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COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards polycyclic-aromatic hydrocarbons (PAHs) in granules or mulches used as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 68(1) thereof,

Whereas:

- (1) Entry 50 of Annex XVII to Regulation (EC) No 1907/2006 contains restrictions with respect to eight polycyclic-aromatic hydrocarbons (PAHs)².
- (2) Rubber granules are used as infill material in synthetic turf pitches. Rubber granules and mulches are also used in loose form on playgrounds or in sport applications, such as golf courses, athletic arenas, horse arena footings, nature trails, or shooting ranges. Those granules and mulches originate predominantly from End of Life Tyres (ELT). One of the main concerns over the use of ELT granules and mulches is the presence of the eight PAHs in the rubber matrix. Granules and mulches are mixtures within the meaning of Article 3(2) of Regulation (EC) No 1907/2006 and hence are not covered by the existing entry 50 of Annex XVII to that Regulation. However, the eight PAHs are listed as carcinogenic category 1B in Annex VI to Regulation (EC) No 1272/2008³. Therefore, entry 28 of Annex XVII to Regulation (EC) No 1907/2006 restricts the supply of granules and mulches to the general public, if those mixtures contain PAHs at concentrations equal to or above 100 mg/kg for BaP or DBAhA, or 1000 mg/kg for the other six PAHs.

¹ OJ L 396, 30.12.2006, p 1.

² 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).

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1).

- (3) To perform the risk characterisation of the granules or mulches containing the eight PAHs, the concentration limits of the individual PAHs in entry 28 of Annex XVII to Regulation (EC) No 1907/2006 cannot simply be summed up. By applying an additivity approach in accordance with the Guidance on the application of Regulation (EC) No 1272/2008⁴ and taking into account the relative contribution of the different PAHs to the PAH content in rubber granules and mulches, the maximum concentration limit for the sum of the eight listed PAHs can be calculated and is approximately 387 mg/kg⁵. The Rijksinstituut voor Volksgezondheid en Milieu (RIVM)⁶ and the European Chemicals Agency (hereinafter ‘the Agency’)⁷ concluded in 2017 that this calculated concentration limit for mixtures of the eight PAHs is too high to guarantee safe supply and use of these granules in synthetic turf pitches. In its evaluation, the Agency recommended lowering the concentration limit of the eight PAHs in granules used in synthetic turf pitches through a restriction under Regulation (EC) No 1907/2006 because the current concentration limits were considered too high to provide adequate protection for human health.
- (4) Based on those conclusions and evaluations, on 17 September 2018 the Netherlands (hereinafter ‘the Dossier Submitter’) submitted to the Agency an Annex XV dossier⁸, proposing a restriction on eight PAHs in granules for use as infill material in synthetic turf pitches and of granules or mulches in loose form on playgrounds or in sport applications.
- (5) The human health endpoint of utmost concern for these eight PAHs is carcinogenicity and the ability to induce genotoxic effects. For non-threshold carcinogens, a dose without a theoretical cancer risk cannot be derived. Therefore, the concentrations of the eight PAHs in granules used as infill material in synthetic turf pitches and in granules or mulches in loose form on playgrounds or in sport applications should be as low as possible.
- (6) The Dossier Submitter took into consideration various exposure scenarios related to the use of granules in synthetic turf pitches, by workers installing and maintaining the pitches and by individuals playing sports on them (professional and amateur outfield players and goalkeepers), and related to granules or mulches used in loose applications on playgrounds and in sport applications, where people and especially children may be exposed. Based on the sampling results by RIVM, excess cancer risks were estimated on the basis of the total concentration of the sum of the eight PAHs currently found in ELT infills. The concentration range found for those mixtures was from 6,7 mg/kg to 21 mg/kg.
- (7) The Dossier Submitter showed that there is an excess cancer risk for workers and general public exposed to rubber granules containing the calculated mixture concentration limit of 387 mg/kg of the sum of the eight PAHs, whereas at a much lower level of concentration the probability that an individual’s exposure to the listed PAHs could result in cancer was estimated considerably lower. The Dossier Submitter concluded that for a large part of producers, concentrations of 15 to 21 mg/kg of the sum of the eight PAHs in ELT landfill are technically and economically feasible, and

⁴ https://www.echa.europa.eu/documents/10162/23036412/clp_en.pdf

⁵ 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.

⁶ <https://www.rivm.nl/bibliotheek/rapporten/2017-0017.pdf>

⁷ https://echa.europa.eu/documents/10162/13563/annex-xv_report_rubber_granules_en.pdf/dbcb4ee6-1c65-af35-7a18-f6ac1ac29fe4

⁸ <https://www.echa.europa.eu/documents/10162/9777e99a-56fb-92da-7f0e-56fcf848cf18>

proposed to apply a concentration limit of 17 mg/kg. The Dossier Submitter estimated that 95 % of the ELT-derived infill material would comply with this concentration limit.

- (8) In order to ensure safe use of any granules or mulches and avoid substitution towards alternatives that may cause the same or even greater concern for human health than recycled rubber, the Dossier Submitter suggested that the restriction should cover mixtures made of recycled rubber and of other materials, may they be virgin or recycled, synthetic or natural materials.
- (9) As the limit value of 17 mg/kg proposed by the Dossier Submitter is significantly lower than the 100-1000 mg/kg limit values that are currently applicable to the granules, the restriction would mean that some ELT-derived granule producers would have to increase the rate of compliance testing and switch to cleaner production input or cease the production of infill material. The restriction would render 5 % of the currently produced granules non-compliant if the application of the restriction were to become effective immediately. Therefore, the Dossier Submitter suggested a transitional period of twelve months to allow a limited but reasonable period for downstream users (turf producers, distributors and companies installing the turf) to continue using granules that have already been supplied to them but do not comply with the proposed limit value of 17mg/kg).
- (10) On 7 June 2019, the Agency's Committee for Risk Assessment (RAC) adopted an opinion⁹ concluding that a PAHs content in rubber granules corresponding to the calculated concentration limit for mixtures in accordance with entry 28 of Annex XVII to Regulation (EC) No 1907/2006 is unacceptable and such levels for non-threshold substances should not be permitted and they do not provide an adequate level of protection to workers and the general public. RAC agreed that the PAH content should be lowered and, recommended a concentration limit of 20 mg/kg of the sum of the eight PAHs in rubber granules. RAC reiterated that the proposed 20 mg/kg limit is not based upon the estimated risk but it is a measure aimed solely at avoiding very high PAH concentrations. RAC furthermore indicated that with respect to risk reduction there is no significant difference between choosing 17 mg/kg over 20 mg/kg, recognising that, except for smokers, the greatest exposure to the general public is not from granules and mulches but from food sources and inhaled air.
- (11) RAC agreed with the Dossier Submitter that, while no supporting information on the content of the eight PAHs in cork, thermoplastic elastomers (TPE) and ethylene propylene diene rubber (EPDM) has been provided, the proposed PAH limit should apply to any other type of synthetic pitch infill material in order to avoid similar or greater risk through regrettable substitution.
- (12) For enforcement reasons, RAC recommended that the restriction with respect to granules or mulches placed on the market for use as infill material in synthetic turf pitches and in loose form on playgrounds or in sport applications require a specific marking referring to a unique batch number. This batch number allows the traceability of the material to a tested batch placed on the market. Furthermore, RAC recommended including definitions for granules, mulches, infill material in synthetic turf pitches and use in loose form on playgrounds and in sport applications.

⁹ <https://echa.europa.eu/documents/10162/0a91bee3-3e2d-ea2d-3e33-9c9e7b9e4ec5>

- (13) On 20 September 2019, the Agency's Committee for Socio-economic analysis (SEAC) adopted its opinion¹⁰, indicating that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks, taking into account its socio-economic benefits and its socio-economic costs. SEAC noted as well the preventive nature of the restriction.
- (14) SEAC agreed that the twelve-month deferral of application of the restriction initially proposed in the Annex XV dossier for a concentration level of 17 mg/kg, would also be appropriate for a concentration level of 20 mg/kg, in order to allow all concerned stakeholders to take the necessary compliance measures.
- (15) The Forum for Exchange of Information on Enforcement was consulted during the opinion making process and its recommendations were taken into account.
- (16) On 12 November 2019, the Agency submitted the opinions of RAC and SEAC to the Commission. Taking into account the Annex XV dossier and the RAC and SEAC opinions, the Commission considers that there is an unacceptable risk to human health from the placing on the market or use of granules or mulches containing PAH as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications that needs to be addressed on a Union wide basis. The Commission concludes that the restriction proposed in the Annex XV dossier, with the modifications proposed by RAC and SEAC, is the most appropriate Union-wide measure to address the risk identified to human health and that its socio-economic impact is limited.
- (17) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction. The application of the restriction should therefore be deferred by twelve months.
- (18) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (19) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen

¹⁰ <https://echa.europa.eu/documents/10162/53688823-bf28-7db7-b9eb-9807773b2109>