

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

Opinion

on an Annex XV dossier proposing restrictions on
Polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting

ECHA/RAC/RES-O-0000007147-73-01/F

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

13 September 2022

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
POLYCYCLIC AROMATIC HYDROCARBONS (PAHs)

13 September 2022

ECHA/RAC/RES-O-000007147-73-01/F

9 September 2022

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

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): Polycyclic aromatic hydrocarbons (PAHs)

EC No.: -

CAS No.: -

This document presents the opinion adopted by RAC and the Committee's justification for its opinion. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration> on **22 December 2021**. Interested parties were invited to submit comments and contributions by **22 June 2022**.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
POLYCYCLIC AROMATIC HYDROCARBONS (PAHs)

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Pietro PARIS

Co-rapporteur, appointed by RAC: Geneviève DEVILLER

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **13 September 2022**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Klaus URBAN

Co-rapporteur, appointed by SEAC: Silke GABBERT

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **9 September 2022**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at <https://echa.europa.eu/restrictions-under-consideration> on **14 September 2022**. Interested parties were invited to submit comments on the draft opinion by **14 November 2022**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**]¹.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and]⁵ 71(1) of the REACH Regulation.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and]³ 71(1)]⁶.

The opinion of SEAC was adopted **by [consensus.] [a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available

¹ Delete the unnecessary part(s)

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in a separate document which has been published at the same time as the opinion.】⁶.

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1. Proposed restriction

Substance Identity (or group identity)	Conditions of the restriction
<p>Polycyclic aromatic hydrocarbons (PAHs)</p> <p>(a) Acenaphthene, CAS No 83-32-9, EC No 201-469-6</p> <p>(b) Acenaphthylene, CAS No 208-96-8, EC No 205-917-1</p> <p>(c) Anthracene, CAS No 120-12-7, EC No 204-371-1</p> <p>(d) Benzo[<i>a</i>]anthracene, CAS No 56-55-3, EC No 56-55-3</p> <p>(e) Benzo[<i>a</i>]pyrene, CAS No 50-32-8, EC No 200-028-5 (Benzo[<i>def</i>]chrysene)</p> <p>(f) Benzo[<i>b</i>]fluoranthene, CAS No 205-99-2, EC No 205-911-9 (Benzo[<i>e</i>]acephenanthrylene)</p> <p>(g) Benzo[<i>e</i>]pyrene, CAS No 192-97-2 EC, No 205-892-7</p> <p>(h) Benzo[<i>ghi</i>]perylene, CAS No 191-24-2, EC No 205-883-8</p> <p>(i) Benzo[<i>j</i>]fluoranthene, CAS No 205-82-3, EC No 205-910-3</p> <p>(j) Benzo[<i>k</i>]fluoranthene, CAS No 207-08-9, EC No 205-916-6</p> <p>(k) Chrysene, CAS No 218-01-9, EC No 205-923-4</p> <p>(l) Dibenzo[<i>a,h</i>]anthracene, CAS No 53-70-3, EC No 200-181-8</p> <p>(m) Fluoranthene, CAS No 206-44-0, EC No 205-912-4</p> <p>(n) Fluorene, CAS No 86-73-7, EC No 201-695-5</p> <p>(o) Indeno[1,2,3<i>cd</i>]pyrene, CAS No 193-39-5, EC No 205-893-2</p> <p>(p) Naphthalene, CAS No 91-20-3, EC</p>	<p>From [<i>date of entry into force of the restriction</i>], clay targets shall not be placed on the market or used for shooting if they contain more than 10 000 mg/kg (1 % by weight of dry mass of the clay target) of the sum of all listed PAHs.</p> <p>From [<i>date + 1 year from entry into force of the restriction</i>], clay targets shall not be placed on the market or used for shooting if they contain more than 50 mg/kg (0.005 % by weight of dry mass of the clay target) of the sum of all listed PAHs.</p>

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No 202-049-5 (q) Phenanthrene, CAS No 85-01-8, EC No 201-581-5 (r) Pyrene, CAS No 129-00-0, EC No 204-927-3	
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1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document.

RAC considers that the restriction proposed by the Dossier Submitter on **polycyclic aromatic hydrocarbons (PAHs), CAS -, EC -** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion.

RAC notes that:

- Clay targets are articles produced using a hot moulding process involving a filler (e.g. milled limestone) and a 'binder' (e.g. coal-tar pitch, high temperature, or other substances). Binders may be substances of unknown or variable composition (UVCB) containing various PAHs constituents. The PAHs composition of a binder is often unknown.
- Many individual PAHs have been formally identified to have carcinogenic and/or PBT/vPvB properties, via harmonised classification and/or identification as SVHC. Minimising releases and exposures to all PAHs is considered to be warranted.
- For reasons of practicality (including enforceability), the proposed restriction is based on a suite of indicator PAHs. The approach is consistent with previous restrictions under REACH on PAHs.
- The selection of indicator PAHs was based on existing rules in the clay target shooting sector.

1.2. THE OPINION OF SEAC

See SEAC opinion.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

The proposed restriction aims at preventing the release of polycyclic aromatic hydrocarbons (PAHs) to the environment from the use of clay targets for shooting.

Clay targets (also known as clay pigeons) are flying (saucer-shaped) targets used by sports shooters and small game hunters to practice. They are produced using binders such as coal tar pitch, high temperature (CTPHT), petroleum pitch or other types of resins.

CTPHT was included in Annex XIV of REACH (the Authorisation List) due to its carcinogenic, persistent, bioaccumulative and toxic (PBT), and very persistent and very bioaccumulative (vPvB) properties (Commission Regulation (EU) No 2017/999). These properties are due to the presence of PAHs. In 2019, ECHA received two applications for authorisation for the use of CTPHT as a binder in clay targets for sports shooting. The Committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) evaluated these applications and concluded that the continued use of CTPHT in clay targets would lead to a risk to human health and the environment through the release of several hundred tonnes of PAHs per year. On 16 March 2022, the Commission decided not to grant authorisation for the use of CTPHT as a binder in the manufacture of clay targets.

Several substances are used as alternative binders to CTPHT for clay targets in the EU. While these alternatives typically have lower concentrations of PAHs than CTPHT, many also contain PAHs. Alternatives with very low PAHs-content and PAHs-free alternatives are also available. In order to ensure a high protection of human health and the environment in the EU and avoid regrettable substitution, the Commission requested ECHA on 2 July 2021 to prepare an Annex XV restriction dossier on substances containing PAHs in clay targets for shooting complementary to, and incorporating, an Article 69(2) restriction proposal for CTPHT in clay targets.

ECHA (hereafter referred to as the Dossier Submitter) concluded that the use of PAHs-containing binders in clay targets poses an EU-wide risk that is not adequately controlled. This applies equally to clay targets containing CTPHT and to those produced with alternative binders that also contain PAHs.

Based on the available information on alternatives and an analysis of the socio-economic impacts of a series of different restriction options underpinned using different concentration limits of PAHs in clay targets, the Dossier Submitter proposes to restrict the placing on the market and use in shooting of clay targets containing more than a 0.005 % by weight of the sum of the concentrations of 18 indicator polycyclic aromatic hydrocarbons (PAHs).

The proposed restriction is both effective in reducing the risk (with a reduction of at least 99.3 % of the baseline releases) and cost-effective (with total costs of 3.6€ million per year, C/E -ratio of 13.5€/kg and marginal abatement cost at 130€/kg).

The proposed restriction is practical and monitorable. As there are very many different PAHs and their presence in the binders is variable, it is practical to base the conditions of the restriction on the concentration of a suite of measurable and well-known PAHs that serve as indicators for the presence of other PAHs. Consequently, limiting the concentration of these 18 indicator PAHs in clay targets also limits the concentration of other PAHs in clay targets. To facilitate the practicality of the restriction, the suite of indicators is aligned with existing rules of the International Sport Shooting Federation (ISSF) for clay targets used in their competitions; which impose a concentration limit of 0.005 % w/w for the sum of 18 indicator PAHs. Calibration standards and analytical methods for enforcement are readily available for the indicator PAHs. Clay targets can be purchased from the markets and sampled to monitor risk reduction.

2.2. Summary of opinion

RAC concluded that targeting the restriction to binder substances containing PAHs in clay targets for shooting is clear and sufficiently justified. RAC and SEAC did not support the applications for authorisation for the use of CTPHT as a binder in clay targets, because the continued use of this substance would pose an unacceptable risk to human health and the environment. Despite the fact that the authorisations were not granted, the concerns raised still apply to clay targets containing CTPHT imported into the EU, as well as to clay targets manufactured with other binders containing PAHs.

RAC supported the general approach, already adopted in previous restrictions, to base the restriction on a concentration limit of selected indicator PAHs. Limiting the concentration of the selected indicator PAHs in clay targets would also be likely to reduce emissions of other PAHs that could be present in some binder substances, as PAHs constituents are expected to occur concurrently.

RAC notes that the hazard assessment of substances containing PAHs in clay targets for shooting is based on information on PAHs with recognised carcinogenic and/or PBT and/or vPvB properties. RAC supports the assumption that PAHs is a group of substances having similar concerns as the PAHs with formally recognised carcinogenic and PBT, vPvB properties.

RAC concludes that the presence of PAHs with non-threshold hazardous properties in clay targets for shooting introduces a need to minimise releases and exposures to protect human health and the environment. RAC agrees that emissions of non-threshold substances are a suitable proxy of risk. This is consistent with previous restrictions where emission characterisation has been the basis for both risk characterisation and the evaluation of the effectiveness of the proposed restriction. RAC agrees with the approach taken by the Dossier Submitter to estimate the releases based on the selected 18 indicator PAHs and that it provides a sufficient basis to conclude that current and potential future uses of PAHs containing clay-targets lead to releases of substances with PBT, vPvB and carcinogenic properties to the environment.

RAC agrees with the Dossier Submitter that, following initial release, a fraction of the larger fragments of clay targets may be collected and disposed of. However, this is considered to be ineffective in limiting the release of PAHs to the environment as releases could still be expected (e.g. from landfills). The collection of fragments would also lead to additional exposure of consumers.

RAC agrees with the Dossier Submitter that, even if not quantified, the PAHs released during the production of clay targets are expected to be several orders of magnitude lower than release from the article service life stage. RAC agrees with the Dossier Submitter that occupational exposure, human exposure from the handling and shooting of clay targets, and related human health (cancer) risks are, whilst not considered quantitatively, supporting evidence to justify the need for a restriction.

RAC agrees with the Dossier Submitter that, under the baseline scenario, at least 270 tonnes of PAHs per year are estimated to be released to the environment from placing on the market and use of PAHs-containing clay targets.

RAC agrees with the Dossier Submitter that the operational conditions and risk management measures currently used are not appropriate and effective in limiting the risk for the environment nor for workers producing the clay targets.

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting should be implemented in all Member States.

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Based on the available information, RAC concludes that the existing regulatory risk management instruments, acknowledging the existing national restrictions in Austria, Belgium and the Netherlands, and the obligations under the persistent organic pollutants (POP) regulation (Regulation (EU) 2019/1021), are insufficient to control the risk of PAHs in clay targets for shooting when considered on an EU wide basis.

RAC agrees a REACH restriction would be the most effective risk management measure to reduce exposure to PAHs from clay targets for shooting containing PAHs and agrees with the Dossier Submitter that there is no justification for derogations.

RAC agrees with the Dossier Submitter to set an interim total 18-PAHs concentration limit of 1 % that would prevent the use of CTPHT as a binder in imported clay targets, but temporarily allow other PAHs containing binders. However, RAC notes that a one-year transitional period would lead to an additional release of at least 150 tonnes of the 18 indicator PAHs.

Four restriction options were analysed with different limits for the sum of the concentration of the 18 indicator PAHs in clay targets. RAC concludes that the proposed restriction option RO3, with a concentration limit of 0.005 % w/w in clay targets for the sum of the 18 indicator PAHs, is capable of reducing the identified risks by about 99 %, in reasonable time, from placing on the market and use of clay targets for shooting.

Only restriction option RO4 would ensure a complete cessation of releases of PAHs from clay targets for shooting as it would allow only natural resin-based clay targets, that do not contain PAHs, on the market. However, due to the ongoing PBT assessment of some resins and rosins and potential concern for reproductive toxicity, RAC cannot currently comprehensively assess the risk reduction achieved by use of these alternatives in clay targets for shooting.

RAC conclude that the proposed restriction (RO3) is practical and enforceable. It can be expected that the analytical methods currently used for the identification and quantification of PAHs in general could be readily adapted for use in clay targets. RAC notes that the proposed restriction is consistent with already existing rules in the sector providing a clear legal basis for companies and enforcement authorities.

RAC consider the risk reduction achieved by the proposed restriction to be monitorable by measuring the concentration of the sum of indicator PAHs in clay targets on the market over time.

RAC concludes that the uncertainties highlighted on the risk characterisation, i.e. hazard and exposure assessments, are minor and do not significantly affect the effectiveness, practicality nor the monitorability of the restriction proposal as regards the ability to reduce the risk deriving from the presence of PAHs in clay targets.

RAC notes that composition information (and corresponding risk profile) of the alternative binders is often incomplete, i.e. for binders with a sum of the concentration of the 18 indicators PAHs below the limit, still allowed to produce clay targets after the entry into force of the restriction. This leads to a residual concern that PAHs, other than indicator PAHs, could be present in binders that are compliant with the conditions of the restriction. It is not possible to address this uncertainty with the information on substances composition that is currently available. Therefore, to confirm the high level of effectiveness anticipated for this restriction, RAC recommends that the presence and concentration of other PAHs (not part of the list of indicators) should be investigated in clay targets placed on the market after the restriction has fully entered into force.

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

3.1.1. Description of and justification for targeting (substance and use scope)

Summary of proposal:

The proposal aims at restricting the presence of substances containing PAHs in clay targets. The Dossier Submitter proposes to restrict the placing on the market and use in shooting of clay targets containing more than a limit concentration of PAHs and has selected 18 PAHs to be used as indicators for the presence of PAHs in general in clay targets.

Four restriction options were analysed with different limits for the sum of the concentration of these 18 indicator PAHs in clay targets (1 %, 0.1 %, 0.005 % and 0.000 1 % by weight).

Based on this analysis, the Dossier Submitter proposes a ban of the placing on the market and use in shooting of clay targets containing more than 1 % by weight of the sum of the concentrations of 18 indicator PAHs applicable immediately from the entry into force of the restriction; one year after the entry into force of the restriction, the concentration limit value will be lowered from 1 % to 0.005 % (w/w) (50 mg/kg).

In practice, limiting the concentration of the indicator PAHs will prevent the use of certain binders, which contain PAHs, to manufacture clay targets, as the concentration of PAHs in these binders is above the concentration limit suggested in the proposed restriction. Alternative binders that would meet the proposed concentration limit would not be restricted.

Because there are very many PAHs and the composition of the binders varies due to their variable and complex nature (substances of unknown or variable composition, complex reaction products or biological materials (UVCB)), it is practical to base a concentration limit on measurable and well-known PAHs that, at the same time, can serve as indicators for the presence of other PAHs. As a consequence, reducing the concentration of indicator PAHs also reduces the concentration of other PAHs in clay targets.

The Dossier Submitter considers that it is practical to align the restriction with existing voluntary rules in the sector. The rules of the International Sports Shooting Federation (ISSF) impose a limit of 0.005 % (w/w) for the sum of 18 indicator PAHs in clay targets, for the Olympic Games, World Championships, World Cups, World Cup Finals and Junior World Cups.

Information on the hazards and concentrations of these 18 PAHs in clay targets is sufficient to underpin the need for a restriction.

RAC conclusion(s):

RAC recognises that the intended target of the restriction is binder substances containing PAHs in clay targets for shooting and that the information on the risks of some PAHs is sufficient to underpin the need for a restriction.

RAC concludes that although the Dossier Submitter did not assess hazards and risks of all PAHs as a group, a conservative approach can be taken to assume that similar concerns apply to all PAHs.

RAC supports the general approach, already adopted in previous restrictions for PAHs, to base the restriction on a concentration limit of selected PAHs in clay targets.

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Key elements underpinning the RAC conclusion:

The aim of this restriction proposal is to protect human health and the environment against the exposure to PAHs with carcinogenic, PBT and/or vPvB properties (hereafter referred to as hazardous properties) released to the environment during clay target shooting activities. The presence of PAHs with such hazardous properties in binder substances, as reported in the Background Document, confirms the risk from the use of clay targets manufactured with these binders, underpinning the need for a restriction.

The Dossier Submitter considered that the selected indicator PAHs have a similar level of concern regarding the carcinogenic and PBT, vPvB properties, but no group assessment of the hazards of PAHs was reported in the Background Document. Some PAHs are formally recognised as having carcinogenic and/or PBT/vPvB properties (i.e. via the CLP regulation and the SVHC identification according to Articles 57(d) and 57(e)) but some are not. However, RAC acknowledges that the lack of harmonised classification or SVHC identification for carcinogenic and/or PBT, vPvB properties is not the result of an assessment that these PAHs lack these properties, but may on the contrary be the result of the lack of data or regulatory effort to assess them. Therefore, RAC supports an assumption that PAHs are a group of substances having similar concern.

Conventional clay target binders are UVCB substances containing mixtures of PAHs as well as additional uncharacterised constituents. The approach to consider suites of PAHs has already been implemented in previous restrictions for PAHs (e.g. entry 50 of Annex XVII of REACH) and is considered also applicable to clay targets. The proposed restriction establishes a concentration limit for PAHs in clay targets using 18 indicator PAHs. The presence of these 18 indicator PAHs in clay targets is assumed by the Dossier Submitter to be indicative of the presence of PAHs in general within clay targets. Confidential Annex 2 of the Background Document reports the composition of 21 binders and reports that the 18 indicator PAHs have not been analysed exhaustively nor consistently in different binders. When analysed, all of the indicators were detected in 15 of the binders (one to three of the indicators were below the detection limit in the other six binders: three CTPHT and three petroleum pitches). Other PAHs were analysed and detected in 13 binders at various concentrations, i.e. from 12 to 15 in CTPHTs, from one to 27 in petroleum pitches, from one to two in petroleum resins, and one to two in the other resins. No correlation can be established between the presence of the indicator PAHs and the total PAHs content of the binder substances because their composition is mostly unknown.

Only CTPHT and petroleum pitch are specifically registered under REACH for use as a binder in clay targets and, although compositions have to be reported in registrations (Annex VI), the composition of the registered reference materials may not reflect all batches or products nor the composition in imported clay targets. Other resins (i.e. eco-resins and natural resins) are also known to be used as binders in clay targets but there are uncertainties related to their identification (names, CAS and EC numbers). Some are considered to be polymers and are therefore not registered under REACH.

RAC notes that there are almost no data on the concentration of PAHs in eco-resins and natural resins. By definition, "eco-resins" should fulfil the PAHs concentration limit of the ISSF rules (and RO3 definition) and contain low concentration of the targeted PAHs; "natural resins" are those that do not contain PAHs (as per RO4). However, RAC notes that five resins reported in the Background Document as "eco-friendly" are known (based on their registration dossiers) to have in some cases very high naphthalene concentrations (higher than the total PAHs content in CTPHT).

The 18 indicator PAHs proposed to implement the restriction will prevent the use of CTPHT, petroleum pitch, petroleum resin and some other resins, listed in the Background Document, to produce clay targets, as the concentration of the selected PAHs in their composition is too high to meet the concentration limit proposed in the restriction (0.005 % w/w for the sum of the concentration of 18 indicator PAHs). However, because composition data are scarce, it is

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not known to which extent other resins would be affected or would still be allowed. The possibility cannot be excluded that alternative binder substances that are compliant with the proposed restriction, based on the suite of 18 indicator, PAHs could theoretically contain high concentrations of other PAHs. The very high concentration of only one indicator PAH (naphthalene, reported in the registration dossiers of some resins, as identified in the Background Document), supports the feasibility of such a scenario. In this scenario, binders containing very low concentrations of the indicator PAHs, but higher concentrations of other PAHs, could still be used under the proposed restriction.

3.1.2. Description of the risk(s) addressed by the proposed restriction

3.1.2.1. Information on hazard(s)

Summary of proposal:

The hazard assessment of the binders used in clay targets is based on the properties of PAHs with known carcinogenic, PBT and vPvB properties, or which are identified as persistent organic pollutants (POP). Although for pragmatic reasons a list of 18 indicator PAHs is the focus of the hazard assessment, other polycyclic aromatic compounds (PACs), such as larger PAHs, alkylated PACs and compounds containing heteroatoms, are also of concern. They are less studied and less frequently regulated but can display toxicity profiles of concern (Andersson and Achten, 2015). Several PAHs and heterocyclic compounds have been quantified in the substances impacted by the restriction, but not consistently.

Many of the PAHs in PAHs-containing binders are genotoxic carcinogens. The data supporting carcinogenicity and genotoxicity has been extensively discussed elsewhere (e.g. RIVM, 2018, ECHA, 2019) and these properties have been formally recognised via harmonised classification² and identification as SVHC³. In addition, three PAHs (not among the 18 PAHs used as indicators) were recently included to Annex VI to CLP⁴ for Carc. 1B and Muta. 2: benzo[*rst*]pentaphene (EC No. 205-877-5), also known as dibenzo[*a,i*]pyrene, dibenzo[*b,def*]chrysene (EC No. 205-878-0), also known as dibenzo[*a,h*]pyrene and dibenzo[*def,p*]chrysene (EC No. 205-886-4), also known as dibenzo[*a,l*]pyrene.

Additional PAHs may be genotoxic carcinogens even if they are not listed in Annex VI to the CLP Regulation. Furthermore, some of the binders are themselves classified as carcinogenic/mutagenic: CTPHT is considered to be a non-threshold carcinogen and has a harmonised classification as Carc. 1A and Muta. 1B; petroleum pitch and resin are classified as Carc. 1B and Muta. 1B in their registration dossiers; the substance EC No. 305-586-4 is classified as carcinogenic and mutagenic in its registration dossier (the exact category depends on its constituents – the most severe classification in the registration dossier is Carc. 1A and Muta 1B); [Resin 3] (confidential identifier) has a harmonised classification as Carc. 1B that applies when the concentration of polycyclic aromatics is above a limit⁵.

² Naphthalene (Carc. 2, H351), benz[*a*]anthracene (Carc. 1B, H350), chrysene (Muta. 2, H341; Carc. 1B, H350), benzo[*def*]chrysene (benzo[*a*]pyrene) (Muta. 1B, H340; Carc. 1B, H350), benzo[*e*]acephenanthrylene (benzo[*b*]fluoranthene) (Carc. 1B, H350), benzo[*e*]pyrene (Carc. 1B, H350), benzo[*j*]fluoranthene (Carc. 1B, H350), benzo[*k*]fluoranthene (Carc. 1B, H350), dibenz[*a,h*]anthracene (Carc. 1B, H350).

³ Benz[*a*]anthracene (according to Article 57(a)), chrysene (according to Article 57(a)), benzo[*a*]pyrene (according to Article 57(a)(b)), benzo[*k*]fluoranthene (according to Article 57(a)).

⁴ 14th ATP, in force from 9 September 2021, and 15th ATP, in force from 1 March 2022.

⁵ Note L: The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346 'Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions – Dimethyl sulphoxide extraction refractive index method', Institute of Petroleum, London. This note applies only to certain complex oil-derived substances in Part 3.

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Nine PAHs have been identified as SVHC according to Articles 57(d) and/or 57(e)⁶. In the Support Document for identification of CTPHT as an SVHC (ECHA, 2009), the Member State Committee concluded that CTPHT is a substance containing at least 5 to 10 % of PAHs-constituents with both vPvB and PBT properties and stressed that it should be considered that residual constituents of CTPHT may have a structure similar to the selected indicator PAHs with PBT or vPvB properties. Similarly, petroleum pitch consists of at least 1.9 % PAHs that are formally identified as vPvB and PBT (SVHC). Petroleum resin contains at least 0.2-0.3 % PAHs that are formally identified as vPvB and PBT (SVHC). In reality, the fraction of PAHs meeting the vPvB or PBT criteria may be much larger.

PAHs are subject to release reduction provisions under the POP Regulation (Annex III, part B, of Regulation (EU) 2019/1021).

RAC conclusion(s):

The hazard assessment of substances containing PAHs in clay targets for shooting is based on information on PAHs with recognised carcinogenic and/or PBT and/or vPvB properties. RAC notes that the hazardous properties of all PAHs as a group were not assessed by the Dossier Submitter. RAC agrees that a conservative approach can be taken to assume that similar concerns apply to all PAHs.

RAC concludes that the presence of PAHs with non-threshold hazardous properties in clay targets for shooting introduces a need to minimise releases and exposures to protect human health and the environment.

Key elements underpinning the RAC conclusion(s):

Several PAHs are known genotoxic carcinogens and/or PBT, vPvB substances that have been extensively evaluated by European agencies (i.e. EFSA and ECHA) and international institutions (e.g. the International Programme on Chemical Safety, the US EPA, the Scientific Committee on Food, the Joint FAO/WHO Expert Committee on Food Additives). The presence of PAHs with non-threshold hazardous properties introduces a need to minimise releases and exposures to protect human health and the environment.

Twenty-one binder substances used for clay target production, out of the 23 reported in the Background Document, are classified as carcinogenic 1A or 1B either by harmonised classification (CTPHT and resin 3) or self-classification (petroleum pitch, petroleum resin and substance EC 305-586-4) under the CLP regulation. CTPHT has been identified as SVHC according to Articles 57(a), 57(d) and 57(e) based on its carcinogenic, PBT and vPvB properties.

Overall, 14 PAHs detected in clay target binders have a harmonised classification for carcinogenicity and/or are recognised as PBT, vPvB, and 1 PAH (without harmonised classification and not SVHC) is an indicator for release reduction provisions for PAHs under the POP regulation (Annex III, part B, of Regulation (EU) 2019/1021). They are all included in the list of 18 PAHs proposed as the basis for the restriction, except dibenzo[*a,h*]pyrene (CAS 189-64-0, EC No. 205-878-0). Dibenzo[*a,h*]pyrene has recently been included in Annex VI of CLP (14th ATP, in force from 9 September 2021) as Carc. 1B and Muta. 2, and is detected in some binders. RAC notes that several binders contain naphthalene, which has a harmonised classification as carcinogenic category 2, and considers that these binders as not suitable

⁶ Anthracene (PBT), phenanthrene (vPvB), fluoranthene (PBT, vPvB), pyrene (PBT, vPvB), benz[*a*]anthracene (PBT, vPvB), chrysene (PBT, vPvB), benzo[*def*]chrysene (benzo[*a*]pyrene) (PBT, vPvB), benzo[*k*]fluoranthene (PBT, vPvB) and benzo[*ghi*]perylene (PBT, vPvB). Due to a lack of data, it has only been concluded that benzo[*b*]fluoranthene fulfils the vP and T criteria, indeno[1,2,3-*cd*]pyrene fulfils the T criteria and dibenzo[*a,h*]anthracene fulfils the vB and T criteria.

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alternatives for producing clay targets.

RAC notes that other PAHs, not included in the list of indicators proposed by the Dossier Submitter, may also have carcinogenic properties or meet the vPvB or PBT criteria. In addition to dibenzo[*a,h*]pyrene, two PAHs have recently been included in Annex VI of CLP as Carc. 1B and Muta. 2, i.e. dibenzo[*a,i*]pyrene (CAS No 189-55-9, EC No. 205-877-5) (14th ATP), and dibenzo[*a,l*]pyrene (CAS 191-30-0, EC No. 205-886-4) (15th ATP, in force from 22 March 2022).

To RAC's knowledge, all formally recognised PBT, vPvB PAHs (via SVHC identification) and indicators under the POP regulation are included in the proposed list of 18 indicator PAHs.

RAC notes that four PAHs measured in clay target binders with notified classifications or self-classifications from registrations in the hazard class carcinogenicity are not included in the list of indicators proposed by the Dossier Submitter (i.e. anthanthrene, carbazole, 1-methylphenanthrene, dibenzo[*a,e*]pyrene).

Three PAHs in the proposed list of indicators, i.e. acenaphthylene (CAS 208-96-8, EC 205-917-1), acenaphthene (CAS 83-32-9, EC 201-469-6) and fluorene (CAS 86-73-7, EC 201-695-5) do not have a harmonised classification as carcinogenic, are not identified as PBT/vPvB and are not indicators under the POP regulation.

RAC notes that other PAHs may receive a harmonised classification or be identified as SVHC in the future.

3.1.2.2. Information on emissions and exposures

Summary of proposal:

The Dossier Submitter considered that 100 % of the clay targets are released to the environment during their use. The Dossier Submitter initially explicitly indicated that releases are to the soil compartment. However, releases to the aquatic compartment may also occur (due to shooting over fresh or marine water, e.g. from a ship). However, the general consideration that 100 % of the clay targets are released to the environment is unchanged and is therefore applicable to the environment as a whole, including soil and water. Once released, clay target fragments are a continuous source of PAHs until eventually virtually all constituents are transferred to other environmental compartments (which can lead to contamination of drinking water, plants, animals (thus food)), or are degraded. In addition, the following assumptions have been used by the Dossier Submitter to estimate the releases:

- 400 million clay targets per year are placed on the EU market in the baseline scenario;
- a clay target typically weighs 105 g and contains about 33 % of binder material.

The releases from the use of clay targets are therefore estimated to about 270 tonnes per year in the baseline scenario. The releases were calculated for the 18 indicator PAHs.

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Table 2. Estimated release of PAHs during the use of clay targets (baseline scenario)

Binder	18 PAHs concentration in binder (%)	PAHs concentration in clay targets (%)	Total, million clay targets	Total annual releases (t of PAHs) per target	Total annual releases (tonnes of PAHs)
CTPHT	7.9	2.6	60	2.7×10^{-6}	164.2
Petroleum Pitch	2.4	0.79	116	8.3×10^{-7}	96.5
Petroleum Resin	0.2 – 0.3	0.07 – 0.10	122	6.9×10^{-8} - 1.0×10^{-7}	8.5 - 12.7
Eco Resin and Natural Resin (sum of 18 PAHs <0.005 % in clay targets) MAX based on limit	0.015	0.005	102	5.2×10^{-9}	0.5
Total			400		269.7 - 273.9

It has been estimated that the releases during the production of the clay targets are negligible, although not nil, compared to the releases during service life.

The exposure of workers and consumers was assessed qualitatively in Sections B.2.2.1 and B.2.3.1 in the Background Document.

The Dossier Submitter identified some uncertainties related to the estimation of releases, which are addressed in Section 3.2 in the Background Document. Specifically, uncertainties on the identity of the binder materials and the alternatives and on the RMMs which may be used (e.g. collection of fragments and their disposal).

RAC conclusion(s):

RAC notes that the assessment of exposure is based on the concentration of the selected 18 indicator PAHs in clay targets, which represent an unknown percentage of the total PAHs content.

RAC agrees that, even if uncertain, the release estimates of PAHs provide a sufficient basis to conclude that the use of clay targets containing PAHs results in releases of substances with PBT, vPvB and carcinogenic properties to the environment.

RAC agrees that, during the use of clay targets, 100 % of the PAHs are released to the environment and all environmental compartments are affected, which can lead to contamination of drinking water, plants, animals and food.

RAC notes that the Dossier Submitter has not estimated the releases from the use of clay targets purchased before the expected entry into force of the restriction, but used after the entry into force. Furthermore, the Dossier Submitter did not estimate the releases of clay targets that are not 'placed on the market' as such (e.g. carried on cruise ships for shooting over water).

RAC recognises that at least approximately 270 tonnes per year of emissions to the environment of PAHs are estimated to result from placing on the market and use of PAHs-containing clay targets under the baseline assumptions. Similar release estimates are obtained when considering only releases of 16 PAHs which are carcinogenic based on harmonised classification and/or are SVHC (PBT/vPvB) and/or POP indicator.

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RAC agrees that, following initial release, a fraction of the larger fragments of clay targets may be collected and disposed of, although this fraction is unknown. On the other hand, the nature and effectiveness of the waste treatment of the collected fraction is similarly unknown and may lead to releases of PAHs to the environment (e.g. from landfills).

RAC agrees that, even if not quantified by the Dossier Submitter, the PAHs released during the production of clay targets are expected to be several orders of magnitude lower than release from the article service life stage.

RAC agrees that occupational exposure and exposure from the handling and shooting of clay targets, as discussed by the Dossier Submitter, are not a main driver for the restriction proposal, but they are considered only qualitatively as supporting evidence to justify the need for a restriction and for the impact assessment.

Key elements underpinning the RAC conclusion(s):

Environmental releases

Table 3 shows the current market situation in the EU and the total releases of PAHs, quantified based on the 18 indicators proposed by the Dossier Submitter and the 16 PAHs, classified for carcinogenicity (based on harmonised classification) and/or are SVHC (PBT/vPvB) and/or POP indicator⁷, which were quantified in the binder substances reported in the Annex 2 of the Background Document. In the baseline, the Dossier Submitter assumed that the authorisations for the use of CTPHT in clay targets would not be granted. This assumption is now confirmed as the authorisation have indeed not been granted⁸.

Table 3. Estimated releases of PAHs during the use of clay targets (baseline scenario)

Binder	Producer in the EU, million clay targets	Imported (UK and Russia), million clay targets	Total, million clay targets	PAHs content in clay targets (%)		Total annual releases of PAHs (tonnes/year)	
				DS list of 18 indicator PAHs	Carc/SVHC /POP indicator PAHs ⁷	DS list of 18 indicator PAHs	Carc/SVHC/POP indicator PAHs ⁷
CTPHT	0	60	60	2.61	2.64	164	166
Petroleum Pitch	116	0	116	0.79	0.75	96	91
Petroleum Resin	122	0	122	0.07	0.07	9	9
Eco Resin* and Natural Resin	72	30	102	0-0.0009 (or below 0.005)	0-0.0009 (or below 0.005)	1 (or below)	1 (or below)
Total	310	90	400			270	267

* Content and releases calculated based on the concentration limit of RO3.

The following assumptions have been used to calculate the baseline release of PAHs to the environment from PAHs-containing binders in clay targets:

⁷ Naphthalene, anthracene, phenanthrene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[a]pyrene, benzo[b]fluoranthene, benzo[e]pyrene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[ghi]perylene, indeno[1,2,3cd]pyrene, dibenzo[a,h]anthracene, dibenzo[a,h]pyrene.

⁸ Decisions available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323\(03\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323(03)&from=EN) and [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323(02)&from=EN)

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- About 400 million clay targets (the range is 300-500) per year are placed on the EU market in the baseline scenario, out of which approximately 300 million are under the scope of the proposed restriction RO3 (see section 1.4 of the Background Document).
- A clay target typically weighs 105 g and contains about 33 % of binder material. The PAHs content in the clay target can be calculated based on the PAHs content in the binder material.
- An initial release to the environment of 100 % of the PAHs in the clay targets is assumed. All environmental compartments are affected by releases, whereas the immediate receiving compartment is soil⁹. Although subsequent transfer from the soil to other environmental compartments is slow, once released, the clay target particles are a continuous source of PAHs, which can lead to contamination of drinking water, plants, animals and food.

About 270 tonnes of PAHs per year of emissions to the environment are estimated to result from placing on the market and use of PAHs-containing clay targets under the baseline assumptions, considering the list of indicators as proposed by the Dossier Submitter.

A similar release of 267 tonnes per year has been estimated by RAC under the baseline scenario, considering the 16 PAHs with harmonised classification for carcinogenicity and/or identified as SVHC (PBT/vPvB) and/or POP indicator, for which data are available regarding their concentration in binders. Among the 16 PAHs, only one substance, dibenzo[*a,h*]pyrene (CAS 189-64-0, EC No. 205-878-0), out of the three carcinogenic PAHs recently added to the CLP-Regulation¹⁰, could be taken into account in this release estimation (for CTPHT and petroleum pitch, but not in the release estimation of petroleum resin, in absence of data). This PAH was detected in four samples of CTPHT and petroleum pitch, and quantified in three samples at concentration representing 0.07 to 1.70 % of the total quantified PAHs. The two other PAHs, dibenzo[*a,i*]pyrene (CAS 189-55-9, EC No. 205-877-5), and dibenzo[*a,l*]pyrene (CAS 191-30-0, EC No. 205-886-4), were not analysed in the reported binder compositions. However, a very similar compound, dibenzo[*a,e*]pyrene, has been detected in the same binders than dibenzo[*a,h*]pyrene and quantified four times (at concentration representing 0.31 to 3.18 % of the total quantified PAHs). Therefore, it is plausible that dibenzo[*a,i*]pyrene and dibenzo[*a,l*]pyrene would also have been detected if they would have been analysed.

In summary, regardless of whether the releases are estimated based on the Dossier Submitter list of PAHs, or based on the PAHs with harmonised classification, that are identified SVHC or that are used as indicator under the POP regulation, about at least 270 tonnes of PAHs are released.

The Dossier Submitter has not estimated the releases from the use of clay targets purchased before the expected entry into force of the restriction, but used after the entry into force. A restriction on the use (in addition to only on the placing on the market) provides an incentive to use the 'stock' before the entry into force of the restriction, as opposed to building a stock of clay targets and using them after the entry into force. In any case, RAC considers that the restriction on use will avoid additional releases caused by shooting the stock of clay targets after the restriction enters into force.

The Dossier Submitter identified and assessed the uncertainties related to the identity of the binder substances and their use in clay targets, and to the release estimate. The estimation of releases is based on indicator PAHs and this may underestimate the release of total PAHs from clay targets containing CTPHT and other identified binders (petroleum pitch, petroleum

⁹ Some clay targets may also be shot over water from cruise ships.

¹⁰ Dibenzo[*a,i*]pyrene (CAS 189-55-9, EC No. 205-877-5), dibenzo[*a,h*]pyrene (CAS 189-64-0, EC No. 205-878-0) and dibenzo[*a,l*]pyrene (CAS 191-30-0, EC No. 205-886-4), 14th and 15th ATP, in force from 9 September 2021 and 22 March 2022.

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resin and other resins containing PAHs) to the environment. The value of 270 tonnes should therefore be considered as a minimum release estimate.

When clay targets are shot, it is assumed that 100 % of the PAHs are released to the environment. Even if the collection of larger fragments from some of the shooting grounds may reduce the potential for harm, this is considered ineffective in limiting the release of PAHs to the environment. Only anecdotal information is available on the fraction of fragments collected in the applications for authorisation for CTPHT (ECHA, 2020, as referenced in the Background Document).

Furthermore, PAHs are released to the environment during the production of clay targets. Although they do contribute to the overall releases, they were not quantified: considering the opinions on the applications for authorisation for the use of CTPHT as a binder in the manufacture of clay targets, the volumes of PAHs released during the production is several orders of magnitude lower than release from the article service life stage (see section B.2.2.2 in the Background Document).

Occupational exposure

The Dossier Submitter has described occupational exposure based on estimations from the applications for authorisation for CTPHT (ECHA, 2020). The processes to produce clay targets are regarded as generally the same regardless of the exact nature of the binder used, and thus the Dossier Submitter considers that the assessment is also relevant for the other PAHs-containing binders impacted by the proposed restriction. It can be assumed that the worker exposure will generally be lower when using other binders than CTPHT.

In the applications for authorisation for CTPHT (ECHA, 2020), applicants considered that PAHs are emitted to air by evaporation and release with limestone dust from the mixers. Exposure estimations were made for benzo[a]pyrene as a marker. Inhalation exposure was modelled with ART 1.5 using the predicted 90th percentile full-shift exposure. In the application of DEZA¹¹ for CTPHT, the exposure estimates (8h-TWA¹²) per worker at sites using solid or liquid CTPHT was 30.93 and 1.4 ng benzo[a]pyrene/m³, respectively (8h-TWA, adjusted for frequency of tasks and personal protective equipment). In the application of Bilbaina¹³ for CTPHT, five worker types were distinguished with exposure estimates ranging from 0.188 to 14.78 ng benzo[a]pyrene/m³ (8h-TWA, adjusted for frequency of tasks and personal protective equipment).

Additionally, dermal exposure to dust is considered possible during preparatory operations. The applicants estimated a dermal load (~2.5 ng/cm²) based on the concentration of benzo[a]pyrene in the airborne dust modelled by ART followed by the worst-case scenario of whole body deposition. RAC considered that additional dermal exposure due to the background contamination in the production hall is expected.

Consumer exposure

Users of clay targets (shooters and persons handling the clay targets) can be regarded as consumers, because the handling of clay targets is not necessarily carried out by professionals, although this cannot be excluded. The Dossier Submitter has described consumer exposure based on estimations from the applications for authorisation (ECHA, 2020). The applicants assumed no dermal exposure for consumers, and estimated exposure in air for benzo[a]pyrene of 0.17 ng/m³ (back-calculated from concentration in one soil sample). RAC considered the exposure estimate of 0.17 ng benzo[a]pyrene/m³ for the handling and shooting of clay targets highly uncertain, especially due to the methodology

¹¹ Available at: <https://echa.europa.eu/documents/10162/65672fb6-1593-b814-05f3-cad6e625170e>.

¹² Time weighed average.

¹³ Available at: <https://echa.europa.eu/documents/10162/fdad0528-0c86-2285-be81-f2f22ee286ba>.

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used. However, RAC expressed understanding of the challenges to reliably estimate exposure of consumers to CTPHT via air from the handling and shooting of clay targets.

3.1.2.3. Characterisation of risk(s)

Summary of proposal:

The Dossier Submitter considered that the emissions of PAHs are a suitable proxy for the risks, following the approach for assessing risks to the environment and to humans exposed via the environment for PBT and vPvB substances as detailed in the RAC opinions on the Applications for authorisation for use of CTPHT in clay targets. The risks related to the carcinogenic properties of the PAHs to human health (workers and consumers) are considered qualitatively.

The Dossier Submitter estimated that about 270 tonnes per year of PAHs with PBT, vPvB and carcinogenic properties are released to the environment from the use of PAHs-containing binders in clay targets under the baseline assumptions.

RAC conclusion(s):

Since several indicator PAHs contained in clay targets are PBT/vPvB substances, RAC agrees with the Dossier Submitter that emissions are a suitable proxy of risk to the environment and to humans exposed via the environment. This is consistent with previous restrictions on PBT and vPvB substances where emission characterisation has been the basis for risk characterisation and assessment of the effectiveness.

Furthermore, several indicator PAHs detected in binders are non-threshold genotoxic carcinogens, further emphasising the need to use emissions as a proxy for risk.

RAC notes that the Dossier Submitter did not evaluate the risks from individual PAHs. Instead, the Dossier Submitter considered that the available evidence on hazards and releases of the indicator PAHs were sufficient to underpin the risk.

RAC recognises that at least about 270 tonnes of PAHs per year of emissions to the environment are estimated to result from placing on the market and use of PAHs-containing clay targets under the baseline assumptions.

Cancer risks from exposure of shooters and persons handling clay targets as well as cancer risks from exposure of workers during the manufacturing of clay targets are considered qualitatively as supporting evidence to justify the need for a restriction and for the impact assessment.

RAC notes that the ongoing releases of clay target binders into the environment will result in long-term human and environmental risks due to exposure to PAHs.

Key elements underpinning the RAC conclusion(s):

PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long periods of time. The effects of such accumulation are unpredictable in the long-term and very difficult to reverse because a cessation of emissions will not result in an immediate reduction of concentrations in the environment. Furthermore, PBT or vPvB substances may have the potential to contaminate remote areas that should be protected from contamination by hazardous substances resulting from human activity.

RAC considered that emissions of PAHs are a suitable proxy for assessing risks to the environment and to humans exposed via the environment. This is consistent with Restriction Task Force guidance (2020) and previous restrictions on non-threshold carcinogens and

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PBT/vPvB substances.

About 270 tonnes of indicator PAHs per year of emissions to the environment are estimated under the baseline assumptions, as presented in Section 3.1.2.2.

RAC acknowledges that estimating releases based on indicator PAHs underestimates the releases of PAHs, as other PAHs may be present in clay targets, and therefore risks in general. However, it is not possible to establish precisely how much the indicator PAHs-based release assessment underestimates the overall releases and risks.

Risk characterisation for workers and consumers exposed from the production, handling and shooting of clay targets performed in the applications for authorisation for CTPHT (ECHA, 2020) using benzo[*a*]pyrene as indicator, is also relevant for the other PAHs-containing binders subject to the proposed restriction. It can be assumed that risks will generally be lower when using other binders than CTPHT.

For workers involved in the production of clay targets, the exposure levels for inhalation (8h-TWA) and lifetime excess risk were assessed by RAC in the two applications for authorisation for CTPHT. Noting that the uncertainties in the exposure assessment also affect the reliability of the risk characterisation, the highest lifetime excess risk of lung cancer was estimated to be 1.7×10^{-4} and the highest lifetime excess risk of bladder cancer was estimated to be 1.2×10^{-4} . RAC did not support the applicants' statement that dermal risk is negligible for workers. For consumers, the highest lifetime excess risks for lung and bladder cancers were estimated to be 5.1×10^{-6} and 3.6×10^{-6} respectively, noting high uncertainties in these figures. RAC also concluded that there is potential for dermal cancers from handling clay targets.

3.1.2.4. Uncertainties in the risk characterisation

RAC conclusions and key elements underpinning the RAC conclusions are presented in section 3.4.1.

3.1.3. Evidence that the risk management measures and operational conditions implemented and/or recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

No detailed assessment of implemented operational conditions and risk management measures was presented in the Background Document. The Dossier Submitter based its proposal on RAC conclusions on the applications for authorisation submitted for this use, which are regarded as the most up-to-date and reliable source for information regarding risk management measures and operational conditions implemented and recommended by the manufactures and/or importers.

Two applications for authorisations were received in 2019 for the use of CTPHT as a binder in clay targets for shooting. The applicants state that larger clay targets fragments are collected and assumed that the collected fragments are handed over to a professional waste company and treated as hazardous waste. In its assessment, RAC considered that "while the collection of larger fragments from some of the shooting grounds may provide some degree of reduction in the potential for release, this has clearly not been demonstrated to be effective in limiting the release of CTPHT to the environment". RAC concluded that the applicants have not demonstrated that risk management measures in place are appropriate and effective in limiting the risk for humans via environment and the environment. The Dossier Submitter further considered that collecting fragments would also lead to additional exposure of consumers. The nature and effectiveness of the waste treatment of the collected fraction is similarly unknown and may lead to releases of PAHs to the environment (e.g. from landfills).

Occupational exposure is not the main driver for the restriction proposal and the exposure

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and risk characterisation for workers during the manufacturing of clay targets is considered qualitatively as supporting evidence to justify the need for a restriction and for the impact assessment. The Dossier Submitter notes that RAC also concluded that the operational conditions and risk management measures were not appropriate and effective in limiting the risk for workers producing the clay targets.

RAC conclusion(s):

RAC notes that the only available information on operational conditions and risk management measures come from the applications for authorisations for the use of CTPHT in clay targets, which are regarded as the most up-to-date and reliable source of information.

RAC considers that the collection of fragments from shooting ground is an ineffective risk management measure and could lead to additional exposure of consumers.

RAC agrees with the Dossier Submitter that the operational conditions and risk management measures are not appropriate and effective in limiting the risk for workers producing the clay targets.

Key elements underpinning the RAC conclusion(s):

In the applications for authorisations for use of CTPHT in clay targets, it was claimed that larger clay targets fragments are collected and treated as hazardous waste. However, the collected fraction of clay targets was unknown and RAC concluded that the applicants have not demonstrated that risk management measures in place were appropriate and effective in limiting the risk for humans via environment and the environment. The nature and effectiveness of the waste treatment of the collected fraction is similarly unknown and may lead to releases of PAHs to the environment (e.g. from landfills). Moreover, it should be considered that collecting fragments would also lead to additional exposure of consumers.

The manufacturing process of clay targets consists of a hot moulding process in which a filler (e.g. milled limestone) and a binder (e.g. CTPHT) are moulded together. In the opinions on the two applications for authorisation (ECHA, 2020), RAC concluded that the operational conditions and risk management measures were not appropriate and effective in limiting the risk for workers.

Users of clay targets (shooters and persons handling the clay targets) can be regarded as consumers, because the handling of clay targets is not necessarily carried out by professionals. In the applications for authorisation (ECHA, 2020), the applicants described some measures aimed at reducing risks for consumers (painting of a fraction of the targets, claimed use of nitrile gloves, training). RAC concluded that the risk management measures proposed in the applications for authorisation have not been demonstrated to be effective in limiting the exposure of consumers (shooters and persons handling the clay targets).

As the end-use of clay targets is not expected to be different when other binders are used, these conclusions are also valid for clay targets produced with other binders.

3.1.4. Evidence that the existing regulatory risk management instruments are not sufficient to control the risk

Summary of proposal:

Following an evaluation of the two applications for authorisation for the use of CTPHT as binder in clay targets for shooting, RAC and SEAC concluded that the continued use of CTPHT in clay targets would lead to a risk to human health and the environment through the release of several hundred tonnes of PAHs per year. The concerns raised equally apply to clay targets that contain CTPHT imported into the EU. In addition, RAC could not conclude whether the use of petroleum pitch instead of CTPHT would lead to an overall reduction in risk, but

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considering the intrinsic properties of petroleum pitch, RAC did not recommend the substitution of CTPHT with this alternative. The same considerations also apply to other binders containing PAHs at a level exceeding the concentration limit proposed by the Dossier Submitter.

PAHs are listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants (POP). They are subject to release reduction provisions; Member States need to have inventories for PAHs released into air, water and land and programmes to reduce, minimise and eliminate releases (article 6 of the Regulation). However, the POP regulation aims to reduce, minimise and eliminate releases of PAHs in general (mainly to air) and it is not targeting specific uses such as the use of PAHs-containing binders in clay targets. For this reason, the Dossier Submitter concludes that the POP regulation is not sufficient to control the risk.

Although some national restrictions exist (in Austria, Belgium and the Netherlands) as described in section B.2.1. of the Background Document, they are not sufficient to control the risk at EU level.

RAC conclusion(s):

RAC and SEAC did not support two applications for authorisation for the use of CTPHT as a binder in clay targets, because the continued use of CTPHT would pose an unacceptable risk to human health and the environment. Even as the authorisations are not granted, the concerns raised apply also to clay targets (containing CTPHT) imported into the EU. The same concern applies equally to other binders containing PAHs at a level exceeding the concentration limit proposed by the Dossier Submitter.

RAC noted that although some national restrictions exist (in Austria, Belgium and the Netherlands), they are not sufficient to control the risk at EU level.

RAC further noted that PAHs are listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants and they are subject to release reduction provisions by the EU Member States (as provided in Article 6 of that regulation). However, the POP regulation is not targeting a specific use, such as the use of PAHs-containing binders in clay targets, neither is meant to ensure minimisation of the releases from a specific use in a harmonised manner among the EU Member States. For this reason, RAC agrees with the Dossier Submitter that the POP regulation is not sufficient to control the risk identified above.

Based on the information available, the RAC concludes that the existing regulatory risk management instruments overall are insufficient to control the risk of PAHs in clay targets for shooting.

3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter concluded that union-wide action is needed to address the risks associated with EU-manufactured or imported clay targets using PAHs-containing substances as a binder material in clay targets. This will ensure that a harmonised high level of protection of the environment can be established across the Union, while maintaining the free movement of goods within the EU. The efficient functioning of the internal market for substances can only be achieved if requirements for substances do not differ significantly between Member States. Some EU countries, i.e. Austria, parts of Belgium (Flanders), and the Netherlands, have already restrictions in place on the use of CTPHT-based clay targets (see Annex XV report section B.2.1). On 16 March 2022, the Commission decided not to grant authorisation

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for the use of CTPHT as a binder in the manufacture of clay targets.

One of the primary reasons to act on a Union-wide basis is the cross-boundary environmental pollution problem, caused by on-going releases from the use of clay targets in all Member States except for Austria and Flanders (Belgium), which have already banned or restricted their use. Due to the PBT and vPvB properties of PAHs contained in CTPHT and other binder materials used in clay targets, the Dossier Submitter expects that environmental impacts may not be limited to the countries where the clay targets with PAHs-containing binder materials are used.

PAHs¹⁴ within the scope of the proposed restriction have been recognised¹⁵ as POP since 29/04/2004, which confirms their potential for persistence and long-range transport. The objective of the POP Regulation is to prohibit, phase out as soon as possible, or restrict the manufacturing, placing on the market and use of POP. Releases of POP may contaminate remote areas that should be protected from further contamination by hazardous substances resulting from human activity.

Furthermore, the fact that clay targets produced with PAHs-containing binder materials, imported as well as produced in the EU, need to circulate freely once on the EU market and support the internal market of substances, stresses the importance of EU-wide action rather than action by individual Member States. In addition, the Dossier Submitter argues that EU-wide action would avoid the potential for distortion of competition on the European market between imported and domestically produced articles that could arise due to the authorisation procedure.

SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with "polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting" should be implemented in all Member States.

SEAC and RAC agree with the Dossier Submitter that the concerns raised equally apply to clay targets that contain PAHs imported into the EU.

Key elements underpinning the SEAC and RAC conclusion(s):

Union-wide action to address the risks associated with EU -manufactured or imported clay targets using PAHs containing substances as a binder material in clay targets is needed to ensure a harmonised high level of protection of the environment across the Union and to ensure the free movement of goods within the Union. In addition, the efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State. Austria, parts of Belgium, and the Netherlands have already restrictions in place for the use of CTPHT based clay targets (see section B.2.1 of the Background Document).

SEAC and RAC generally support the union-wide approach for the following reasons:

- Releases of PAHs from the use of clay targets containing PAHs is a multi-local and cross-boundary environmental problem. Releases occur in all Member States except for Austria, Flanders (Belgium) and the Netherlands that have already banned or

¹⁴ The following indicators are used: benzo[*b*]fluoranthene (benzo[*e*]acephenanthrylene), benzo[*k*]fluoranthene, benzo[*a*]pyrene (benzo[*def*]chrysene), indeno[1,2,3*cd*]pyrene.

¹⁵ PAHs are listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants (POP). They are subject to release reduction provisions under the POP Regulation, but they are not listed in the Stockholm Convention.

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restricted the use of these types of clay targets.

- Due to the PBT and vPvB properties of PAHs contained in CTPHT and other binder materials, the human health and environmental impacts may not be limited to the countries where the clay targets with PAHs-containing binder materials are used.
- PAHs are recognised under the POP Regulation since 29/04/2004, which confirms their potential for persistence and long-range transport.
- Furthermore, the fact that clay targets produced with PAHs-containing binder materials, imported as well as produced in the EU, need to circulate freely once on the EU market and support the internal market of substances, stresses the importance of EU-wide action rather than action by individual Member States.
- Only a restriction will prevent imports of clay targets that do not meet the PAHs concentration limits proposed here. An EU-wide action would avoid the potential for distortion of competition on the European market between imported and domestically produced articles that could arise due to the authorisation procedure. European producers have already begun to substitute to more eco-friendly binder substances and have raised concerns over the imbalance of regulation between the imported and domestically produced clay targets.
- Restriction of PAHs by an approach using a list of indicator PAHs and an indication of a sum limit value has been previously applied in other restrictions according to REACH Annex XVII.

3.3. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

3.3.1. Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

As REACH authorisation does not cover placing on the market of the substance in articles, and the concerns raised equally apply to clay targets that contain CTPHT imported into the EU, these present an EU-wide risk and thus, based on REACH Article 69(2), ECHA was required to prepare an Annex XV restriction dossier. Several alternative substances to CTPHT are currently used as a binder for clay targets in the EU. While they generally have lower concentrations of PAHs than CTPHT, many of the alternatives also contain PAHs. Alternatives with very low PAHs-content and PAHs-free alternatives are also available. To ensure a high level of protection of human health and the environment in the EU, and to avoid regrettable substitution, the Commission requested ECHA on 2 July 2021 to prepare an Annex XV restriction dossier on substances containing PAHs in clay targets for shooting, incorporating the Article 69(2) dossier for CTPHT.

The Dossier Submitter has not included any derogations in its proposal. Instead, a phased entry into force is proposed with regard to the PAHs content. The restriction would come into force in two phases:

Phase 1: From [*date of entry into force of the restriction*], clay targets shall not be placed on the market or used for shooting if they contain more than 10 000 mg/kg (1 % by weight of dry mass of the clay target) of the sum of all listed PAHs.

Phase 2: From [*date + 1 year from entry into force of the restriction*], clay targets shall not be placed on the market or used for shooting if they contain more than 50 mg/kg (0.005 % by weight of dry mass of the clay target) of the sum of all listed PAHs.

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RAC conclusion(s):

RAC agrees a REACH restriction would be the most effective risk management measure to reduce exposure to PAHs from clay targets for shooting.

RAC supports the general approach to base the restriction on a concentration limit of selected indicator PAHs in clay targets with a phased entry into force and without derogations.

RAC agrees with the rationale of the Dossier Submitter to set an interim total 18-PAHs concentration limit of 1 % that would prevent the use of CTPHT as a binder in imported clay targets, but temporarily allow other PAHs containing binders. However, RAC notes that a one-year transitional period would lead to an additional release of at least 150 tonnes of the 18 indicator PAHs.

Key elements underpinning the RAC conclusion(s):

RAC considers that even as the Commission has decided to refuse an authorisation for the use of CTPHT in clay targets, the possibility to import clay targets containing CTPHT in the EU remains. As REACH authorisation does not cover placing on the market of the substance in articles, and the concerns raised equally apply to clay targets that contain CTPHT imported into the EU, these present an EU-wide risk.

A REACH restriction is necessary to avoid the import of clay targets for shooting containing CTPHT in the EU and a regrettable substitution with alternatives of CTPHT to manufacture clay target for shooting consecutive to the REACH authorisation of CTPHT.

Several alternative substances to CTPHT are currently used as binders for clay targets in the EU. While they generally have lower concentrations of PAHs than CTPHT, many of them indeed contain PAHs. Alternatives with very low PAHs-content and PAHs-free alternatives are also available.

An interim concentration limit value of 1 % (w/w) for the sum of the 18 indicator PAHs is proposed to apply from the entry into force of the restriction. This interim limit would immediately prevent the use of CTPHT as a binder in imported clay targets, but temporarily allow other PAHs containing binders for a transitional period. One year after the entry into force of the restriction the concentration limit will be lowered to 0.005 % (w/w). It is noted that this one-year transitional period would lead to an additional release of at least 150 tonnes of 18 indicator PAHs.

Justification for the opinion of SEAC

Summary of proposal:

See SEAC opinion.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.3.2. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter estimated that at least 270 tonnes of PAHs per year will be released to the environment from placing on the market of PAHs-containing clay targets and their use in shooting under the baseline assumptions (i.e. without any restriction). The Dossier Submitter has analysed four different restriction options that are progressively stricter in terms of the permitted PAHs-content in clay targets. Each of the restriction options sets a specific concentration limit value for the 18-indicator PAHs. The effectiveness of the restriction options, expressed as tonnes of avoided releases per year once the transitional period is over, is presented in Table 4 below. Under RO 3 (the proposed restriction), 99 % of the releases would be avoided.

Table 4. Summary of the proposed restriction options

Restriction scenarios	18-PAHs concentration limit (in clay target) w/w	Restricted substances (of those currently on the market)	Reduction in PAHs releases compared to baseline (tonnes of 18 indicator PAHs per year)	Remaining releases to the environment (tonnes of 18 indicator PAHs per year)
RO1	1 %	CTPHT	114	156
RO2	0.1 %	CTPHT and Petroleum Pitch	247	23
RO3	0.005 %	CTPHT, Petroleum Pitch, Petroleum Resin, Other PAHs-containing resin binders above the limit	268	2
RO4	0.0001 %	CTPHT, Petroleum Pitch, Petroleum Resin, other resin binders, eco resins	270	0

The Dossier Submitter notes that these figures (which takes into account available information on the concentration of the 18 indicators PAHs in binders only) may underestimate the risks from release of CTPHT and other binders to the environment if it is not capturing all PAHs in the binder matrix, as discussed in the assessment of uncertainties in section 3.2 of the Background Document. The releases of other PAHs (not part of the 18 indicators, but that may also be present in the binders) would also be reduced. This cannot be quantified based on available information. The estimates based on 18 indicators PAHs provides an indication on how the cost-effectiveness ratio is comparatively affected under each restriction option.

The Dossier Submitter also assessed the impact of removing fragments from shooting grounds. Indeed, a fraction of the larger fragments of clay targets may be collected and disposed of, although the fraction of clay targets that is collected is unknown. Collecting fragments would also lead to additional exposure of consumers or professionals. The nature and effectiveness of the waste treatment of the collected fraction is similarly unknown and may lead to releases of PAHs to the environment (e.g. from landfills). For these reasons, the Dossier Submitter has not taken into account any removal of fragments in its proposal.

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RAC conclusion(s):

RAC notes that the Dossier Submitter has quantified the effectiveness of the proposed restriction based on the releases of 18 indicators PAHs which are used as proxy for the risk.

RAC agrees that the proposed restriction option RO3, with a concentration limit of 0.005 % w/w in clay targets for the sum of the 18 indicator PAHs, would avoid 99 % of the release of PAHs estimated under the baseline assumption.

RAC notes that only restriction option RO4 would, in theory, ensure zero release of PAHs from clay targets for shooting by keeping only natural resin-based clay targets with zero PAH concentration on the market. RAC, however, considers that, when using the current incomplete information on the content of PAHs in binders, the release reduction potential of RO4 is (within the margins of uncertainty of release estimations) closely similar as of RO3, and therefore RO3 can be considered sufficiently effective. Additionally, RAC notes that due to the ongoing assessment of some resins and rosins for their PBT profile and potential concern for reproductive toxicity, RAC cannot currently assess comprehensively the risk reduction of these alternatives in clay targets for shooting.

RAC concludes that the Dossier Submitter proposal (RO3) is effective in reducing the identified risks, in reasonable time, from placing on the market and use of clay targets for shooting manufactured with the binder substances described in the Background Document. RAC notes that for PAHs that are persistent or very persistent, the proposed restriction is effective with regard to the minimisation of new releases, but that it does not affect the already existing environmental exposures.

RAC highlights that there is a small uncertainty regarding releases of other PAHs (not captured by the proposed restriction RO3) from clay targets that would remain on the market after the entry into force of the restriction.

Key elements underpinning the RAC conclusion(s):

The effectiveness of the proposed restriction is measured by the reduction of risks from the releases of PAHs as a group, quantified by considering 18 indicators PAHs. In order to evaluate how the effectiveness of the restriction would be affected in terms of capacity of reducing the releases and exposures of PAHs, RAC has evaluated which binders described in the Background Document would be restricted due to their concentrations of these PAHs as reflected in the Table 5 below.

Table 5. Impact of the indicator PAHs on binders used to manufacture clay targets

	CTPHT	Petroleum pitch	Petroleum resin	Other resins			
	EC 266-028-2	EC 269-110-6		[Resin 2]*	EC 305-586-4	[Resin 1]*	[Resin 3]*
Classification of binders (CLP)** and SVHC status	Carc. 1A (HC), PBT/vPvB (SVHC)	Carc. 1B (SC)			Carc. 1A (SC)		Carc. 1B (HC)
Dossier Submitter proposal (RO3) (18 PAHs)							

Red: affected under RO3 and RO4 (sum of concentration of PAHs > 0.005 % in clay targets).

Yellow: affected under additionally under RO4 (sum of concentration of PAHs > 0.0001 % in clay targets).

White: unknown impact.

* Identifiers confidential but known to Committees.

** HC: Harmonised classification, SC: Self-classification.

Under the restriction option RO3, CTPHT (EC 266-028-2), petroleum pitch (EC 269-110-6),

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petroleum resin (EC 269-110-6), and Distillates (petroleum), cracked, ethylene manuf. by-product, C9-10 fraction (EC No. 305-586-4) would not be allowed anymore to produce clay targets, as the concentration of PAHs in the clay targets would exceed the limit under RO3. According to the Background Document (section 1.2.1.2), RAC notes that Distillates (petroleum), cracked, ethylene manuf. by-product, C9-10 fraction (EC No. 305-586-4), promoted as suitable alternatives by producers, can contain significant level of naphthalene (based on registration information). For this reason, RAC supports using naphthalene as an indicator, as proposed by the Dossier Submitter, to avoid regrettable substitution with binders which otherwise could not be affected by the restriction. As the above mentioned binder is self-classified as Carc. 1A/1B/2 and Muta. 1B/2 (depending on the registration), this is not considered a suitable alternative by RAC.

Based on information on its composition¹⁶, it is likely that Resin 2 could still be used to manufacture clay targets, provided that the concentration limit in the clay target is not exceeded.

The impact of the proposed restriction cannot be measured for Resin 1 and Resin 3 due to the lack of data on their composition. For Resin 1, the registration dossier claims that no PAHs are present in the composition but the substance may contain naphthalene originating from the starting materials. Should the concentration of naphthalene be below or above the proposed concentration limit value, when incorporated in clay targets, then this substance would be allowed or not under the proposed restriction. Resin 3 has a harmonised classification as carcinogenic 1B (which applies when the concentration of polycyclic aromatics is above a limit, see section 3.1.2.1 and footnote 5) and the lack of information on its composition introduces minor uncertainty as to whether the proposed restriction will be effective in reducing the risk from the use of this binder. RAC considers that Resin 3 is not a suitable alternative to manufacture clay targets due to its harmonised classification.

Because the binders that would not be allowed anymore under the proposed restriction could also contain other PAHs, RAC considers that limiting the concentration of the 18 indicator PAHs in clay targets will in practice also prevent the emissions of these other PAHs. Such an approach has already been used and implemented in previous restrictions for PAHs.

RAC supports the approach to assess the effectiveness of the restriction options and agrees that the proposed restriction option RO3, with a concentration limit of 0.005 % w/w in clay targets for the sum of the indicator PAHs, would allow to avoid 99 % of the releases of PAHs estimated under the baseline assumption.

Under the restriction option RO4, only clay targets with a PAHs concentration below 0.0001 % w/w would remain on the EU market. This restriction option could be adopted in theory given the availability of natural resin-based clay targets alternatives with a concentration of PAHs of 0 %. This would mean that the desirable zero-pollution objective would be achieved with the highest minimisation of PAHs releases from clay targets for shooting. However, it is worth also noting that some resins and rosins are currently scrutinised for their PBT profile and potential concern for reproductive toxicity related to non-PAHs substances, as reported in the Background Document. Therefore, RAC cannot currently assess comprehensively the risk reduction of using these alternatives in clay targets for shooting. RAC does not recommend substitution of binders in clay targets to other binders having carcinogenic or PBT/vPvB properties.

¹⁶ 19 PAHs have been measured in Resin 2, including the 18 indicator PAHs of the Dossier Submitter proposal, and dibenz[*a,c*]anthracene.

3.3.3. Socio-economic impact

Justification for the opinion of SEAC

3.3.3.1. Costs

Summary of proposal:

See SEAC opinion.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.3.3.2. Benefits

Summary of proposal:

See SEAC opinion.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.3.3.3. Other impacts

Summary of proposal:

See SEAC opinion.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.3.3.4. Proportionality

Summary of proposal:

The Dossier Submitter has calculated the incremental cost/effectiveness (C/E) ratios, expressed as euros per kg of avoided releases, to compare the restriction options against each other (rather than against the baseline). The C/E ratio increases subsequently from RO1 to RO4, reflecting increasing average costs per kg of PAHs abatement in relation to the baseline. The Dossier Submitter proposes RO3 as the preferred restriction option. This is motivated as follows:

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- (i) Significantly higher effectiveness compared to RO2 and RO1 - RO3 leads to a reduction of yearly emissions of about 99 %.
- (ii) There seems to be sufficient availability of eco resin in the EU to meet the demand for binder such that the amount of clay targets produced annually remains unchanged. According to the Dossier Submitter, EU-based clay target producers are already producing eco-friendly clay targets.
- (iii) Practicality and monitorability: RO3 aligns with the rules of the International Sports Shooting Federation (ISSF), which impose a limit of 0.005 % w/w for the sum of 18 indicator PAHs in clay targets, and which has been adopted for the Olympic Games, World Championships, World Cups, World Cup Finals and Junior World Cups. This is seen to provide a clear legal basis for companies and enforcement authorities that is consistent with already existing rules in the sector.

Furthermore, the Dossier Submitter proposes a transitional period of one year after entry into force of the restriction. During this period, clay target producers will be allowed to use binder with a PAHs concentration of maximum 1 %, based on the use of 18 PAHs indicator substances. This means that during the transition period either petroleum pitch (PAHs concentration 1 %), petroleum resin (PAHs concentration 0.1 %), eco resin (PAHs concentration 0.005 %) or natural resin (PAHs concentration 0 %) can be used. Petroleum pitch is the cheapest option (no price difference with CTPHT).

The Dossier Submitter sees a need for such a transitional period in order to avoid any shortage of useable clay targets in the EU. The Dossier Submitter considers a one-year transitional period sufficient to allow clay target manufacturers to find suppliers of those binder materials that are not under the scope of the proposed restriction, and to enable clay target producers to implement any adjustments to their manufacturing processes. However, the transitional period is estimated to lead to additional emissions of up to 150 tonnes of the 18 indicator PAHs.

RAC and SEAC conclusion(s):

RAC notes that the assessment of the risk reduction capacity by the Dossier Submitter is based on the release of 18 indicator PAHs.

RAC concludes that the Dossier Submitter proposal (RO3) is capable in reducing the identified risks, in reasonable time, from placing on the market and use of clay targets for shooting.

RAC notes that only the restriction option RO4 would allow to ensure zero release of PAHs from clay targets for shooting by keeping only natural resin-based clay targets with zero PAH concentration on the market.

RAC points out that there are uncertainties regarding the composition and the risk profile of the alternative binders, i.e. the binders with a sum of the concentration of the 18 indicators PAHs below the limit, still allowed to manufacture clay targets after the entry into force of the restriction. These uncertainties are described in section 3.4.1.

Key elements underpinning the RAC and SEAC conclusion(s):

The RAC conclusions and evaluation related to the effectiveness of the proposed restriction in reducing the risks are presented in section 3.3.2.

3.3.3.5. Uncertainties in the assessment of proportionality

Uncertainties in the evaluation of RAC are described in section 3.4.1.

3.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers that it is practical to base a concentration limit on measurable and well-known PAHs. They also serve as indicators for the presence of other PAHs. The proposed restriction option is aligned with the rules of the ISSF, which impose a limit of 0.005 % w/w for the sum of 18 indicator PAHs in clay targets for their competitions. The Dossier Submitter considers that sampling of clay targets and sample preparation is relatively straightforward, as the matrix is rather simple (binder and filler) and homogeneous, and that calibration standards and analytical methods are readily available for the targeted 18 PAHs.

In terms of the other main criteria for a restriction, practicality and monitorability, the Dossier Submitter sees all restriction options as equivalent.

RAC and SEAC conclusion(s):

RAC and SEAC support the view of the Forum that the proposed restriction will be enforceable provided that a specific analytical method is developed defining the necessary harmonised testing approach by the time it enters into force.

RAC supports the view of the Forum that it can be expected that the techniques currently in use for the identification and quantification of PAHs in general could be adapted for identification and quantification of the 18 indicator PAHs in clay targets with a suitable limit of detection (LOD). RAC notes that the proposed restriction is consistent with already existing rules in the sector providing a clear legal basis for companies and enforcement authorities.

RAC and SEAC conclude that the proposed restriction (RO3) is practical and enforceable.

Key elements underpinning the RAC and SEAC conclusion(s):

The RAC and SEAC assessment takes into account the Forum Advice, made available to the Committees on 3 May 2022, and Forum responses to questions from rapporteurs. The Forum noted that the Background Document referred to several articles about analysing PAHs and to the Compendium of analytical methods, but that no standard and validated method (ISO or CEN methods) for the analysis of the 18 indicator PAHs in clay target is described. Following the Forum Advice, the Dossier Submitter has updated the Background Document to include information on the sampling, samples preparation, extraction method and analytical method based on the national restriction in Austria and the German methods AfPS GS 2014:01 PAK and AfPS GS 2019:01 PAK, which are also used by industry to check compliance with the ISSF rule.

The sampling of clay targets (e.g. buying articles available on the market) is not foreseen to cause any problems. Clay targets can easily be collected from manufacturers, retailers or shooting ranges and analysed.

Although there is currently no specific method available for all listed PAHs, it seems feasible that a new working method can be proposed with due consideration for the specific matrix type and the specific PAHs pattern in question. RAC and SEAC, therefore, consider the proposed restriction for PAHs in clay targets for shooting to be enforceable. The enforceability is affected by the matrix and the availability of a validated method covering all the listed PAHs (including availability of reference materials and of deuterated standards for each PAHs analysed). Analytical methods are available for different matrices for all 18 PAHs proposed by the Dossier Submitter and for the three recently classified PAHs as described in RAC box in section E.7 of the Background Document.

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Forum is promoting a method (including sample preparation) developed by Austria based on AfPS GS 2014:01 PAK for their national restriction of PAHs in clay pigeons covering 16 PAHs¹⁷ (i.e. all 18 indicator PAHs except benzo[*e*]pyrene and benzo[*j*]fluoranthene). The limit value for the sum of these 16 PAHs is 10 mg/kg. According to the laboratory in this Member State, the detection limit (LOD) for the sum of the 16 PAHs is within the range of 0.1 to 0.4 mg/kg (dry mass) depending on the composition of the clay target.

Forum noted that the method originally developed for REACH Annex XVII entry 50 could also be applied to the matrix PAHs-containing binder/ground limestone for the 18 indicator PAHs and the three recently classified PAHs. Although the matrices are very different, GC-MS¹⁸ analysis is highly sensitive with LODs at 0.1-0.2 ng/ml for each of the PAHs analytes and 0.05-0.2mg/kg (FDA studies). It is expected that this analysis would be relevant using these studies as a guide in lieu of a fully validated GC-MS method for this specific matrix.

Forum is promoting a German method, AfPS GS 2014:01 PAK, that has often been used to analyse the 18 indicator PAHs in compliance with the requirements of the Product Safety Act for the award of the GS mark. However, this particular method is intended to be used for plastics, rubber, cosmetics etc. and not for the type of matrix in clay targets. Since 10 April 2020, this method is reworked and published as AfPS GS 2019:01 PAK containing only 15 of the PAHs proposed in this restriction (i.e. all 18 indicator PAHs except acenaphthylene, acenaphthene and fluorene).

During a telephone call between the SEAC rapporteur and the project manager for the development of AfPS GS 2014:01 PAK and AfPS GS 2019:01 PAK in the Federal Institute of Materials Research and Testing (BAM) of 8 April 2022, and reported in the Background Document as a SEAC box, the rapporteur asked whether a specific method for PAHs in clay targets for shooting is needed. BAM-1.7 "Organic Trace and Food Analysis" sees no need for new development on methodology/certified reference material (CRM) for PAHs in binder material of clay targets. Hence, the method, including the CRM originally developed for REACH Annex XVII entry 50, could also be applied to the matrix PAHs-containing binder/ground limestone. In the case of clay target powder, the binder will probably be completely dissolved in toluene, no purification step should be necessary. Limestone is a "good-natured" matrix, will absorb/retain almost nothing of the analyte and thus hardly falsify/disturb the chemical analysis.

For evaluating the practicability of the restriction proposal, SEAC does not expect any major problems with adapting AfPS GS 2014:01 PAK and AfPS GS 2019:01 PAK for this restriction proposal. The methods are well established and have been used since 2014.

The limit values in the restriction proposal are clear and the reference to the LOD used in the national restriction in Austria is given in the Background Document. In the AfPS GS 2019:01 PAK guideline, the sum of the PAHs from individual contents > 0.2 mg/kg is established. For the analysis of PAHs in clay targets (planned sum value limit 0.005 mg/kg) a validation of the method seems appropriate. Since there is an existing entry in Annex XVII banning PAHs in other solid matrices at a lower limit than proposed in this restriction, the Forum assumes that the limit value of RO3 (0.005 %) is higher than the LOD. From the experience of enforcement activities in Austria, the Forum assumes that a limit value of 0.0001 % (RO4) would be feasible but considers that it has to be verified by practical experimentation. It must be ensured that the limit of quantification of each individual PAH component can actually be achieved with the test method. An effective method is, for example, to increase the sample weight from the current 500 mg into the range of grams. Given the size of the clay targets, this should not be a problem later on. Besides increasing the sample weight, the toluene

¹⁷ Acenaphthene, acenaphthylene, anthracene, benz[*a*]anthracene, benzo[*a*]pyrene, benzo[*b*]fluoranthene, benzo[*ghi*]perylene, benzo[*k*]fluoranthene, chrysene, dibenz[*a,h*]anthracene, fluoranthene, fluorene, indeno[1,2,3-*cd*]pyrene, naphthalene, phenanthrene, pyrene.

¹⁸ Gas chromatography with mass spectrometry.

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extract could also be concentrated. Another possibility would be a so-called "large volume injection" in the GC-MS measurement.

A comparison of the AfPS GS 2014:01 PAK and AfPS GS 2019:01 PAK methods shows only differences in the list of PAHs. While AfPS GS 2014:01 PAK still contains 18 PAHs, the version AfPS GS 2019:01 PAK has only 15 PAHs listed as analytes. According to BAM-1.7, the basis for the PAHs selection in these methods could presumably be a mix of the long-standing 16 US EPA PAHs list and the new 8 PAHs according to REACH Annex XVII entry 50 for consumer products (18 PAHs in the AfPS GS 2014:01 PAK, as in the Dossier Submitter's proposal). The reduction from 18 to 15 is due to the omission of acenaphthene, acenaphthylene and fluorene. Toxicologically, the focus is more on the larger PAHs, so the smaller PAHs such as naphthalene, acenaphthylene, acenaphthene and fluorene are less relevant. In addition, the smaller PAHs such as naphthalene, acenaphthylene, acenaphthene and fluorene are more volatile, associated with higher measurement uncertainties. In addition, one of them (acenaphthylene or acenaphthene) does not show fluorescence, which somewhat impairs HPLC fluorescence analysis (no problem with GC-MS).

Based on BAM 1.7, SEAC estimates that the cost to develop a specific CRM based on ground clay targets would be about € 100 000-200 000. This is the experience from the production of the CRM for REACH Annex XVII entry 50 (here BAM-B001¹⁹). The development of such a CRM takes about 2-3 years. The costs are determined by the complexity of process steps: Processing the raw material, homogenizing the shredded material, five analyses of 18/15 PAHs, round robin tests with different analytical methods, one-year testing for storage stability, certification by an external body, packaging, deep-freeze storage until dispatch.

A restriction setting the list of 18 indicator PAHs proposed by the Dossier Submitter is considered practical as it aligns with the existing rules of the International Sports Shooting Federation (ISSF) that have been adopted for the Olympic Games, World Championships, World Cups, World Cup Finals and Junior World Cups.

To increase the practicality of the restriction and facilitate the procurement of compliant resins by clay targets manufacturers, RAC recommends that suppliers of resins provide information to manufacturers of clay targets on the concentration of PAHs in the resins, by the time of entry into force of this restriction.

3.3.5. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

Monitoring of the restriction is performed by measuring the concentration of indicator PAHs in the clay targets. The Dossier Submitter considers that the restriction is monitorable (see section 2.4 of the Background Document) and that monitorability of all restriction options is identical, since they are all based on an 18 PAHs-limit.

RAC and SEAC conclusion(s):

RAC and SEAC note that the Dossier Submitter propose to monitor the results of the

¹⁹ CRM BAM-B001 "Polycyclic aromatic hydrocarbons in rubber toy" is intended to be used for performance control and validation of analytical methods for the determination of PAH in rubber toys, for example for enforcement of REACH Annex XVII Entry 50. The reference material may also be applicable for other similar consumer products. BAM-B001 was produced and certified under the responsibility of Bundesanstalt für Materialforschung und -prüfung (BAM). In addition to the in-house study at BAM, two interlaboratory comparison studies were conducted to support and confirm the certification of BAM-B001.

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implementation of the restriction by measuring the concentration of the sum of indicator PAHs in clay targets.

RAC and SEAC consider the restriction generally monitorable. Clay targets can easily be collected from manufacturers, retailers or shooting ranges and analysed.

Due to the uncertainties raised in section 3.4.1, RAC recommends that the presence and concentration of other PAHs (not part of the list of indicators) are also monitored in clay targets placed on the markets after the entry into force.

Key elements underpinning the RAC and SEAC conclusion(s):

Monitoring of the restriction is performed by measuring the concentration of indicator PAHs in the clay targets and therefore relies on the availability of analytical methods. Analytical methods are discussed in section 3.3.4. RAC and SEAC do not expect any major issue related to analysis of PAHs in clay targets.

As described in section 3.3.2 and 3.4.1, RAC notes that it is not currently possible to confirm that the 18 indicator PAHs selected by the Dossier Submitter would always ensure that binders of clay targets, still allowed after the entry into force of the restriction, do not contain PAHs other than the 18 indicator PAHs, at concentrations which, when taken together with the 18 indicators, would lead to exceeding the concentrating limit. Therefore, RAC recommends that after the restriction has fully entered into force, the presence and concentration of PAHs (other than the 18 indicator PAHs) in clay targets placed on the market are investigated. This would allow to confirm the anticipated effectiveness of the restriction in reducing the releases of PAHs in general.

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. RAC

Summary of proposal:

Uncertainties are listed, prioritised and assessed in section 3 of the Background Document. Based on the identified uncertainties and the corresponding prioritisation, the uncertainty analysis is divided into three parts to feed into a later conclusion on best and worst-case estimates. The following uncertainties have been considered:

- Part A: Regulatory uncertainties. The baseline was built on the assumption that the applications for the use of CTPHT as a binder in clay targets are not granted an authorisation. However, this baseline was subject to regulatory uncertainty, and an alternative scenario would have been possible where an authorisation would have been granted for these applications. On 16 March 2022, the Commission decided not to grant authorisation for the use of CTPHT as a binder in the manufacture of clay targets and therefore this uncertainty is not relevant anymore.
- Part B: Uncertainties related to the releases. On one hand, a fraction of the larger fragments of clay targets may be collected and disposed of, which may reduce the releases; in another hand, the release estimate based on 18 indicator PAHs may underestimate the risks from release of CTPHT and other binders to the environment if it is not capturing all PAHs in the binder matrix.
- Part C: Uncertainties related to the identity of the binder materials. There are uncertainties on the identity (identifiers and composition) of the known binders. Other substances containing PAHs, not identified in this report, may also be used for clay target production.

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RAC conclusion(s):

There are a number of uncertainties identified in the proposal that are outlined in the Background Document. RAC agrees that the main uncertainties that affect the environmental exposure assessment and the risk characterisation are related to:

- The quantity of clay targets placed on the market in the EU and the exact share of clay targets produced with different binder materials.
- The identity and composition of the binder materials.
- The release estimate based on indicator PAHs, as it can be expected that there are more PAHs in clay targets than those considered to calculate the releases.
- The removal rate of clay target fragments, which is not known.

In addition, RAC identified other uncertainties due to:

- The potential mixture effects of PAHs which have not been assessed by the Dossier Submitter and could lead to increased risk.
- The potential presence of PAHs (other than the 18 indicator PAHs) in binders still allowed after the entry into force of the restriction (i.e. when the sum of the concentration of the 18 indicator PAHs in these clay targets is below the limit).
- The absence of PAHs group assessment for carcinogenic and/or PBT, vPvB properties.

RAC considers that the uncertainties highlighted are minor and do not significantly affect the effectiveness, practicality nor the monitorability of the restriction proposal as regards the ability to reduce the risk deriving from the presence of PAHs in clay targets.

As described in section 3.3.5, RAC recommends that the presence and concentration of PAHs other than the 18 indicators could be investigated in clay targets remaining on the market after the restriction has fully entered into force, to address the remaining minor uncertainties associated with the anticipated effectiveness of the proposal.

Key elements underpinning the RAC conclusion(s):

Clay targets have traditionally been produced with CTPHT as a binder but EU clay target manufacturers are switching to alternatives partly due to ISSF rules for the clay targets used in the competition, and partly due to regulatory pressure (i.e. Annex XIV listing of CTPHT). There is an uncertainty on the exact market share between these alternative binders and the market situation is expected to be further affected by the decision to not grant authorisation for the use of CTPHT as a binder in the manufacture of clay targets.

The use of indicator PAHs to estimate the release of PAHs from clay targets is a source of uncertainties in the risk characterisation, since binder substances are UVCB with only limited information on their composition. This applies especially for the alternatives to CTPHT. As the releases are estimated by taking into account only the concentration of the indicator PAHs but not the whole PAHs content, which has not been analysed in the binders, PAHs releases are likely underestimated. Furthermore, currently, only CTPHT and petroleum pitch substances are registered under REACH for use as binder in clay targets and the composition data provided in the registration dossiers may not reflect batches or products from manufacturers with higher (or lower) levels of PAHs, nor the composition in imported clay targets. RAC notes that registrants have an obligation to report compositions as requested in Annex VI of REACH. The current release estimates do not take into account the variability of concentration of the indicator PAHs within each binder.

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Other resins (i.e. eco-resins and natural resins) are used as binders in clay targets. There are uncertainties related to their identification (names, CAS and EC numbers) and their constituents. Some binders are claimed as "eco-resins" although they do not meet the definition of the ISSF due to high level of naphthalene. There is neither data on their market share. It is therefore uncertain whether the number of targets made with "eco-resins", as provided by stakeholders, and taken into account to estimate the releases as presented in

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Table 2, was appropriately allocated. This could result in an underestimation of the releases in the baseline scenario.

RAC notes that the risk due to the presence of PAHs in “eco-resins” (i.e. with a concentration of the 18 indicator PAHs below 0.005 %) is evaluated by considering the limit value of 0.005 %. This may overestimate the releases, as some of these resins may have in reality a lower concentration of PAHs.

RAC acknowledges that a fraction of larger fragments of clay targets may be collected and disposed of, but this fraction is unknown. The collection of fragments would also lead to additional exposure of consumers. Moreover, the nature and effectiveness of the waste treatment of the collected fraction is similarly unknown and may lead to releases of PAHs to the environment (e.g. from landfills).

RAC notes that the Dossier Submitter hasn't performed a group assessment to justify the assumption that all PAHs have a similar level of concern as the PAHs with confirmed carcinogenic and/or PBT, vPvB properties. RAC notes that the Dossier Submitter has not assessed the hazard, and therefore the risk, for each PAH individually, and in particular for the individual PAHs with no harmonised classification for carcinogenicity nor SVHC identification for PBT/vPvB properties (acenaphthene, acenaphthylene, fluorene and indeno[1,2,3-*cd*]pyrene). Rather, the Dossier Submitter based its hazard assessment on information on PAHs with recognised carcinogenic and/or PBT and/or vPvB properties.

Moreover, dibenzo[*a,h*]pyrene is not included in the 18 indicator PAHs list of the Dossier Submitter. However, RAC considers that its harmonised classification as carcinogen cat.1B, as well as the available data demonstrating its presence in some binders, are sufficient to conclude that it contributes to releases, and hence to the risks, but at a such low level, based on analytical information, that it does not change the total releases, considering the margin of uncertainty of the release estimates under the baseline assumptions. Neither the Dossier Submitter nor RAC attempted to characterise the risks for the two other recently classified carcinogenic PAHs, dibenzo[*a,i*]pyrene, and dibenzo[*a,l*]pyrene, since no analytical data is available to confirm and quantify their presence in the binder substances.

RAC notes that the co-occurrence of many PAHs in clay targets could lead to mixture effects in relation to effects of individual PAHs, which have not been assessed by the Dossier Submitter.

Due to the current uncertainties concerning the identity and composition of binder substances (especially the so-called “eco resins” and “natural resins”), it is not possible to confirm that the 18 indicator PAHs selected by the Dossier Submitter would always ensure that clay targets (manufactured with binders still allowed after the entry into force of the restriction, i.e. when the sum of the concentration of the 18 indicator PAHs in these clay targets is below the limit) do not contain PAHs other than these 18 indicator PAHs. In the case where other PAHs would be present in the clay targets, should their concentration be added to the concentration of the 18 indicators, it is possible that the sum of the concentration would exceed the concentration limit of 0.005 % in clay targets. In particular, the three PAHs that were recently classified as carcinogenic (dibenzo[*a,h*]pyrene, dibenzo[*a,i*]pyrene and dibenzo[*a,l*]pyrene) are not considered by the Dossier Submitter in its proposal. RAC notes that no data is available to assess the consequence of taking into account the concentration of these three PAHs together with the concentration of the 18 indicators for the binders still allowed to manufacture clay targets after the entry into force of the restriction. However, due to the nature of the substances, it cannot be excluded that these three PAHs could be present in some of these binders. Therefore, RAC recommends that the presence and concentration of PAHs other than the 18 indicators could be investigated in clay targets remaining on the market after the restriction has fully entered into force, to address the remaining minor uncertainties associated with the anticipated effectiveness of the proposal.

3.4.2. SEAC

Summary of proposal:

See SEAC opinion.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

4. REFERENCES

None.