not find a statistical difference in PAH content before and after 2010, whilst a statistically significant difference is found between EU and non-EU ELT, both PAHs concentrations appear to be below 20 mg/kg and are in compliance with the extender oil restriction. Imports of passenger car tyres and of bus and truck tyres have been growing over the last 5-8 years (ETRMA Statistics Report 2017[16]). This trend may slightly increase the PAHs content in ELT put on the EU market. However, it is questionable whether this potential increase would be significant. Use of non-ELT crumb rubber from other sources has been indicated as a potential source of infill material that may contain higher PAHs content. However, no clear source could be found confirming this observation. Also no information is available that this use may be increasing in the EU.

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

PAHs in alternative (non ELT) infill materials

With respect to non-ELT infill, the majority of the infill will be virgin material (personal communication synthetic turf sector, personal communication professor Noordermeer and Dr. Dierkens). These materials could in theory contain PAHs if for example carbon black or PAH containing oils are used in the production. The latter is deemed unlikely in case of EPDM as PAH containing oils are said not to match with the material. Carbon black could be used in in the production of EPDM. However, in practice this would probably not happen as customers prefer coloured infill. If alternative infill (e.g. EPDM) is made of recycled material, it probably contains carbon black and therefore may contain PAHs. A large proportion of EPDM articles used on the market contain carbon black (e.g. roofing sheets, floor mats etc.) and hence black carbon containing EPDM will be abundant in the waste stage. The analysis of alternatives shows that some low quantities in PAHs have been found in EPDM based on limited information available (See Annex E.2 and Appendix E2).

[15] 15% in Italy, for other countries no information is available. It is unknown to the Dossier Submitter whether this 15% is representative for the EU.

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

1.5.4. Number of people potentially exposed

1.5.4.1. Athletes and children playing on synthetic turf

In Figure 3, the number of athletes is summarised. Although football is by far the largest sport played on synthetic turf pitches in the EU, other ball games (rugby, Gaelic sports, baseball, and lacrosse) use long pile artificial turf pitches too. As many of these artificial pitches use infill material other than sand, the size of population that comes in direct contact with potentially PAH-containing infill material is considerable. It has been estimated that the number of registered players for the four previously mentioned sports in the EU exceeds 20 million (inclusive 71 049 professional football players). However, when accounting for unregistered players, the number may well be in excess of 38 million individuals (estimated based on personal communication: UEFA 2017, World Rugby 2016, European Lacrosse Federation 2017 and GAA 2017, see Annex A.2.3.4.). The actual number, when factoring in other sports, events, and activities that are taking place on artificial turf pitches across the EU, may be noticeably higher.

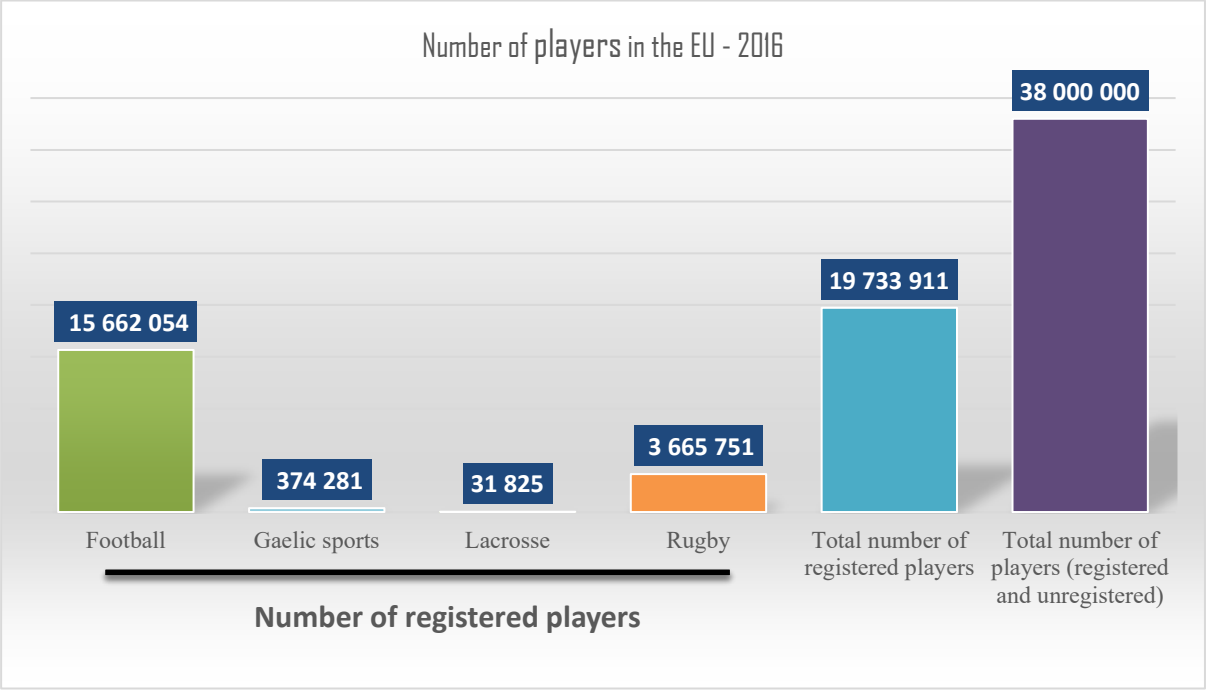


Figure 3: Number of registered and unregistered players in the EU, 2016. Source: UEFA, Gaelic Athletic Association, European Lacrosse Federation, World Rugby. Numbers per Member Sate are specified in table A 3 in Annex A.2.3.4.

As no clear prognosis is available to the Dossier Submitter, for the Restriction dossier no further growth of the player population is assumed between 2018 and 2028.

The Dossier Submitter has insufficient information to define the actual number of individuals that make use of mini-pitches and playgrounds that make use of loose granules or mulches every year. As a best-informed guess, the Dossier Submitter assumes that half of the European synthetic turf mini-pitches (45 000 in 2012, 63 000 in 2018 and 70 000 in 2020)

are using performance infill. Based on this assumption the Dossier Submitter estimates 31 500 mini-pitches with infill are used in the EU in 2018.

To construct a proxy for the number of frequent users of a mini-pitch, user estimates for Cruyff Courts in the Netherlands are used. On average 280 children a week make use of a Cruyff court. Of these children 9 out of 10 are assumed to be frequent users of the pitch. Assuming 252 frequent users per pitch and 31 500 mini-pitches, the population users of mini-pitches in the EU is 7.9 million children. To put these numbers into perspective: there are almost 80 million children from 0-14 years old in the EU[17], so these estimates correspond to almost 10 % of the EU population in this age cohort.

In the risk assessment it is assumed that all athletes make use of synthetic turf every time they play (both training and matches). This will be true for some players in some countries and therefore it is an appropriate assumption in the scope of a realistic worst-case risk assessment. However, this frequency of use will not be reality in practice for most players in the EU and thus is expected to be an overestimate for tha actual situation in the EU. There will be football players that only make use of artificial turf with recycled rubber granules and there will be football players that never make use of artificial turf with recycled rubber granules. In between the two extremes, there will be players that make use of different types of fields. Based on the available information, it is not possible to estimate the population actually exposed and the population at risk in the baseline situation that are relevant for the impact assessment.

1.5.4.2. Installation and maintenance workers

Based on information available in Annex A, B and D, and by making additional assumptions, a proxy for the number of workers for installation and maintenance of artificial turf in the EU is calculated (see Textbox D 1. in Annex D). In total, it is estimated that between 4 000 and 14 000 workers are involved in installation and maintenance of synthetic turf pitches. It is assumed that currently, 90 % of the synthetic turf contains ELT infill (both for pitches and mini-pitches), that workers installing and maintaining pitches will do that for all types of infill used and that all workers will thus come in to contact with ELT infill.

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

2. Impact assessment

2.1. Introduction

For the impact assessment, a societal cost benefit approach is used as the overall method to derive estimates of the welfare effects to society of two restriction options compared to the baseline situation (see section 1.5 and Annex D). This section starts with an investigation of possible Risk Management Options (RMO's) and the selection of the two Restriction Options that will be further evaluated in the Impact assessment. Section 2.3 and 2.4 presents an overview of the identified impacts of these two restriction options compared to the baseline situation to various actors in society, in which the most relevant impacts have been further worked out: economic impacts, wider economic impacts, human health impacts, environmental impacts and social impacts.

Where possible, quantitative estimates have been derived to give an impression of the expected order of magnitude of the impacts, and if possible, quantified impacts have also been monetised. Furthermore, the distribution of impacts has been analysed to see what actors are expected to gain from the restriction and what actors are expected to lose. Note that a full description of the impact assessment and how the impacts have been derived is given in Annex E. In Annex E also the various data and assumptions that were used in the calculations are presented and explained. The outcomes of the calculations are presented in Annex E to facilitate the reproducibility of calculations. The calculations were performed to get an idea of the order of magnitude of the expected welfare effects. All outcomes have therefore been rounded in this Annex XV Dossier.

The outcomes of this impact assessment are used as the basis to come to a restriction proposal that is deemed best for society as a whole by a reflection of proportionality with regard to the remaining risk, affordability and practicability.

2.2. Risk Management Options

Various risk management options can be used to address the risk of PAHs in granules and mulches in sport and play applications. An overview of the RMO's that have been considered is presented in Table 12 below including a brief description of the RMO and the Dossier Submitters' considerations with respect to risk reduction capacity, proportionality to the risk and practicalibity. Further evaluation of the RMO's is provided in Annex E1. Restriction Options RO1 and RO2 have been further considered in the Impact Assessment and elaborated evaluation of the risk reduction capacity, proportionality and practicability of these RO's are given in the following sections.

Note that the choice to focus on the risks of PAHs and carcinogenicity defines what risk management options may be relevant, other risk management options that may be relevant for potential risks of the use of ELT granules and mulches in sport and play applications (e.g. for human health or the environment due to other hazardous

substances/microplastics) have not been considered here as these are out of the scope of this proposal.

Table 12: Overview of possible risk management options (RMO's). Further elaboration on the various RMO's considered is provided in Annex E1.

Risk management option	**Description**	**Considerations with respect to risk reduction capacity, proportionality to the risk and practicalibity**
R(M)O1: Sum content limit value of 17 mg/kg for REACH-8 PAHs	In this RO, a concentration limit for the sum of the REACH-8 PAHs is set at 17 mg/kg for granules and mulches in sport and play applications. The limit value here is set on the 95 percentile of the PAH content currently found in ELT derived infill in the EU as this value is expected to be the lowest value that is technically feasible and achievable for tyre recycling sector in the EU and will result in acceptable risk levels.	This option is assessed further in the impact assessment, defined as RO1. This is the proposed restriction option.
R(M)O2: SUM content limit value of 6.5 mg/kg for REACH-8 PAHs	In this restriction option (RO) a concentration limit for the sum of the REACH-8 PAHs is set at 6.5 mg/kg for granules and mulches in sport and play applications. In this RO, the limit value is derived from the selected acceptable excess lifelong cancer risk level of 1 in a million under the worst case scenario conditions for the highest exposed population (i.e. professional goalkeepers).	This option is assessed further in the impact assessment, defined as RO2
RMO3: Content limit for all carcinogenic PAHs	Comparable to the proposed RO, however, it covers 2-3 more PAHs	Limited expected added value in terms of risk reduction as the REACH-8 PAHs serve as marker substances, furthermore this option is not in line with current entry 50 restriction in REACH and expected additional compliance costs. This RMO is disregarded by the Dossier Submitter.
RMO4: Migration limit	Comparable to the proposed RO, however, migration limit in stead of concentration limit	Migration better relates to the actual risk and a migration limit may because of that be preferred. However, the proposed restriction accounts for migration in the risk assessment and therefore is deemed sufficient. Migration limit is expected to be less practical and enforceable. This RMO is disregarded by the dossier submitter.
RMO5: Limit value consistent with the PAH limit values applicable to articles and toys	In this restriction option, the limit value is set consistent with the limit value that applies to articles or toys in paragraphs 5 and 6 of entry 50 in Annex XVII of REACH and applies to individual PAHs (instead of a sum limit of REACH-8 PAHs)	There is no scientific basis for this restriction option as exposure to PAHs from articles and toys may be very different compared to the use of granules and mulches in sport and play applications. In practice, the impacts of this option may be comparable to RO2. This RMO is disregarded by the dossier submitter.
RMO6: Limiting the PAH	In analogy with the exisiting	Effectiveness of this RMO in terms of risk

Risk management option	Description	Considerations with respect to risk reduction capacity, proportionality to the risk and practicalibity
concentration in carbon black	extender oil restriction limiting PAHs in tyres in the oils used in tyre production, also the PAH concentration in the carbon black feedstock of tyres can be reduced with a legal limit	reduction of the use of garnules and mulches in sport and play applications is expected to take years or decade(s) as tyre manufacturers would need time to adapt and it takes a tyre life time before any effect would be seen in ELT granules and mulches. Furthermore, the dossier submitter has no information on the technical and economic feasibility of this RMO. This RMO is disregarded by the dossier submitter.
RMO7: Further reduction of PAH limit value in extender oils used in tyre manufacture	This RMO would sharpen the limit value of the existing extender oil restriction, entry 50 1-4 REACH Annex XVII	Based on the current limit value and the current PAH concentrations in ELT it is estimated that only a minor part of PAHs in ELT come from extender oils. Further reduction of the current limit value thus is expected to have limited risk reduction capacity. This option would also require a lot of time to have an effect on ELT material. This RMO is disregarded by the dossier submitter.
RMO8: Amendement of harmonized classification in Annex VI of CLP	PAH concentrations in ELT derived granules do normally not exceed current CLP concentration limits applicable for classification of mixtures and restricting supply to the general public. Lowering the existing specific concentration limit for REACH-8 PAHs via amendement of the harmonized classification could in theory render Annex XVII entry 28 more restrictive and as a consequence control risks to consumers	This RMO has been disregarded as the current CLP guidance on classification Category 1B genotoxic carcinogens does not provide the possibility to lower the specific concentration limits.
RMO9: Risk Communication	Via campaigns advice could be given to athletes and other users of these facilities to adapt behaviour in order to minimise their exposure to the granules	This RMO has been disregarded as the effectiveness is expected to be limited.

The impact assessment of the following two restriction options has been carried out:

Restriction option 1 (RO1) ('17 mg/kg limit value'): this restriction option prohibits the placing on the market of granules and mulches as infill material on synthetic turf pitches or in loose form on playgrounds and sport applications if these materials contain more than 17 mg/kg (0.0017 % by weight of this component) of the sum of the listed PAHs. The specific limit value reflects the 95th percentile of the REACH-8 PAH concentration in measurements taken from synthetic turf pitches, i.e. at the moment 5 % of the ELT volume sold and hence 5 % of ELT pitches in the EU are expected to be above this concentration limit.

Restriction option 2 (RO2) ('6.5 mg/kg limit value'): this restriction option prohibits the placing on the market of granules and mulches as infill material for synthetic turf pitches or

in loose form on playgrounds and sport applications if these materials contain more than 6.5 mg/kg (0.00065 % by weight of this component) of the sum of the listed PAHs. The specific limit value reflects the REACH-8 PAH concentration below which the excess lifetime cancer risk of all individuals exposed stays below 1 x 10^{-6}.

2.2.1. Scoping choices for the impact assessment

The scope of the restriction proposal is the scope of the impact analysis: the European Union plus Norway, Iceland and Liechtenstein (EEA31). The temporal scope is a period of 10 years after entry into force and considers the period 2019-2028. It is noted that the actual introduction of the restriction may follow later, but this is not expected to have a major influence on the outcome of the impact assessment. The scope of 10 years is taken as this is the expected lifetime of artificial turf pitches that make use of performance infill. After 10 years, the restriction is expected to be at full capacity, having all new and existing pitches meeting the concentration limit proposed in the restriction within this period of time. Monetary estimates have been calculated in 2018 Present Value and have been discounted at a discount rate of 4 %.

This restriction dossier intends to cover PAH concentrations in both granules made of recycled rubber and granules made of other materials (recycled or virgin, synthetic or natural). As the Dossier Submitter expects that the restriction will mainly affect recycled rubber materials, the life cycle of tyres and the life cycle of artificial turf supply chains are covered within this impact assessment. Both full size sport-pitches (mainly used for football) and multi-purpose mini-pitches with performance infill are covered. The use of mulches has not been included in this impact assessment as this use is expected to be minor compared to the use in artificial turf pitches and as the information available on mulches is limited. The impact assessment pays attention to various actors that are in one way or another connected to these two supply chains as they are the ones that may face effects of the restriction.

2.3. Identification of impacts of RO1, 17mg/kg limit value

Table E 20 in Annex E3 identifies the impacts of RO1 per relevant actor. This table gives an explanation of the underlying assumptions made in the analysis and the sources upon which these have been based. This table serves as a starting point for further assessment of impacts that are further described and (partly) quantified in the following sections, Annex E4-E9. In Table 13 of this dossier, the relevant impacts of RO1 compared to the baseline situation are described qualitatively and (if possible) quantitatively, summarising the information presented in Annex E3-E9. Part of the potential impacts indicated in table E 20 in Annex E3 are not included in Table 13 as these are expected to be very uncertain, not or less relevant and therefore where not further investigated in the impact assessment. Some however, are considered in the uncertainty analysis presented in Annex F (e.g. potential early replacement). In paragraph 1.5 of this Dossier (and in detail in Annex D), the baseline (current situation) in terms of the use of artificial turf and infill in the EU and the expected

trends that would occur without the introduction of any new regulatory measure are described.

RO1 proposes to set a concentration limit at the 95th percentile of the distribution of PAH concentrations currently found in ELT-derived performance infill in the EU (see Figure 2). This suggests that 5 % of the infill produced in the EU does currently not comply with the proposed limit value. It is expected that in RO1 ELT-derived granules and mulches will still be used in sport and play applications. Furthermore, in RO1 it is expected that, EU tyre recycling companies will take measures to comply with the limit value e.g. by improving tyre input selection or that they search for alternative markets for a small part of their ELT output. The ELT performance infill sector and test laboratories indicated that there is variation in the results of PAHs tests depending on the test method and the lab performing the tests and that this causes uncertainty whether or not batches comply with the limit value. The Dossier Submitter did not find any scientific study showing this effect and therefore it is not known whether this in practice will be an issue.

The price of ELT infill is assumed to increase slightly due to the additional measures that are to be taken. This may make alternative infill somewhat more competitive. However, as alternatives remain significantly more expensive compared to ELT, this is assumed not to affect the quantities of ELT infill sold. The Dossier Submitter assumes that the number of new and total number of pitches installed per type of infill material in RO1 is comparable to the baseline situation, implying a slight reduction in the use of ELT and increase in the use of alternatives. As the percentage of ELT-derived infill above the limit value is at maximum 5 %, the Dossier Submitter assumes that all companies are capable to remain in business. This implies no major effects for tyre manufacturers, car/truck drivers, non-ELT performance infill producers, artificial turf producers, artificial pitch installation and maintenance companies, natural grass construction companies and, waste managers of artificial turf.

Table 13: Overview of the relevant effects of RO1, 17 mg/kg limit value, compared to the baseline situation

Impact	Actor	RO1: Identified effects in case of a 17 mg/kg limit value:	Assessed costs and benefits in the first 10 years after the restriction has come into force
Economic	Formulators of recycled rubber mixtures	• Extra costs for measures to guarantee compliance	Measures can be that tyre recyclers improve selection of tyre input or that recyclers sell the non-compliant infill (5 %) on an alternative market. The latter is used for quantification of the costs. It is assumed that costs of measures will be similar or lower compared to costs to sell non-compliant material on an alternative market. It is expected that the minimum price for infill with a PAHs concentration above the limit value is based on the price paid on the energy market (a slightly positive price for tyre-derived fuel granules). Comparing this to the price paid for ELT infill material, the total loss of the ELT sector is estimated to be between €20 and 50 million (mid scenario of €40 million).
		• Increase in costs to test for PAH content to guarantee compliance	Assuming an average cost for testing of € 130 per amount of infill leaving the factory gate required for a pitch and that half of the ELT infill sold in the EU is currently not tested, the total compliance costs related to extra tests are estimated to be close to € 5 million.
Health risk	Artificial pitch installation and maintenance companies	• Reduction in health risk due to prevention of infill with PAH content above 17 mg/kg	Exposure and health risk reduction due to a shift of the baseline distribution of PAH concentrations in ELT granules and mulches in the EU to below 17 mg/kg, see arrow on the left side of Figure 4. Furthermore, high PAH concentrations are avoided that may occur in the baseline due to the high limit value for mixtures that currently applies to granules and mulches in sport and play applications, see arrow on the right side of Figure 4.
Economic	Municipality/ sport clubs/ schools/ private-sector companies	• (Slightly) increased price of artificial turf with ELT derived infill	As sports (including football) in Europe are a merit good, local authorities support it by giving subsidies and providing access to publicly owned sport facilities for free or at a reduced price. Based on this, the Dossier Submitter assumes that in the EEA31 local authorities will finance the extra costs for the pitches and playgrounds that make use of infill/ loose granules/ mulch. Depending on the institutional system, this will e.g. lead to increase in local municipality tax and costs are thus expected to be (indirectly) paid by EU citizens. These total costs are between €25 and 55 million.
Health risk	Athletes (e.g. football player, goalkeeper, including professionals), parents and little siblings,	• Reduction in health risk due to prevention of infill with PAH content above 17 mg/kg	High PAH concentrations pose a cancer risk to the users of artificial turf pitches or sport and play facilities that make use of recycled rubber granules or mulches that will be reduced in this RO. As indicated in Table 15, a shift from the current limit value (estimated at 387 mg/kg for the sum of REACH-8 PAHs[1]) to 17 mg/kg limit will result in an excess lifetime cancer risk reduction of $5.7x10^{-5}$ for the professional keeper and $4.2x10^{-5}$ for the outfield amateur player. This reduction will only be relevant for few specific individuals/sport clubs as high PAH concentrations

Impact	Actor	RO1: Identified effects in case of a 17 mg/kg limit value:	Assessed costs and benefits in the first 10 years after the restriction has come into force
	children playing	• Change in societal concern related to potential health effects of the use of recycled rubber infill	are expected to be incidents and is indicated by the arrow on the right side of Figure 4. Furthermore, a larger group of users of pitches are expected to have some level of risk reduction as the PAH concentration of ELT on all (re)installed pitches is expected to be reduced to below 17 mg/kg. The expected risk reduction from a shift from 21 mg/kg (99 percentile of the baseline) to 17 mg/kg (95 percentile) is estimated at $6.1x10^{-7}$ for the professional keeper and $4.6x10^{-7}$ for the outfield amateur player (see Table 15). This is indicated by the arrow at the left of Figure 4. Note that in practice many actors may have lower levels of risk reduction and the risk assessment takes a realistic worst-case approach. The number of avoided cancer cases is expected to be limited in this scenario and is estimated at <2 avoided cases in a 10 year period assuming risk reduction from 21 to 17 mg/kg at the level of the professional keeper for the full target population (athlethes, users of mini-pitches and workers). Note that this theoretical maximum estimate of avoided cancer cases does not include high PAH concentrations (above 21 mg/kg). Societal concerns for human health effects may be reduced as high PAH concentrations are avoided. Some concern may also remain as ELT remains to be used in sport and play applications and may be linked to other health and/or environmental concerns[2].
Social Economic	Citizens /general EU population	• Change in societal concern related to potential health effects of the use of recycled rubber infill • Potential slight increase in costs for sport pitches and public playground	Societal concern for human health effects may be reduced as high PAH concentrations are avoided. Some concern may also remain as ELT remains to be used in sport and play applications and may be linked to other health and/ or environmental concern[2]. The market price of ELT infill is could increase slightly due to the additional measures that are to be taken. In the impact analysis, no effect on the market price of ELT is taken into account.
Economic	National government	• Increased enforcement costs (compliance costs)	Assuming the average administrative cost of enforcing a restriction as calculated by ECHA (approximately €55 000 a year per Member Sate), the net present value of compliance costs over the 10-year period is around € 15 million.

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

[2] Note that societal concerns are motivated by numerous factors. These may include besides risk, personal normative references, values and believes about the hazards.

2.4. Identification of impacts of RO2, 6.5 mg/kg limit value

Table E 21 in Annex E3 identifies the impacts of RO2 per relevant actor. This table gives an explanation of the underlying assumptions made in the analysis and the sources upon which these have been based. This table serves as a starting point for further assessment of impacts that are further described and (partly) quantified in the following sections, Annex E4-E9. In Table 14 of this Dossier, the relevant impacts of RO1 compared to the baseline situation are described qualitatively and (if possible) quantitatively, summarising the information presented in Annex E3-E9. Part of the potential impacts indicated in table E 21 in Annex E3 are not included in Table 14 as these are expected to be very uncertain, not or less relevant and therefore where not further investigated in the impact assessment. Some however, are considered in the uncertainty analysis presented in Annex F (e.g. potential early replacement). In paragraph 1.5 of this Dossier (and in detail in Annex D), the baseline (current situation) in terms of the use of artificial turf and infill in the EU and the expected trends that would occur without the introduction of any new regulatory measure are described.

Currently 14 % of the ELT-derived infill is expected to comply with the 6.5 mg/kg concentration limit value (see Figure 2), and it is expected not to be possible for recycling companies to assure stable PAH concentrations over time at or below this limit value. The Dossier Submitter assumes that this implies end of market for rubber granules in artificial turf (mini-)pitches and the loss of applications on sport pitches and playgrounds. In RO2 it is assumed that for infill in newly installed (only no-ELT) pitches and refills, 43 % EPDM, 43 % TPE, 14 % cork will be used in the first year after the introduction of the restriction.

Furthermore, a gradual introduction of up to 5 % of no infill installation is assumed over the 10 years following entry into force (and 40 % EPDM, 40 % TPE, 15 % cork). These shares reflect the Dossier Submitter's best estimate based upon responses received during the 24 November 2017 workshop and personal communication with actors in the artificial turf market. Artificial turf systems without infill are currently developed by artificial turf producers (personal communication artificial turf sector). The Dossier Submitter assumes no substitution to natural grass in this scenario mainly because of the fact that more land is required for natural grass compared to artificial turf and for climate reasons (see Annex E section on alternatives). This is in line with the signals received from stakeholders during the 24 November 2017 workshop.

Due to societal concern, some existing pitches may face early replacement (See Annex E8). In this impact analysis, the Dossier Submitter does not quantify early replacement and assumes that the total number of artificial turf pitches per year (including growth of pitches) is the same as in the baseline. This uncertainty of the analysis is refected upon in section 3 and Annex F.

Table 14: Overview of the identified effects of RO2, a 6.5 mg/kg limit value, compared to the baseline situation

Impact	**Actor**	**RO2: Identified effects in case of a 6.5 mg/kg limit value:**	**Assessed costs and benefits in the first 10 years after the restriction has come into force.**
Economic	Producers of recycled rubber mixtures	• End of market for rubber granules in artificial turf and lose applications on sport pitches and playgrounds	The total selling price of ELT granules in the baseline is estimated to be around € 840 million. RO2 implies end-of-life market for ELT infill, a loss in revenues of € 840 million.
		• Increase of other options of ELT/rubber recycling • Increase in costs of tyre recycling	As can be seen in figure A 2 in Annex A, various options for recycling of tyres are available. It is unclear, however, what the demand for other options is. What is known is that these other options are less profitable compared to their use as ELT performance infill. As landfilling is forbidden in the EU, alternative use of ELT will either be other types of ELT material reuse or energy recovery (in cement kilns). For this assessment, three different scenarios are developed (energy recovery at a cost, energy recovery at a small price and material reuse at a price below ELT infill). Based on these scenarios, the order of magnitude of the alternative income is assumed to be between minus € 110 million and € 380 million. In the middle scenario, it is assumed that granules are sold on the energy market at a slightly positive price implying an alternative revenue of € 20 million. Assuming that production costs are fixed the total surplus loss costs for the producers of recycled rubber mixtures are estimated at (€ 840-€20) € 820 million. These costs may be passed on to car/truck companies or drivers, due to the producer responsibility for ELT.
Wider economic		• Potential change in company structure and jobs	The Dossier Submitter assumes that any potential job losses in the tyre recycling sector are likely to be offset by an increase in jobs in the artificial turf sector, especially in the production of alternative infill material. Thus, any detrimental effect of jobs will at most result in temporary unemployment of some workers who may have to shift jobs because of the restriction. An estimate of potential losses in jobs of 400 full time equivalents is derived. Making use of the ECHA approach for valuing job losses (Dubourg, 2016, ECHA 2016), the total present value of job losses due to RO2 are estimated to be around € 40 million.
Economic	Tyre manufacturers	• Potential increase in price of new tyres	Tyre manufacturers are responsible for the management of ELTs. It is unclear which actor will pay the price of the increase in the costs of tyre recycling. To avoid double counting, the Dossier Submitter takes these costs into account once as overall societal costs paid by the EU population.
Economic	Non-ELT performance infill producers	• Increased market for non-ELT performance infill in newly installed pitches, re-fill and in potential early replacement of existing pitches and in refill of existing pitches	As no ELT derived infill can be used anymore, alternative types of infill are expected to be used for all newly installed artificial pitches and for refills. Increase in demand of these other types of infill materials could reduce price due to economies of scale or could increase price in case of market shortage. In the 24 November 2017 workshop it was said that within some years increased production capacity can be realized by the market and thus, market shortage is not to be expected. Whether price may be reduced

Impact	Actor	RO2: Identified effects in case of a 6.5 mg/kg limit value:	Assessed costs and benefits in the first 10 years after the restriction has come into force.
			due to economies of scale is not known and is not further considered. The Dossier Submitter assumes that the increase in demand will not affect price. The total extra societal costs related to other types of performance infill are estimated to be around € 2 400 million.
Economic	Artificial turf producers	• Increase in demand of specific types of artificial turf systems and elements within that system • Market opportunity for innovative artificial field turf structures, like turf without infill	Due to the fact that virgin infill is more expensive, artificial turf with alternative (virgin) infill makes use of another system that require less infill (shorter pile + shockpad[1]). This alternative system has other material requirements. Somewhat less material will be needed for the turf itself, a shockpad is needed below the turf that is not used in case of ELT and the system makes use of a larger amount of sand infill. The total extra costs related to other types of artificial carpet are estimated to be around € 1 000 million. The total extra societal costs of sand infill are estimated to be around € 170 million.
Economic	Artificial pitch installation and maintenance companies	• Increased market because of other installation requirements for artificial turf systems with alternative infill/ no-infill	Different artificial turf systems have other installation costs. The total extra societal costs of installation are estimated to be around € 210 million.
		• Increased market due to (slightly) more frequent maintenance in case of cork (and EPDM and TPE infill)	Based on the information available on the maintenance costs in case of alternative infill, a slight increase in maintenance costs in case of EPDM and TPE and a substantial increase in case of cork is assumed[2]. Without having information, the Dossier Submitter assumes that artificial turf without infill require equal maintenance compared to ELT. The total extra societal costs of maintenance are estimated to be around € 150 million.
Health risk		• Reduction in health risk for employees responsible for installation and maintenance due to reduction in PAHs content • Potential reduction of other human health risk for employees due reduction in other hazardous chemicals	For new installations and maintenance, contact of employees with ELT derived infill will (gradually) be replaced by contact with alternative types of infill. PAH concentrations in recycled rubber granules pose an excess cancer risk to workers that will be reduced to zero in this RO over a period of 10 years. Although there is uncertainty around the actual composition of the alternatives used (e.g. EPDM and TPE infill) and there appears to be variation in composition between infill producers (see Annex E2), in general virgin EPDM and TPE are expected to contain no or less hazardous chemicals (including PAHs) compared to ELT. With respect to cork, limited information is available to conclude upon potential health hazards of chemicals, however, these are deemed unlikely. Related to the potential use of pesticides/herbicides/fungicides during maintenance there is no information to conclude upon differences between various types of infill and potential related risks. The exposure and health risk reduction due to a shift of the baseline distribution of PAH concentrations in ELT granules and mulches in the EU to 0 mg/kg is indicated in Figure 4, see arrow on the left side of graph. Furthermore, high PAH concentrations are avoided that may occur in the baseline due to the high limit value for mixtures that currently applies to granules and mulches in sport and play applications, see arrow on

Impact	Actor	RO2: Identified effects in case of a 6.5 mg/kg limit value:	Assessed costs and benefits in the first 10 years after the restriction has come into force.
			the right side of the graph in Figure 4.
Economic	Municipality/ sport clubs/ schools/ private-sector companies	• Increased costs for newly installed (mini-) pitches and for replacement of (mini-) pitches and potential change in maintenance costs	As sports (inclusive football) in Europe are merit goods, local authorities support it by giving subsidies and providing access to publicly owned sport facilities at a reduced price or for free. The increased price for artificial turf systems are assumed to be financed by local authorities. Depending on the institutional system, this will e.g. lead to increase in local municipality tax and costs are thus expected to be (indirectly) paid by EU citizens. The overall extra costs for artificial turf systems with EPDM, TPE and cork infill and no-infill systems compared to artificial turf with ELT-derived infill are estimated to be around € 3 000 million.
Health risk	Athletes (e.g. football players, goalkeepers, including professionals), parents and little siblings, children playing	• Reduction in health risk due to reduction in PAHs for professional/amateur players, keepers, children/adults playing (sports) • Potential reduction of other human health risk due to reduction in other hazardous chemicals	Contact of the users of pitches with ELT derived infill will gradually be replaced by contact with alternative types of infill. Although there is uncertainty around the actual composition of e.g. EPDM and TPE infill and there appears to be variation in composition between infill producers (see Annex E2), in general virgin EPDM and TPE are expected to contain less hazardous chemicals (including PAHs) compared to ELT. With respect to cork, limited information is available to conclude upon potential health hazards of chemicals, however, these are deemed unlikely. Related to the potential use of pesticides/herbicides/fungicides during maintenance there is no information to conclude upon differences between various types of infill and potential related risks for end users of pitches. High PAH concentrations pose a cancer risk to the users of artificial turf pitches or sport and play facilities that make use of recycled rubber granules or mulches that will be reduced in this RO. As indicated in Table 15, a shift from the current limit value (estimated at 387mg/kg for the sum of REACH-8 PAHs[3]) to 0 mg/kg limit will result in an excess lifetime cancer risk reduction of $5.9x10^{-5}$ for the professional keeper and $4.4x10^{-5}$ for the outfield amateur player. This reduction will only be relevant for few specific individuals/sport clubs as high PAH concentrations are expected to be incidents. The avoidance of high PAH concentration is indicated by the arrow on the right side of Figure 4. Furthermore, a larger group of users of pitches are expected to have some level of risk reduction as the PAH concentrations that are found in the baseline situation (see Figure 2) will be reduced to zero for all (re)installed pitches. The expected risk reduction is a shift from 21mg/kg (99 percentiel of the baseline) to 0 mg/kg is estimated at $3.2x10^{-6}$ for the professional keeper and $2.4x10^{-6}$ for the outfield amateur player. This is indicated by the arrow at the left of Figure 4. Note that in practice many actors may have lower levels of risk reduction and the risk assessment takes a realistic worst-case approach. The number of avoided cancer cases is expected to be limited in this scenario and is estimated at <12 avoided cases in a 10 year period assuming risk reduction from 21 to 0 mg/kg at the level of the professional keeper for the full target population (athlethes, users of mini-pitches and workers). Note that this theoretical maximum estmate of avoided cancer cases does not include high PAH concentrations

Impact	Actor	RO2: Identified effects in case of a 6.5 mg/kg limit value:	Assessed costs and benefits in the first 10 years after the restriction has come into force.
			(above 21 mg/kg).
Social		• Change in societal concern related to the use of recycled rubber infill	In some EU countries (e.g. Netherlands, France) there is societal concern linked to the use of ELT/recycled rubber infill material on artificial turf. It is expected that in 10 years' time, all pitches using (ELT derived) recycled rubber will be replaced by artificial pitches using other types of infill, which will in time end the societal concern related to health issues. The restriction is intended for the newly installed pitches and intends not to affect the existing pitches. This may lead to increased societal concern related to the use of recycled granules on existing pitches[4]. This may lead to early replacement of existing pitches. Early replacement is not further considered in the impact assessment, however, it is qualitatively decribed in the uncertainty analysis.
		• (Perceived) change in performance quality (depending of the system/infill change)	Other types of infill or other types of artificial pitches (no infill) may have other (perceived) sport technical performance characteristics. Various actors in the pitch, for example are not very enthusiastic about the performance of cork. Or actors may have a preference for the performance of a specific type of infill or system. All types of infill and pitches included in this analysis, however, can comply with the FIFA Pro qualification and thus can meet this benchmark of performance quality.
Economic	Waste managers of artificial turf	• Change in waste composition may influence the waste handling possibilities	The Dossier Submitter assumes that the costs of waste management are more or less equal for different systems, with as exception TPE for which better recycling options exist. The restriction does not affect the type of end of life treatment of artificial turf systems (landfilling, incineration or recycling) as no further information is available. The total extra societal benefits of waste management are estimated to be around € 30 million.
Environmental risk	Citizens /general EU population	• Reduction of environmental risk due to reduction in PAHs (and potentially other hazardous chemicals)	ELT derived infill will (gradually) be replaced by alternative types of infill. Although this is out of scope of the risk assessment and this has not been further evaluated in the dossier, there is environmental concern related to the use of ELT infill e.g. due to potential leakage of hazardous chemicals to soil and water systems (e.g. zinc) (see Annex E.7.2.1). Although there is uncertainty around the actual composition of EPDM and TPE infill as alternatives and there appears to be variation in composition between infill producers (see Annex E2), in general virgin EPDM and TPE are expected to contain less hazardous chemicals (including PAHs) compared to ELT. With respect to cork, limited information is available to conclude upon potential environmental hazards of chemicals, however, these are deemed unlikely. Related to the potential use of pesticides/ herbicides/ fungicides during maintenance there is no information to conclude upon differences between various types of infill and potential related environmental risks. As no further information is available about the actual reduction in other environmental impacts this is not considered further in this assessment. However, it may give relevant impacts in RO2.

Impact	Actor	RO2: Identified effects in case of a 6.5 mg/kg limit value:	Assessed costs and benefits in the first 10 years after the restriction has come into force.
		• Change in other environmental effects (CO2, microplastics)	Replacement of ELT infill by cork or replacement of the artificial pitch by a no infill system will reduce the amount of microplastics that enter the environment. Also, replacement of ELT with EPDM or TPE will reduce the emission of microplastics as lower quantities of infill are used in these systems and as these materials tend to spread less easily to the environment (Weijer and Knol, 2017). Over 10 years, more than 30 000 tonnes less performance infill will be emitted to the environment due to a change to other type of pitches (alternative performance infill and no-infill). Replacement of recycled rubber infill by virgin EPDM or TPE will increase CO2 emissions (see Annex E2). The total societal costs of carbon are estimated to be around € 60 million.
Social		• Change in societal concern related to the use of recycled rubber infill	In some EU countries (e.g. Netherlands, France) there is societal concern linked to the use of ELT/recycled rubber infill material on artificial turf. It is expected that in 10 years' time, all pitches using (ELT derived) recycled rubber will be replaced by artificial pitches using other types of infill, which will in time end the societal concern related to health issues. The restriction is intended for the newly installed pitches and intends not to affect the existing pitches. This may lead to increased societal concern related to the use of recycled granules on existing pitches.[4] This may lead to early replacement of existing pitches. Early replacement is not further considered in the impact assessment, however, it is qualitatively decribed in the uncertainty analysis. Some environmental issues may remain as majority of the alternatives are expected to be synthetic materials as well (EPDM and TPE; microplastics) and for example EPDM also contains (lower) quantities of zinc that may pose an environmental concern as well and as ELT may be used in an e-layer below artificial turf pitches using non-ELT infill material.
Economic	National government	• Increased enforcement costs (compliance costs)	As the difference between ELT derived infill and alternative types of infill is visual, limited (expensive) tests are expected to be needed. Furthermore, at least in parts of the EU where there is a societal concern around the use of recycled rubber infill, actors in society may well check compliance. In other parts of the EU, some visual inspection may be performed. Based on the average administrative costs of enforcement, the net present value of compliance costs is estimated to be to be around € 15 million.

[1] A shockpad is used to obtain proper shock absorption in the system. Shockpads are mainly made of foam. ELT is used in so called e-layers, which have a shock damping effect as well. Note that there may be environmental issues related to the use of ELT as shock absorbance system underneath artificial turf systems (RIVM 2018).

[2] Personal communication synthetic turf sector and Bouwman consulting, 2016 (online: http://loudoun.granicus.com/MetaViewer.php?view_id=68&clip_id=4389&meta_id=96276).

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

[4] Note that societal concerns are motivated by numerous factors. These may include besides risk, personal norms, values and believes about the hazards

Table 15: Theoretical and reasonable maximum reduction in excess cancer risk of RO1 and RO2 based on lifelong exposure (70 years)

- This covers risk on cancer incidence
- Theoretical reduction in excess cancer risk = excess cancer risk at limit value for mixtures minus excess cancer risk at RO limit value
- Reasonable maximum reduction in excess cancer risk = excess cancer risk at P99 of the baseline minus excess cancer risk at RO limit value
- For RO1 the risk value at 17 mg/kg is used, for RO2 the risk value at 6.5 mg/kg and 0 mg/kg are included. Note that the latter is expected to be the actual risk value after implementation of RO2 as it is assumed that ELT granules and mulches are not used anymore in this scenario

Sub-population	**Theoretical reduction in excess cancer risk**			**Reasonable maximum reduction in excess cancer risk**		
	RO1 (387 to 17 mg/kg)	RO2 (387 to 6.5 mg/kg)	RO2 (387 to 0 mg/kg)	RO1 (21 to 17 mg/kg)	RO2 (21 to 6.5 mg/kg)	RO2 (21 to 0 mg/kg)
Professional outfield player	$4.4x10^{-5}$	$4.5 x10^{-5}$	$4.6 x10^{-5}$	$4.7x10^{-7}$	$1.7x10^{-6}$	$2.5 x10^{-6}$
Professional goalkeeper	$5.7 x10^{-5}$	$5.8 x10^{-5}$	$5.9 x10^{-5}$	$6.1 x10^{-7}$	$2.2 x10^{-6}$	$3.2 x10^{-6}$
Amateur outfield player	$4.2 x10^{-5}$	$4.3 x10^{-5}$	$4.4 x10^{-5}$	$4.6 x10^{-7}$	$1.6 x10^{-6}$	$2.4 x10^{-6}$
Amateur goalkeeper	$5.4 x10^{-5}$	$5.5 x10^{-5}$	$5.6 x10^{-5}$	$5.8 x10^{-7}$	$2.1 x10^{-6}$	$3.1 x10^{-6}$

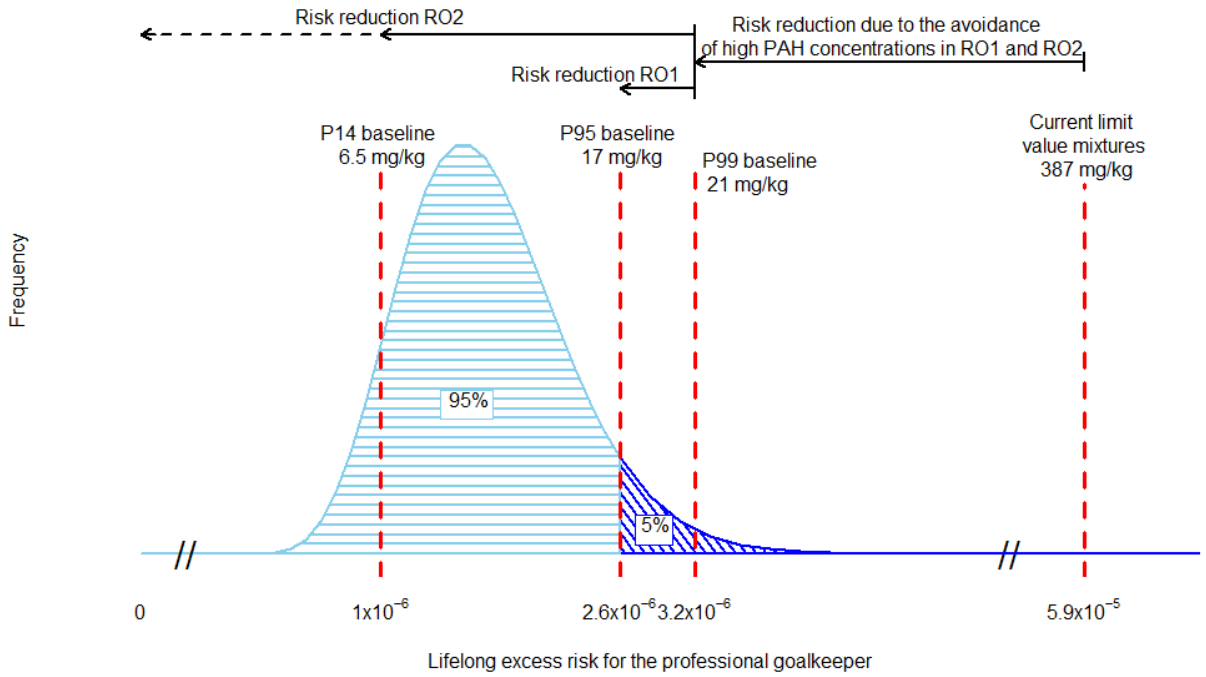


Figure 4: Schematic presentation of the risk levels and risk reduction of RO1 and RO2 compared to the baseline situation. Risk values included in the figure represent the lifelong risk values of the professional goalkeeper at various sum REACH-8 PAH concentrations. Area under the curve represents the frequency of risk values in the sub-population of the professional goalkeepers. Note that the risk levels for a large part of the total population (including professional goal keepers) are expected to be (much) lower than the values indicated in the figure and that risks for these individuals are expected to be at acceptable levels in the baseline already. Avoidance of high risk situations is expected to be relevant for a small part of the population.

2.5. Practicability and monitorability

2.5.1 Practicality

Practicality is assessed in terms of implementabilty, enforceability and manageability. Details are reported in Annex E.9.1 and E.9.2

The proposed restriction is considered practical since it is implementable, manageable and enforceable. The only difference between RO1 and RO2 is the level of the concentration limit. In either case the restriction is easily understandable for affected parties which are the formulators and suppliers of granules and mulches on the EU market for use as infill in synthetic turf pitches and in loose form in sport applications and in playgrounds. The restriction targets the placing on the market (including import) of the granules and mulches as well as their use. The restriction has a clear scope and defines a sum concentration limit for REACH-8 PAHs that have a harmonised EU classification as carcinogenic Category 1B which is a clear legal basis for companies and enforcement authorities consistent with the existing restriction on PAHs in entry 50 of REACH Annex XVII. The sum concentration limit for REACH-8 PAHs under RO1 and RO2 is clear and unambiguous and therefore the proposed restriction is expected to be enforceable by national enforcement bodies across the EEA31. Enforcement costs are estimated to be to be around € 15 million (See Sections 2.3 and 2.4). Some generic issues however need specific attention and these are outlined below. The Dossier Submitted notes that some factors may negatively impact EU-wide enforceability of the proposed measure. Such factors are: 1) the possible differences between Member Sates in the interpretation of the product or waste status of ELT derived granules or mulches marketed for uses as in the scope of the restriction 2) a proper common understanding across stakeholders in the EU of the terminology used (e.g. performance infill, mulches, loose form, sport applications etc.) and 3) current absence of EU harmonised methodology for PAH extraction and analyses from rubber and other matrices.

In addition, during discussions with stakeholders, the Dossier Submitter became aware of some alternatives suppliers claiming specific materials used as infill (other than ELT) to be articles rather than mixtures. Finally, guidance may be needed for enforcers on the applicability of the proposed restriction to coated and coloured granules and mulches. Some guidance[18] developed recently by ECHA for PAHs in article covered by Annex XVII entry 50.5 and 50.6 may be referred to.

Limited information is availbable on the extent to which these factors may be of influence currently and how these will develop in the future. These issues are discussed in more detail in Annex E.9.2.

[18] Guideline on the scope of restriction entry 50 of Annex XVII to REACH: Polycyclic aromatic hydrocarbons in articles supplied to the general public, 7 March 2018.

2.5.2 Monitorability

The implementation of the proposed restriction may be monitored by surveillance programmes of national enforcement bodies and existing reporting systems. Reporting can be done on the level of compliance. Measurements carried out by independent test institutes, media, or green and consumer groups may supplement the monitoring information obtained at national level. Information on market trends as regards the use of ELT derived granules and mulches and alternative materials may provide valuable additional information on the regulatory effectiveness of the restriction (See Annex E.9.3).

2.6. Distributional impacts

2.6.1. Distributional impacts of RO1 compared to the baseline

Table 16 below summarizes the main impacts of RO1 compared to the baseline. The table also indicates the distribution of effects over various actors and indicate which actors are expected to face what kind of impact.

RO1 implies some costs to society due to increased costs for tyre waste management, as a relatively small amount of ELT infill is expected not to comply with RO1. This may incur an extra cost as companies:

i. Need to take measures to reduce PAH content to comply with RO1, or;
ii. Need to sell non-compliant ELT granules for alternative use at a lower price. The latter has been quantified to get an impression of the potential size of the costs. These costs are expected to be indirectly paid by EU citizens/car owners e.g. because of increased prices of tyres, or by municipalities/ owners of pitches as they pay a higher price for ELT performance infill.
iii. In addition, it is expected that to guarantee compliance, the infill for each pitch will be tested on PAHs concentration. The costs for these tests are assumed to be paid by the owners of pitches as they pay a higher price for ELT performance infill. Owners are expected to be often municipalities and these costs are expected to be passed on to all EU citizens.

RO1 will result in health benefits for society due to the avoidance of high PAH concentrations that may occur between 17 and 387 mg/kg in the current situation. Consequent reduction in PAH exposure may result in a (probably small) reduction in cancer cases within the EU. These health benefits are a gain for athletes that play sport, children that play and workers that install and maintain synthetic turf pitches.

At last, there may be societal benefit because of a reduction in societal concern for health effects as high PAH concentrations are avoided. However, social concern may also remain as recycled rubber granules and mulches remain to be used in this scenario and e.g.have issues related to the environment. This potential effect will especially be relevant for users of pitches. Note that societal concerns are motivated by numerous factors. These may include besides risk, personal normative references, values and believes about the hazards. The expected overall impact on social concern is unknown.

Table 16: Distribution of impacts of RO1 compared to the baseline over various actors (quantified in million € over 10 years, 4% discounted, unless stated differently)

Actors **Impacts**	*Formulators of recycled rubber mixtures*	*Artificial pitch installation producers*	*Maintenance companies*	*Test companies (labs)*	*Municipalities/owners of pitches*	*Athletes, children playing*	*EU citizens*	*National government*	**Impacts to society**
Cost of compliance for ELT recyclers	-40 (-20 to -50)				(x[1])		x[1]		-40 (-20 to -50)
Increase of test costs for ELT recyclers				5	x[1]				-5
Enforcement costs								-15	-15
Health risk and impacts reduction (carc. PAHs)		+ Risk reduction for 4 000-14 000 workers[2] Avoidance of risks of high PAH concentrations				+ Risk reduction for around 45 million individuals[2] Avoidance of risks of high PAH concentrations			+ Avoidance of <2 cancer cases Avoidance of high risk situations[3]
Social impacts						Change in societal concern; as high PAH concentrations for new pitches are avoided, societal concern may be reduced; concerns may remain for existing pitches			+/-

[1] The actor that most probably has to pay for these costs

[2] Due to the avoidance of high PAH concentrations that may occur between 17 and 387 mg/kg in the baseline. Actors included are all registered and unregistered athletes and the users of mini-pitches. Note that there may be some double counting in this figure as some of the athletes may also be using mini-pitches.

[3] Note that although all actors may have some level of risk reduction in RO1, the risk level of a large part of the population is expected to be at acceptable levels in the baseline already. Avoidance of high risk situations is expected to be relevant for a small part of the population.

2.6.2. Distributional impacts of RO2 compared to the baseline

Table 17 below summarizes the main impacts of RO2 compared to the baseline. The table also indicates the distribution of effects over various actors and indicate which actors are expected to face what kind of impact.

RO2 implies costs to society due to increased costs for tyre waste management, increased costs for artificial turf and because of an increase in greenhouse gas emissions. The first group of actors in society that lose because of the restriction are the recyclers/ producers of rubber mixtures, e.g. the ELT waste managers that produce ELT derived granules and mulches. These actors are faced with a loss in revenue as ELT infill cannot be sold anymore and alternative waste management of ELT is expected to be less profitable. This loss is expected to be indirectly paid by EU citizens/car owners e.g. by an increased price of tyres.

Artificial turf producers, alternative infill producers and installation and maintenance companies are expected to gain from the restriction due to an increase in their sales. Increased costs for artificial turf pitches are expected to be paid by the owners of pitches, which are often expected to be municipalities. Although there may be differences between EU counties, in general, it is expected that this increase in costs is paid indirectly by EU citizens via an increase in municipality tax.

There will be losses in jobs in the ELT sector and an increase in jobs for in the alternative infill sector as a consequence of the restriction. This may result in temporal unemployment for those workers that need to change jobs because of the restriction.

Increase in greenhouse gas (GHG) emissions (CO_2-equivalents) due to replacement of ELT infill with virgin infill material is a negative impact of RO2 incurred by everybody.

RO2 will result in health benefits for society due to the avoidance of high PAH concentrations that may occur between 6.5 and 387 mg/kg in the current situation. Consequential reduction in PAH exposure may result in a reduction in cancer cases in the EU. These risk reductions have a beneficial impact on athletes, children that play and workers that install and maintain synthetic turf pitches. In additions, RO2 may result in potential risk and impact reduction to health and the environment due to i) potential effects of other PAHs; (not included in REACH 8-PAHs);ii) potential other effects of PAHs; iii) potential effects of other hazardous substances in ELT both to human health and the environment; iiii) due to a reduction in emissions of microplastics from synthetic turf pitches. All these effects have a beneficial impact on athletes, children playing and workers in contact with ELT infill and/or the general EU population. These effects, however, are out of scope of this restriction proposal and have not been further assessed in the risk assessment. The impact assessment briefly discusses these potential effects.

At last, there may be a reduction in societal concern, at least after 10 years after entry into force of the restriction all pitches with ELT infill are expected to be replaced by alternatives. Some societal concern however may remain in the first 10 years after entry into force as the restriction is implemented for new pitches and does not (directly) affect existing pitches. This potential effect will especially be relevant for users of pitches. Note that societal concerns are motivated by numerous factors. These may include besides risk, personal normative references, values and believes about the hazards. Social concern may result in the early replacement of existing pitches. This will be discussed in section 3 on uncertainties.

Table 17: Distribution of impacts of RO2 compared to the baseline over various actors (quantified in million € over 10 years, 4 % discounted, unless stated differently)

Actors **Impacts**	*Artificial turf producers*	*Formulators of recycled rubber mixtures*	*Virgin performance infill producers*	*Sand infill company*	*Artificial pitch installation*	*Maintenance companies*	*Waste managers of artificial turf*	*Municipalities/owners of pitches*	*Athletes, children playing*	*EU citizens*	*National government*	***Impacts* to society**
Alternative recycling of ELT		20 (-110 to 380)								x[1]		-20
Chance in artificial turf system (incl. infill)	1030	-840	2380	170	210	150	-30	x[1]				-3070
Enforcement costs											15	-15
Wider economic impacts	Potential increase in jobs	Potential job losses 400 fte	Potential increase in jobs							40		-40
Health risk and impacts reduction (carc. PAHs)					++ Risk reduction for 4 000-14 000 workers Avoidance of risks of high PAH concentrations				++ Risk reduction for around 45 million individuals[2] Avoidance of risks of high PAH concentrations			++ Avoidance of <12 cancer cases Avoidance of high risk situations[3]
Health risks reduction of other effects and other substances					Potential risk reduction due to other hazardous effects of REACH-8 PAHs, other PAHs,				Potential risk reduction due to other hazardous effects of REACH-8 PAHs, other PAHs,			

Actors **Impacts**	*Artificial turf producers*	*Formulators of recycled rubber mixtures*	*Virgin performance infill producers*	*Sand infill company*	*Artificial pitch installation*	*Maintenance companies*	*Waste managers of artificial turf*	*Municipalities/owners of pitches*	*Athletes, children playing*	*EU citizens*	*National government*	***Impacts* to society**
					and other hazardous substances in ELT +?				and other hazardous substances in ELT +?			+?
Environmental risk reduction										Potential reduction in environmental impact from zinc, cobalt, mineral oil from ELT		+?
GHG emissions										-80		-80
Microplastics										Reduction in microplastics, 30 000 ton		+ Reduction in microplastics, 30 000 ton
Social impacts									Change in societal concern; for new pitches concern will be reduced, concerns may remain for existing pitches and could lead to early replacement of existing pitches			++/- Stop of societal concern after 10 years

[1] The actor that most probable has to pay for these costs

[2] Actors included are all registered and unregistered athletes and the users of mini-pitches. Note that there may be some double counting in this figure as some of the athletes may also be using mini-pitches.

[3] Note that although all actors may have a risk reduction in RO2, the risk level of a large part of the population is expected to be at acceptable levels in the baseline already. Avoidance of high risk situations is expected to be relevant for a small part of the population.

2.7. Proportionality to the risk

2.7.1. Comparison of costs and benefits of RO1 compared to the baseline

RO1 may pose some costs to society due to measures that ELT recycling companies may take to reduce PAH concentrations in infill and mulches or because of sales losses if a small part of the produced ELT mixtures cannot be sold (as infill) anymore and as extra regular tests may be performed to prove compliance with the restriction. Furthermore, there may be costs for autorities for enforcement activities. The overall societal costs of RO1 are estimated to be around 40-70€ million over a 10-year period.

The health benefit of RO1 is the reduction in cancer risk due to the avoidance of PAH concentrations that may occur between 17 mg/kg and 387 mg/kg in the current situation. As indicated in Figure 4, this will result in a health risk reduction as the distribution of PAH concentration in granules and mulches will shift to below 17 mg/kg. A shift from 387 mg/kg to 17 mg/kg limit will result in an excess lifetime cancer risk reduction of $5.7x10^{-5}$ for the professional keeper and $4.2x10^{-5}$ for the outfield amateur player. This reduction in risk is expected to be relevant for few specific individuals/sport clubs only, as high PAH concentrations are expected to be incidents. Furthermore, a larger group of users of pitches are expected to have some level of risk reduction as the PAH concentration of ELT on all (re)installed pitches is expected to be reduced to below 17 mg/kg. The expected risk reduction from a shift from 21 mg/kg (99 percentile of the baseline) to 17 mg/kg (95 percentiel) is estimated at $6.1x10^{-7}$ for the professional keeper and $4.6x10^{-7}$ for the outfield amateur player (see Table 15). Note that the risk assessment takes a realistic worst-case approach and in practice many actors will have lower levels of risk reduction. The number of avoided cancer cases is expected to be limited in this scenario, and may depend on the actual occurrence of high PAH concentrations on pitches in the baseline situation. Using the risk reduction from 21 mg/kg REACH-8 PAHs (99^{th} percentile) in the baseline situation to the 17 mg/kg limit value of RO1 for the professional keeper, a theoretical maximum number of avoided cancer cases is estimated at <2 cancer cases in the EU over a 10 year period in RO1[19]. The risk reduction of high PAH concentrations above >21 mg/kg is thus not covered in this estimate. Arrows in Figure 4 provides an illustration of the expected risk reduction of RO1 for the population at stake. Besides potential health benefits, RO1 may reduce societal concern for human health effects as an additional benefit as it will guarantee that PAH concentrations in infill material and mulches placed on the market are at or below 17 mg/kg and that unacceptable risk levels are thereby avoided. Some concern may also remain as ELT remains to be used in sport and play applications and may be linked to other health and/ or environmental concern.

Direct comparison of costs and benefits is difficult as only part of the benefits could be quantified. The quantified potential benefits of <2 avoided cancer cases in the theoretical maximum estimate appears to be limited compared to the quantified costs. The actual

[19] See for Annex E.6.5. for more information. Note that the estimate is a theoretical maximum estimate in the sense that it assumes that the full target population (althletes, mini-pitch users and workers) have risk reduction levels at the value of the professional keeper, while majority of actors are expected to have lower risk and risk reduction levels.

benefits in terms of avoided cancer cases is probably lower than the calculated quantified benefit. However, the societal gain of avoiding unacceptable risk levels could be subtantial, as there is societal concern related to the use of ELT granules as infill in several Member Sates.

2.7.2. Cost-effectiveness, affordability and proportionality of RO1

The societal costs of RO1 can be further evaluated to get an idea of the implication of these costs for society. In Table 18 total costs or RO1 are expressed in various unit values. Depending on the unit value, total costs for full size pitches, mini-pitches or both were used. Costs are given for a 10-year period and are discounted at 4 %.

From Table 18 it can however be concluded that costs are expected to be affordable for actors in society. In particular the additional societal cost per pitch is estimated to be less than €1 600. As a reference, the costs for installing a full-size artificial ELT pitch (exclusive substructure) are € 223 000, see Annex E2. This suggests that under RO1 the relative cost increment per pitch would be less than 1 %[20].

Overall, as the costs of this restriction option are expected to be limited and bearable for the actors at stake, as (very) high PAH concentrations and consequent risk levels are avoided for the population that comes into contact with granules or mulches in sport and play applications, as the residual cancer risk from PAH exposure will be at an acceptable level, and as social concern related to human health effects may be reduced due to avoidance of high PAH concentrations, the Dossier Submitter concludes that this restriction option is proportional.

Table 18: Societal costs of RO1 (€ over 10 years, discounted at 4 %, only societal costs due to market impacts included) per unit value. Estimates have been rounded; see for the specific results Annex E.11. Note that the actors indicated under 'unit of input' are not necessarily the actors that in practice pay for the costs and that the societal costs estimates included in the table may be paid by various actors. Estimates are meant to get an idea of the implication of these costs for society.

	Societal costs over 10 years	**Unit of input**	**Societal costs per unit of input**
Cost per cancer case avoided	*€ 40-70 million*	*<2 cancer cases avoided (theoretical maximum)*	*>€ 20-35 million per cancer case avoided*
Costs per EU citizen	*€ 40-70 million*	*500 million citizens*	*€ 0.08-0.13 per EU citizen*
Costs per full size pitch (2028)	*€ 35-55 million*	*34 000 pitches*	*€ 1 000-1 600 per full size pitch (football)*
Costs per registered football players	*€ 35-55 million*	*15 million football player*	*€ 2.30-3.60 per registered football player*
Costs per registered and unregistered football players	*€ 35-55 million*	*38 million football player*	*€ 0.90-1.50 per registered and unregistered football player*
Costs per mini-pitch (2028)	*€ 5-10 million*	*55 000 mini-pitches*	*€ 90-180 per mini-pitch*
Costs per mini-pitch user	*€ 5-10 million*	*8 million mini-pitch user*	*€ 0.65-1.30 per mini-pitch user*

[20] Societal costs are inclusive enforcement costs

2.7.3. Comparison of costs and benefits of RO2 compared to the baseline

RO2 is estimated to cost society around € 3 100 million due to market impacts (tyre recycling, artificial turf market and enforcement costs) and €80 million for additional greenhouse gas emissions over a 10-year period.

The benefit of the restriction is the reduction in health risk due to a reduction in exposure to carcinogenic PAHs from ELT and potentially other recycled rubber infill and mulches. Contact of the users of pitches with ELT derived infill will gradually be replaced by contact with alternative types of infill. Although there is uncertainty around the actual composition of e.g. EPDM and TPE infill and there appears to be variation in composition between infill producers (see Annex E2), in general virgin EPDM, TPE and cork are expected to contain no or less hazardous chemicals (including PAHs) compared to ELT (see table E2-1 in Appendix E2). As indicated in Table 15, a shift from the current limit value (estimated at 387 mg/kg for the sum of REACH-8 PAHs) to 0 mg/kg limit will result in an excess lifetime cancer risk reduction of $5.9x10^{-5}$ for the professional keeper and $4.4x10^{-5}$ for the outfield amateur player. This reduction will only be relevant for few specific individuals/sport clubs as high PAH concentrations are expected to be incidents. Furthermore, a larger group of users of pitches are expected to have some level of risk reduction as the PAH concentrations that are found in the baseline situation (Figure 2) will be reduced to zero for all (re)installed pitches. The expected risk reduction is a shift from 21 mg/kg (99 percentile of the baseline) to 0 mg/kg is estimated at $3.2x10^{-6}$ for the professional keeper and $2.4x10^{-6}$ for the outfield amateur player. Note that in practice many actors will have lower levels of risk reduction and the risk assessment takes a realistic worst-case approach. Accounting with a risk reduction from 21 mg/kg REACH-8 PAHs (99^{th} percentile) in the baseline situation to the 0 mg/kg, a theoretical maximum number of avoided cancer cases is estimated at <12 cancer cases in the EU over a 10 year period in RO2[21]. The risk reduction of high PAH concentrations above >21 mg/kg is thus not covered in this estimate. Arrows in Figure 4 provide an illustration of the expected risk reduction of RO2 for the population at stake. Besides potential health benefits, RO2 is expected to reduce societal concern for harmfull effects as an additional benefit as it will stop the use of recycled (ELT) granules and mulches in a period of around 10 years.

Although human health benefits of a reduction in PAH concentrations could only partly be quantified and direct comparison of costs and benefits is thus difficult, the order of magnitude of costs is so much higher compared to the quantified benefits, that further information/quantification of benefits related to PAHs are not expected to change the balance of costs and benefits. RO2 is therefore assessed not to be a proportional restriction option to address the risks posed by carcinogenic PAHs in ELT granules. It is noted, however, that the restriction may have other benefits to society. Other health impacts of PAHs and other hazardous substances in ELT may pose an additional negative effect to human health and/or the environment that may be avoided in RO2. These effects were not

[21] See for Annex E.6.5. for more information. Note that the estimate is a theoretical maximum estimate in the sense that it assumes that the full target population (althletes, mini-pitch users and workers) have risk reduction levels at the value of the professional keeper, while majority of actors are expected to have lower risk and risk reduction levels.

assessed in detail in this restriction proposal and have not been further quantified. It is therefore not possible to assess their impact on the overall proportionality of RO2.

It should be mentioned that other risk management options than the ones assessed in this restriction proposal may be better suitable to deal with these other concerns. ECHA, on request of the European Commission, is currently performing a broader study looking at potential risks of these other substances that may be of concern to human health or the environment.

2.7.4. Cost-effectiveness and affordability of RO2

The societal costs of RO2 are further evaluated to get an idea of the implication of these costs for society. In Table 19 below costs are expressed in the costs per various units of input (e.g. pitches, athletes) and impact (avoided cancer cases). Costs are given for a 10-year period. In the table, only the costs that are relevant for the unit in which the cost is expressed have been included. For example, if costs per mini-pitch are calculated, only the extra costs for mini-pitches due to a shift to alternative artificial turf systems have been included in the estimate. Because of this, in some of the estimates total costs have been included; in others, only a subsection of the costs was used. Furthermore, only societal costs due to market impacts have been included. Societal costs of greenhouse gas emissions have been left out of this analysis as this is another type of cost figure.

From Table 19 it can be concluded that costs may be substantial. If society finds it important to eliminate cancer risk associated with ELT-derived infill material, then EU citizens may be willing to pay a price for that. At least in the Netherlands, it is seen that some actors (municipalities) indeed are willing to pay this price for a reduction in risk and the related concern in society. Based on this experience, the Dossier Submitter concludes that it may be affordable for some actors in society. As reference, for the costs per full-size pitch estimate, the costs for a full-size artificial ELT pitch (exclusive substructure) are estimated at €223 000, see Annex E2. This suggests that under RO2 the relative cost increment per pitch would be roughly 30 %.

Overall, the costs of this restriction option may be substantial. (Very) high PAH concentrations and consequent risk levels are avoided for the population that comes into contact with granules or mulches in sport and play applications, and the residual cancer risk from PAH exposure will go to zero. Social concerns related to human health effects will be reduced over time as high PAH concentrations are avoided. The Dossier Submitter concludes that RO2 is not proportional, but as some EU citizens appear to be willing to pay the price, this RO may be affordable to some actors in society.

Table 19: Societal costs of RO2 (€ over 10 years, discounted at 4 %, only societal costs due to market impacts included) per unit value. Estimates have been rounded; see for the specific results Annex E.11. Note that the actors indicated under 'unit of input' are not necessarily the actors that in practice pay for the costs and that the societal costs estimates included in the table may be paid by various actors. Estimates are meant to get an idea of the implication of these costs for society.

	Societal costs over 10 years	**Unit of input/ impact**	**Societal costs per unit**
Cost per cancer case avoided	€3 100 million	<12 cancer cases avoided (theoretical maximum)	>€260 million per cancer case avoided (theoretical maximum)
Costs per EU citizen	€3 100 million	500 million citizens	€6,- per EU citizen
Costs per full size pitch (2028)	€2 500 million	34 000 pitches	€73 000 per full size pitch (football)
Costs per registered football player	€2 500 million	15 million football player	€160 per registered football player
Costs per registered and unregistered football player	€2 500 million	38 million football player	€70 per registered and unregistered football player
Costs per mini-pitch (2028)	€600 million	55 000 mini-pitches	€11 000 per mini-pitch
Costs per mini-pitch user	€600 million	8 million mini-pitch users	€80 per mini-pitch user

2.7.5. Comparison of effectiveness, practicability and monitorability of RO1 and RO2

Table 20 presents a summary of the impacts of RO1 and RO2 compared to the baseline, to facilitate comparison of these two restriction options. The effectiveness of RO1 is lower compared to RO2 and involves the health gain due to the avoidance of high PAH concentrations that may occur between 17 and 387 mg/kg in the current situation due to the high concentration limit for PAHs in mixtures according to Annex XVII of REACH. RO2 is expected to eliminate the excess cancer risk of REACH-8 PAHs from infill material and mulches as it is expected that ELT performance infill will no longer be marketed at a 6.5 mg PAH/ kg limit value and the alternatives are assumed to contain no or very low levels of PAHs[22].

With respect to costs, it may be clear from the above sections that the societal costs of RO1 are limited compared to the substantial costs for society under RO2. A possible important additional benefit of both RO1 and RO2 is that both RO's may reduce societal concern related to human health risks and RO2 may also reduce societal concern related to environmental risks. Such effects would become apparent on the longer term (10 years) as both RO's are restrictions for placing on the market of granules and mulches for sport and play applications and thus would not affect ELT infill on existing pitches[23]. Predicting the short-term effect of the RO's on societal concern is difficult. The practicability (implementability, enforceability, manageability and monitorability) of RO2 and RO1 are expected to be comparable, as for both restriction there is no major additional

[22] Note that EPDM may contain PAHs if produced from recycled material. However, majority of EPDM used is expected to be virgin material and is not expected to contain PAHs.
[23] Note that the potential indirect effect of early replacement due to societal concern is not incuded in the analysis, but may be relevant, especially in RO2.

administrative burden on public authorities expected in terms of cost for implementation, monitoring, inspection and enforcement.

Table 20: Comparison of impacts of RO1 and RO2 compared to the baseline. Plusses and minuses indicate whether impacts are expected to be positive or negative for society and how they compare for RO1 and RO2. Plusses and minuses and qualitative estimates are the Dossier Submitters estimates based on the impact assessment.

Impact category	**Explanation**	**RO1**	**RO2**
Effectiveness (risk reduction)	*Human health (PAHs)*	+	++
	Human health (other effects/substances)	No change	+
	Environment (substances)	No change	++
	Environment (GHG)	No change	-
	Environment (microplastics)	No change	+
Economic impacts	*Tyre recycling and artificial turf market*	€ -70 to -40 million	€ -3 100 million
Wider economic impacts	*Company structure, job losses*	No change	€ -40 million
Social impacts	*Societal concern*	+/-	++/-
Practicability	*Implementability, enforceability manageability, monitorability*	+	+
Proportionality and affordability conclusion		Proportional and affordable	Not proportional, may be affordable to some actors

3. Assumptions, uncertainties and sensitivities

To describe the baseline and the impacts of RO1 and RO2, data have been interpreted and assumptions have been made by the Dossier Submitter. Assumptions were described and underpinned by the Dossier Submitter as far as possible in the relevant Annexes D and E. However, some uncertainties remain, especially with regard to the expected benefits of the restriction. The Dossier Submitter considers that these uncertainties may have an effect on the (quantitative) estimates of costs and benefits in the impact assessment. However, the overall conclusions on proportionality are not expected to change. Annex F provides an overview of the main uncertainties in the impact assessment of RO1 and RO2 compared to the baseline.

With respect to RO1, societal costs may be higher compared to the current estimate, e.g. if early replacement of existing pitches would occur as a result of the restriction. Costs could also be lower if for example less action needs to be taken to comply with the 17 mg/kg limit than estimated or if testing for PAHs already happens in the baseline situation by the majority of tyre recyclers and thus these costs appear to be overestimated. On the other hand, testing costs could be higher if the testing is more expensive than estimated in the analysis. The benefits of RO1 might be overstated, particularly because some of the worst case assumptions made in the theoretical maximum estimate of avoided cancer cases and as the underlying exposure assessment reflects a reasonable worst-case scenario. Benefits might also be underestimated (in the quantitative description of benefits), e.g. if high PAH concentrations happen to occur more often in the baseline situation than suggested by the available measurement data on which the impact assessment was based or if due to RO1 reduction in societal concern appears to be substantial. Overall, benefits and costs of RO1 are not expected to substantially change due to the uncertainties mentioned.

With respect to RO2, although some uncertainties may affect estimates of both costs and benefits, the overall effect on costs are expected to be more prominent as these are estimated to be orders of magnitude larger than the (quantified) upper bound of the benefits (avoided cancer cases). Effects on costs may go in both directions. For example, if quantities of infill/mulches appear to be underestimated, or if (part of the) existing pitches will face early replacement, costs may turn out to be substantially higher than estimated. It may, however, also be the case that alternatives become cheaper at increased demand or that the price difference between synthetic turf with ELT infill and alternative synthetic turf systems decreases significantly if costs are to be made to clean up environmental pollution if ELT is used. Due to this, societal costs of RO2 may be much smaller than estimated. What the net effect of all these uncertainties on the costs of RO2 will be, is not known. With respect to the benefits, the main uncertainty is on the 'other health and environmental benefits' that are out of scope of this restriction proposal and are therefore not further considered. The size of these other potential benefits is unknown. These other benefits are not the driver for this restriction proposal and other risk management measures may be more appropriate to address them. ECHA is further evaluating other potential risks related to the use of ELT infill in artificial turf systems in a separate project.

Overall, looking at both RO1 and RO2, uncertainties are not expected to change proportionality conclusions for this restriction proposal having the scope of carcinogenicity and PAHs, as the order or magnitude of effects are not expected to be changed.

4. Conclusion

The conclusion of the Dossier Submitter's hazard, exposure, risk assessment is that due to the permitted levels of eight carcinogenic Polycyclic Aromatic Hydrocarbons (REACH-8 PAHs) control of the human health risks following use of ELT-derived granules as infill material in synthetic turf pitches and granules or mulches applied in loose form on playgrounds and sport applications is not guaranteed. Human health risks are assessed for football players (including goalkeepers), playing children and for workers involved in installation and maintenance of pitches and playgrounds. Exposure estimates are combined in a range of lifelong exposure scenarios. The current limit values for the eight carcinogenic PAHs in mixtures supplied to the general public are not protective as the excess cancer risk following lifelong exposure of the general public to the granules and mulches containing REACH-8 PAHs up to the limit value is $5.9x10^{-5}$ (professional goalkeeper scenario). In the baseline situation looking at the PAH concentrations found in ELT infill material in the EU, a risk value of $3.2x10^{-6}$ is estimated at the 99 percentile (21 mg/kg for REACH-8 PAHs) and $2.6x10^{-6}$ at the 95 percentile (17 mg/kg for REACH-8 PAHs; professional goalkeeper scenario).

To indentify the most appropriate measure to address these risks, an analysis of risk management options (RMOs) was conducted, including other restriction options under REACH, other existing EU legislation and other possible Union-wide RMOs. The Dossier Submitter assessed two potential Restriction Options (ROs) as possible appropriate and evaluated these two RMO's, RO1 (17 mg/kg limit value) and RO2 (6.5 mg/kg limit value).

To decide whether the restrictions are promising from a societal perspective, the socio-economic impacts of RO1 and RO2 were assessed. The conclusions of this assessment are the following:

RO1: The Dossier Submitters assessed RO1 as affordable and proportional to society.

- (very) High PAH concentrations and consequent risk levels are avoided for the population that comes into contact with granules or mulches in sport and play applications.
- The residual cancer risk from PAH exposure will be at an acceptable level.
- Societal concern related to human health effects may be reduced as high PAH concentrations are reduced in a 10 year period as high PAH concentrations are avoided.
- No major additional administrative burden on public authorities expected in terms of cost for implementation, monitoring, inspection and enforcement.
- Relatively limited societal costs that are assessed to be affordable.

RO2: The Dossier Submitter assessed RO2 as possibly affordable for some actors, but not as proportional to society as a whole.

- (very) High PAH concentrations and consequent risk levels are avoided for the population that comes into contact with granules or mulches in sport and play applications.
- Cancer risk due to PAHs is reduced to zero, as the Dossier Submitter expects the end-of-market for recycled (ELT) granules at a 6.5 mg PAHs/kg limit value.
- Societal concern related to human health effects and related to environmental effects will be reduced in a 10 year period as high PAH concentrations are avoided.

- Possible ancillary benefits that were not analysed in detail, e.g. other health and environmental effects (which are out-of-scope for this restriction).
- No major additional administrative burden on public authorities expected in terms of cost for implementation, monitoring, inspection and enforcement.
- Relatively high societal costs.
- Some actors in the EU appear to be willing to pay the price, this RO may be affordable to some actors in society.

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

The proposed restriction option on PAHs in granules used as infill in synthetic turf pitches and mulches or granules used in loose form on playgrounds and in sport applications is described as follows:

Polycyclic-aromatic hydrocarbons (PAH) (a) Benzo[a]pyrene (BaP) CAS No 50-32-8 (b) Benzo[e]pyrene (BeP) CAS No 192-97-2 (c) Benzo[a]anthracene (BaA) CAS No 56-55-3 (d) Chrysen (CHR) CAS No 218-01-9 (e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2 (f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3 (g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9 (h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3	1. Granules or mulches shall not be placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications if these materials contain more than 17 mg/kg (0.0017 % by weight of this component) of the sum of the listed PAHs. 2. The restriction shall apply 12 months after its entry into force

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