

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

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on

Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting

13 September 2022

CONTENTS

Sι	ımmary	1
Re	eport	5
1.	The problem identified	5
	1.1. Manufacture and uses	6
	1.2. Hazard, exposure/emissions and risk	9
	1.2.1. Identity of the substance(s), and physical and chemical properties	9
	1.2.2. Justification for grouping	
	1.2.3. Classification and labelling	
	1.2.4. Hazard assessment	30
	1.2.5. Release to the environment	34
	1.2.6. Exposure of workers and consumers	36
	1.2.7. Risk characterisation	37
	1.3. Justification for an EU wide restriction measure	38
	1.4. Baseline	39
2.	Impact assessment	42
	2.1. Introduction	42
	2.2. Alternatives	43
	2.2.1. Technical feasibility and comparison of the binder substances	44
	2.2.2. Identity, physico-chemical properties and hazards of alternatives	47
	2.2.3. Availability of the alternatives	51
	2.3. Risk management options	52
	2.4. Restriction options	53
	2.5. Assessment of restriction option 1	54
	2.5.1. Economic impacts	54
	2.5.2. Human health and environmental impacts	55
	2.5.3. Proportionality	55
	2.6. Assessment of restriction option 2	55
	2.6.1. Economic impacts	55
	2.6.2. Human health and environmental impacts	56
	2.6.3. Proportionality	56
	2.7. Assessment of restriction option 3	57
	2.7.1. Economic impacts	
	2.7.2. Human health and environmental impacts	58

BACKGROUND DOCUMENT - PAHs in clay targets for shooting

2.7.3. Other impacts	58
2.7.4. Proportionality	59
2.8. Assessment of restriction option 4	59
2.8.1. Economic impacts	59
2.8.2. Human health and environmental impacts	60
2.8.3. Other impacts	60
2.8.4. Proportionality	61
2.9. Comparison of restriction options	61
3. Assumptions, uncertainties and sensitivities	68
3.1. Part A: Regulatory uncertainty	71
3.2. Part B: Uncertainty related to the releases	74
3.3. Part C: The identity of the binder materials	76
3.4. Part D: Time path of the price difference between clay targets produced with different binders	
3.5. Summary of the uncertainty analysis	79
4. Conclusion	82
References	83
Annex A: Manufacture and uses	85
A.1. Manufacture, import and export	85
A.2. Uses	86
A.2.1. Manufacture of clay targets	86
A.2.2. End-use of clay targets (article service life)	87
A.3. Uses advised against by the registrants	88
Annex B: Information on hazard and risk	89
B.1. Identity of the substance(s) and physical and chemical properties	89
B.2. Exposure assessment and emissions characterisation	89
B.2.1. Summary of the existing legal requirements	89
B.2.2. Manufacturing of clay targets	91
B.2.3. End-use of clay targets (article service life)	92
B.3. Risk characterisation	92
Annex E: Impact Assessment	95
E.2.2. Identification of potential alternative substances and techniques fulfilling the function	95
E.7. Practicality, enforceability and monitorability	103
Annex G: Stakeholder information	108

BACKGROUND DOCUMENT - PAHs in clay targets for shooting

TABLES

Table 1. Summary of the 18 indicator PAHs in the scope of the proposed restriction 10
Table 2. Summary of physico-chemical properties of the 18 indicator PAHs 12
Table 3. Substance identity (CTPHT)
Table 4. Concentration of 18 indicator PAHs in the European Composite Sample of CTPHT (Bilbaina 0148-01, DEZA 0149-01, registration dossiers, 2021)
Table 5. Summary of physico-chemical properties of CTPHT (ECHA 2009b) 16
Table 6. Substance identity (petroleum pitch)
Table 7. Concentration of 18 indicator PAHs in the European Composite Sample of Petroleum Pitch (registration dossiers, 2021)
Table 8. Summary of physico-chemical properties of petroleum pitch (Chemical Safety Report of the lead registrant, May 2016)
Table 9. Substance identity of EC No. 305-586-4
Table 10. Summary of physico-chemical properties of EC No. 305-586-4 (disseminated registration dossier, accessed July 2021)
Table 11. Physico-chemical properties of [Resin 1] (disseminated registration dossier, accessed July 2021)
Table 12. Physico-chemical properties of [Resin 3] (disseminated registration dossier, accessed July 2021)
Table 13. Concentration of the sum of 18 PAHs in clay targets
Table 14. Classification and labelling of the 18 indicator PAHs
Table 15. Classification and labelling of substances identified in 1.2.1.2
Table 16. Concentration of 18 indicator PAHs in substances identified under section 1.2.1 and the harmonised classification, PBT/vPvB formal identification as SVHC and POP status of the individual indicator PAHs
Table 17. Estimates of clay targets by binder placed on the EU market in 2019 (in million targets)
Table 18. The baseline market situation and the total releases of tonnes of 18 indicator PAHs per year (assumed non-authorisation of CTPHT)
Table 19. Clay targets produced with alternative binders, price and PAH-content 42
Table 20. Technical comparison of the clay targets produced with CTPHT and other binder materials
Table 21. PAHs concentration, physico-chemical properties and hazards of [Resin 2] 48
Table 22. PAHs concentration, physico-chemical properties and hazards of [Resin 4] 49
Table 23. Summary of the proposed restriction options
Table 24. RO1 1 % restriction on 18 indicator PAHs, ex-post market situation 55
Table 25. RO2 0.1 % restriction on 18 indicator PAHs, ex-post market situation 56
Table 26. RO3 0.005 % restriction on 18 indicator PAHs, ex-post market situation 57
Table 27. RO4 0.0001 % restriction on 18 indicator PAHs, ex-post market situation 60

BACKGROUND DOCUMENT - PAHs in clay targets for shooting

Table 28. Comparison of restriction options
Table 29. Cost-effectiveness of recent REACH restrictions
Table 30. Identified uncertainties in the assessment
Table 31. Prioritisation of the identified uncertainties
Table 32. Parts of the uncertainty analysis
Table 33. Alternative baseline considering the regulatory uncertainty related to the decisions to grant or deny an authorisation for CTPHT as a binder in clay targets
Table 34. Cost-effective analysis of Restriction Options if CTPHT as a binder in clay targets is granted an authorisation
Table 35. Cost-effective analysis of Restriction Options – If restriction applies also to the exports by restricting the PAH containing binders in production
Table 36. Cost-effective analysis of Restriction Options with a 50 % removal rate – worst-case scenario in terms of avoided releases
Table 37. Cost-effectiveness analysis of restriction options under the assumption of higher 18 indicator PAHs contents
Table 38 Summary of the uncertainty analysis
Table 39. Worst-case and best-case estimates for the marginal abatement costs
Table 40. Combined exposure and risk characterisation for production workers
Table 41. Combined exposure and risk characterisation for production workers 94
Table 42. Substances of the "rosins" group registered with uses as binder/binding agents 96
Table 43. Patents
FIGURES
Figure 1. General Specifications for Clay Targets, ISSF General technical rules (ISSF, 2020b)7
Figure 2. Types of clay targets (FITASC, 2021)
Figure 3. Abatement cost curve for the clay target restriction options
Figure 4. Abatement cost curve for clay target restriction options if CTPHT as a binder in clay targets is granted an authorisation

Summary

Coal tar pitch, high temperature (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 polycyclic aromatic hydrocarbons (PAHs) in the substance.

In 2019, ECHA received two applications for authorisation for the use of CTPHT as a binder in clay targets for sports shooting (also known as clay pigeons). The binder ensures that targets are sufficiently strong but also sufficiently brittle so that when they are hit by a projectile (typically fired from a gun) a clear disintegration of the target can be observed. 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.

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 needed to prepare an Annex XV restriction dossier. 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 alternative substances to CTPHT are currently used as a binder for clay targets in the EU. While generally they have lower concentrations of PAHs than CTPHT, many of the alternatives also contain PAHs. Alternatives with very low PAH-content and PAH-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.

For practical reasons, the Dossier Submitter proposes a concentration limit for the sum of 18 indicator PAHs in clay targets that shall not be exceeded. The reasons are:

• The hazardous properties of the binders are due to the presence of PAHs. Because there are very many PAHs and their presence in the binders is variable (UVCB substances¹), it is practical to base a limit on measurable² 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. In practice, limiting the concentration of these 18 PAHs in clay targets will prevent the use of certain binders to manufacture clay targets, as the concentration of PAHs in these binders is too high to meet the concentration limit suggested in the proposed restriction.

 $^{^{\}rm 1}$ UVCB substance: substance of unknown or variable composition, complex reaction products or biological materials

² Analytical methods exist to analyse the amount of these 18 PAHs in the clay targets.

• It is practical to align the restriction with the rules³ of the International Sports Shooting Federation (ISSF), which impose a limit of 0.005 % w/w for the sum of the concentration of 18 indicator PAHs in clay targets, for the Olympic Games, World Championships, World Cups, World Cup Finals and Junior World Cups. Aligning the 18 PAHs within the scope of the proposed restriction with existing voluntary standards provides a clear legal basis for companies and enforcement authorities that is consistent with already existing rules in the sector.

Following an analysis of four restriction options with different concentration limits for the sum of 18 indicator PAHs in clay targets (1 %, 0.1 %, 0.005 % and 0.0001 % (w/w)), the Dossier Submitter proposes a concentration limit for the sum of 18 indicator PAHs of less than 0.005 % by weight in the clay target.

It is estimated that the proposed restriction would reduce emissions to the environment of the 18 indicator PAHs with PBT, vPvB and carcinogenic properties by approximately **270 tonnes per year** and would cost **€3.6 million per year**. The average abatement cost was estimated to be €13.5/kg and the marginal abatement cost was estimated to be €130/kg. The proposed restriction would reduce emissions of PAHs in clay targets by 99 % relative to the baseline. An uncertainty analysis confirmed that the analysis was robust irrespective of the identified uncertainties.

An interim concentration limit value of 1 % (w/w) for the sum of the concentrations of the 18 indicator PAHs is proposed to apply from the entry into force of the restriction. This interim limit would immediately prevent the import of clay targets made with CTPHT as a binder, but temporarily allow other PAH containing binders for a transitional period. One year after the entry into force of the restriction the concentration limit value will be lowered from 1% to 0.005% (w/w). The reasons are:

- The continued use of CTPHT in clay targets during a one year transitional period would lead to a release of 114 tonnes of the 18 indicator PAHs with PBT, vPvB and carcinogenic properties, and would have no or limited economic benefits as similarly priced alternative binders are already available. It would appear that markets have already adapted to the increasing regulatory pressure on CTPHT. For these reasons, the Dossier Submitter does not consider a transitional period would be required for CTPHT and therefore, it is proposed that a restriction of CTPHT would be effective immediately from entry into force of the restriction⁴.
- For the other substances subject to the conditions of the restriction, the entry into effect is proposed to be postponed for one year from the entry force. A one-year

³ General Technical Rule 6.3.6. ISSF establishes Technical Rules to govern the conduct of shooting events recognised by the ISSF (ISSF General Regulations, 3.3). According to these rules "Clay targets used in the Olympic Games, World Championships, World Cups, World Cup Finals and Junior World Cups must be eco-friendly targets that comply with appropriate international standards". The definition of eco-friendly targets is available at: Definition eco-friendly.pdf

⁴ In the event that the Commission does not grant authorisations for the use of CTPHT in clay targets, the non-authorised use of the substance must cease immediately i.e., no 'grace period' or transitional arrangements are foreseen. The absence of a transitional period for the proposed restriction would be consistent with this. See also Q&A 1853 on the ECHA website: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1853.

transitional period is considered to be the minimum sufficient period to allow clay target manufacturers to find new suppliers of binder materials and to implement any adjustments to their manufacturing processes without significant risk of disruption of the market occurring. However, the transitional period is estimated to lead to release of up to 150 tonnes of 18 indicator PAHs.

Proposed restriction (Restriction Option 3)

The restriction would come into force in two phases:

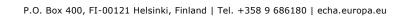
Clay targets for shooting shall not be placed on the market or used for shooting where the sum of the concentrations by weight of the 18 indicator PAHs is greater than 1 % (w/w) in the clay targets from entry into force of the restriction.

Clay targets for shooting shall not be placed on the market or used for shooting where the sum of the concentrations by weight of the 18 indicator PAHs is greater than 0.005 % (w/w) in the clay target 1 year from entry into force of the restriction.

Substar	nces	Conditions of the restriction		
Polycycl	lic aromatic hydrocarbons (PAHs)	From [date of entry into force of the		
(a)	Acenaphthene, CAS No 83-32-9, EC No 201-469-6	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		
(b)	Acenaphthylene, CAS No 208-96- 8, EC No 205-917-1	weight of dry mass of the clay target) of the sum of all listed PAHs.		
(c)	Anthracene, CAS No 120-12-7, EC No 204-371-1	From [date + 1 year from entry into force of the restriction], clay targets shall not be placed on the market or used for shooting		
(d)	Benz[a]anthracene, CAS No 56- 55-3, EC No 200-280-6	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.		
(e)	Benzo[def]chrysene, CAS No 50- 32-8, EC No 200-028-5 (benzo[a]pyrene)			
(f)	Benzo[e]acephenanthrylene, CAS No 205-99-2, EC No 205-911-9 (benzo[b]fluoranthene)			
(g)	Benzo[e]pyrene, CAS No 192-97- 2, EC No 205-892-7			
(h)	Benzo[<i>ghi</i>]perylene, CAS No 191- 24-2, EC No 205-883-8			
(i)	Benzo[<i>j</i>]fluoranthene, CAS No 205-82-3, EC No 205-910-3			
(j)	Benzo[<i>k</i>]fluoranthene, CAS No 207-08-9, EC No 205-916-6			
(k)	Chrysene, CAS No 218-01-9, EC No 205-923-4			
(1)	Dibenz[a,h]anthracene, CAS No			

53-70-3, EC No 200-181-8

- (m) Fluoranthene, CAS No 206-44-0, EC No 205-912-4
- (n) Fluorene, CAS No 86-73-7, EC No 201-695-5
- (o) Indeno[1,2,3-cd]pyrene, CAS No 193-39-5, EC No 205-893-2
- (p) Naphthalene, CAS No 91-20-3, EC 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



Report

1. The problem identified

Coal tar pitch, high temperature (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 polycyclic aromatic hydrocarbons (PAHs) in the substance.

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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 needed to prepare an Annex XV restriction dossier.

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It is estimated that the placing on the market of PAH-containing clay targets results in emissions of 18 indicator PAHs with PBT, vPvB and carcinogenic properties of approximately 270 tonnes per year. When such clay targets are shot, *initially* 100 % of the PAHs are released to the environment during the article service life of clay targets. 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. Furthermore, PAHs are released to the environment during the production of clay targets⁶.

In addition, there are excess cancer risks for workers, shooters and persons handling the clay targets that are exposed to PAHs in clay targets (mainly lung, bladder and skin cancers, ECHA,

⁵ Decisions available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323(02)&from=EN and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323(02)&from=EN

⁶ The release from the manufacturing of clay targets with PAH-containing binders is orders of magnitude lower than from the article service life. An estimate for CTPHT-containing clay targets is reported in section B.2.2.2.

2018⁷). These risks were not quantified as part of this assessment, were considered in a qualitative manner.

1.1. Manufacture and uses

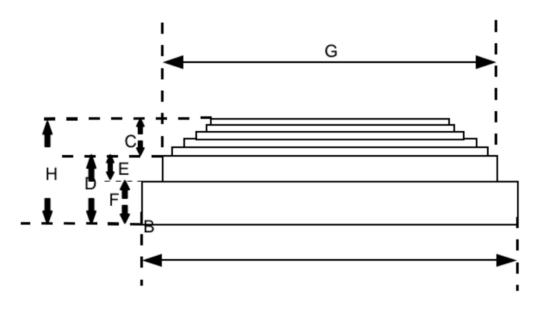
Clay targets (also known as clay pigeons) are used for sport shooting. They are designed as flying (saucer-shaped) targets for sports shooters and small game hunters to practice on. Clay targets are designed in accordance with precise specifications with regard to their weight and dimensions and are required to conform to international standards.

The International Sport Shooting Federation (ISSF) technical rules (ISSF, 2020b) define the characteristics of targets used in ISSF-recognised shooting events (including the Olympic Games, World Championships, World Cups, World Cup Finals, Continental Championships, Continental Games, Junior World Championships and Junior World Cups). They weigh about 105 grams (105 \pm 5 g), have a diameter of 110 mm (110 \pm 1 mm) and are 25-26 mm in height.

The ISSF technical rules also limit the PAH content of clay targets used in Olympic Games, ISSF World Championships and World Cups (eco-friendly targets), see section 1.2.1.1. The clay targets that are proposed to be restricted would **not** meet these criteria.

https://echa.europa.eu/documents/10162/17229/ctpht rac note en.pdf.

⁷ Significant associations between PAH exposure and several other cancer types have been documented. These associations are briefly described in the *Note on reference dose-response relationship for the carcinogenicity of pitch, coal tar, high temperature and on PBT and vPvB properties* agreed by RAC (RAC-45, 8 June 2018).



		E-Rotating Ring Height	7 mm ± 1 mm
B-Base Ø 110 mm ± 1 mm F		F-Base Height	11 mm ± 1 mm
C-Dome Height* 8 mm ± 1 mm		G-Rotating Ring	95 mm – 98 mm
D-Base & Ring Height	18 mm ± 1 mm	H-Total Height	25 mm to 26 mm

Figure 1. General Specifications for Clay Targets, ISSF General technical rules (ISSF, 2020b)

Other sizes of clay targets are also available for various other disciplines of sport shooting. FITASC (Federation Internationale de Tir aux Armes Sportives de Chasse) refer to different types of targets for its events: normal standard targets (as in Figure 2), rabbit, midi, super mini, battue and flash. Mini and super mini targets are smaller than the standard targets, the battue is thinner to fly faster, and the rabbit is thicker so it can roll on the ground. "Flash targets" contain in addition coloured powder so as to release a puff of smoke when hit.

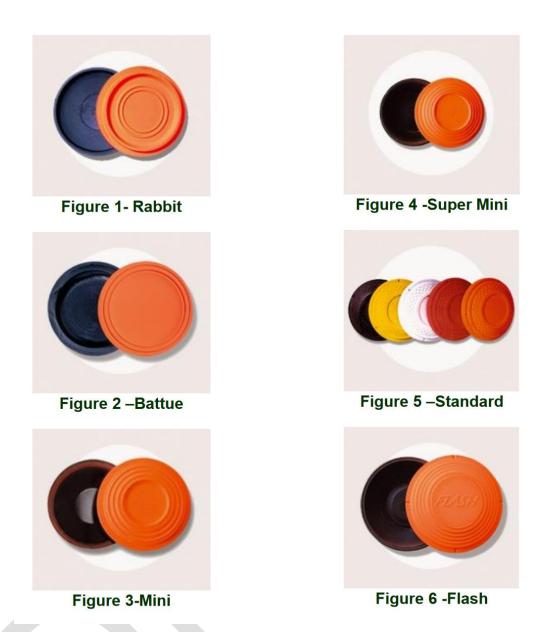


Figure 2. Types of clay targets (FITASC, 2021)

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 at a ratio of about 2:1. Typically, the moulding process is undertaken using a rotary press or 'carousel'. The binder material used, when mixed with the filler material under a stable and consistent production process, will ensure that targets remain consistent in their composition when moulded. The viscosity of the binder affects the manufacturing process (high viscosity requires higher process temperature, and low viscosity may cause the substance to seep from the moulds and lead to an inconsistent binder-to-filler ratio in the end targets).

All PAH-containing binders are used with the same basic production technique of mixing binder and filler, followed by moulding and further treatment.

1.2. Hazard, exposure/emissions and risk

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

1.2.1.1. Polycyclic aromatic hydrocarbons

The proposed restriction establishes a concentration limit for 18 PAHs in clay targets. There are other polycyclic aromatic compounds (homocyclic, heterocyclic and alkylated) which may be of concern. Reducing the amount of these 18 indicator PAHs in clay targets will also reduce the amount of other polycyclic aromatic compounds that could also be present in clay targets. Such an approach has already been used and implemented in previous restrictions for PAHs⁸.

The reasons for the choice of these 18 PAHs as relevant indicators are the following:

- The hazardous properties are due to the presence of PAHs, but because there are very many PAHs and the composition of the binders varies due to their variable and complex nature (UVCB substances), 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 these 18 indicator PAHs also reduces the concentration of other PAHs in clay targets.
- It is practical to align the restriction with the rules of the ISSF. Indeed, the General Technical Rule 6.3.6 of ISSF⁹ requires that "clay targets used in the Olympic Games, ISSF World Championships and World Cups, must be eco-friendly targets" and "clay targets used in Continental Games and Championships should be eco-friendly targets."
 To meet the definition of "eco-friendly" targets, the total concentration of the specified 18 PAHs has to be below < 50 mg/kg (i.e. 0.005 % w/w) and in addition shall comply with the following specific limits:</p>
 - < 1 mg/kg for benz[a]anthracene, chrysene, benzo[a]pyrene, benzo[e]acephenanthrylene¹⁰, benzo[e]pyrene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[ghi]perylene, indeno[1,2,3-cd]pyrene, dibenz[a,h]anthracene;
 - < 10 mg/kg for naphthalene;</p>
 - < 50 mg/kg for the total of seven PAHs (acenaphthylene, acenaphthene, fluorene, anthracene, phenanthrene, fluoranthene, pyrene).</p>

Aligning the 18 PAHs provides a clear legal basis for companies and enforcement authorities that is consistent with already existing rules in the sector. This is assumed to facilitate acceptance and implementation by producers of clay targets and enforceability of the restriction.

The selected PAHs include the 12 indicator PAHs which were the basis of the substance of very high concern (SVHC) identification of CTPHT (ECHA, 2009b). The selected PAHs also include the 16 PAHs identified by the U.S. Environmental Protection Agency (U.S. EPA) (naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene,

⁸ PAHs restricted under entry 50.

⁹ Definition of eco-friendly targets available at: https://www.issf-sports.org/getfile.aspx?mod=docf&pane=1&inst=31&iist=29&file=ISSF Rule Interpretation for 2017 _ISSF Rules 6.3.6 Definition eco-friendly.pdf. Accessed August 2021.

 $^{^{10}}$ Referred to as benzo[b]fluoranthene in the ISSF rule.

anthracene, fluoranthene, pyrene, benz[a]anthracene, chrysene, benzo[e]acephenanthrylene, benzo[k]fluoranthene, benzo[a]pyrene, dibenz[a,h]anthracene, benzo[ghi]perylene and indeno[1,2,3-cd]pyrene), which have been recognised for decades as substances of concern; this ensures that analytical methods are readily available (Wise et al., 2015; Andersson and Achten, 2015). In addition, benzo[e]pyrene and benzo[j]fluoranthene (not part of the 16 US EPA PAHs) are included in the scope of Entries 28 and 50 of REACH Annex XVII because they are carcinogenic. They are also included in the scope of the restriction on granules and mulches used as infill materials¹¹. Therefore, analytical methods are also readily available for these two substances. See also Section E.7.

- Limiting the amount of these 18 PAHs will in practice prevent the use of certain binders to manufacture clay targets, as the concentration of PAHs in these binders is above the concentration limit suggested in the proposed restriction.
- Information on the hazards and concentrations of these 18 PAHs is sufficient to underpin the need for a restriction. Data is available on the concentration of these 18 PAHs in binder substances used for clay target production (registration data) and in clay targets (ISSF, 2020).

Table 1. Summary of the 18 indicator PAHs in the scope of the proposed restriction.

Chemical name	EC number	CAS number	Molecular formula	Molecular weight	Chemical structure
Naphthalene	202- 049-5	91-20-3	C ₁₀ H ₈	128.17	
Acenaphthylene	205- 917-1	208-96- 8	C ₁₂ H ₈	152.20	
Acenaphthene	201- 469-6	83-32-9	C ₁₂ H ₁₀	154.21	
Fluorene	201- 695-5	86-73-7	C ₁₃ H ₁₀	166.22	
Anthracene	204- 371-1	120-12- 7	C ₁₄ H ₁₀	178.23	
Phenanthrene	201- 581-5	85-01-8	C ₁₄ H ₁₀	178.23	
Fluoranthene	205- 912-4	206-44- 0	C ₁₆ H ₁₀	202.25	
Pyrene	204- 927-3	129-00- 0	C ₁₆ H ₁₀	202.25	
Benz[a]anthracene	200- 280-6	56-55-3	C ₁₈ H ₁₂	228.29	

¹¹ https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181d5746d

P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | echa.europa.eu

Chemical name	EC number	CAS number	Molecular formula	Molecular weight	Chemical structure
Chrysene	205- 923-4	218-01- 9	C ₁₈ H ₁₂	228.29	
Benzo[<i>def</i>]chrysene (Benzo[<i>a</i>]pyrene)	200- 028-5	50-32-8	C ₂₀ H ₁₂	252.31	
Benzo[e]acephenanthrylene (Benzo[b]fluoranthene)	205- 911-9	205-99- 2	C ₂₀ H ₁₂	252.31	
Benzo[<i>e</i>]pyrene	205- 892-7	192-97- 2	C ₂₀ H ₁₂	252.31	
Benzo[j]fluoranthene	205- 910-3	205-82-	C ₂₀ H ₁₂	252.31	
Benzo[k]fluoranthene	205- 916-6	207-08- 9	C ₂₀ H ₁₂	252.31	
Benzo[<i>ghi</i>]perylene	205- 883-8	191-24- 2	C ₂₂ H ₁₂	276.33	
Indeno[1,2,3-cd]pyrene	205- 893-2	193-39- 5	C ₂₂ H ₁₂	276.33	
Dibenz[a,h]anthracene	200- 181-8	53-70-3	C ₂₂ H ₁₄	278.35	

Table 2. Summary of physico-chemical properties of the 18 indicator PAHs.

Substance	Melting/freezi ng point [°C]	Boiling point [°C]	Vapour pressure [Pa] at 25 °C	Water solubility [µg/L]	Log K _{ow}	Density [g/cm³]	Source
Naphthalene	81	217.9	10.4	31700 at 25°C	3.4	1.154	WHO (1998)
Acenaphthylene	92-93	-	0.89	-	4.07	0.899	WHO (1998)
Acenaphthene	95	279	0.29	3930 at 25 °C	3.92	1.024	WHO (1998)
Fluorene	115-116	295	8.0 x 10 ⁻²	1980 at 25 °C	4.18	1.203	WHO (1998)
Anthracene	216.4	342	9.4 x 10 ⁻⁴	47	4.68	1.283	ECHA 2009b
Phenanthrene	100.5	340	2.6 x 10 ⁻²	974	4.57	0.980	ECHA 2009b
Fluoranthene	108.8	375	1.2 x 10 ⁻³	200	5.20	1.252	ECHA 2009b
Pyrene	156	360	1.0 x 10 ⁻³	125	4.98	1.271	ECHA 2009b
Benzo[a]anthracene	160.7	435	7.6 x 10 ⁻⁶	10.2	5.91	1.226	ECHA 2009b
Chrysene	253.8	448	5.7 x 10 ⁻⁷	1.65	5.81	1.274	ECHA 2009b
Benzo[<i>def</i>]chrysene (Benzo[<i>a</i>]pyrene)	175	496	7.3 x 10 ⁻⁷	1.54	6.13	1.35	ECHA 2009b
Benzo[e]acephenanthrylene (Benzo[b]fluoranthene)	168.3	481	3.3 x 10 ⁻⁶	1.28	6.12	-	ECHA 2009b
Benzo[e]pyrene	178.7	493	7.4 x 10 ⁻⁷	5.1 at 23 °C	6.44	-	WHO (1998)
Benzo[j]fluoranthene	165.4	480	2.0 x 10 ⁻⁶	2.5	6.12	-	WHO (1998)
Benzo[k]fluoranthene	217	480	1.3 x 10 ⁻⁷	0.93	6.11	=	ECHA 2009b
Benzo[ghi]perylene	277	545	1.4 x 10 ⁻⁸	0.14	6.22	1.329	ECHA 2009b
Indeno[1,2,3-cd]pyrene	163.6	536	1.7 x 10 ⁻⁸	0.1	6.58	-	ECHA 2009b
Dibenz[a,h]anthracene	266.6	524	3.7 x 10 ⁻¹⁰	0.82	6.50	1.282	ECHA 2009b

1.2.1.2. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting

The proposed restriction proposes to introduce a concentration limit of 0.005 % (50 mg/kg) for the 18 indicator PAHs in clay targets. The concentration limit will determine which binder substances would be restricted for use in clay targets, i.e. only binders with sufficiently low PAH concentrations would not be restricted. Based on the available information, the identifiers of the substances that would be restricted under the proposed restriction options are given in the sections below.

Pitch, coal tar, high-temp. (CTPHT) as well as several known alternatives to CTPHT in clay targets (e.g., Petroleum Pitch and Petroleum Resin) are assumed to be within the scope of the proposed restriction. Alternative binders that would meet the proposed concentration limit would not be restricted.

The terms 'Petroleum Resin' and 'Eco Resin', whilst widely used within the sector, have no consistent use or definition and do not strictly correspond to EC and CAS numbers. The terms are known to be used to designate several UVCB substances, therefore it is not always clear which substances are meant by different actors when these terms are used. Furthermore, even for the substances that were specifically identified with EC and CAS numbers, information on their composition is lacking in REACH registration dossiers. Other substances containing PAHs, not identified in this report, may also be used for clay target production, and hence the substances explicitly identified below should not be considered as an exhaustive list of substances that would be affected by the proposed restriction.

Confidential information on substance identity is provided in a separate confidential annex.

Pitch, coal tar, high-temp. (CTPHT)

CTPHT is a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials) characterised by a variable and high content of PAHs and heterocyclic compounds. It is the residue from the distillation of high temperature coal tar (CAS No. 65996-89-6) under vacuum in closed systems. It is a complex hydrocarbon consisting of three- to seven-membered condensed ring aromatic hydrocarbons (90 %) and of high molecular weight compounds, their (poly)methylated derivatives, heterocyclic compounds and benzocarbazoles (EU RAR, 2008). The exact composition varies due to the variable and complex nature of CTPHT, as well as due to variations in the distillation temperature. CTPHTs of different composition may be named with different synonyms hinting at their intended use, e.g., binder pitch or impregnating pitch (ECHA 2009b).

Table 3. Substance identity (CTPHT)

EC number	266-028-2
EC name	Pitch, coal tar, high-temp.
Description	The residue from the distillation of high temperature coal tar. A black solid with an approximate softening point from 30°C to 180°C. Composed primarily of a complex mixture of three or more membered condensed ring aromatic hydrocarbons.
CAS number	65996-93-2
Synonyms	Coal tar pitch high temperature, anode pitch; binder pitch; clay target binder; electrode pitch; hard pitch; impregnating pitch; soft pitch; vacuum pitch; Carbo Pitch; Carbomasse; Coal Tar Pitch; Electrode Binder; Refractory Binder; smola

The composition of a 'European Composite Sample' for CTPHT is provided in Table 4. The 'European Composite Sample' is a reference material for CTPHT which is stated to be representative for the CTPHT produced by all companies in the consortium 'REACH for Coal Chemicals' (R4CC). However, as this composition analysis is based on only one sample and the composition is variable within and across manufacturers, the composition of this composite sample may not reflect batches or products from manufacturers with higher (or lower) levels of PAHs.

Importantly, CTPHT in imported clay targets is subject to the proposed restriction (assuming the authorisations would not be granted) and it is at this time not clear whether the reported composition adequately reflects the typical composition of CTPHT in imported targets.

Table 4. Concentration of 18 indicator PAHs in the European Composite Sample of CTPHT (Bilbaina 0148-01, DEZA 0149-01, registration dossiers, 2021)

РАН	EINECS No.	CAS No.	Concentration in substance (%)
Naphthalene	202-049-5	91-20-3	See confidential annex
Acenaphthylene	205-917-1	208-96-8	See confidential annex
Acenaphthene	201-469-6	83-32-9	See confidential annex
Fluorene	201-695-5	86-73-7	See confidential annex
Anthracene	204-371-1	120-12-7	0.057
Phenanthrene	201-581-5	85-01-8	0.302
Fluoranthene	205-912-4	206-44-0	0.835
Pyrene	204-927-3	129-00-0	0.726
Benz[a]anthracene	200-280-6	56-55-3	0.599
Chrysene	205-923-4	218-01-9	0.835
Benzo[<i>def</i>]chrysene (Benzo[<i>a</i>]pyrene)	200-028-5	50-32-8	0.873
Benzo[e]acephenanthrylene (benzo[b]fluoranthene)	205-911-9	205-99-2	1.125
Benzo[e]pyrene	205-892-7	192-97-2	See confidential annex
Benzo[j]fluoranthene	205-910-3	205-82-3	See confidential annex
Benzo[k]fluoranthene	205-916-6	207-08-9	0.393
Benzo[<i>ghi</i>]perylene	205-883-8	191-24-2	0.550
Indeno[1,2,3-cd]pyrene	205-893-2	193-39-5	0.618
Dibenz[a,h]anthracene	200-181-8	53-70-3	0.078
Sum 18 indicator PAHs in substance			7.9

nd: below limit of detection

The PAH-concentrations in impregnating pitch and binder pitch, two compositions of CTPHT, as reported in (ECHA, 2009b), are higher: **14.1** % and **10.1** %, respectively (this value is likely an underestimate as benzo[j] fluoranthene was not measured).

Table 5 summarises the general physico-chemical properties of CTPHT.

Table 5. Summary of physico-chemical properties of CTPHT (ECHA 2009b)

Property	Value
Physical state at 20°C and 101.3 kPa	Black solid
Melting/freezing point	65-150 °C (softening range)
Boiling point	>360 °C (at 1013 hPa)
Vapour pressure	<10 Pa (at 20 °C) <1000 Pa (at 200 °C)
Water solubility	~0.04 mg/L (16 EPA PAHs)
Partition coefficient n-octanol/water (log value)	not applicable
Density [g/cm3]	1.15-1.40 at 20 °C
Flash point [°C]	>250
Auto flammability [°C]	>450
Explosive properties	Not explosive
Oxidizing properties	Not oxidizing

Petroleum pitch

Petroleum pitch is also a UVCB substance. Like CTPHT, it is composed primarily of a complex combination of three or more membered, condensed ring aromatic hydrocarbons.

Table 6. Substance identity (petroleum pitch)

EC number	269-110-6				
EC name	Pitch, petroleum, arom.				
Description	The residue from the distillation of thermal cracked or steam-cracked residuum and/or catalytic cracked clarified oil with a softening point from 40°C to 180°C (104°F to 356°F). Composed primarily of a complex combination of three or more membered condensed ring aromatic hydrocarbons.				
CAS number	68187-58-6				
Synonyms	petroleum pitch; petro pitch; aromatic hydrocarbon resin; petroleum resins				

The REACH registrants provided an analytical report of the PAH content of a 'European Composite sample' of petroleum pitch as shown in Table 7.

Table 7. Concentration of 18 indicator PAHs in the European Composite Sample of Petroleum Pitch (registration dossiers, 2021)

PAH	EINECS No.	CAS No.	Concentration in substance(%)
Naphthalene	202-049-5	91-20-3	-
Acenaphthylene	205-917-1	208-96-8	
Acenaphthene	201-469-6	83-32-9	
Fluorene	201-695-5	86-73-7	
Anthracene	204-371-1	120-12-7	
Phenanthrene	201-581-5	85-01-8	
Fluoranthene	205-912-4	206-44-0	
Pyrene	204-927-3	129-00-0	
Benz[a]anthracene	200-280-6	56-55-3	
Chrysene	205-923-4	218-01-9	16 of 18 PAH present.
Benzo[<i>def</i>]chrysene (Benzo[<i>a</i>]pyrene)	200-028-5	50-32-8	See confidential annex
Benzo[e]acephenanthrylene (Benzo[b]fluoranthene)	205-911-9	205-99-2	
Benzo[e]pyrene	205-892-7	192-97-2	
Benzo[j]fluoranthene	205-910-3	205-82-3	
Benzo[k]fluoranthene	205-916-6	207-08-9	
Benzo[<i>ghi</i>]perylene	205-883-8	191-24-2	
Indeno[1,2,3-cd]pyrene	205-893-2	193-39-5	
Dibenz[a,h]anthracene	200-181-8	53-70-3	
Sum 18 indicator PAHs in substance			2.4

nd: below limit of detection

The registrants indicated that the 'European Composite sample' is a combination of different samples of petroleum pitch provided by multiple European producers (registrants of petroleum pitch), and therefore may represent a typical composition of petroleum pitch. However, as the composition is known to be variable within and across manufacturers, the composition of this composite sample may not reflect batches or products from manufacturers with higher (or lower) levels of PAHs. The concentrations of the 18 indicator PAHs reported in the individual registration dossiers of petroleum pitch are up to **5.7** % (this value is likely an underestimate as benzo[j]fluoranthene and benzo[e]pyrene were not measured).

Furthermore, it is not clear whether the estimate is representative for the typical composition of petroleum pitch in imported targets.

A sum of about 2.6 % of 18 indicator PAHs was obtained from measured data provided by ISSF (2020) on PAHs in clay targets with petroleum pitch as a binder. This result provides some confirmation of the PAHs content estimate of petroleum pitch based on the European Composite Sample. However, drawing firm conclusions is difficult as most of the registration data are incomplete.

In the opinions on the applications for authorisation for use of CTPHT as a binder in the manufacture of clay targets, RAC could not conclude whether the implementation of petroleum pitch would lead to an overall reduction in risk (ECHA, 2020). Considering the intrinsic properties of petroleum pitch, RAC did not recommend the substitution of CTPHT with

this alternative. The composition information above supports the opinion of RAC. When looking at the indicator PAHs that were the focus in the assessment for the purposes of identifying CTPHT as SVHC for its PBT and vPvB properties, it is clear that the same PAHs are also present in petroleum pitch. RAC considered it plausible that petroleum pitch would meet the PBT and vPvB criteria.

Should only the use of CTPHT be restricted, substitution with petroleum pitch (amongst others) is likely. This is because targets using petroleum pitch are the least expensive alternative for the consumers (shooters) and based on the information provided in the applications for authorisation, it is also the least expensive option to implement for the EU producers currently using CTPHT. Table 8 summarises the general physico-chemical properties of petroleum pitch.

Table 8. Summary of physico-chemical properties of petroleum pitch (Chemical Safety Report of the lead registrant, May 2016)

Property	Value
Physical state at 20°C and 101.3 kPa	solid
Melting/freezing point	117 °C at 101.3 kPa
Boiling point	N/A; decomposes after > 400 °C
Vapour pressure	~ 0.004 Pa at 20 °C
Water solubility	0.00154 mg/L at 20 °C (value for benzo[a]pyrene)
Partition coefficient n-octanol/water (log value)	6.13 at 20 °C (average of published values for benzo[a]pyrene)
Density [g/cm3]	1.21 at 20 °C
Flash point [°C]	186 °C at 1013 hPa
Auto flammability [°C]	480 °C at 1013 hPa
Explosive properties	information waived
Oxidizing properties	information waived

Petroleum resin

"Petroleum resin" appears to be one of the main alternative binders currently in use. Several manufacturers of clay targets state that they use petroleum resin (ISSF, 2020). However, it is uncertain what substance(s) is or are described by this generic name. The term "hydrocarbon resin" is also used by ISSF and by industry.

ISSF (2020) refers to "petroleum resin" as a substance with EC No. 269-110-6, which seems to indicate that petroleum resin and petroleum pitch are registered with the same numerical identifier. However, according to ISSF (2020), the PAH-content of clay targets using petroleum resin is about 12 times lower than those using petroleum pitch (0.07 % and 0.8 % of 18 indicator PAHs in clay targets, respectively). ISSF refers to this substance as an HCR (hydrocarbon resin) variation of petroleum pitch (EC No. 269-110-6).

Not all registrants of EC No. 269-110-6 (pitch, petroleum, arom.) have provided concentrations of indicator PAHs specific to their own substance. Based on the registration data as such, it could not be confirmed that compositions including lower amounts of PAH are indeed manufactured in or imported to the EU. However, direct exchanges with registrants revealed that a lower-PAH composition of petroleum pitch (still registered as petroleum pitch)

is available from at least one company. This lower-PAH composition of petroleum pitch is registered to be used for clay target production and reportedly has an aggregate PAH content in the range of **0.2-0.3** %¹² (which would correspond to about 0.07-0.10 % in clay targets, i.e., similar to 0.06% reported by ISSF, 2020).

Other resins containing PAHs

Other resins can be used as binders in clay targets. There are uncertainties related to the identification of these substances (names, CAS and EC numbers), and uncertainties related to their constituents as they are UVCBs and information on composition is lacking in registration dossiers. Moreover, some of them have been regarded as polymers and are therefore not registered. It should also be noted that none of the substances listed in this section are explicitly registered for a use in clay targets¹³. The binders were identified through exchanges with ISSF and manufacturers of resins.

Resins with a "very low PAH content" are described as "eco resin" by manufacturers of resins and the ISSF. As many substances may be labelled as "eco resin" and the term is loosely defined, it is difficult to determine what would be a typical concentration of PAHs in "eco resin". Indeed, substances defined as "eco resins" can actually contain high amounts of PAHs¹⁴. It is therefore important to note that this generic label is not useful for distinguishing between substances that would or would not be restricted under the proposed restriction.

For the purposes of the impact assessment, it has been assumed that the concentration of the 18 indicator PAHs in 'eco resins' is <0.015 % w/w. This is in line with the definition of 'eco-friendly' targets (<0.005 %), considering that a clay target consists of about one third binder. Some resins would meet this definition while others would not. Resins that are used in the production of clay targets that meet the definition of 'eco-friendly' targets are called "Eco resin and natural resin" in this report and are not proposed to be restricted. They are not described in this section but in section 2.2 on alternative binders as they may be used as alternatives when the proposed restriction enters into effect.

Several resins used in clay targets have been identified from exchanges with ISSF and manufacturers of resins. They are presented below. This list may not be exhaustive.

A substance identified using CAS No. 94733-07-0 and EC No. 305-586-4 has been identified by ISSF (2020) as "Eco Resin (HCR)". A list of identifiers used to describe the substance is given in Table 9.

 $^{^{12}}$ Analytical data (available in the confidential annex), show that not all of the 18 indicator PAHs were detected and quantified (benzo[e]pyrene was not analysed for, dibenz[a,h]anthracene was quantified as the sum of dibenz[a,h+a,c]anthracene, and benzo(b+k+j)fluoranthene quantified together in one of the two samples).

¹³ Search performed with Text Analytics on registration database on 22/03/2021 and 15/09/2021. Only CTPHT EC No. 266-028-2 and petroleum pitch EC No. 269-110-6 are registered for such uses.

¹⁴ Based on information obtained from ISSF (2020) and from companies (via their applications for authorisation and direct exchanges in 2021, information confidential but available to ECHA), and depending on which PAHs are considered.

Table 9. Substance identity of EC No. 305-586-4

EC number	305-586-4				
EC name	Distillates (petroleum), cracked, ethylene manuf. by-product, C9-10 fraction				
Description	A complex combination of hydrocarbons obtained by distillation of residual oils from the cracking of petroleum or natural gas. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C10 and boiling in the range of 150°C to 210°C (302°F to 410°F).				
CAS number	94733-07-0				
Synonyms	C9-10nh; C9-fraction ethylene manufacturing; Fluid products of pyrolysis (FRACTION C9); Residues of rectification of the benzene (CORB); distillates(petroleum), naphta-raffinate pyrolyzate-derived, gasoline-blending; C9+Mixed Aromatic hydrocarbons; C9-Cut				

According to ISSF (2020), clay targets made with this substance have a PAHs concentration up to 0.0003 %-0.005 %, which (under the assumptions of 33 % content of binder in the clay target article) corresponds to around 0.0009-0.015 % PAHs in the substance. However, the registration data contradict these values. Different registrants report very different PAHs concentrations, concentration ranges of PAHs are very wide within a registration, and furthermore the registration data does not appear to support the information from ISSF. Indeed, naphthalene (one of the 18 indicator PAHs) is reported in its composition (in addition to other PAHs not part of the 18 indicators PAHs). The typical concentration of naphthalene in this resin is much higher than the proposed limit value of 0.005 % in clay targets (details are confidential but available to ECHA). Thus, unless there would be low-PAH compositions of this substance, the use of this substance would be restricted under the proposed restriction. As the 18 PAHs to be restricted are identical to those set by the ISSF rule concerning clay targets in competitions, this substance would also fail to be qualified in ISSF competitions.

Table 10 summarises the general physico-chemical properties of this substance.

Table 10. Summary of physico-chemical properties of EC No. 305-586-4 (disseminated registration dossier, accessed July 2021)

Property	Value
Physical state at 20°C and 101.3 kPa	liquid
Melting/freezing point	4.8-32.2 °C at 101.3 kPa
Boiling point	80-182 °C
Vapour pressure	186-10 000 Pa at 20 °C
Water solubility	20-1880 mg/L at 20-25 °C
Partition coefficient n-octanol/water (log value)	2.13-5.8 at 20 °C
Density [g/cm3]	0.876-0.98 at 20 °C
Flash point [°C]	46.4 °C at 1013 hPa
Auto flammability [°C]	457 °C at 1013 hPa
Explosive properties	information waived
Oxidizing properties	information waived

Another substance **[Resin 1]** (identifiers claimed confidential) was identified in the confidential documentation of an application for authorisation for the use of CTPHT as a binder in the manufacture of clay targets. This binder is stated to be used in eco targets. The registration dossier claims that no PAHs are present in the composition. However, the substance may contain naphthalene originating from the starting materials. No data is provided on the concentration of naphthalene in the substance, but should it be above the suggested concentration limit value in the conditions of the restriction, then this substance would not be allowed under the proposed restriction. Table 11 summarises the physicochemical properties of [Resin 1].

Table 11. Physico-chemical properties of [Resin 1] (disseminated registration dossier, accessed July 2021)

Property	Value
Physical state at 20°C and 101.3 kPa	Liquid
Melting/freezing point	-14 °C
Boiling point	300 °C
Vapour pressure [Pa]	0.03 Pa at 20 °C
Water solubility [mg/L]	1 mg/L at 20 °C
Partition coefficient n-octanol/water (log value)	9.5 at 25 °C
Density [g/cm3]	1.1 at 20 °C
Flash point [°C]	158 °C at 1013 hPa
Auto flammability [°C]	375 °C at 1013 hPa
Explosive properties	information waived
Oxidizing properties	information waived

Additionally, the identifiers of two substances were communicated to ECHA by a registrant of petroleum pitch that is discontinuing the supply of petroleum pitch for clay target production

and has developed these two alternatives instead: [Resin 3] and [Resin 4]. These substances are commonly called 'hydrocarbon resins' and supplied as PAH-free polymer binders for clay target production in the EU as of 2021. However, [Resin 3] is likely to contain PAHs as described below. [Resin 4] would not be restricted and thus is an alternative binder described in section 2.2.2.

The PAH content in **[Resin 3]** (EC number claimed confidential) is claimed to be zero. However, the analytical data in registration dossiers contradict this claim and indicate that it does contain PAHs. No data is available on the concentration of PAHs in the substance, but should it be above the limit, this substance would not be allowed under the proposed restriction. The physico-chemical properties of [Resin 3] are given in Table 12.

Table 12. Physico-chemical properties of [Resin 3] (disseminated registration dossier, accessed July 2021)

Property	Value
Physical state at 20°C and 101.3 kPa	Liquid
Melting/freezing point	0 °C
Boiling point	207-750 °C
Vapour pressure	10 Pa at 20 °C
Water solubility [mg/L]	information waived
Partition coefficient n-octanol/water (log value)	information waived
Density [g/cm3]	0.81-0.97 at 15 °C
Flash point [°C]	98-344 °C at 1013 hPa
Auto flammability [°C]	N/A
Explosive properties	information waived
Oxidizing properties	information waived

1.2.1.3. Concentration of 18 indicators PAHs in clay targets - summary

Table 13 provides the typical concentration of the sum of 18 PAHs in clay targets. The typical concentration is estimated assuming that clay targets are composed of 33 % of binder.

Table 13. Concentration of the sum of 18 PAHs in clay targets

Binder	18-PAHs concentration in binder	18-PAHs concentration in clay targets		
CTPHT	7.9 % *	2.6 % (26 000 mg/kg)		
Petroleum pitch	2.4 % *	0.8 % (8 000 mg/kg)		
Petroleum resin	0.2-0.3 %	0.07-0.1 % (700-1000 mg/kg)		
EC No. 305-586-4	Confidential information	High concentration due to naphthalene		
[Resin 1]	Unknown (naphthalene)	Unknown (naphthalene)		
[Resin 3]	Unknown (PAHs)	Unknown (PAHs)		

^{*} Based on EU composite sample

Under the proposed restriction, a concentration limit of 0.005 % w/w (50 mg/kg) is suggested.

It cannot be excluded that other PAH-containing substances could be used as binders in clay targets. Only CTPHT and petroleum pitch are explicitly registered for the use to produce clay targets and hence the other substances were identified based on exchanges with ISSF, companies and external searches, but there is no way to confirm that this represents an exhaustive list. Furthermore, for substances that have been identified, information on substance composition in registration dossiers is usually too scarce to be able to conclude firmly on the PAH concentration in these substances. In particular, information on the identity of the substances, manufacturing process, starting materials, and on the composition with regards with their PAHs content is usually lacking, and when available, not reported in a way that would allow data analysis. Therefore, all substances, even if not identified in the sections above, which – when incorporated in clay targets – would result in a sum of the concentrations of the 18 indicator PAHs greater than 0.005 % (w/w) in clay targets, are subject to the proposed restriction.

1.2.2. Justification for grouping

The 18 indicator PAHs in the binders have similar structures, physico-chemical properties, and PBT, vPvB and carcinogenic properties as discussed in sections 1.2.1, 1.2.3 and 1.2.4. For this reason, it is a well-established practice in risk assessment and management involving complex UVCB substances containing PAHs to make use of indicator PAHs. The grouping goes beyond the 18 indicator PAHs as these are indicators of concern also for undefined fractions of PAHs in the binders that may have similar PBT, vPvB and carcinogenic properties.

Due to the complex nature of the PAH-containing binder materials, in practice, any restriction on the binder materials in clay targets should be based on a concentration limit of the sum of indicator PAHs in the clay targets (as these are the constituents underpinning the risk).

The PAH-containing binders are used with the same basic production technique of mixing binder and filler, followed by moulding and further treatment. The exposure and use patterns therefore are similar as well.

1.2.3. Classification and labelling

The classification and labelling of the 18 indicator PAHs is given in Table 14 below.

Table 14. Classification and labelling of the 18 indicator ${\sf PAHs^{15}}$

Chemical name	EC number	CAS number	Harmonised classification and labelling	Self-classifications in registrations	C&L notifications for classification of additional properties
Naphthalene	202-049-5	91-20-3	Index No. 601-052-00-2: Acute Tox. 4*, H302 (1) Carc. 2, H351 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Carc. 2, H351 Flam. Solid 2, H228 Acute Tox. 4, H302 (without *) Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Flam. Liquid 2, H225 Flam. Solid 1, H228 Oxid. Liquid 1, H271 Acute Tox. 2, H300 Asp. Tox. 1, H304 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Acute Tox. 2, H330 Carc. 2, H350 STOT RE 1, H372 STOT RE 1 H373 (eyes, blood) Aquatic Chronic 2, H411 Aquatic Chronic 3, H412
Acenaphthylene	205-917-1	208-96-8		Not registered	Acute Tox. 1, H310, H330 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Acute Tox. 1, H330 STOT SE 3, H335 (respiratory system, lungs)
Acenaphthene	201-469-6	83-32-9	-	Aquatic Chronic 1, H410	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 (lungs) Aquatic Acute 1, H400 Aquatic Chronic 2, H411
Fluorene	201-695-5	86-73-7		Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 (lungs) Aquatic Chronic 2, H411
Anthracene	204-371-1	120-12-7	-/	Skin Irrit. 2, H315	Skin Sens. 1, H317

¹⁵ Accessed 24/08/2021

Chemical name	EC number	CAS number	Harmonised classification and labelling	Self-classifications in registrations	C&L notifications for classification of additional properties
				Eye Irrit. 2, H319 Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Eye Irrit. 2A, H319 STOT SE 3, H335 (respiratory tract, lungs) Carc. 2, H351
Phenanthrene	201-581-5	85-01-8		Not registered (revoked)	Acute Tox. 4, H302 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319 Eye Irrit. 2A, H319 STOT SE 3, H335 (respiratory tract/system, lungs) Carc. 2, H351 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Aquatic Chronic 1, H410 (M-factor: 10)
Fluoranthene	205-912-4	206-44-0		Not registered	Acute Tox. 4, H302 Acute Tox. 4, H332 Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Pyrene	204-927-3	129-00-0		Aquatic Chronic 1, H410	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Acute Tox. 2, H330 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Acute 1, H400 (M-factor: 10) Aquatic Chronic 1, H410 (M-factor: 10)
Benz[<i>a</i>]anthracene	200-280-6	56-55-3	Index No. 601-033-00-9: Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Not registered	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Acute 1, H400 (M-factor: 100)

Chemical name	EC number	CAS number	Harmonised classification and labelling	Self-classifications in registrations	C&L notifications for classification of additional properties
					Aquatic Chronic 1, H410
Chrysene	205-923-4	218-01-9	Index No. 601-048-00-0: Muta. 2, H341 Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Not registered	Muta. 2, H341 Carc. 1A, H350 Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Benzo[<i>def</i>]chrysene (Benzo[<i>a</i>]pyrene)	200-028-5	50-32-8	Index No. 601-032-00-3: Skin Sens. 1, H317 Muta. 1B, H340 Carc. 1B, H350 (SCL: C ≥ 0,01 %) Repr. 1B, H360FD Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Not registered	Skin Sens. 1, H317 Muta. 1B. H340 Carc. 1B H350, specific concentration: ≥0.01 Carc. 1B H350, specific concentration: >0.1 Carc. 1B. H350 Repr. 1B. H360FD Repr. 2. H360 Repr. 1B. H360 Aquatic Acute 1. H400 Aquatic Acute 1, H400 (M-factor: 10) Aquatic Chronic 1. H410 Aquatic Chronic 1, H410 (M-factor: 10) Aquatic Chronic 4. H413
Benzo[e]acephenanthr ylene (benzo[b]fluoranthene)	205-911-9	205-99-2	Index No. 601-034-00-4: Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Not registered	Carc. 1B. H350 Aquatic Acute 1. H400 Aquatic Chronic 1. H410
Benzo[<i>e</i>]pyrene	205-892-7	192-97-2	Index No. 601-049-00-6: Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Not registered	Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Benzo[<i>j</i>]fluoranthene	205-910-3	205-82-3	Index No. 601-035-00-X: Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Not registered	Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Chemical name	EC number	CAS number	Harmonised classification and labelling	Self-classifications in registrations	C&L notifications for classification of additional properties
Benzo[<i>k</i>]fluoranthene	205-916-6	207-08-9	Index No. 601-036-00-5: Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Not registered	Carc. 1B, H350 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Benzo[<i>ghi</i>]perylene	205-883-8	191-24-2	-	Not registered	Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Aquatic Chronic 4, H413
Indeno[1,2,3- cd]pyrene	205-893-2	193-39-5	-	Not registered	Carc. 2, H351
Dibenz[<i>a,h</i>]anthracene	200-181-8	53-70-3	Index No. 601-041-00-2: Carc. 1B, H350 (SCL: C ≥ 0,01 %) Aquatic Acute 1, H400 Aquatic Chronic 1, H410 (M=100)	Not registered	Carc. 1B, H350 Carc. 1B, H350, specific concentration: ≥0.01 Aquatic Chronic 1, H410 Aquatic Acute 1, H400

⁽¹⁾ the "*" indicates that manufacturers or importers must apply at least this minimum classification, but must classify in a more severe hazard category in the event that further information is available which shows that the hazard(s) meet the criteria for classification in the more severe category (see Annex VI, Section 1.2.1 of the CLP Regulation)

Classification and labelling of the substances identified in 1.2.1.2 is given in Table 15 below.

Table 15. Classification and labelling of substances identified in $1.2.1.2^{16}$

Name	EC No.	CAS No.	Harmonised classification and labelling	Self-classifications in registrations	C&L notifications for classification of additional properties
СТРНТ	266-028-2	65996-93-2	Index No. 648-055-00-5: Muta 1B, H340 Carc. 1A, H350 Repr. 1B, H360FD	Skin Sens. 1, H317 Muta. 1B, H340 Carc. 1A, H350 Repr. 1B, H360 Aquatic Chronic 4, H413	Repr. 1B H360 (fertility) Repr. 1B H360FD Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Petroleum pitch, Petroleum resin	269-110-6	68187-58-6	-	Skin Sens. 1A, H317 Muta 1B, H340 Carc. 1B, H350 Repr. 1B, H360 Aquatic Chronic 4, H413	Repr. 1B, H360FD
Distillates (petroleum), cracked, ethylene manuf. by-product, C9-10 fraction (1)	305-586-4	94733-07-0		Muta. 1B, H340 Muta. 2, H341 Carc. 1A, H350 Carc. 1B, H350 Carc. 2, H351 Repr. 2, H361 Repr. 2, H361d Flam. Liquid 3, H226 Acute Tox. 4, H302 Asp. Tox. 1, H304 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Acute Tox. 3, H331 Acute Tox. 4, H332 STOT RE 1, H372 (haematopoietic system, hearing organs) STOT RE 2, H373 (nervous system, neuropsychological effects, auditory dysfunction, effects on colour vision, haematopoietic system)	STOT RE 2, H373 Repr. 2, H361

¹⁶ Accessed 18/06/2021

				STOT SE 3, H335 (respiratory system, lungs) STOT SE 3, H336 (central nervous system) Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Aquatic Chronic 2, H411	
[Resin 1]	Confidential	Confidential	-	Skin Sens. 1A, H317 Aquatic Chronic 3, H412	-
[Resin 3]	Confidential	Confidential	Carc. 1B, H350, note L	Carc. 1B, H350	Skin Irrit. 2, H315 Eye Damage 1, H318 Eye Irrit. 2, H319 Acute Tox. 4, H332 Repr. 2, H361 Aquatic Chronic 2, H411 Aquatic Chronic 4, H413

⁽¹⁾ The classification depends on the constituents (the compositions vary and so do the classifications).

1.2.4. Hazard assessment

The hazard assessment of the binders used in clay targets is mainly based on their concentration of PAHs with known carcinogenic, PBT and vPvB properties. PAHs are identified as persistent organic pollutants (POPs). In addition, several of the PAHs are known germ cell mutagens, are toxic to the reproduction, skin sensitisers or are toxic to the aquatic environment (see Table 14).

Table 16 summarises the carcinogenicity (harmonised classification/SVHC identification), PBT/vPvB identification as SVHC and POP status of the individual indicator PAHs for substances identified in section 1.2.1.2.

Although for pragmatic reasons (as stated in section 1.2.1.1) 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 higher toxicity profiles (Andersson and Achten, 2015). A few alkylated PACs and heterocyclic compounds have been quantified in the substances impacted by the restriction, but not consistently. Thus, it makes it difficult to assess to which extent the list of 18 PAHs underestimates the risks for carcinogenic, PBT and vPvB properties of the binders (i.e., the fraction of the substance that has these properties).

PBT and vPvB properties, POP

The Support Document for identification of CTPHT as an SVHC (ECHA 2009b) concluded that CTPHT is a substance containing at least 5 to 10 % of PAH-constituents with both vPvB and PBT properties. Nine PAHs have been identified as SVHC according to Articles 57(d) and/or $57(e)^{17}$.

ECHA (2009b) stressed that while the PBT assessment relied only on 12 indicator PAH-constituents of CTPHT (i.e., the PAHs with a concentration ≥ 0.1 %), it should be considered that other constituents of CTPHT may have a structure similar to the selected indicator PAHs and that fractions of these other constituents may have PBT or vPvB properties as well.

Similarly, petroleum pitch consists at least of 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 POPs Regulation¹⁸. The following four indicator compounds shall be used for the purpose of emission inventories: benzo[a]pyrene, benzo[b]fluoranthene, benzo[k]fluoranthene and indeno[1,2,3-cd]pyrene. Member States need to have inventories for PAHs released into air, water and land and

¹⁷ These PAHs are: anthracene (PBT only), phenanthrene (vPvB only), fluoranthene, pyrene, benz[a]anthracene, chrysene, benzo[a]pyrene, benzo[k]fluoranthene and benzo[ghi]perylene. No definitive conclusion was reached in the Support Document for benzo[b]fluoranthene, indeno[(1,2,3-cd]pyrene and dibenzo[a,h]anthracene on their PBT/vPvB properties, due to a lack of data. However it has 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.

¹⁸ PAHs are listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants (POPs).

programmes to reduce, minimise and eliminate releases. Monitoring of PAHs is not mandatory. The PAHs are not listed in the Stockholm Convention.

Carcinogenicity

Many PAHs (and likely other constituents) of the PAH-containing binders are genotoxic carcinogens.

As detailed in Table 14, nine PAHs have harmonised classifications as Carc. 1B or Carc. 2 (naphthalene). Additionally, there are C&L notifications as Carc. 1B or Carc. 2 for anthracene, and as Carc. 2 for phenanthrene and indeno[1,2,3-cd]pyrene. Benz[a]anthracene, chrysene, benzo[def]chrysene and benzo[k]fluoranthene have been identified as SVHC for their carcinogenic properties according to Article 57(a). Benzo[def]chrysene and chrysene are also classified for germ cell mutagenicity in category 1B and 2, respectively, and thus no safe threshold can be derived. In addition to these PAHs, additional PAHs may be genotoxic carcinogens even if they are not listed in Annex VI to the CLP Regulation. The data supporting these conclusions on carcinogenicity and genotoxic mode of action has already been extensively discussed elsewhere (e.g. RIVM, 2018; ECHA, 2018; ECHA, 2019) and is not discussed again in this report.

CTPHT is considered to be a non-threshold carcinogen (ECHA, 2018) and has a harmonised classification as Carc. 1A and Muta. 1B (see Table 15). No threshold can be determined below which exposure would be safe. Lung, bladder and skin cancers are identified as the key cancer risk endpoints for exposure to CTPHT, these are the cancers for which data specific to CTPHT exposures exist from animal studies and industrial epidemiology (ECHA 2018).

Similarly, petroleum pitch and resin are classified as Carc. 1B and Muta. 1B in their registration dossiers.

The substance EC No. 305-586-4 is self-classified as carcinogenic and mutagenic (exact category depends on its constituents – the most severe classification in the registration dossier is Carc. 1A and Muta 1B).

The registered substance with the EC number corresponding to [Resin 3] has a harmonised classification as Carc. 1B.

In addition, three additional PAHs were included to Annex VI to CLP for Carc. 1B and Muta. 2 (14th ATP¹⁹, in force from 9 September 2021 and 15th ATP, in force from 1 March 2022):

- benzo[*rst*]pentaphene (EC No. 205-877-5) (14th ATP)
- dibenzo[*b,def*]chrysene (EC No. 205-878-0, also known as dibenzo[*a,h*]pyrene) (14th ATP)
- dibenzo[*a,l*]pyrene (EC No. 205-886-4, also known as dibenzo[*def,p*]chrysene) (15th ATP)

These three PAHs are not among the 18 indicator PAHs. Due to lack of data, their presence and concentration in the binders is not known, with the exception of dibenzo[a,h]pyrene which is present in the composite sample of CTPHT, and in 2 individual compositions of petroleum pitch.

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¹⁹ Adaptation to Technical Progress

Table 16. Concentration of 18 indicator PAHs in substances identified under section 1.2.1 and the harmonised classification, PBT/vPvB formal identification as SVHC and POP status of the individual indicator PAHs

			PAHs con	centration (%	%)		CLH for		Indicator	
РАН	СТРНТ	Petroleu m pitch	Petrole um resin	EC 305- 586-4	[Resin 1]	[Resin 3]	CEH 101 Carc (SVHC)	PBT/vPvB (SVHC)	PAHs in POP regulation	
Naphthalene				high amount*			Carc. 2	-	-	
Acenaphthylene	See conf.			_			-	-	-	
Acenaphthene	annex			-	<u>o</u>	<u>e</u>	-	-	-	
Fluorene				-	available	available	-	-	-	
Anthracene	0.057			_	ava	ava	Carc. 1B**	PBT (SVHC 57(d))	-	
Phenanthrene	0.302			-		on	-	vPvB (SVHC 57(e))	-	
Fluoranthene	0.835			-	ormati	ormati	-	PBT and vPvB (SVHC 57(d) and 57(e))	-	
Pyrene	0.726	nex	conf. annex	-	ve inf	ve infc	-	PBT and vPvB (SVHC 57(d) and 57(e))	-	
Benz[a]anthracene	0.599	conf. annex		conf.	conf.	-	Likely present but no quantitative information	-ikely present but no quantitative information	Carc. 1B (SVHC 57(a))	PBT and vPvB (SVHC 57(d), 57(e))
Chrysene	0.835	See	See	-	out no qu	out no qu	Carc. 1B (SVHC 57(a))	PBT and vPvB (SVHC 57(d), 57(e))	-	
Benzo[<i>def</i>]chrysene (Benzo[<i>a</i>]pyrene)	0.873				oresent b	oresent b	Carc. 1B (SVHC 57(a)) ^δ	PBT and vPvB SVHC 57(d), 57(e)	Yes	
Benzo[e]acephenanthr ylene (Benzo[b]fluoranthene)	1.125			-	Likely p	Likely p	Carc. 1B	vP, T	Yes	
Benzo[e]pyrene	See conf.			-			Carc. 1B	-	-	
Benzo[j]fluoranthene	annex			-]		Carc. 1B	-	-	

			PAHs concentration (%)				CI II for		Indicator
PAH	СТРНТ	Petroleu m pitch	Petrole um resin	EC 305- 586-4	[Resin 1]	[Resin 3]	CLH for Carc (SVHC)	PBT/vPvB (SVHC)	PAHs in POP regulation
Benzo[k]fluoranthene	0.393			-			Carc. 1B (SVHC 57(a))	PBT and vPvB (SVHC 57(d), 57(e))	Yes
Benzo[<i>ghi</i>]perylene	0.550			-			-	PBT and vPvB (SVHC 57(d) and 57(e))	-
Indeno[1,2,3- cd]pyrene	0.618			-				Т	Yes
Dibenz[<i>a,h</i>]anthracene	0.078			-			Carc. 1B	vB, T	-
Sum 18 indicator PAHs	7.9	2.4	~0.2- ~0.3	high amount					

nd: below limit of detection; φ also Muta. 2 (harmonised); δ also Muta. 1B and Repr. 1B (harmonised), SVHC 57(b), 57(c).

^{*} values confidential but available to ECHA

^{**} not harmonised – classification in registration dossier

RAC box

RAC highlights the following hazardous properties of additional PAHs reported in the compositions of binders:

Substance	Carcinogenicity classification CLP regulation (EC No 1272/2008) [1]	PBT/vPvB SVHC REACH regulation (EC No 1907/2006)	POP indicator POPs regulation (EC No 2019/1021)
Dibenzo[<i>a,h</i>]pyrene (CAS 189-64-0)	1B (H) 1B (N) 2 (N)	-	-
Anthantrene (CAS 191-26-4)	1B (N)	-	-
Carbazole (CAS 86-74-8)	2 (N)	-	-
1-methylphenanthrene (CAS 832-69-9)	2 (N)	-	-
Dibenzo[a,e]pyrene (CAS 192-65-4)	1B (N) 2 (N)	-	-

^[1] H = harmonised classification, SC = self-classification, N = notified classification.

1.2.5. Release to the environment

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 further contamination by hazardous substances resulting from human activity because the intrinsic value of pristine environments should be protected.

The properties of the PBT and vPvB substances lead to increased uncertainty in the estimation of risk to human health and the environment. This means that, in accordance with section 4 of Annex I of REACH, hazard assessment and exposure estimation cannot be carried out with sufficient reliability. Since the PAH-containing binders are vPvB and PBT-substances, the focus in this restriction proposal is on the characterisation of emissions, which serve as a proxy for risk.

Furthermore, many PAHs (and likely other constituents) of the PAH-containing binders are genotoxic carcinogens, emphasising the need to minimise exposure of humans via the environment, and therefore release to the environment.

During use the clay targets are released 100 % to the environment. RAC (ECHA, 2020) is of the opinion that this inevitably means that $initially^{20}$ 100 % of the volume of CTPHT in clay

²⁰ Following initial release, RAC (ECHA 2020) acknowledges that a fraction of the larger fragments of clay targets may be collected and disposed of.

targets is released to the environment, i.e. mainly to the soil compartment (e.g. shooting grounds, agricultural land, nature areas), but possibly also to the aquatic compartment (e.g. due to shooting from ships over fresh or marine water). Although subsequent transfer of PAHs from one compartment to other environmental compartments is slow, once released, the clay target particles are a continuous source of PAHs until eventually virtually all constituents of CTPHT are transferred to other environmental compartments or are degraded (ECHA, 2020). The Dossier Submitter considers that the same reasoning applies to other PAH-containing binders.

Following initial release, 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 unknown²¹. 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).

Although subsequent transfer of PAHs from the clay targets in the soil compartment to other environmental compartments is slow, once released, the clay target particles are a continuous source of PAHs until eventually all PAH constituents of PAH-containing binders are transferred to other environmental compartments (which can lead to contamination of drinking water, plants, animals (thus food)), or are degraded.

The following assumptions are made to calculate the release of PAHs to the environment from PAH-containing binders in clay targets:

- About 400 million clay targets 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 2.4 for a summary of restriction options).
- A clay target typically weighs 105 g based on the rules of ISSF (see Figure 1) and contains about 33 % of binder material. Given the 18 PAH-content of the binder material, the 18 PAH-content in a clay target can be calculated. The Dossier Submitter did not take into account the various existing weights of the clay targets, as it is assumed that these parameters are identical under each restriction option and no information on the exact number of each type of clay targets placed on the market was available. Hence, the estimated releases can be compared from one RO to the other even if not covering the full range of existing weights.
- An *initial* release to the environment of 100 % of the 18 indicator PAHs in the clay targets is assumed.
- The 18 indicator PAHs represent about 8 % of the mass of CTPHT; 2.4 % of the petroleum pitch; 0.2 to 0.3 % of petroleum resin; 0-003 % of [Resin 2]. This corresponds to an *initial* release of 270 tonnes per year of 18 indicator PAHs. However,

²¹ The only available estimate in the applications for authorisation for CTPHT is from an interview with the manager from a shooting club in Copenhagen who estimated that about 75-85 % by weight of the clay targets are collected as fragments. RAC considered this to be purely anecdotal information in its opinion on the applications for authorisation (ECHA 2020).

there is uncertainty on the exact identity of the substances and their use in clay targets.²²

- A release estimate based on 18 indicator PAHs will underestimate the risks from release of CTPHT and other identified binders (petroleum pitch, petroleum resin and other resins containing PAHs) to the environment. This assumption is subject to a sensitivity analysis in section 3.
- On the other hand, a fraction of the larger fragments of clay targets may be collected and disposed of, thus reducing the initial release. This assumption is subject to a sensitivity analysis in section 3.
- 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 conclusion, approximately **270 tonnes per year** of emissions to the environment of PAHs with PBT, vPvB and carcinogenic properties are estimated to result from placing on the market of PAH-containing clay targets under the baseline assumptions.

1.2.6. Exposure of workers and consumers

As occupational exposure is not a main driver for the restriction proposal the exposure of workers to PAHs in binders (other than CTPHT²³) during the manufacturing of clay targets is discussed only qualitatively in section B.2.2.1. Occupational exposure. The exposure of workers is considered qualitatively as supporting evidence to justify the need for a restriction and for the impact assessment. Even though the proposed restriction would not prevent manufacturing of PAH-containing clay targets for export, it is assumed that the overall production volume of PAH-containing clay targets would decrease which would result in a reduction of worker exposure to PAHs.

As exposure to PAHs from the handling and shooting of clay targets is similarly not a main driver for the restriction proposal, and considering the challenges to reliably estimate this exposure (see also section B.2.3.1. Consumer exposure), the exposure of consumers is considered qualitatively as supporting evidence to justify the need for a restriction and for the impact assessment.

²² For example, it is difficult to allocate the substance EC 305-586-4 and [Resin 3], as they are considered as eco resin and PAH-free resin, respectively, by manufacturers, thus the number of clay targets placed on the market is likely included in the "eco and natural resin" category used by industry; however as they contain PAHs the releases from their use in clay targets could be even higher than for CTPHT. The concentration of PAHs in [resin 1] is also unknown and thus releases from this substance cannot be quantified.

 $^{^{23}}$ Because RAC and SEAC did not support authorisation for use of CTPHT in clay targets, this restriction proposal is based on the assumption that authorisations will not be granted and therefore CTPHT would not be allowed to be used as a binder in clay targets in the EU.

1.2.7. Risk characterisation

Since CTPHT is a vPvB and PBT-substance, RAC did not support a quantitative risk characterisation in its evaluation of the applications for authorisation for use of CTPHT as a binder in the manufacture of clay targets (ECHA 2020). RAC considered that emissions of CTPHT are a suitable proxy for assessing risks to the environment and to humans exposed via the environment (ECHA 2020). This is consistent with previous restrictions on PBT and vPvB substances where only a qualitative assessment has been made. The same reasoning applies to other PAH-containing binders.

Approximately **270 tonnes per year** of emissions to the environment of PAHs with PBT, vPvB and carcinogenic properties are estimated to result from the PAH-containing binders in clay targets under the baseline assumptions (see Table 18).

RAC considers CTPHT to be a non-threshold carcinogen (ECHA, 2018 and 2020). 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 (for further considerations regarding cancer risks for workers see section B.3).

RAC box

RAC highlights that the risk has not been characterised for each PAH individually, as described in the following table:

	Substance	Hazards (harmonised classification for carcinogenicity, SVHC PBT, vPvB)	Exposure (occurrence data in binder substances)	Characterised risk
	Acenaphthylene (CAS 208-96-8)	-	Yes	No
	Acenaphthene (CAS 83-32-9)	-	Yes	No
	Fluorene (CAS 86-73-7)	-	Yes	No
DS list of	Naphthalene (CAS 91-20-3)	Carcinogen cat.2	Yes	Yes
of 18	Anthracene (CAS 120-12-7)	PBT	Yes	Yes
	Phenanthrene (CAS 85-01-8)	vPvB	Yes	Yes
indicator PAHs	Fluoranthene (CAS 206-44-0)	PBT, vPvB	Yes	Yes
AHS	Pyrene (CAS 129-00-0)	PBT, vPvB	Yes	Yes
	Benzo[a]anthracene (CAS 56-55-3)	Carcinogen cat.1B PBT, vPvB	Yes	Yes
	Chrysene (CAS 218-01-9)	Carcinogen cat.1B PBT, vPvB	Yes	Yes
	Benzo[a]pyrene	Carcinogen cat.1B	Yes	Yes

	(CAS 50-32-8)	PBT, vPvB		
	Benzo[b]fluoranthene (CAS 205-99-2)	Carcinogen cat.1B	Yes	Yes
	Benzo[<i>e</i>]pyrene (CAS 192-97-2)	Carcinogen cat.1B	Yes	Yes
	Benzo[j]fluoranthene (CAS 205-82-3)	Carcinogen cat.1B	Yes	Yes
	Benzo[k]fluoranthene (CAS 207-08-9)	Carcinogen cat.1B PBT, vPvB	Yes	Yes
	Benzo[<i>ghi</i>]perylene (CAS 191-24-2)	PBT, vPvB	Yes	Yes
	Indeno[<i>1,2,3cd</i>]pyrene (CAS 193-39-5)	(POP indicator)	Yes	No
	Dibenzo[a,h]anthracene (CAS 53-70-3)	Carcinogen cat.1B	Yes	Yes
z	Dibenzo[<i>a,h</i>]pyrene (CAS 189-64-0)	Carcinogen cat.1B	Yes	Yes
New C1	Dibenzo[<i>a,i</i>]pyrene (CAS 189-55-9)	Carcinogen cat.1B	No	No
B	Dibenzo[<i>a,l</i>]pyrene (CAS 191-30-0)	Carcinogen cat.1B	No	No

1.3. Justification for an EU wide restriction measure

A union-wide action to address the risks associated with EU manufactured or imported clay targets with PAH containing substances as a binder material in clay targets is needed to ensure a harmonised high level of protection of 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).

One of the primary reasons to act on a Union-wide basis is the cross-boundary environmental problem. Releases from the use of clay targets occur in all Member States except for Austria and Flanders (Belgium) that have already banned their use. Due to the PBT and vPvB properties of CTPHT and other binder materials, the environmental impacts may not be limited to the countries where the clay targets with PAH-containing binder materials are used.

PAHs²⁴ are recognised²⁵ as POPs since 29/04/2004 which confirms their potential for persistence and long-range transport. The objective of the POPs Regulation is to prohibit,

²⁴ The following four PAHs are used as indicators: Benzo[e]acephenanthrylene (Benzo[b]fluoranthene), Benzo[k]fluoranthene, Benzo[def]chrysene (Benzo[a]pyrene), Indeno[1,2,3-cd]pyrene

²⁵ PAHs are listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants (POPs). They are subject to release reduction provisions under the POPs Regulation, but they are not listed in the Stockholm Convention.

phase out as soon as possible, or restrict the manufacturing, placing on the market and use of POPs. Release of those substances may contaminate remote areas that should be protected from further contamination by hazardous substances resulting from human activity because the intrinsic value of pristine environments should be protected.

Furthermore, the fact that clay targets produced with PAH-containing binder materials, imported as well as produced in 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, 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.

1.4. Baseline

Currently, some 400 million clay targets are placed on the EU market annually. The EU is a net exporter of clay targets as exports amount to at least 200 million targets while approximately 90 million targets are imported annually (ISSF, 2020).

Clay targets have traditionally been produced with CTPHT (Pitch, coal tar, high-temp., EC No. 266-028-2) as a binder and limestone as a filler material at a ratio of 1:2 (i.e., about 33 % CTPHT). ISSF (2020) estimated that around 4 500 tonnes of CTPHT in clay targets are placed on the EU market per year (thus including imports and excluding exports). The market share of the CTPHT-based clay targets in Europe is approximately 30 % in 2019.

At least 15 years ago many EU clay target manufacturers started switching to alternatives to CTPHT (EU RAR, 2008). Other binder materials used are petroleum pitch, petroleum resin, eco resin or organic binders such as natural resin. The largest producers in the EU already produce the vast majority of their targets using either petroleum resin, eco resin or natural resin as binder materials.

Nevertheless, two upstream applications for authorisation for the use of CTPHT as a binder in the manufacture of clay targets were received in 2019, and thus this use of CTPHT in the EU could continue at least until the Commission decides not to grant an authorisation or until a review period expires (without receipt of a review report) in case an authorisation would be granted²⁶. The publicly reported annual tonnage for the use of CTPHT in clay targets is 1 000 to 10 000 tonnes in both applications for authorisation. A significant fraction of the volume is exported (confidential estimates are available to ECHA).

Among the other binders, petroleum pitch (Pitch, petroleum, arom., EC No. 269-110-6) stands out as another substance with a high PAH-content (about 2.4 % of the 18 indicator PAHs). At least one of the largest manufacturers in the EU is using petroleum pitch (ISSF, 2020), although the exact production volume unknown.

Table 17 shows the current market situation in the EU, where the last column sets the range for petroleum pitch and petroleum resin clay targets in the market, so that the uncertainty on the exact share between these two binders on the market is depicted. Note that the market

²⁶ This use of CTPHT as a binder in the manufacture of clay targets in the EU is now banned because the Commission decided not to grant any authorisations, as of 16 March 2022

is currently evolving, since many producers are already substituting to alternative binder materials. This is 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).

Table 17. Estimates of clay targets by binder placed on the EU market in 2019 (in million targets)

Binder	Consumption, Produced in EU	Consumption, Imported (from the UK and Russia)	Total Consumpti on*	Range
Coal Tar Pitch High temperature	65	60	125	
Petroleum Pitch	51	0	51	0-102
Petroleum Resin	122	0	122	72-174
Eco resin and natural resin (PAH <50mg in clay targets)	72	30	102	
Total	310	90	400	300-500

^{*} Consumption = production - exports + imports

Source: ISSF (2020)

The market situation will be affected by the decision on the applications for authorisation for the use of CTPHT as a binder in the manufacture of clay targets²⁷. In the opinion, RAC estimated that the releases to environment from the article service life are hundreds of tonnes per year of PAHs with PBT, vPvB and carcinogenic properties, and was unable to propose additional authorisation conditions to limit the risk. SEAC concluded that the applicants did not demonstrate that there are no suitable alternatives available for the clay target manufacturers. ECHA considers as the baseline for the assessment that the authorisation will not be granted, but relaxes this assumption in the uncertainty analysis in section 3. Should a negative decision be issued, the EU-production would cease (65 million targets per year), and only imported CTPHT based clay targets (60 million targets per year) would remain on the EU market. As the baseline assumption is subject to regulatory uncertainty, it will be tested in the sensitivity analysis in section 3.

The baseline assumes that targets with CTPHT as a binder can no longer be placed on the market and that they would be replaced with targets with the least expensive alternative binder, namely petroleum pitch. These would either be produced by those companies in the EU currently applying for an authorisation, or by other suppliers in the market which would meet the low-cost market demand with petroleum pitch-based clay targets. Also, as clay targets manufactured with petroleum pitch as a binder cost the same as those manufactured with CTPHT as a binder, it is assumed that there would not be any significant increase in imports (Table 18).

The total releases under the baseline are calculated considering the typical weight of a clay target (105 g), the concentration of PAHs in clay targets for each substance used as binder (1.2.1.3) and 100 % of the amount released to the environment.

Table 18. The baseline market situation and the total releases of tonnes of 18 indicator

²⁷ This assumption is now confirmed following the Commission decision not to grant authorisations.

PAHs per year (assumed non-authorisation of CTPHT)

Binder	Producer in EU, million clay targets	Imported (UK and Russia), million clay targets	Total, million clay targets	PAH content in clay targets (%)	Total annual releases tonnes of PAHs
СТРНТ	0	60	60	2.6	163
Petroleum Pitch	116	0	116	0.8	97
Petroleum Resin	122	0	122	0.07	9
Eco Resin and Natural Resin	72	30	102	0-0.0009 (or below 0.005)	1 (or below)
Total	310	90	400		270

2. Impact assessment

2.1. Introduction

The impact assessment is based on a comparison of different options to restrict PAH-containing binders in clay targets. The costs of each restriction option is measured in terms of loss in consumer surplus, and the benefits as reductions in releases of PAHs to the environment. The releases are used as a proxy for assessing risks to the environment and to humans exposed via the environment, which RAC considered appropriate in its opinions on applications for authorisation for the use of CTPHT in clay targets (ECHA, 2020).

Table 19 presents the price and PAH-content of clay targets produced with alternative binders. Most of the information related to the amounts of different types of clay targets, their market shares, and unit prices, come from the ISSF market survey that was performed on ECHA's request with predefined questions (ISSF, 2020).

As stated above, clay targets can be produced using different binders with varying PAH-content. The most affordable clay targets are produced with CTPHT and petroleum pitch, with a retail price of approximately €0.07 per target. According to ISSF (2020), there is no significant difference in price between these two binder types. CTPHT based clay targets have an 18 PAH-concentration of approximately 2.6 %, while petroleum pitch-based clay targets have an 18 PAH-concentration of approximately 0.8 %, making petroleum pitch a somewhat better option compared to CTPHT.

Producers are also using binders with a much lower PAH-content compared to either CTPHT or petroleum pitch. A common alternative binder on the market is petroleum resin. The average unit price per clay target for clay targets produced with petroleum resin is 0.075, whereas the average PAH-concentration of such a target is 0.07%.

Eco resin based clay targets are more costly, with a unit price of 0.084, but the 18 indicator PAH-concentration are assumed for the purposes of the impact assessment to be below 0.005%. Since all clay targets with 18 indicator PAH-concentration up to 0.005% would be allowed under the proposed restriction, an assumption of a 0.005% concentration is made for convenience in the impact assessment; however, in reality, there is a large variation in the PAH-content of so called eco resin clay targets (see section 1.2.1.2.4). Natural resin is the costliest option, with a unit price of 0.089, but clay targets produced with natural resin do not contain PAHs.

Table 19. Clay targets produced with alternative binders, price and PAH-content

Clay target binder	Retail price (in €) per target	18 PAH-concentration in clay targets
Coal Tar Pitch high temperature	0.070	2.6 %
Petroleum Pitch	0.070	0.8 %
Petroleum Resin	0.075	0.07 %
Eco Resin	0.084	<0.005 %
Natural Resin	0.089	0 %

Source: ISSF (2020), and registration data

Since the price for the consumer (i.e., the shooter) is the same for targets containing CTPHT

and petroleum pitch, and assuming that EU producers of clay targets cannot continue using CTPHT as a binder, there would be no producer surplus losses following a restriction of CTPHT only. This scenario corresponds to RO1 in the impact assessment. Thus, a restriction of CTPHT only would result in a zero cost to both consumers and producers, with a sharp reduction in the PAH-releases to the environment (by avoiding emissions from imported targets).

Should a stricter PAH-limit be set, such as the proposed 0.005 % 18 PAH-limit, then the lower-cost options listed in Table 19 would disappear from the EU market. This would come at a cost in terms of consumer surplus which would have to be weighed against the corresponding reduction in PAH-releases. A conservative assumption about the consumer surplus loss is that the price elasticity of demand at observable prices and quantities of targets consumed is 0, meaning that even at higher prices the demand would remain fixed, and shooters would continue to consume the same number of targets as they currently do. This results in an upper limit for the loss in consumer surplus, as the increase in price would be solely paid for by the consumers. No producer surplus effects are anticipated in the EU should the restriction only concern CTPHT or CTPHT and petroleum pitch. However, more strict restriction options (i.e., those with lower PAH concentration limits) would have producer surplus effects, which are described qualitatively in the analysis.

Enforcement costs are incremental costs to society to comply with requirements of a restriction that has come into effect. These costs are likely to be borne by two main groups of stakeholders: enforcement authorities and the industry placing clay targets on the market. Enforcement costs can be broken down in two main cost groups: administrative and analytical or testing costs. The former costs consist of incremental administrative costs for staff salaries, materials, equipment and overhead to be incurred to ensure compliance. Analytical testing costs include costs to develop testing methods and to test whether products meet the requirements of the restriction. Standard analytical methods exist to measure the 18 PAH-concentration in clay targets (see E.7).

ECHA (2017) estimates the incremental administrative costs for restrictions at approximately €55 000 per year using the fixed budget approach (i.e., enforcement authorities have a limited budget for enforcement, which they allocate to enforcing restrictions on the basis of the expected risk of non-compliance). The Dossier Submitter recognises the limitations of this approach. However, in the absence of other estimates, it is assumed that a restriction on the placing on the market as proposed would result in administrative enforcement costs of €55 000 per year, regardless of the RO.

2.2. Alternatives

Alternative substances considered in this section are the substances that would ensure a PAH concentration in clay targets < 0.005 % w/w, as proposed under RO3.

The reference point used in the assessment and comparison of alternatives is the binder substance Pitch, coal tar, high-temp. (CTPHT). CTPHT, Petroleum Pitch, Petroleum Resin and other PAH-containing resin binders are proposed to be restricted.

Binders that are used in the production of clay targets that meet the definition of 'eco-friendly' targets are called "Eco resin and natural resin" in this report and are not proposed to be

restricted²⁸. They may be used as alternative binders when the proposed restriction enters into effect.

2.2.1. Technical feasibility and comparison of the binder substances

In the applications for authorisation for use of CTPHT as a binder in the manufacture of clay targets, the technical feasibility of alternatives is assessed based on four criteria. The relevance of these criteria was confirmed by ISSF (2020). These criteria apply to the performance properties of the final product (clay targets), rather than to the binder substances as such.

The criteria comprise: 1. Strength, 2. Breakability characteristics, 3. Softening point and 4. Processability.

1. Strength

Clay targets must be strong enough to withstand transportation, storage and loading as well as being thrown from traps at very high speeds. Given the high forces involved, a common problem within clay target shooting is the breaking up of clay targets when launched. Indeed, this occurrence in the sport is known as a 'No target'. It is therefore critical that the clay targets are manufactured to be strong enough to ensure that the number of 'No targets' occurring is kept to as low as possible.

The strength-criterion can be assessed quantitatively by counting i) how many no-targets there are, and ii) how many discs break on average during storage and transportation.

2. **Breakability**

In addition to the strength requirement, targets must be sufficiently brittle (or frangible) so that when they are hit, the marksman can clearly tell by the explosive disintegration of the target that the hit has been registered. If the composition of the target is such that a pellet will merely chip a fragment off the target, then the chip will be so small that it is not clearly visible, and the shot will not be scored as a hit. This criterion can be assessed qualitatively by the visibility of hits.

3. **Softening point**

The binder material needs to be able to withstand heat without softening. If the softening point is too low this can impart unacceptable thermal resistance properties on the end product (i.e., on a hot day this may cause the clay targets to become deformed or adhere together in the storage, rendering them unusable). The ECHA website notes that CTPHT, for example, can be identified as "a black solid with an approximate softening point from 30 °C to 180 °C". Other binder materials should have a softening point within a similar range. This criterion can be assessed by the softening point temperature ranges of various alternatives.

²⁸ Market actors may label certain binders as eco-resins whilst not meeting the definition of 'eco-friendly' targets: such binders would be within the scope of the proposed restriction.

4. **Processability**

The manufacturers must be able to use the substance in their production. The manufacturing process for clay targets consists of a hot moulding process in which milled limestone and binder are moulded together. Typically, the moulding process is undertaken using a rotary press or 'carousel'. The binder material used, when mixed with the filler material under a stable and consistent production process, will ensure that targets remain consistent in their composition when moulded.

The viscosity of alternative substances may affect their technical/economic feasibility if it is either too high or too low. If too high, the process may be required to run at higher temperatures and will become more expensive. Alternatively, if the viscosity of the binder is too low, this may cause the substance to seep from the moulds and lead to an inconsistent binder-to-filler ratio in the end targets.

Applicants of the authorisation for use of CTPHT as a binder in the manufacture of clay targets assessed their short-listed alternatives against these criteria in a qualitative manner.

The applicants stated that clay targets produced with **Petroleum Pitch** are not equivalent in quality compared to clay target produced with CTPHT. This claim was not supported by comparing the alternatives with the established criteria. It was also claimed that use of alternative binders at the production stage is more complex. However, the key issue with the use of Petroleum Pitch as an alternative is its PAH content (similar to CTPHT) and resulting environmental releases, as shown in section 1.2.1.2.2. Petroleum Pitch, therefore, is proposed to be restricted.

With respect to **Petroleum Resin** based clay targets, applicants did not consider them as a short-listed alternative and did not provide any analysis of their technical properties. Clay targets produced with Petroleum Resin are widely available, and based on industry sources (ISSF, 2020), there is no difference to be reported between the quality of such targets and the more traditional ones produced with CTPHT as a binder.

Applicants did not short-list any of the alternatives falling into group of **eco resin** based clay targets and did not provide any analysis of their technical properties. There is strong evidence that the technical feasibility of such targets is comparable to traditional targets produced from CTPHT. This information was confirmed by several industry sources (ISSF, 2020), representatives of the shooters (Finnish Sport Shooting Federation (FSSF), 2021) as well as by a large-scale manufacturer of clay targets that use eco-resin as a binder (Eurotarget, 2020). It should be noted that eco resin-based clay targets, also meeting the requirements of eco-friendly clay targets by ISSF, are used in the ISSF-competitions where the quality requirements are expected to be the highest. For example, in the Olympic Games in Tokyo, the eco-friendly clay targets of a European company were used. Prior to the competitions, ISSF has the possibility to check the clay targets, so that they meet very strict technical requirements concerning the strength and breakability characteristics. The eco targets of various producers have been shown to meet these criteria. However, these standards are not public information. The clay target market is already substituting to eco resin-based clay targets, with many producers only marketing/producing them, and many shooting clubs having already switched to shooting only eco-friendly clay targets. (FSSF, 2021).

With respect to **natural resin** category, out of which Pine (rosin) resin substances is the most common example, it is stated in the applications for authorisation for use of CTPHT as a binder

in the manufacture of clay targets that the use of this group of resins can cause production and coating problems. It is also stated that clay targets produced with such resins may be more fragile and more likely to develop cracks compared to the ones produced with CTPHT. The Dossier Submitter has not found such evidence from any of the interviews and cannot confirm these technical problems related to the use of natural resin. However, there is some evidence (ISSF, 2020; 2021) that natural resin-based clay targets might not function well at high temperatures: the clay targets produced with natural resin may soften beyond 30 to 40 degrees Celsius. Information received in the consultation on the Annex XV report (#3576), confirmed that the performance of "Gum rosin derivatives o[r] modified natural resin" is acceptable and are currently in use in international competitions.

Following a request from ECHA, ISSF (2020) collected information regarding the technical criteria from EU clay target manufacturers. The main results of the survey are presented in Table 20. Next to the information presented in the table, the respondents indicated that the most important determinant of the quality is the manufacturer's know-how, as the quality control and packaging have a real effect on the product supplied. It was stated that while a good manufacturer can make a good target with any of the alternative binding materials, there are some differences related to how well clay targets behave in hot temperature conditions, as also stated above. The information collected did not reveal any information on the processability characteristics of different substances. The softening point -criterion was not assessed per different binder substances, but only by comments on the thermal resistance properties of the end-product.

Table 20. Technical comparison of the clay targets produced with CTPHT and other binder materials

Binder material	Under the scope of restriction	Strength	Breakability	Comment on the thermal resistance properties of the end-product
Coal Tar Pitch high temperature	RO1-RO4	Skill in manufacturing determines	Skill in manufacturing determines	Stable to temperature variations
Petroleum Pitch	RO2-RO4	the strength of targets- No difference compared to CTPHT	the breakability characteristics	Stable to temperature variations
Petroleum Resin (HCR variation)	RO3-RO4		- No difference compared to CTPHT	Stable to temperature variations
"Eco Resin"	RO4			Stable to temperature variations; Some eco-friendly clay targets are sensitivity to low or high temperatures.
Natural Resin (Rosin)	With 0 PAH- content, not under the scope of any restriction option			Sensitive to temperature variations. Can be "sticky" and deformed by high temp. Can become harder by low temp.

In conclusion, based on the technical comparison, there are technically feasible alternatives in case of RO1 to RO3: Most eco-friendly clay targets produced with eco resins are equal in comparison to CTPHT clay targets. For RO4, there could be difficulties in finding clay targets that perform well in low or high temperatures.

2.2.2. Identity, physico-chemical properties and hazards of alternatives

Only CTPHT and petroleum pitch are explicitly registered for use as binders in clay targets. Other substances used for that purpose are registered in a way where the use is either not explicit (e.g., under a generic "binder" use), or the use is not registered at all. Information on low PAH and PAH-free alternatives was obtained from the applications for authorisation for use of CTPHT as a binder in the manufacture of clay targets (ECHA 2020), from ISSF, from registrants of petroleum pitch, from manufacturers of clay targets and from relevant patents.

Under the proposed restriction, a limit of 0.005 % w/w for the sum concentration of 18 indicator PAHs would be established and therefore only resins with very low or no PAH content would remain, so-called eco and natural resins. In the applications for authorisation, Pine (rosin) resin was mentioned as an alternative binder. However, based on the industry sources (ISSF, 2020; Eurotarget, 2020; registrants of petroleum pitch, 2020) it is not the only alternative raw material suitable as a binder in clay targets that has either a very low or no PAH-content.

Below are some examples of substances that are alternatives to CTPHT, petroleum pitch, petroleum resin and other resins containing PAHs above the limit proposed in the restriction.

As indicated in section 0, 'eco resin' is a generic term which does not, as such, guarantee that the concentration of PAHs will be below the limit. Only the measured concentration of PAHs in clay targets defines if the substance complies with the proposed restriction. Nevertheless, the substances that have been explicitly identified as low-PAH and PAH-free alternatives are detailed below, as they form the basis of the impact assessment.

Three substances have been designated as "eco resins" by ISSF and companies. The available registration data of one of these substances show a high concentration in naphthalene, and thus this substance falls in the scope of the proposed restriction (see section 0). The two other "eco resins" with lower PAH-content (below the proposed concentration limit) are described below.

Low PAH and PAH-free synthetic resins

Based on information from an EU-based manufacturer, one substance [Resin 2] (substance identity information confidential) contains 0.0027 % PAHs (sum of the concentration of all measured PAHs, which include all 18 indicator PAHs except benzo[e]pyrene (not analysed for), and dibenz[a,h]anthracene being quantified as the sum of dibenz[a,h+a,c]anthracene). Therefore, the available data support the claim that this substance is a relevant "eco resin" for use in clay targets. However, this substance is not registered, as according to the company, it meets the polymer definition, and in total the substance contains less than 0.1 % of PAHs. The starting monomer is unknown. [Resin 2] is used as a binder (SPIN database²⁹). PAHs concentration, physico-chemical properties and hazards are given in Table 21 below.

Table 21. PAHs concentration, physico-chemical properties and hazards of [Resin 2]

Trade Name	PAHs concentration	Physico- chemical properties	Classification ³⁰
[Resin 2]	Sum of PAHs*:	No	Notifications:
	0.0027 %	information ³¹	Skin Sens. 1, H317
			Aquatic Chronic 3, H412

^{*} All indicator 18 PAHs, except benzo(e)pyrene which has not been analysed; dibenz[a,h]anthracene has been quantified as the sum of dibenz[a,h+a,c]anthracene

When assuming that clay targets are composed of 33 % binder the concentration of the sum of 18 PAHs in the articles is estimated to be up to 0.0009 % (i.e., 9 mg/kg) when applied to the substance identified above.

It should be noted that, based on the available information, one PAH is present in this substance at a slightly higher concentration than the concentration limit (1 mg/kg) for this individual PAH according to the ISSF rule for eco-targets. However, in view of the uncertainties regarding the calculation of the concentration and considering that only one data point is available, this substance would still be a suitable alternative, should such an individual limit concentration be proposed, provided that the concentration in the clay targets is below this limit.

30 C&L inventory, accessed 24/08/2021

²⁹ Accessed 21/06/2021.

³¹ Databases searched (21/06/2021): Comptox, ChemNetBase, ChemSpider, eChemPortal.

[Resin 4] has been described as being a polymer. The CAS No. is claimed as confidential by the company but known to ECHA. The PAH content is reported to be zero but there is no supporting data available as the substance is not required to be registered. It is reported to be used as a binder (SPIN database³²) and is listed as an HPV (high production volume) chemical by the OECD. The PAH concentration, physico-chemical properties and hazards are given in Table 22 below.

Table 22. PAHs concentration, physico-chemical properties and hazards of [Resin 4]

Trade Name	PAHs concentration	Physico-chemical properties ³³	Classification ³⁴
[Resin 4]	Claimed to be zero	No information ³⁵	Notifications: Eye Irrit. 2, H319

Natural resins (rosins)

Pine (rosin) resins have also been identified as existing PAH-free alternatives. Pine (rosin) resins are UVCB substances and PAHs are not expected to be present in their composition, as, even if they contain multiple aromatic rings, these are not condensed. About 60 'rosins' are registered under REACH. As of March 2021, 38 have been registered with technical functions as "binder" or "binding agent" (many of them in quantities above 1 000 tonnes per year) (see E.2.2. Identification of potential alternative substances and techniques fulfilling the function). It is possible that other similar "rosin" substances could also be used for that purpose but the registration data do not enable to investigate this aspect further. It is unknown which of these 38 substances could be potentially suitable alternatives to CTPHT in clay targets. Although some of them appear to be already used for the manufacture of clay targets, currently none are registered for this specific use.

The quality of pine (rosin) resin required in the production of clay targets is a modified form (derivative) of the main (from market quantity perspective) products: gum rosin, wood rosin or tall oil rosin (ECHA 2020). The pine (rosin) resin substance shortlisted by Bilbaina de Alquitranes S.A. in the application for authorisation for CTPHT (ID 0147-01) has no harmonised classification (the exact substance identification is available to ECHA but claimed confidential). Other identifiers of rosins are cited by Deza a.s. in its analysis of alternatives (application for authorisation ID 0148-01):

- Rosin (CAS No. 8050-09-7, EC No. 232-475-7)
- Crude Tall Oil and Tall oil (CAS No. 8002-26-4, EC No. 232-304-6)
- Tall-oil pitch (CAS No. 8016-81-7, EC No. 232-414-4)

ISSF (2020) refers to EC No. 232-110-6 as the identifier of "Natural Resin (Rosin)", however, this is not a valid EC No. 36.

It is noted that Rosin (EC No. 232-475-7), "Rosin, maleated" (EC No. 232-480-4), "Resin acids and Rosin acids, sodium salts" (EC No. 263-144-5) and "Rosin, hydrogenated" (EC No.

33 Based on registration data, accessed 21/06/2021

³² Accessed 21/06/2021.

³⁴ C&L inventory, accessed 24/08/2021

³⁵ Databases searched (21/06/2021): Comptox, ChemNetBase, ChemSpider, eChemPortal.

³⁶ It is plausible that this is a clerical error and that it probably refers to rosin.

266-041-3) were assessed by Finland and it was concluded³⁷ that they do not meet the PBT nor the vPvB criteria. On the other hand, the substance "Resin acids and Rosin acids, hydrogenated, esters with glycerol" (EC No. 266-042-9) has also been evaluated by Finland and the conclusion³⁸ states that "the majority of the constituents of the substance are not PBT and not vPvB, under aerobic conditions". However, no conclusion was reached yet for one constituent fraction and for transformation products which may be formed under anaerobic conditions. The closely related substance "Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol" (EC No. 264-848-5) is currently being evaluated³⁹ for PBT concern. The result of these assessments will bring further insight on whether some of these potential alternatives could be advised against.

Like CTPHT and petroleum pitch, pine (rosin) resins are generally skin sensitisers: among the 38 registered substances, one has a harmonised classification as Skin Sens. 1 and 18 others have either self-classifications or notifications as skin sensitisers. It is further worth mentioning that tall oil (EC No. 232-304-6) is not self-classified by registrants but a minority (25 out of 900) of C&L notifications reported classification as Muta. 2, Repr. 1B H360 FD, STOT SE 1, STOT RE 1, Aquatic acute 1, Aquatic Chronic 1. Other substances of this group usually display self-classifications/notifications of eye and skin irritation and aquatic chronic toxicity.

Bilbaina and Deza stated in their applications for authorisation that the use of alternative binders can be concluded to result in a reduction of risk. Based on the (confidential) information presented by the applicants on the intrinsic properties of the substance, RAC agreed that the health and environmental hazards associated with pine (rosin) resin are of less concern than those of CTPHT. Based on available registered data and classification notifications for the other registered substances of the rosin group that are used as binders, health and environmental hazards would indeed seem to be of less concern than those associated with the substances listed in section 1.2.1.2.

Other alternative substances and alternative technologies

Other alternative substances or technologies have been identified in the applications for authorisation (ID 0147-01 and 0148-01): sulphur (EC No. 231-722-6), various plant-based materials, calcium / plaster, flour-based targets, peat / clay, sodium silicate / dextrin, lignosulphate, various organic and inorganic materials, natural waxes and fats, shaved or cracked ice, water, snow or carbon dioxide, sodium bicarbonate, sand, sugar, paraffin, and laser-based reusable targets. In the applications for authorisations, sulphur (or sulfur, EC No. 231-722-6, CAS No. 7704-34-9) was second among the short-listed alternatives. Sulphur is not registered for use in clay targets, but it has registered uses as a binder. It is currently classified as Skin Irrit. 2, H315 (harmonised classification) and a proposal⁴⁰ has been made to also classify it as Eye Irrit. 2, H319 and STOT SE 3, H335. RAC adopted its opinion on 18

³⁷ Conclusions available at: https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff94d, https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff94d, https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff94d, https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff94d, https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff94d, https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff94d.

³⁸ Conclusion available at: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9747.

³⁹ Evaluation available at: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e981e.

⁴⁰ https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e185544484.

March 2022 and proposes to retain the classification as Skin Irrit. 2, H315 only. There are also notifications as Flam. Sol. 1 and 2, H228; Self-react. C, H242; Acute Tox. 4, H302, H332; STOT SE 3, H335 (respiratory tract); and Aquatic Chronic 3, H412.

A further search performed in the European Patent Office database⁴¹ revealed 110 patents, among which 28 were patents for alternatives to pitch-based clay targets, filed between 1977 and 2020. The full list with identified components is given in E.2.2. Identification of potential alternative substances and techniques fulfilling the function. Some alternatives are presented as less expensive than pitch-based clay targets, with equally good performance characteristics. However, some of the proposed alternatives could also lead to concerns, i.e. for instance the use of plastic material (polystyrene, polypropylene) which could lead to the emission of microplastics, or the use of other hazardous substances e.g. brominated polystyrene, zinc borate, or boric acid. In addition to alternative binders, some patents also promote the use of pure clay which is shaped into targets using alternative methods (e.g., through low temperature firing to achieve desired characteristics). A few patents also suggest the use of reusable targets coupled with a laser receiving sensor, or video images. It is noteworthy that the content of binder can be lower than in pitch-based clay targets.

It is not known to which extent these alternatives are currently in use for clay targets production, but this shows that alternatives do exist, should CTPHT, petroleum pitch and petroleum resin be restricted.

2.2.3. Availability of the alternatives

The availability of these alternatives is assessed in the applications for authorisation with regard to the volume of the alternative substances available in EU.

Petroleum Pitch (alternative only under RO1) is widely available in the market with an annual tonnage of 10 000 – 100 000 tonnes. However, regulatory availability is questioned by the applicants for authorisation themselves because of the high PAH-content of Petroleum Pitch, and possible future regulatory action. It is also pointed out in the applications that Petroleum Pitch used in clay targets exceeds by far the 0.005 % PAH limit that is imposed by the ISSF. Several registrants of petroleum pitch expressed their intention to withdraw the use in clay targets from their registration dossiers, showing that industry is already switching to substances with lower PAH-content.

In the applications for authorisations, sulphur was second among the short-listed alternatives. It was considered to be widely available in EU; however, there was no information how widely it was used as a binder in clay targets. Based on an industry survey (ISSF, 2020), it is not considered as an alternative by the European producers, at least on a larger scale. It is unlikely that it would be one of the most used alternatives in the short-term.

With regards to clay targets produced with eco- and natural-resin, pine (rosin) resin was discussed in the applications. It was noted that the availability of these resins on the EU market cannot be compared to that of CTPHT. The trade association Hydrocarbon Resins, Rosin Resin & Pine Chemicals Producers Association (HARRPA) estimated that the existing production of "crude tall oils" (CTO, raw material generated in the wood pulp production process and used for at least some eco- and natural-resins) for bio-based chemicals has a capacity of 600 000 tonnes per year. Some 30-40 % of this volume relates to tall oil rosins

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^{41 &}lt;a href="http://worldwide.espacenet.com">http://worldwide.espacenet.com, with key word "clay target*", accessed 21/06/2021

and even a smaller share to resins which are relevant for the clay target manufacture. However, the CTO refining capacity is known to be expanding.

The availability issue of the eco- and natural resins also came up in interviews with industry (Eurotarget, 2020). However, the availability itself was not considered such a significant issue; instead, it was noted that the market price for the binder would possibly affect the price of the final product. The impact of this price difference is analysed later in the sections 2.4 onwards of the Impact Assessment.

It should be pointed out that in general, the availability of alternative binders does not seem to be a critical issue within EU for RO3. Already nearly 30 % of targets are produced with various different eco resins as the binder. Eurotarget (2020) confirmed that, should such a restriction be implemented, their company alone could, in theory, increase production to satisfy the surplus in demand. However, there is anecdotal evidence that pine rosin, used in the natural resin-based clay targets, is not as easily available for the clay target manufacturers: manufacturers have informed that the price has gone up, and availability is sometimes an issue (Eurotarget, 2020; FSSF, 2021). The Dossier Submitter is unable to conclude that pine rosin is available for the clay target manufacturers at the required tonnage in case it would be the only available alternative binder substance. If pine rosin alone would be used as a binder, approximately 13 000 annual tonnage would be required for the clay targets shot in Europe.

Among the other substances identified as alternatives, [Resin 2] is not registered (being a polymer) but information in the SPIN database reveals that the substance was placed on the market in Sweden, Norway and Denmark in quantities between around 100 to 420 tonnes per year from 2000 to 2019. [Resin 4] is not registered but it has been listed as an HPV (high production volume) chemical by the OECD, and according to SPIN database, it was placed on the market in Sweden in quantities between around 370 to 2 500 tonnes per year from 2000 to 2019 (increasing since 2012).

2.3. Risk management options

As indicated in the previous sections, there are significant releases to the environment from the use of PAH-containing binder materials in clay targets for shooting. These releases are considered to pose a risk that is not adequately controlled.

The Dossier Submitter has analysed four different restriction options that are progressively stricter in terms of the permitted PAH-content in clay targets. Each of the restriction options sets a specific concentration limit value for the 18-indicator PAHs. Apart from the specific concentration limit, all of the restriction options are identical in terms of their conditions. However, for the proposed restriction option, the Dossier Submitter proposes a two-phase approach.

Dossier Submitter assumed for the purposes of the restriction proposal that the authorisations will not be granted for the use of CTPHT as a binder in clay targets for shooting, as explained in section 1.4. If the Commission decided to refuse an authorisation in these two applications, the possibility to import clay targets containing CTPHT in the EU remains.

For this reason, it is proposed that the restriction of CTPHT (RO1) would take an effect as soon as possible from entry into force of the restriction. This is to ensure that the import of such clay targets would cease as soon as possible after the production in EU would cease, and the clay targets with the highest emissions would be eliminated from the EU markets. Even a one-year transitional period for restricting CTPHT in clay targets would lead to an additional

release of 114 tonnes of 18 indicator PAHs, while the benefits of such a transitional period would be very limited, since clay targets made with alternative substances are widely available, and it would appear that markets have already adapted to the increasing regulatory pressure on CTPHT. The immediate restriction of CTPHT can be achieved by setting an interim total 18-PAHs concentration limit of 1% that would prevent the use of CTPHT as a binder, but temporarily allow other PAH containing binders.

The Dossier Submitter sees a need for such a period for other substances under the scope of the proposed restriction since an immediate ban (or a very short transition period) could result in short-term scarcity of useable clay targets, and thus additional consumer surplus and producer surplus impacts. A one-year transitional period is considered to be sufficient to allow clay target manufacturers to find new suppliers of those binder materials that are under the scope of the proposed restriction, and to implement any adjustments to their manufacturing processes. However, the transitional period is estimated to lead to releases up to 150 tonnes of 18 indicator PAHs.

2.4. Restriction options

A summary of the proposed restriction options is given in Table 23. Each of the options was assessed against its effectiveness in emission reduction and in terms of its economic cost. In terms of the other main criteria for a restriction, practicality and monitorability, the Dossier Submitter sees all restriction options as equivalent.

To support the practicality, 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 hazardous properties of the binders are due to the presence of PAHs. Because there are very many PAHs and their presence in the binders is variable, it is practical to base a limit on a measurable and well-known PAHs that serve as indicators for the presence of other PAHs. The Dossier Submitter considers that calibration standards and analytical methods are readily available for the targeted 18 PAHs (see Annex E.7.). Clay targets can be bought from the markets and sampled.

The Dossier Submitter sees that the proposed restriction option is practical and monitorable.

Table 23. Summary of the proposed restriction options.

Restriction scenarios	18-PAH concentration limit (in clay target) w/w	Restricted substances (of those currently in the market)	Reduction in PAH 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 %	СТРНТ	114	156
RO2	0.1 %	CTPHT and Petroleum Pitch	247	23
RO3	0.005 %	CTPHT, Petroleum Pitch, Petroleum Resin, Other PAH- containing resin binders above the limit	268	2
RO4	0.0001 %	CTPHT, Petroleum Pitch, Petroleum Resin, other resin binders, eco resins	270	0

2.5. Assessment of restriction option 1

2.5.1. Economic impacts

Restriction option 1 (RO1) sets a 1 % concentration limit on the 18 indicator PAHs in clay targets. The 1 % limit would in practise mean that clay targets produced with CTPHT as a binder could no longer be placed on the market in EU. Other shortlisted alternatives have been reported to result in clay targets with a 1 % concentration of 18 indicator PAHs lower than 1 %.

The most likely response of producers would be to replace lower-cost clay targets, earlier produced with CTPHT as a binder, by clay targets that use petroleum pitch as a binder. As this would only have an effect on imported clay targets (under the baseline, it is assumed that CTPHT is not authorised for use as a binder in clay targets in EU), there could be a positive producer surplus effect following RO1, as it would provide for a level playing field between EU producers and importers. The market situation following RO1 is depicted in Table 24.

Table 24. RO1 1 % restriction on 18 indicator PAHs, ex-post market situation

Binder	Producer in EU, millions of clay targets	Imported (UK and Russia), millions of clay targets	Total, millions of clay targets	Total annual releases tonnes of PAHs
СТРНТ	0	0	0	0
Petroleum Pitch	116-176	0-60	176	146
Petroleum Resin	122	0	122	9
Eco Resin and Natural Resin	70	30	102	1
Total	310-370	30-90	400	156

This restriction option would come at almost zero costs, since no negative producer surplus impacts take place, and consumers would have access to similarly priced clay targets. However, annual enforcement costs of €55 000 are foreseen under RO1.

2.5.2. Human health and environmental impacts

Under RO1, CTPHT is eliminated from the EU clay target market, while an annual increase of 60 million petroleum pitch containing clay targets is predicted. This would lead to a net reduction in the 18 indicator PAH releases of 114 tonnes per year. The avoided emissions serve as a proxy for assessing the risks to the environment and to humans exposed via the environment.

While RO1 would eliminate approximately 42 % of the total PAH releases, the problem of high PAH releases from clay target shooting is not fully addressed. Out of the remaining 156 tonnes of annual 18-PAH releases, 94 % are contributable to clay targets produced with petroleum pitch as a binder. The remaining annual emission ex-post RO1 also represent the maximum releases that can be contributed to the proposed transitional period. However, it extremely likely that in reality the releases over the transitional period are less than 156 tonnes. The maximum would require that all current producers and importers of CTPHT would switch to petroleum pitch for exactly for one year. Next to this, all petroleum resin-based clay target producers would substitute exactly at one year. The 156 tonnes of 18 indicator PAHs releases is thus the upper limit for the negative impact of the one-year transitional period.

2.5.3. Proportionality

This restriction option would come at a marginal cost of €55 000 and would eliminate 114 tonnes of 18 PAH releases per year from the environment. **The corresponding C/E -ratio** of RO1 is **0.46 €/kg** of avoided PAH releases.

2.6. Assessment of restriction option 2

2.6.1. Economic impacts

Under RO2, with a 0.1 % concentration limit for the 18 indicator PAHs, also clay targets produced with petroleum pitch as a binder would be banned from being placed on the EU market. Thus, the RO2 would ban clay targets using either CTPHT or petroleum pitch as a binder. The Dossier Submitter considers it possible that also some clay targets produced with

low-PAH compositions of petroleum resin would have to be withdrawn from the EU market (see section 1.2.1.2)

Again, the assumption is that producers would move to targets produced with the least costly alternative binder, which is petroleum resin. It is further assumed that EU producers would be able to satisfy the total demand for clay targets on the basis that firms using this binder have already a strong position in the market. The latter assumption was confirmed by an industry source (Eurotarget, 2020). The market situation following RO2 is depicted in Table 25.

For the consumer, clay targets with petroleum resin are 0.5 cents more expensive per unit compared to clay targets that use either CTPHT or petroleum pitch as a binder. This difference in price will have a negative impact on the consumer surplus, with an estimated value of approximately \leq 0.9 million per year. Again, enforcement costs of \leq 55 000 per year are included.

Table 25. RO2 0.1	% restriction on	18 indicator PAHs	, ex-post market	situation

Binder	Producer in EU, millions of clay targets	Imported (UK and Russia), millions of clay targets	Total, millions of clay targets	Total annual releases tonnes of PAHs
СТРНТ	0	0	0	0
Petroleum Pitch	0	0	0	0
Petroleum Resin	298	0	298	22
Eco Resin and Natural Resin	72	30	102	1
Total	370	30	400	23

2.6.2. Human health and environmental impacts

With a concentration limit of 0.1 % for the 18 indicator PAHs, petroleum pitch-based clay targets are banned from the EU market, resulting in an annual incremental reduction of 133 tonnes of 18 indicator PAHs releases compared to RO1; and a total annual reduction of releases of 247 tonnes per year. The incremental reduction is attributable to the substitution of petroleum pitch by petroleum resin, which has a considerably lower PAH-content. The avoided emissions serve as a proxy for assessing the risks to the environment and to humans exposed via the environment.

RO2 also reduces the exposure of workers and consumers from handling PAH-containing clay targets, and due to carcinogenic properties of some of the PAHs in petroleum pitch, the risk of cancer cases. If the reduction in exposure is assumed to be proportionate to the reduction in 18 PAHs content, compared to the baseline, the exposure is reduced by over 50%.

2.6.3. Proportionality

This restriction option would come at an annual cost of €0.93 million and would result in a total reduction of 247 tonnes of 18 indicator PAH releases per year from the environment. The corresponding C/E-ratio of RO2 is 3.8 €/kg of avoided 18 indicator PAH releases. Compared to RO1, RO2 would result in an incremental reduction of 133 tonnes of PAH releases

per year at an incremental cost of €0.9 million per year, resulting in a marginal abatement cost of **6.6 €/kg**.

2.7. Assessment of restriction option 3

2.7.1. Economic impacts

RO3 is consistent with the 18 indicator-PAH limit set by the ISSF for official competitions. The ISSF has recently changed their rules towards the use of "Eco-friendly" clay targets in its championships (ISSF, 2020b). Eco-friendly here means an 18 PAH-concentration below 0.005 %. **RO3 is the restriction option proposed by the Dossier Submitter.**

In practice, RO3 would imply that only eco resin-based and natural resin-based clay targets would remain in the EU-market, but it is conceivable that some clay targets marketed today as eco resin clay targets would fall under the scope of this restriction option, called other PAH containing resins in this report. The direct impact would be that CTPHT, petroleum pitch and petroleum resin-based clay targets would be replaced by either eco resin-based or natural resin-based clay targets. As natural resin-based clay targets have only a minor share of the market, the Dossier Submitter expects that the foremost substitute of CTPHT, petroleum pitch and petroleum resin will be eco resins as discussed under section 2.3.

Since EU based clay target producers are already producing eco-friendly clay targets, and an industry source claims that, in theory, the resulting excess demand of eco-friendly clay targets could be served by a single EU producer (Eurotarget, 2020), it is assumed that most of the eco-targets sold in EU would also be produced in EU. Compared to the baseline, this could have positive producer surplus impacts. However, as there are also imports of eco-friendly clay targets, it is also possible that there would be an increase of imported eco-friendly clay targets (mainly from UK). For this reason, the positive producer surplus impact of RO3 is not quantified.

Table 26 shows the market situation following the implementation of RO3. Clay targets that use eco resin as a binder are 0.9 cents more expensive than those using petroleum resin as a binder, and 1.4 cents more expensive than those using either CTPHT or petroleum pitch as a binder. This difference in price will have an impact on the consumer surplus. Compared to RO2, the incremental annual cost in the form of consumer surplus loss would be €2.7 million (€3.6 million compared to the baseline). Again, enforcement costs of €55 000 per year are included.

Table 26. RO3 0.005 % restriction on 18 indicator PAHs, ex-post market situation

Binder	Producer in EU, millions of clay targets	Imported (UK and Russia), millions of clay targets	Total, millions of clay targets	Total annual releases tonnes of PAHs
СТРНТ	0	0	0	0
Petroleum Pitch	0	0	0	0
Petroleum Resin	0	0	0	0
Eco Resin and Natural Resin	370	30 (with possible increase)	400	2

Total	370	30 (with	400	2
		possible		
		increase)		

It should be noted that the ISSF rule establishes concentration limit for the sum of the 18 PAHs but also limits in the concentration of individual PAHs in "eco-friendly" clay targets (see 1.2.1.1). When considering the available data on PAHs concentrations in the binders listed above, the same binders would be restricted even if limits for individual PAHs were introduced, as the individual concentrations are above the limits for the same binders which also exceed the limit for the sum of all 18 PAHs. Therefore, based on the available data, there would be no added value of specifying limits for the individual PAHs in addition to the limit (0.005 %) for the sum.

2.7.2. Human health and environmental impacts

With a concentration limit of 0.005 % for the 18 indicator PAHs, CTPHT, petroleum pitch and petroleum resin-based clay targets would effectively be removed from the EU-market, and compared to RO2 a further annual reduction of 21 tonnes of PAH releases per year is estimated to result from RO3. Compared to the baseline releases of 270 tonnes per year, less than two tonnes of PAH releases per year would remain, corresponding to an abatement effectiveness of 99.3 %. Since it has been conservatively assumed that eco-friendly clay targets would be just below the concentration limit of 0.005 %, it is possible that the reduction could be even greater. The avoided emissions serve as a proxy for assessing the risks to the environment and to humans exposed via the environment.

RO3 also reduces the exposure of workers and consumers from handling PAH-containing clay targets, the risk of cancer cases. If the reduction in exposure is assumed to be in proportion to the reduction in 18 PAHs content, compared to the baseline, the exposure is reduced by over 59%, or by an incremental 9% of baseline exposure compared to RO2.

2.7.3. Other impacts

It should be noted that, for RO1 and RO2, producer surplus losses in the EU have not been considered to be relevant. In response to an information request, ISSF (2020) explained that, while substitution from CTPHT and petroleum pitch would be relatively easy for the EU industry, restricting the use of petroleum resin could also entail producer surplus impacts. This is because the corresponding price increase in clay targets could result in a reduction in the demand for the clay targets. The price of eco-friendly clay targets is 1.4 cent higher compared to a traditional clay target. As 25 clay targets are shot per a round, this would increase the cost of a round by around 35 cents. An average shooter shoots around 100 rounds per season, increasing the price per season by 35 euros. For a competitive clay target shooter, the number of rounds can amount to more than 1 000 rounds per season. Compared to the other costs of the sport, this increase in the price is of shooting is relatively low (FSSF, 2021). With the assumption of a price elasticity of 0, these producer surplus effects from a lower demand of clay targets are already effectively taken into account when assessing the loss in consumer surplus and are not further quantified.

Based on one industry comment, clay shooting could be more difficult in hot temperature conditions because of a lower softening point of eco resin. However, this information was contested by another producer of clay targets. Eco-friendly clay targets are already used in all the main competitions, both in cold and hot temperature conditions. It is possible that

some producers might have to adjust their manufacturing processes to be able to produce high quality eco-friendly clay targets. Next to this, some producers might have to find new suppliers for their binder materials. Due to these reasons, and to avoid any shortage of clay targets in the EU markets, the Dossier Submitter proposes a transitional period of one year for RO3. The negative impact of such a transitional period is higher emission during the transitional period. While the ex-post situation of RO1 sets the upper limit for this impact, the ex-post situation of RO3 sets the lower limit, implying a range of 21 to 156 tonnes of 18 indicator PAHs releases.

Based on the comments received in the consultation on the Annex XV report, there is a possibility that some companies have better market availability with existing supply chains for low-PAH binders. Dossier Submitter acknowledges that RO3 might lead to asymmetric impacts between clay target producers in the EU so that it is possible that some clay target producers could even face problems with continuation of their business, while some clay target manufacturers could increase their market share. These problems could be mitigated with a longer transitional period, however, also the releases of PAHs would continue during any longer period.

2.7.4. Proportionality

This restriction option would have an annual cost of $\in 3.6$ million and would result in a total reduction of 268 tonnes of 18 indicator PAH releases per year to the EU environment. **The corresponding C/E-ratio** of RO3 **is 13.5 C/kg** of avoided PAH releases. Compared to RO2, RO3 would result in an incremental reduction of 21 tonnes of PAH releases per year at an incremental cost of $\in 2.7$ million per year, resulting in a marginal abatement cost of **130.0 C/kg**.

2.8. Assessment of restriction option 4

2.8.1. Economic impacts

Given the available alternatives, a restriction could in theory bet set so that only clay targets with zero % PAH-concentration are allowed to be placed on the EU market. This would mean that only natural resin-based clay targets would remain in the market. A limit value for the 18 indicator PAHs of 0.0001 % w/w would achieve such a zero-pollution objective. Table 27 shows the market situation following RO4.

Clay targets that use natural resins as a binder are 0.4 cents more expensive than clay targets that use eco resins as a binder, and 1.9 cents more expensive than clay targets that use CTPHT or petroleum pitch as a binder. It is conceivable that the price increment of 27 % compared to the current low-cost options would have an effect on the total number of clay targets sold in the EU. This would mean that each round of 25 clay targets would be some 50 cents more expensive, and for an average clay target shooter with 100 rounds per season, the increase in cost would be 50 euros. However, the conservative assumption of a zero-price elasticity of demand would still allow estimating the impact on consumer surplus. Compared to RO3, the additional annual cost under RO4 in the form of consumer surplus loss would be $\[mathcal{e}$ 2 million ($\[mathcal{e}$ 5.6 million compared to the baseline). Again, enforcement costs of $\[mathcal{e}$ 55 000 per year are included.

Table 27. RO4 0.0001 % restriction on 18 indicator PAHs, ex-post market situation

Binder	Producer in EU, millions of clay targets	Imported (UK and Russia), millions of clay targets	Total, millions of clay targets	Total annual releases tonnes of PAHs	
СТРНТ	0	0	0	0	
Petroleum Pitch	0	0	0	0	
Petroleum Resin	0	0	0	0	
Eco Resin	0	0	0	0	
Natural Resin	370	30	400	0	
Total	370	30	400	0	

2.8.2. Human health and environmental impacts

Compared to RO3 a further annual reduction of 2 tonnes of PAH releases is estimated for RO4, corresponding to a total annual reduction of 270 tonnes of PAH releases. However, since RO3 is based on the conservative assumption that eco-friendly clay targets are just under the limit of 0.005 %, in reality, the incremental reduction compared to RO3 could be lower. The avoided emissions serve as a proxy for assessing the risks to the environment and to humans exposed via the environment.

RO4 also reduces the exposure of workers and consumers from handling PAH-containing clay targets, and due to carcinogenic properties of some of the PAHs in petroleum resins, the risk of cancer cases. If the reduction in exposure is assumed to be in proportion to the reduction in 18 PAHs content, compared to the baseline, the exposure is reduced by 60 %, but compared to RO2, the incremental reduction is only 0.9 % of baseline exposure. Remaining worker exposure is due to the possibility to produce clay targets for export with higher PAHs content. The impacts of a (complementary) ban on use is discussed in section 3.1.

2.8.3. Other impacts

Affecting eco resin binders next to the CTPHT, petroleum pitch and petroleum resin, this restriction option would also entail producer surplus impacts. This is because the price increase of clay targets could lead to a reduction in the demand for the clay targets. Clay shooting could be hard in hot temperature conditions (from 30 to 40 Celsius degrees upwards), due to lower softening point of the natural resin. It is also likely that availability issues would occur if only natural resin would be allowed. Next to this, the increase in the demand of natural resin-based binders (e.g., pine rosin) could lead to a price increase of the binder substances, leading to further consumer surplus and producer surplus impacts. These matters are only described qualitatively, since no quantitative information regarding these effects is available.

Based on the comments received in the consultation on the Annex XV report, there is a possibility that some companies have better market availability with existing supply chains for low-PAH binders. The Dossier Submitter acknowledges that it is likely that RO4 would lead to asymmetric impacts between clay target producers in the EU so that it is likely that some clay target producers could even face problems with continuation of their business, while some clay target manufacturers would increase their market share. These problems could be

mitigated with a longer transitional period, however, also releases of PAHs would continue during any longer period. With a one-year transitional period, it is possible that producers would not be able to supply enough to satisfy the EU demand.

2.8.4. Proportionality

This restriction option would come at an annual cost of €5.6 million, and would result in a total reduction of 270 tonnes of PAH releases per year to the EU environment. **The corresponding C/E-ratio** of RO4 **is 20.8 €/kg** of avoided PAH releases. Compared to RO3, RO4 would result in an incremental reduction of 2 tonnes of PAH releases at an incremental cost of €2 million per year, resulting in a marginal abatement cost of **952.4 €/kg**. However, considering the qualitatively described elements of the analysis, the marginal abatement cost could also be significantly greater.

2.9. Comparison of restriction options

The four restriction options are summarised in Table 28. The figures represent annual increments in costs and reductions in PAH releases. Taking a multi-year approach would not change the ratios but would naturally have an impact on both the total costs and total reductions in releases. The first column indicates the respective restriction option. The second column reports the total annual costs of the restriction option, and the third column provides estimates of the total annual reduction in PAH releases for each restriction option. C/E ratios based on this data are presented in the fourth column. The next columns indicate the incremental annual cost and incremental reduction in PAH releases compared to the preceding restriction option. The corresponding incremental C/E-ratios allow for a comparison of the restriction options against each other (rather than against the baseline).

Tabl	e 28	3. (Com	parison	of	restriction	options

Restriction option (concentration of PAH)	Total Costs €million per year	Total emission reduction of tonnes of PAHs per year	C/E- ratio €/kg	Incremental Change in Costs €million per year	Incremental reduction of tonnes of PAH releases per year	Incremental C/E-ratio €/kg
1 (1 %)	0.0	114	0.5	0.1	113	0.5
2 (0.1 %)	0.9	247	3.8	0.9	133	6.6
3 (0.005 %)	3.6	268	13.5	2.7	21	130.0
4 (0.0001 %)	5.6	270	20.8	2.0	2	952.4

The incremental C/E-ratio can be interpreted as a marginal abatement cost for PAH-releases. While the marginal abatement cost per tonne of PAH releases is $0.5 \, \text{€/kg}$ for the first 114 tonnes of PAHs, it is $6.6 \, \text{€/kg}$ for the next 133 tonnes of PAH releases, $130 \, \text{€/kg}$ for the next 21 tonnes of PAHs, and 952 $\, \text{€/kg}$ for the remaining two tonnes of PAHs. To assess the cost-effectiveness of the restriction options, the incremental C/E -ratios should be used. For example, RO4 has only an incremental effect of avoiding less than two tonnes of PAH releases per year with an incremental cost of $\, \text{€2}$ million, making the marginal abatement cost close to $1 \, 000 \, \text{€/kg}$. The average C/E -ratio for the total avoided releases and total costs is still reasonably low at $20 \, \text{€/kg}$, which is explained by the significantly less costly avoided releases

following RO1, RO2 and RO3. It should be noted that the proposed restriction option 3, has an abatement effectiveness in minimum of 99.3 % of baseline releases.

It should be noted that the table represents the annual costs and emission reductions once the transitional period is over. The impacts over the transitional period are not included in the assessment. During the suggested transitional period, clay target producers still have an option to use all other binders except CTPHT. However, it is not clear how many producers will substitute to binder materials that are not under the scope of RO3 even before the transitional period is over. Due to these uncertainties, the impacts of the transitional period have been described qualitatively. Finally, it should also be noted that the annual impacts also represent benefits and emission reductions annualised over an extended timeline (e.g., 20 years), if the same discount rate is applied both to the costs and emission reductions.

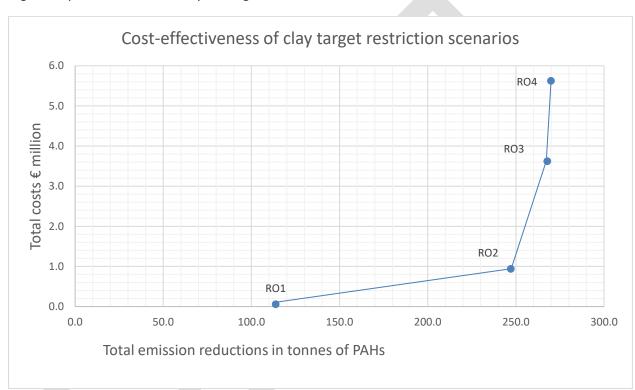


Figure 3 provides the corresponding abatement cost curve.

Figure 3. Abatement cost curve for the clay target restriction options

To assess the proportionality of the various restriction options with regard to the risk identified cost-effectiveness ratios were compared to those of previous REACH restrictions to avoid releases of PBT(-like) substances. As can be seen from Table 29, the average abatement costs for all restriction options are low compared to other recent REACH restrictions (perhaps with the exception of lead in shot in wetlands). However, when assessing proportionality, one should also consider the high marginal abatement cost for RO4, which means that the final two tonnes of emissions reduced are much more expensive compared to first 268 tonnes, making the marginal abatement cost close to 1 000€/kg.

Table 29. Cost-effectiveness of recent REACH restrictions

Restriction under REACH	€/kg p.a., central value
-------------------------	--------------------------

Lead in shot in wetlands	9
Lead in PVC (under opinion making)	308
D4, D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734
PFOA	1 649

A recent study by Oosterhuis et al. (2017) investigated this issue more closely. It concludes that, although cost estimates of previously adopted actions do not allow the derivation of a value for society's willingness-to-pay for reductions in PBT presence, use, and emissions, the available evidence suggests that measures costing less than $\[\in \]$ 1000 per kg of PBT use or emission reduction would usually not be rejected for reasons of disproportionate costs, whereas measures with costs above $\[\in \]$ 50 000 per kilogram PBT are likely to be rejected. The Dossier Submitter notes that this is also the finding of SEAC's PBT approach. $\[\in \]$

In relation to RO4, the qualitatively described cost items must be added. As stated above, the higher price per unit under these restriction options would likely reduce overall demand for clay targets, resulting in unquantified producer surplus losses. Moreover, the availability of the alternative substances is not certain, and a significant increase in the demand for those substances could have an impact on current market prices. The clay targets produced with natural resin binders can become soft and unusable in temperatures over 30 to 40 degrees Celsius. While based on the analysis, RO4 can further lead to a decrease of two tonnes of 18 indicator PAH releases per year (or 0.7% of the baseline releases), this is based on the conservative assumption that eco-friendly clay targets produced with eco resins are just below the 0.005 % concentration limit. In practise, the avoided releases of RO4 can be significantly lower.

The Dossier Submitter proposes RO3 as the preferred restriction option, on the basis of unifying the rules with the industry standard, its effectiveness to reduce over 99 % of the 18-PAH releases, and the availability of alternatives. Based on these elements, the Dossier Submitter considers the proposed restriction (RO3) to be the most proportionate of the options assessed. In terms of practicality and monitorability, the restriction options are identical since they are all based on an 18 PAH-limit. As explained in section 2.4, Dossier Submitter considers the proposed restriction option to be practical and monitorable.

SEAC box

1) SEAC has made complimentary analysis regarding 1) the quantitative impacts of transitional periods, and 2) the quantitative impacts of dual discount rates on cost-effectiveness of restriction options. **Evaluation of restriction options**

The assessment of restriction options RO1-RO4 does not include impacts occurring during the transition period. SEAC considers that the proposed introduction of a transition period in addition to the main restriction options – here RO1 to RO4 – should also be taken into

42

https://echa.europa.eu/fi/documents/10162/13580/approach for evaluation pbt vpvb substances seac en.pdf

account when assessing the costs and benefits of the proposed restriction.

Incorporating the costs and benefits that occur during the transition period is important for:

- i. Providing a comprehensive overview of the costs and benefits associated with the proposed restriction over the entire time period with the purpose of improving comparability with the proportionality of restrictions that have previously been adopted; and
- ii. Enabling a consistent evaluation of restriction options throughout the entire time period.

A consistent evaluation of restriction options is especially important when – as is the case here – the transition period does not only imply a delay of the entry-into-force of the (main) restriction option but includes an additional policy measure such as the different concentration limit suggested here. Inclusion of the costs and benefits that occur during the transition period is important for reaching a transparent and clear conclusion on whether the implementation of a transition period is a more cost-effective option than implementation of one of the main restriction options without a transition period.

In the proposed restriction, each restriction option consists of a *combination* of measures for progressively replacing PAH-containing binder: (i) a restriction measure which is adopted during the transition period (period 1), which is followed by (ii) a restriction measure which applies to all subsequent years (period 2). Applying cost-effectiveness analysis to this set of combinations of measures reveals a shortlist of restriction option combinations from which the decision-maker can choose.

Table 1 presents results from SEAC's evaluation, assuming equal discounting of costs and emissions (with a discount rate of 4%). Grey-shaded rows indicate those (combinations of) measures which are not cost-effective because they are dominated by other (combinations of) measures that achieve a higher annual emission reduction at an equal or lower total annual cost.

Table 1: Annual estimate of costs and avoided emissions and average and incremental cost-effectiveness ratios associated with restriction options assuming a transition period (based on a discount rate of 4% for costs and avoided emissions)

Total annual Period 1 Period 2 Total annual emission Incremental (transition (remaining assessment costs C/E ratio reduction [tons of C/E ratio period): [€/kg] period): [€ 18 indicator [€/kg] Ban of ... million/year] Ban of... PAHs/year] CTPHT (RO1) CTPHT (RO1) 0.1 164 0.5 0.5 CTPHT & petroleum CTPHT (RO1) 0.9 238 3.7 6.6 pitch (RO2) CTPHT & CTPHT & petroleum petroleum 0.9 247 3.8 6.6 pitch (RO2) pitch (RO2) CTPHT, petroleum CTPHT (RO1) pitch & petroleum 13.1 241¹ 3 4 257 resin (RO3) CTPHT, petroleum CTPHT (RO1) pitch, petroleum resin 5.2 259 20.2 960¹ & eco resin (RO4) CTPHT & CTPHT, petroleum pitch & petroleum petroleum 3.4 266 12.9 130 pitch (RO2) resin (RO3)

CTPHT, petroleum pitch & petroleum resin (RO3)	CTPHT, petroleum pitch & petroleum resin (RO3)	3.6	268	13.5	130
CTPHT & petroleum pitch (RO2)	CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	5.3	268	19.8	3 112 ¹
CTPHT, petroleum pitch & petroleum resin (RO3)	CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	5.4	270	20.3	952
CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	5.6	270	20.8	952

¹ The combination of measures are ordered based on an increasing volume of avoided emissions. If the total annual emission reduction associated with a certain combination of measures can be exceeded by another measure at a similar or lower cost, the combination of measures with higher total costs is 'dominated' and has to be excluded from the list of relevant policy options. The final list of relevant policy options consists of the (combinations of) measures which are undominated, ordered according to increasing incremental cost-effectiveness ratios. Note that incremental C/E ratios of 'RO2+RO3' and of 'RO3+RO4' denote the incremental C/E ratios to the nearest undominated option, i.e. 'RO2+RO2' and 'RO3+RO3', respectively.

2) Impact of the discount rate on the cost-effectiveness of restriction options

For evaluating the selected restriction options, the Dossier Submitter used a social discount rate of 4% for both costs and avoided emissions. SEAC considers equal discounting of costs and benefits, approximated by avoided emissions, not alone as a sufficient approach, and notes that additional sensitivity analysis is needed to explore the impacts of different discounting choices on the cost-effectiveness of restriction options.

Considering that PAH containing clay targets have already been used for decades⁴³, and due to PAH persistence, it seems reasonable to assume that environmental damage from PAH pollution, e.g. reduced environmental quality and ecosystem functioning, has been increasing over time. Considering further that the precise shape of the damage function is not known, it cannot be ruled out that marginal damages, i.e. the damage caused by one additional tonne of emissions, are increasing with the pollution level and thus have been growing over time (which is equivalent to assuming a convex damage curve). If this is the case, relative prices between environmental values and market values have changed over time, which would suggest the use of differential discounting. In light of this, SEAC recommends the use of a sensitivity analysis to explore the robustness of the results based on different discounting approaches.

Table 2 presents the average and incremental C/E ratios when dual discounting is used, i.e. when emissions are discounted with 0% instead of 4%. Dual discounting does not affect annual costs but causes the values of the annual avoided emissions to be higher compared to the equal discounting approach. The reason is that emissions occurring later in time

⁴³ Cf. Nattrass (1975): The development of international clay pigeon shooting. MSc thesis, Department of Physical Education, University of Alberta, Canada.

contribute more to the present value of emissions under the time path considered, which, in turn, increases annual values. While a discount rate of 0% does not change the order of cost-effective options, it changes the numerical values of average and incremental C/E ratios. SEAC notes that the use of differential discount rates results in lower cost-effectiveness ratios overall, i.e. all combinations of restriction options become more cost-effective compared to equal discounting. Furthermore, with differential discounting the incremental cost-effectiveness ratio of using of petroleum resin during the transition period and eco-resin thereafter ('RO2+RO3') improves compared to using eco resin immediately ('RO3+RO3').

Table 2: Annual estimate costs and avoided emissions and average and incremental cost-effectiveness ratios associated with restriction options assuming a transition period (based on a discount rate of 4% for costs and 0%

for avoided emissions)

t <u>or avoided em</u>	13310113)				
Period 1 (transition period): Ban of	Period 2 (remaining assessment period): Ban of	Total annual costs [€ million/ year]	Total annual emission reduction [tons of 18 indicator PAHs/year]	C/E ratio [€/kg]	Incremental C/E ratio [€/kg]
CTPHT (RO1)	CTPHT (RO1)	0.1	164	0.3	0.3
CTPHT (RO1)	CTPHT & petroleum pitch (RO2)	0.9	347	2.5	4.5
CTPHT & petroleum pitch (RO2)	CTPHT & petroleum pitch (RO2)	0.9	356	2.6	6.6
CTPHT (RO1)	CTPHT, petroleum pitch & petroleum resin (RO3)	3.4	375	9.0	127¹
CTPHT (RO1)	CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	5.2	378	13.9	650¹
CTPHT & petroleum pitch (RO2)	CTPHT, petroleum pitch & petroleum resin (RO3)	3.4	384	9.0	88
CTPHT, petroleum pitch & petroleum resin (RO3)	CTPHT, petroleum pitch & petroleum resin (RO3)	3.6	385	9.4	130
CTPHT & petroleum pitch (RO2)	CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	5.3	387	13.7	1148¹
CTPHT, petroleum pitch & petroleum resin (RO3)	CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	5.4	388	14.1	647
CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	CTPHT, petroleum pitch, petroleum resin & eco resin (RO4)	5.6	389	14.5	952

¹ The combination of measures are ordered based on an increasing volume of avoided emissions. If the total annual emission reduction associated with a certain combination of measures can be exceeded by another measure at a similar or lower cost, the combination of measures with higher total costs is 'dominated' and has to be excluded from the list of relevant policy options. The final list of relevant policy options consists of the (combinations of) measures which are undominated, ordered according to increasing incremental cost-effectiveness ratios. Note that incremental C/E ratios of

 $^{RO2+RO3'}$ and of $^{RO3+RO4'}$ denote the incremental C/E ratios to the nearest undominated option, i.e. $^{RO2+RO2'}$ and $^{RO3+RO3'}$, respectively.



3. Assumptions, uncertainties and sensitivities

In this section, the Dossier Submitter assesses how uncertainties related to the key assumptions of the impact assessment presented in section 2 would affect the benefits and costs, i.e., the cost-efficiency, of the restriction options.

The uncertainty and sensitivity analysis are based on the EFSA's framework to deal with uncertainty in regulation⁴⁴. Based on the examination of every part of the assessment, a list of identified uncertainties was compiled. This includes uncertainties associated with the inputs (e.g., data, estimates, other evidence) or the methodologies (e.g., statistical methods, calculations or models, reasoning, expert judgement) applied to the scientific assessment (see Table 30).



⁴⁴ https://www.efsa.europa.eu/en/efsajournal/pub/5123

Table 30. Identified uncertainties in the assessment

	Identified uncertainties							
Part of the underlying assessment	No.	No. Description of uncertainty		Assess- ment, metho- dology				
Section 1.3.	1	Exact quantity of clay targets placed in the markets in EU and the exact share of clay targets produced with different binder materials	Х					
Baseline	2	Regulatory uncertainty related to the decision of the applications for authorisation and baseline ⁴⁵	Х					
Section 1.1.1.	3	The exact identity of the binder materials and 18 PAH-content	X					
Section 1.1.4 and Section 2	4	The removal rate of clay target fragments	X					
Section 1.1.4 and Section 2	5	The release estimate is based on 18 indicator PAHs and will underestimate the risks	Х					
Section 2	6	A price elasticity of demand of 0 was assumed and this will overestimate the cost of the restriction options in terms of its effects on consumer surplus		Х				
Section 2.3	7	Some variance in the prices is expected per manufacturer / cost difference between clay targets produced with different binders can vary over time						
Section 1.1	8	If a restriction on the use as a binder is						

As a part of a preliminary screening of identified uncertainties with respect to their contribution to the overall uncertainty of the assessment, the prioritisation was made (see Table 31).

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⁴⁵ The restriction proposal was developed before the Commission had made a decision on granting or not granting the authorisations for the use of CTPHT as binder in clay targets. As of 16 March 2022, the Commission decided not to grant the authorisations. Therefore the assumption made by the Dossier Submitter is confirmed. The analysis of this uncertainty is still included in the Background Document for transparency.

Table 31. Prioritisation of the identified uncertainties

	Identified uncertainties		Overview of influences and known impacts on other parts of the assessment
2 & 8	Regulatory uncertainty		If authorisation is granted to one or several of the clay target manufacturers in Europe, each restriction option will carry out also significant producer surplus effects ⁴⁵ / If a restriction is applied on the use a binder, additional producer surplus impacts are expected
4 & 5	Uncertainty related to the releases (PAH-content and removal rate)	Priority 1	Assuming that release would be only 50 % compared to 100% in the main analysis, the change in the calculated value of C/E-ratios would double (increase by 100 %). / The reverse would hold in case the use of 18 indicator PAHs would underestimate the total PAH releases by 50%; the C/E-ratio would decrease by 50 %
1	Exact quantity and the exact share of clay targets produced with different binder materials placed in the markets in EU	Priority 2	The quantities will have an impact on the total cost and total release estimates; however, the marginal abatement costs would remain as they are in the main analysis. While the total costs and total release estimates are important, the effectiveness of each restriction option should be judged based on the marginal abatement costs.
3 & 8	The exact identity of the binder materials and 18 PAH-content	Priority 2	The identity and the PAH-content of binder materials is subject to uncertainty. The uncertainty may have an impact on which alternative binder materials are allowed under each restriction option.
6	The price elasticity of demand of 0	Priority 3	A higher price elasticity of demand would result in lower total costs of each restriction option
5	Price variance	Priority 3	A small variance in the prices will have a minimal impact on the eventual C/E -ratios and marginal abatement costs. / The time-path of the cost difference between different binders can have a moderate impact on the eventual C/E -ratios and marginal abatement costs. However, DS has no information that would hint at significant changes over time.

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 parts of the uncertainty analysis are shown in Table 32.

Table 32. Parts of the uncertainty analysis

	Identified uncertainties	Part of the uncertainty analysis
2 & 8	Regulatory uncertainty	Part A
4	18 PAH-content as an approximation of the PAH releases	Part B
5	Removal rate of the clay target fragments	
3	Exact substance identity and 18 PAH-content	Part C
7	Price variance	Other impacts discussed qualitatively in the summary
6	The price elasticity of demand of 0	section, but the impacts of the time-path of cost
1	Exact quantities	differences quantified in Part D.

3.1. Part A: Regulatory uncertainty

The baseline is 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 is subject to regulatory uncertainty, and an alternative scenario is possible where an authorisation is granted for these applications⁴⁵. The baseline market situation, as in section 1.3, would have to be replaced by the actual market situation.

Should a restriction be implemented based on this alternative scenario, the impacts would be also different compared to the baseline analysis. In this case, there would be a negative producer surplus impacts on those EU producers that currently use CTPHT as a binder. These negative producer surplus impacts would be a result of the restriction rather than the negative authorisation decision and would need to be taken into account in the impact assessment of the restriction. The alternative baseline is summarised in Table 33.

Table 33. Alternative baseline considering the regulatory uncertainty related to the decisions to grant or deny an authorisation for CTPHT as a binder in clay targets

Binder	Producer in EU, million clay targets	Imported (UK and Russia), million clay targets	Total, million clay targets	Total annual release s tonnes of 18 indicat or PAHs
СТРНТ	66	60	125	343
Petroleum Pitch	51	0	51	42
Petroleum Resin	122	0	122	9
Eco resin and natural resin (PAH <50mg)	72	30	102	0.5
Total	310	90	400	395

Now, should the use of CTPHT be restricted, the PAH-releases from the clay targets that use CTPHT as a binder would be eliminated. As the assumption is that producers would move to the least costly alternative binder, petroleum pitch clay targets would take the market share of the CTPHT clay targets. The annual reduction in PAH-releases would be approximately 239 tonnes of PAH releases in total.

Based on the applications for authorisation, the profit margin for the affected EU producers is at most one cent per target. This profit margin can be used to estimate the loss in producer surplus that would take place in EU as a proxy for 1) the possible frictional losses as other producers could possibly not immediately satisfy the market demand, and 2) the loss in the current machinery used to produce clay targets with CTPHT as a binder that would lose some of its value due to the restriction. This profit loss would correspond to an annual loss of producer surplus of approximately €0.7 million.

The market situation and the remaining PAH-releases would be identical to those reported in sections 2.4-2.8, and also the incremental costs and benefits would not be different from those presented in section 2. Only the total costs would differ by the amount of the estimated loss of producer surplus of €0.7 million for all ROs.

Table 34 depicts the cost-effectiveness analysis of restriction options RO1-RO4 under the assumption that the use of CTPHT as a binder is granted an authorisation. As one can see, the uncertainty related to the decision of granting an authorisation for the uses of CTPHT as a binder does not alter the conclusions of the analysis. While the total costs of the restriction options change, the marginal abatement costs differ only for RO1 whose marginal abatement cost would now be around 3 €/kg rather than 0.5 €/kg.

Table 34. Cost-effective analysis of Restriction Options if CTPHT as a binder in clay targets is granted an authorisation

Restriction option	Total Costs €million per year	Total emission reduction of tonnes of PAHs per year	C/E- ratio €/kg	Incremental Change in Costs €million per year	Incremental reduction of tonnes of 18 indicator PAH releases per year	Incremental CE-ratio €/kg
RO1	0.7	239	3	0.7	239	3
RO2	1.6	372	4.3	0.9	133	6.6
RO3	4.3	393	10.9	2.7	21	130.0
RO4	6.3	395	15.9	2.0	2	952.4

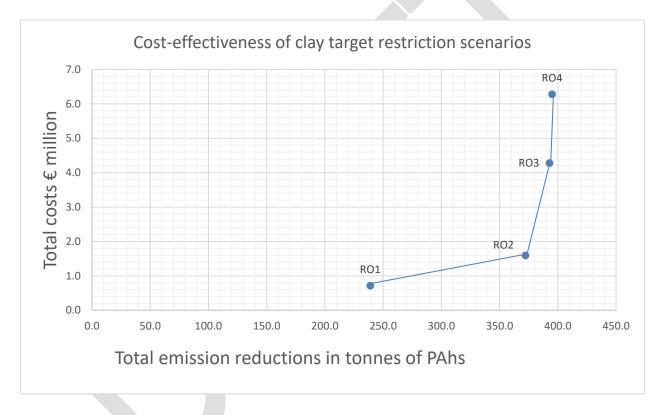


Figure 4. Abatement cost curve for clay target restriction options if CTPHT as a binder in clay targets is granted an authorisation

Another source of regulatory uncertainty comes from the scope of the restriction. Restriction options are built on to the assumption that restriction is applied for placing PAH containing clay targets on the EU market. However, the recent EU Chemicals Strategy for Sustainability⁴⁶ states that the EU will lead by example and ensure that hazardous chemicals banned in the EU are not produced for export either. Thus, the decision-maker may want to opt for a restriction that applies to the use of the PAH containing binders in the production of clay targets rather than the placing on the market of the resulting clay targets. The restriction on

⁴⁶ https://ec.europa.eu/environment/strategy/chemicals-strategy_en

use as a binder can be considered as a complementary element to the restriction options 1-4.

This restriction scope would have an impact on EU exports. Indeed, the EU is a net exporter of clay targets, with approximately 200 million clay targets exported annually (mostly to North America). A restriction on the use of PAHs in binders could leave the EU producers at a competitive disadvantage in export markets.

While the Dossier Submitter does not have any exact information on the exported quantities of different types of clay targets, indicative figures may be estimated based on the EU production, and on the assumption that different types of clay targets are currently exported at similar shares as used in the EU. Based on these premises, the annual exports would consist of 79 million clay targets using petroleum pitch as a binder, 83 million clay targets using petroleum resin as a binder, and 48 million clay targets using eco resin as a binder. RO1 would have no impact on the exports, since under the baseline, it is assumed that CTPHT is not granted an authorisation to be used as a binder anymore. RO2 would have an impact on the petroleum pitch-based clay targets, RO3 on the petroleum resin-based clay targets, and RO4 also on the eco resin clay targets. Based on the assumption of a profit margin of one cent per target (as made by the applicants for authorisation), and assuming that all affected exports would be lost, the producer surplus losses related to the drop in exports can be estimated and added to the total costs of each restriction option (see Table 35.)

The ban on use further reduces the exposure of workers from handling PAH-containing clay targets, and the risk of cancer cases. If the reduction in exposure is assumed to be in proportion to the reduction in 18 PAHs content, compared to the baseline, RO3 with the ban on use, reduced the exposure by 99%.

Table 35. Cost-effective analysis of Restriction Options – If restriction applies also to the exports by restricting the PAH containing binders in production

Restriction option	Total Costs €million per year	Total emission reduction of tonnes of PAHs per year	C/E- ratio €/kg	Incremental Change in Costs €million per year	Incremental reduction of tonnes of 18 indicator PAH releases per year	Incremental CE-ratio
RO1	0.1	114	0.5	0.1	114	0.5
RO2	1.7	247	7.0	1.7	133	12.5
RO3	5.2	268	19.6	3.5	21	170
RO4	7.7	270	28.6	2.5	2	1183

3.2. Part B: Uncertainty related to the releases

As stated in section 0., during the use 100 % of the clay targets are released to the environment. In its opinions on the applications for authorisation, RAC was of the view that this inevitably means that initially 100 % of the CTPHT is released to the environment; i.e. mainly to the soil compartment (e.g. shooting grounds, agricultural land, and nature areas). The same consideration should apply to the alternative binder substances. However, two main sources of uncertainty related to the releases are: 1) a fraction of the larger fragments of clay

targets may be collected and disposed of, thus reducing the actual release; 2) the release estimate is based on 18 indicator PAHs and this 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.

For point 1), the applicants applied a removal rate of 50 % of the clay target fragments. This means that 50 % of the mass of the fragmented clay targets would be manually collected from the shooting grounds. Assuming that the fragments are disposed of as waste in a way that would prevent all releases from waste, this 50 % decrease in the releases would naturally decrease the reduction in the releases of all of the restriction options by a corresponding 50 %.

If the potential underestimation of using only the 18 indicative PAHs is not accounted for, the analysis with a 50 % removal rate is likely to overestimate the costs of the restriction in relation to the reduction of the releases. Thus, the CE-ratios in Table 36, which depicts the CE-ratios for the 50 % release factor, can be considered the higher boundary for the CE-ratios in terms of uncertainty related to the releases.

As seen from Table 36, a 50 % removal rate translates into 50 % of avoided releases, and subsequently doubles the C/E -ratios and the marginal abatement cost.

For point 2), as mentioned, the use of 18 indicator PAHs is an approximation that underestimates the avoided releases of PAHs in general, because these 18 indicator PAHs represent only a fraction of the total PAH content of the binders and thus estimated releases limited of 18 indicators PAHs do not account for the concentrations of any other PAHs. Due to the existence of an existing standard (ISSF rule), information on the concentration of 18 PAHs is reasonably consistently available for the most widely used binders, which allows to compare the expected releases from the use of these binders in clay targets. The underestimation related to estimating releases based on 18 indicators PAHs (and not more PAHs) cannot be quantified since the concentration of other PAHs in PAHs-containing binders is mostly unknown. Although registration information shows that the binders can contain PAHs, quantification depends entirely on whether PAHs (other than the 18 indicators) were analysed and the data reported. This analysis is not available in registrations of CTPHT, petroleum pitch, petroleum resin and other resins in a systematic and exhaustive way that would allow a quantification. It means that the proposed restriction is expected to lead to an overall reduction of releases of PAHs in general, that is greater than the releases that have been quantified.

Thus, if more indicator PAHs were used than 18, the C/E -ratios and marginal abatement costs could decrease significantly. The results in Table 36, with a 50 % removal rate and only the 18 indicator PAHs included, should only be used as an indication of how increasing the removal rate would affect the C/E -ratios. If for example, it would be assumed that the use of 18 indicator PAHs underestimates the releases by 50 %, the C/E -ratios would be as in the main impact analysis in sections 2.4 onwards.

Table 36. Cost-effective analysis of Restriction Options with a 50 % removal rate – worst-case scenario in terms of avoided releases

Restriction option	Total Costs €million per year	Total emission reduction of tonnes of PAHs per year	C/E- ratio €/kg	Incremental Change in Costs €million per year	Incremental reduction of tonnes of PAH releases per year	Incremental CE-ratio
RO1	0.5	57	1.0	0.0	57	1.0
RO2	0.9	124	7.6	0.9	67	13.2
RO3	3.6	134	27.2	2.7	10	260.0
RO4	5.6	135	41.6	2.0	1	1904.8

3.3. Part C: The identity of the binder materials

A first consideration is that other substances containing PAHs, not identified in this report, may also be used for clay target production. Substances that were explicitly identified during the preparation of this restriction (see B.1) are used for the purpose of the impact assessment but should not be considered as an exhaustive list of substances to be restricted.

A second consideration is that the identity (identifiers and composition) of the known binders is also uncertain. This is particularly true for binders other than CTPHT and petroleum pitch. These substances are UVCBs and the composition data in registration dossiers are too scarce to allow proper identification of the substances, in terms of PAH content and boundary composition but also names, EC and CAS numbers. Furthermore, generic names are used by manufacturers of clay targets to refer to the binder used (such as "petroleum resin", "eco resin"), but as discussed in 1.2.1.2, these terms are vague and are rarely confirmed by data and are sometimes even contradictory. For instance, substance EC No. 305-586-4 is referred to as "eco resin" in the exchange with ISSF (2020) but is not an eco resin based on the concentration of PAHs (as in registration dossiers) compared to the PAH concentration limit for eco resin. Similarly, the substance [Resin 3] is considered as a PAH-free resin by its manufacturer but the registration data contradicts this claim. It is thus not possible to quantify the concentration of the 18 PAHs and to allocate the substance EC 305-586-4 and [Resin 3] to the appropriate category in the impact assessment: the number of clay targets placed on the market is likely included in the "eco and natural resin" category; however as they contain PAHs the releases from their use in clay targets could be even higher than for CTPHT. The concentration of PAHs in [Resin 1] is also unknown. These uncertainties cannot be quantified (as the market share of these resins and releases from their use is unknown) but could lead to over or underestimation of the releases and costs.

Thirdly, as explained in section 1.2.1.2, the 18 PAHs concentration information are typically based on limited samples or composite samples, and the 18 PAHs concentration figures used in section 2 (impact assessment) are in the type of central estimates. The boundaries of the composition are not reflected within the estimate. By applying the higher concentration figures in section 1.2.1.2 for the 18 PAHs concentration of the binder materials, a best-case scenario can be calculated in terms of the effectiveness of the proposed restriction options to

reduce 18 PAH releases. These figures for the 18 PAHs concentration would be 4.7 % for the CTPHT, 1.8 % for the petroleum pitch and 0.1 % for the petroleum resin. Again, we assume that a substance can be referred to as "eco resin" only if the concentration levels of the 18 PAHs are below 0.005 % w/w. It needs to be noted that this scenario only represents a best-case scenario in terms of efficiency of reducing 18 PAHs. As stated in section 1.2.4, other PACs, such as larger PAHs, alkylated PAHs and heterocyclic PACs, are also of concern. They are less studied and less included in regulatory framework but can display higher toxicity profiles. Due to scarcity and lack of quantitative data, these are excluded from the impact analysis, so that even the best-case scenario can be considered conservative in terms of efficiency of the restriction options.

If one considers the higher 18 PAH concentration estimates, both CTPHT and petroleum pitch would be restricted under RO1 (>1 % concentration), and petroleum resin under RO2 (>0.1 % concentration). Table 37 shows the cost-effectiveness based on this scenario.

Table 37. Cost-effectiveness analysis of restriction options under the assumption of higher 18 indicator PAHs contents

Restriction option	Total Costs €million per year	Total emission reduction of tonnes of PAHs per year	C/E- ratio €/kg	Incremental Change in Costs €million per year	Incremental reduction of tonnes of 18 PAH releases per year	Incremental CE-ratio	
RO1	0.9	5021	1.86	0.9	502	1.86	
RO2	22.7	535	5.1	1.8	33	55	
RO3	Identical in terms of efficiency with RO2, since with the higher 18 PAH concentration estimates, Petroleum Resin producers would move already to Eco Resin under RO2. However, RO3 would make sure that all other binder materials over 0.005 % in 18 PAH concentration would not be placed on the market.						
RO4	5.6	537	10.5	2.9	1	2743	

One more piece of sensitivity analysis related to the identity of the binder materials can be considered appropriate to reflect how relaxing the assumption of 0.005 % 18 indicator PAH-content of eco-friendly targets would impact the analysis. If for example the 18 indicator PAH-content of one of the eco resin binders is applied (see Table 21), it results into clay targets with only a 0.0009 % 18-indicator PAH content. The avoided releases of RO4 go down to one-fifth and the cost-efficiency figure goes up by five-fold. This would result into marginal abatement cost of over $5 000 \ \text{€/kg}$ for RO4, or considering the lower bound for the avoided releases as in Table 36., into marginal abatement cost more than $10 000 \ \text{€/kg}$.

3.4. Part D: Time path of the price difference between clay targets produced with different binders

Cost estimates for the different restriction options are expressed as annualised values. The costs of the restriction options are based on the loss of consumer surplus due to higher prices of the clay targets the stricter the PAH-content limit is.

The cost difference can be constant, but can also vary over time (i.e. decrease or increase). Assuming that production processes have already been established for most of the alternative binders, there can be arguments for assuming gradually decreasing marginal costs of binder production after the entering into force of the restriction. Decreasing marginal costs would cause the retail price for alternative binders and, consequently, the market price for clay targets, to decrease over time. This would result into a smaller price difference between the cheap (i.e., CTPHT or Petroleum Pitch based clay targets) and the alternatives. We simulate such impacts by assuming that the price difference between CTPHT and each alternative would be halved during the 20-year assessment period. This would result into approximately 24% lower C/E -ratios and marginal abatement costs compared to the baseline. For the proposed restriction, RO3, this would mean that the marginal abatement cost in the baseline of 130€/kg would decrease to approximately 98€/kg.

Similarly, an increasing demand for binders with a low PAH concentration can cause the price difference between CTPHT and alternative binders to increase during the assessment period. This can happen if there is considerably more demand for the alternative binder materials

without a sufficient increase in the supply. It is not possible to confirm how likely such a scenario is, but for the sensitivity analysis it is assumed that this would double the difference between the cheapest clay targets and their alternatives during the 20-year assessment period. This would result in around 44% higher C/E -ratios and marginal abatement costs compared to the baseline. For the proposed restriction, RO4, this would mean that the marginal abatement cost in the baseline of $130 \mbox{e}/\mbox{kg}$ would increase to approximately to $186 \mbox{e}/\mbox{kg}$.

3.5. Summary of the uncertainty analysis

Regulatory uncertainty is partly related to the decisions of the Commission to either grant or deny an authorisation for the use of CTPHT as a binder in clay targets. In the baseline we assume that the decision is negative so that it is in align with the opinions. In Part A of the uncertainty analysis, we do sensitivity analysis with an alternative baseline, where the decisions grant an authorisation for the use. In this case, we can expect negative producer surplus effects in the range of $\{0.7 \text{ million}\}$. However, this does not have an effect on the marginal abatement costs and does not affect the Dossier Submitter's proposal for the chosen restriction option.

Another source of regulatory uncertainty comes from the scope of the restriction. Restriction options are built on to the assumption that restriction is applied for placing PAH containing clay targets in the market. If the decision-maker decides to opt for a restriction that applies for use of the PAH containing binders in the production of clay targets, the restriction would also have an impact on the EU exports. EU is a net exported of clay targets, with approximately 200 million clay targets exported annually. A restriction on the use as a binder could leave European producers at a competitive disadvantage in those markets that they are currently exporting to. This scenario would raise the marginal abatement cost of the proposed RO3 from 130 €/kg to 170 €/kg.

The uncertainty related to the releases can have an impact on two directions. If clay target fragments are collected from the shooting grounds, the reduction of releases is proportionally lower. This increases the costs per avoided release. A 50 % removal rate doubles the cost per avoided release, so that both the C/E-ratios and marginal abatement costs increase by a factor of two. However, the use of 18 indicator PAH as the basis for the estimate of avoided releases underestimates the potential releases. In the baseline, we assume these two effects to balance each other out. The uncertainty related to the actual PAH-content of the clay targets has an opposite effect compared to the uncertainty related to the removal rate. If the actual PAH-content is for example twice as high as the 18 indicator PAH-content, the reduction in releases doubles. This makes each C/E- ratio and marginal abatement cost 50 % lower. The results with a 50 % removal rate and 18 indicator PAHs should be regarded as a worst-case scenario in terms of avoided releases, and the C/E -ratios and marginal abatement costs should be regarded as worst-case estimates in terms of efficiency of the restriction options. This scenario would raise the marginal abatement cost of the proposed restriction option 3 from 130-260 €/kg, and by assuming that also exports are concerned, to 340 €/kg.

In part C, the uncertainty related to the 18 PAH content of binder materials is addressed. By applying the highest 18 PAH content in binder materials in the samples, the marginal abatement costs are considerably lower. However, due to unmeasured PAHs, this should not be regarded as a true best-case scenario in terms of efficiency of the restriction options. This

scenario would decrease the marginal abatement cost of the proposed RO3 from 130 €/kg to 55 €/kg.

Table 38 Summary of the uncertainty analysis

	Uncertainties	Part of the uncertainty analysis	Contribution to uncertainty in each part of uncertainty analysis	
2 & 8	Regulatory uncertainty	Part A	Alternative baseline, assuming granted authorisation, has an effect of €0.7 million over the total costs. Has no impact on the abatement costs per restriction options. However, has a large impact on the total avoided releases of RO1. Having a restriction applied also the exports, would increase the marginal abatement costs. For the proposed restriction option, the increase would be approximately 30 %.	
4	18 PAH-content as an approximation of the PAH releases	Part B	Should the 18 indicator PAH content underestimate the releases by for example 50 %, the C/E- ratio and marginal abatement cost would be reduced by 50 %.	
5	Removal rate of the clay target fragments		Should for example 50 % of the clay target fragments be collected, the C/E -ratio and marginal abatement cost would increase by 100 %.	
3	The identity of the binder materials and 18 PAH content	Part C	RO2 and RO3 would result in the same total change in costs and reduction of releases. RO2 would be significantly costlier compared to the baseline, however, the proposed restriction option RO3 would result be significantly cheaper in terms of marginal abatement costs. However, RO4 could be far more costly.	

4	The time path of the cost difference between clay targets produced with different binder materials	Part D	If the price difference is halved during the 20-year assessment period, the marginal abatement costs would decrease by approximately 24% compared to the baseline. If the price difference is doubled during the 20-year assessment period, the marginal abatement costs would increase by approximately 42% during the assessment period.
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To demonstrate how the uncertainties of the different parts work together in causing uncertainty about the outcome of the assessment, a worst case-scenario can be constructed based on the uncertainty analysis. The worst-case estimate can be established by combining the worst-case estimates under parts A and B. The Part C considers a baseline with a more severe assumptions on the 18 PAH content of the binder materials and represents a best-case scenario in terms of efficiency and avoided releases per restriction option. Based on the uncertainty analysis, even under the worst-case scenario, when comparing the marginal abatement cost against the proportionality criteria, discussed in section 2.9., RO1, RO2 and RO3 can be considered to be proportionate to the risk. The minor uncertainties that were set aside related to the price variance, exact quantities and price elasticity of demand, would only have marginal impacts on the quoted figures. However, RO4 could be one of the most expensive restrictions implemented under REACH in terms of cost-effectiveness.

Table 39. Worst-case and best-case estimates for the marginal abatement costs

Restriction option / Worst-case with combined uncertainty of Part A and B	Marginal abatement cost €/kg	Restriction option / Best-case scenario with uncertainty of Part C quantified	Marginal abatement cost €/kg
RO1	1	RO1	1.9
RO2	25	RO2	55
RO3	340	RO3	55
RO4	10 668	RO4	(952) 2743

As stated in section 2.9, to assess the proportionality to the risk of the proposed restriction, the comparison of the cost-effectiveness with the cost-effectiveness of former measures to avoid PBT(-like) substances can provide some indication.

Given the combined impact of the identified uncertainties in the assessment, it must be deemed almost certain that RO1 and RO2 are proportionate to the risk, and extremely likely that RO3 is proportionate to the risk. The Dossier Submitter cannot conclude on the proportionality of RO4.

4. Conclusion

Based on the analysis, the Dossier Submitter proposes a restriction with the conditions that clay targets shall not be placed on the market or used for shooting if the total concentration of the individually listed PAHs substances (the sum of the concentration of all listed PAHs) is more than 50 mg/kg (0.005 %) by weight of the clay targets. As to the timing of the restriction, Dossier Submitter proposes a two-phase approach: 1) Clay targets for shooting shall not be placed on the market or used for shooting where the sum of the concentrations by weight of the 18 indicator PAHs is greater than 1 % (w/w) in the clay targets from entry into force of the restriction, and 2) clay targets for shooting shall not be placed on the market or used for shooting where the sum of the concentrations by weight of the 18 indicator PAHs is greater than 0.005 % (w/w) in the clay target 1 year from entry into force of the restriction.

Several drop in alternatives to CTPHT are currently in the market, such as Petroleum Pitch, Petroleum Resin, Eco Resin(s) and Natural Resin. Although most of the alternatives contain PAHs in concentrations lower than that of the CTPHT, the PAH-containing alternatives also present a risk to the environment and human health. By definition, Eco Resin and Natural Resin have a substantially lower or no PAH-content. It is estimated that placing on the market of clay targets results in emissions to the environment of approximately 270 tonnes per year of 18 indicator PAHs with PBT, vPvB and carcinogenic properties.

Due to the complex nature of CTPHT and other binder materials, in practice, any restriction on the binder materials in clay targets should be based on a concentration limit of the sum of indicator PAHs in the clay targets (as these are the constituent substances underpinning the risk). Targeting PAHs in articles, rather than specific substances used in the manufacturing process of clay targets, would also efficiently ensure that all PAHs-containing binders would be covered by the restriction, even if not well identified. The proposed restriction options establish a concentration limit in clay targets for 18 indicator polycyclic aromatics hydrocarbons (PAHs).

There are other polycyclic aromatics compounds (homocyclic, heterocyclic and alkylated) which can be of concern. Reducing the amount of these 18 indicators PAHs in clay targets is believed to also reduce the amount of any other less well identified compounds.

Since the PAH-containing binders are vPvB and PBT-substances, the focus is on the characterisation of emissions. The impact assessment is based on the comparison of different options to restrict PAH-containing binders in clay targets. All restriction options are identical in terms of practicality and monitorability. Sampling of clay targets and sample preparation is relatively straightforward, as the matrix is rather simple (binder and filler). Standard calibration materials for each of the 18 PAHs and analytical methods are widely available. The costs of each restriction option are measured in terms of loss in consumer surplus, enforcement costs, and producer surplus; and the benefits as reductions in releases of PAHs to the environment. RO1 sets an 18 PAH concentration limit (in clay targets) to 1 %; RO2 to 0.1 %; RO3 to 0.005 % and RO4 to 0.0001 %. Based on the impact assessment in section 2 and the uncertainty analysis in section 3, the Dossier Submitter concludes that RO1, RO2 and RO3 can be considered proportionate to the risk identified, while the proportionality of RO4 is less clear. The 18 PAH concentration limit of RO3 is also aligned with the industry standard in clay targets in ISSF-competitions.

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Annex A: Manufacture and uses⁴⁷

A.1. Manufacture, import and export

CTPHT is the residue from the distillation of high temperature coal tar. In 2009, coal tar distillation occurred at 11 manufacturing sites, owned by seven different companies, in nine EU Member States (ECHA, 2009a). These sites had a total distillation capacity of around 2 475 kilotonnes per year (kt/y). The actual manufacture (distillation) of coal tar derivatives was however quoted around 2 000 kt/y (ECHA, 2009a). With regard to the import/export balance of CTPHT, the EU Risk Assessment Report (EU RAR, 2008) notes that in 2004 import and export of CTPHT from/into EU were respectively around 92 kt/y and 355 kt/y; the RAR estimated the total EU use of CTPHT to be around 554 kt/y (EU RAR, 2008). According to the Chemical Data Reporting (CDR) data submitted to US-EPA under the Toxic Substances Control Act (TSCA), the volume exported out of the USA was 19,240 tonnes in 2014 (CDR, 2014). According to ECHA (2015a) information on the registration data, the amount of CTPHT manufactured and/or imported into the EU was in the lower part of the range 1 000 000 -10 000 000 t/y. A small share of the tonnage was reported as being exported outside the EU (ECHA 2015a). One sector association commenting during the public consultation on the draft 6th recommendation (ECHA 2015a, ECHA 2015b) indicates an actual tonnage manufactured and/or imported in EU of approximately 800 000 – 900 000 t/y, of which 320 000 t are directly exported (data collection from year 2013). Furthermore, according to ECHA (2015a) the volume for uses in the scope of authorisation (e.g. formulation of mixtures, uses in clay targets, uses in mixtures for corrosion protection, uses in metallurgic smelting, uses in refractory products) was estimated to be >10 000 t/y. Data in SPIN database show a decline in the total tonnage from early 2000 to 2017 (Denmark), 2018 (Finland) and 2019 (Sweden); however in Norway the declared tonnage has been increasing up to ~ 200 000 tonnes in 2018.

According to current registration information as of 30 April 2021, CTPHT is registered at 100 000 - 1 000 000 tonnes per year⁴⁸.

Based on the applications for authorisations, the tonnage for uses in the scope of authorisation is between 57 008 and 744 008 t/y.

Pitch, petroleum, arom. (EC No. 269-110-6, CAS No. 68187-58-6) is currently registered at $10\ 000-100\ 000\ t/y$. There are 7 active registrations⁴⁹.

Distillates (petroleum), cracked, ethylene manuf. by-product, C9-10 fraction (EC No. 305-586-4, CAS No. 94733-07-0) is currently registered at 10 000-100 000 t/y by 1 active registrant 50 , and at 10 000-100 000 t/y by 4 other registrants 51 .

⁴⁷ If an Annex is not included then the numbering of the Annexes should be amended so they run A to F. For example if no Annex on Justification for action on a Union-wide basis (Annex C in the template then Annex D: Baseline should be renumbered Annex C: Baseline).

⁴⁸ https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/15300/1 (30/04/2021)

⁴⁹ https://echa.europa.eu/registration-dossier/-/registered-dossier/14150/1/2 (28/06/2021)

⁵⁰ https://echa.europa.eu/registration-dossier/-/registered-dossier/2068/1/2 (28/06/2021)

⁵¹ https://echa.europa.eu/registration-dossier/-/registered-dossier/2103/1/2 (28/06/2021)

[Resin 1] is currently registered at $1000-10\ 000\ t/y$. There is one active registration⁵².

[Resin 3] is currently registered at 100 000-1 000 000 t/y. There are 58 active registrations⁵³.

A.2. Uses

A.2.1. Manufacture of clay targets

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. Typically, the moulding process is undertaken using a rotary press or 'carousel'. The binder material used, when mixed with the filler material under a stable and consistent production process, will ensure that targets remain consistent in their composition when moulded. The viscosity of the binder affects the manufacturing process (high viscosity requires higher process temperature, and low viscosity may cause the substance to seep from the moulds and lead to an inconsistent binder-to-filler ratio in the end targets).

Clay targets must be strong enough to withstand transportation, storage and loading as well as being thrown from traps at very high speeds. They must be sufficiently brittle or frangible so that when they are hit, the marksman can clearly tell by the explosive disintegration of the target that the hit has been registered. The binder material needs to be able to withstand heat without softening, as it can affect the thermal resistance properties of the end product (i.e. on a hot day the clay targets could be deformed or adhere together in the storage, rendering them useless).

At the time of writing, a total of 8 applications for authorisation for three 3 different uses of CTPHT have been submitted to ECHA (ECHA, 2020). The use of CTPHT as a binder in the manufacture of clay targets (2 applications) is of interest for this restriction proposal⁵⁴.

In these two applications for authorisation (ECHA, 2020), the following manufacturing steps are described:

- Delivery and transfer of CTPHT in solid or liquid form into heated (about 180 °C) storage tanks
- Transfer to the mixer then to the moulding machines in closed system
- Operation of the moulding machines, which are equipped with integrated closed water cooling systems and build-in local exhaust ventilation
- Painting (spraying booths), drying of targets
- Packing of the finished products
- Maintenance operations.

⁵² Accessed 06/07/2021. Identifiers confidential: refer to confidential annex.

⁵³ Accessed 06/07/2021. Identifiers confidential: refer to confidential annex.

⁵⁴ Other uses applied for are 1) the use of CTPHT to formulate mixtures for various industrial uses (5 applications); these applications only cover the formulation uses, but not the downstream use of the mixtures or of 'neat' CTPHT as the applicants consider these to be intermediate uses (e.g. production of prebake electrodes for aluminium smelters or production of carbon black); opinions have been adopted by RAC and SEAC; and 2) the industrial use of CTPHT as precursor in carbon-carbon composite parts in civilian and military aerospace launchers (1 application); authorisation has been granted under number REACH/21/1/0.

RAC concluded that "the operational conditions and risk management measures [were] not appropriate and effective in limiting the risk for workers", as "the applicant[s] [have] not demonstrated that the hierarchy of control is respected for the transfer stations for solids as they do not prevent worker exposure, and the efficiency of the general ventilation could not be demonstrated".

No RMMs have been described to limit the releases of CTPHT to air. It is stated that there are no releases to water and soil. RAC considered that "the absence of any treatment of exhaust emissions from especially the moulding machines, mixer units and holding tanks [was] not appropriate". RAC concluded that "the operational conditions and risk management measures [were] not appropriate and effective in limiting the risk for the environment and humans exposed via the environment.

As the processes to produce clay targets is regarded as generally the same regardless of the exact nature of the binder used, it is considered that the manufacturing process described for CTPHT also applies for the other binders subjected to the proposed restriction.

A.2.2. End-use of clay targets (article service life)

The targets are flung into the air by a device called a "trap", to create moving targets for shooters to shoot at (ECHA, 2009a). Clay targets are used for shotgun events. Users are regarded as consumers (shooters and persons handling the clay targets). As reported in the RAC and SEAC opinion on the applications for authorisation of CTPHT in clay targets (ECHA, 2020), "clay target shooting is predominantly an amateur pastime (the SEA states that the clay target industry is a "low-sophistication industry where users are predominantly amateur shooters"). Handling of clay targets and charging of traps may not necessarily be tasks carried out by professionals (i.e. as a paid occupation) and may be carried out by amateurs (including shooters). This has been confirmed by the applicant in responses to questions, although the majority of the targets would be sold to 'dedicated shooting grounds'. It is therefore the view of RAC that in terms of risk management of CTPHT in clay targets the situation for professionals may be considered to be akin to that of consumer". There are several sporting disciplines (e.g. trap, skeet and sporting shooting) where clay targets are launched at various height, angle and speed.

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). No specific measures are described to limit the risks from exposure to CTPHT during shooting of the targets. 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 (ECHA, 2020).

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. 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 are in place which are not appropriate and effective in limiting the risk for humans via environment and the environment (ECHA, 2020). In this Background Document, the Dossier Submitter considers that a fraction of the larger fragments of clay targets may be collected and disposed of following initial release, but notes that the fraction

of clay targets that is collected is unknown⁵⁵. 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).

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.

A.3. Uses advised against by the registrants

There are no uses advised against in the registrations of the substances which would be impacted under the proposed restriction, not for the alternatives.



⁵⁵ The only available estimate in the applications for authorisation for CTPHT is from an interview with the manager from one shooting club in Copenhagen who estimated that about 75-85 % by weight of the clay targets are re-collected as fragments. RAC considered this is purely anecdotal information in its opinion on the applications for authorisation (ECHA 2020).

Annex B: Information on hazard and risk

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

The search for substances used in clay targets has been conducted based on:

- A search⁵⁶ of information in registration database for substances registered to produce clay targets or with service life of the substance in clay targets returned only CTPHT (EC No. 266-028-2) and petroleum pitch (EC No. 269-110-6).
- information from applications for authorisation for the use of CTPHT in clay targets
- exchanges with ISSF
- exchanges with registrants of petroleum pitch (EC No. 269-110-6)
- for alternative substances, patent search (search performed on http://worldwide.espacenet.com, with keyword "clay target*", accessed 21/06/2021)
- for alternative substances, starting from the identified rosins, expansion of the search to other rosins with registered uses as binder/binding agents.

Refer to the confidential annex for the full description of the identified binder substances and their PAHs content.

B.2. Exposure assessment and emissions characterisation

B.2.1. Summary of the existing legal requirements

Austria, certain areas in Belgium, and the Netherlands have already restricted the use of CTPHT based clay targets.

In Austria, there is a national ban^{57} on the manufacture, placing on the market and use of clays targets containing a mass fraction PAHs of more than > 10 mg/kg (based on the dry matter). The following PAHs are covered by the national ban:

- Acenaphthene (CAS No. 83-32-9)
- Acenaphthylene (CAS No. 208-96-8)
- Anthracene (CAS No. 120-12-7)
- Benz[a]anthracene (CAS No. 56-55-3)
- Benzo[*a*]pyrene (CAS No. 50-32-8)
- Benzo[b]fluoranthene (CAS No. 205-99-2)
- Benzo[ghi]perylene (CAS No. 191-24-2
- Benzo[k]fluorathene (CAS No. 207-08-9)
- Chrysene (CAS No. 218-01-9)
- Dibenz[a,h]anthracene (CAS No. 53-70-3)
- Fluoranthene (CAS No. 206-44-0)
- Fluorene (CAS No. 86-73-7)

⁵⁶ A search was performed with Text Analytics on registration database on 22/03/2021 and 15/09/2021, in IUCLID field "3 Manufacture, use and exposure." Using the key words "clay target" OR "clay pigeon" OR "clay pigeons" OR "clay pigeons"

⁵⁷ Verordnung des Bundesministers für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft über weitere Verbote und Beschränkungen bestimmter gefährlicher Stoffe, Zubereitungen und Fertigwaren (Chemikalien-Verbotsverordnung 2003 – Chem-VerbotsV 2003).

- Indeno[1,2,3-*cd*]pyrene (CAS No. 193-39-5)
- Naphthalene (CAS No. 91-20-3)
- Phenanthrene (CAS No. 85-01-8)
- Pyrene (CAS No. 129-00-0).

In Belgium (Flemish region), it is prohibited⁵⁸ to use or have clay targets containing environmentally hazardous substances in concentrations exceeding 10 mg/kg for the sum of anthracene, benzo[a]anthracene, benzo[k]fluoranthene, benzo[a]pyrene, chrysene, phenanthrene, fluoranthene, indeno[1,2,3-cd]pyrene, naphthalene and benzo[ghi]perylene.

The Dossier Submitter has assessed that if a limit of 10 mg/kg was considered instead of the one proposed in the current restriction, then also the alternative [Resin 2] would be indirectly restricted.

In the Netherlands, a restriction was in place until 2017⁵⁹. According to the restriction it was forbidden to use or possess clay pigeons with concentrations of PAHs above 10 mg/kg dry matter⁶⁰. In 2017, the decree that restricted PAHs in clay pigeons was repealed⁶¹ and integrated into the broader environmental legislation "Activiteitenregeling milieubeheer". The ban has been replaced with a requirement to implement mitigating measures. When clay pigeons are present at a shooting range with concentrations exceeding 10 mg PAHs/kg dry matter, the shooting range needs to implement soil protection and nets or screens along the area where soil protection is applied. It is also required to periodically collect the remains. (Article 3.116 of Activiteitenregeling milieubeheer⁶²).

PAHs are also listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants (POPs). 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). For the purpose of emission inventories, the following four compound indicators shall be used: benzo(a)pyrene, benzo(b) fluoranthene, benzo(k)fluoranthene and indeno(1,2,3-cd)pyrene. Monitoring is not mandatory because they are in part B of Annex III (article 10). PAHs are not listed in Annex IV (substances subject to waste management provisions set out in Article 7). PAHs are not listed in the Stockholm Convention. Inventories for the releases of PAHs can be found in the European Industrial Emissions Portal⁶³ and are covering releases to air and water in the sector of energy, metals, minerals, chemicals, waste and waste water, paper and wood, food and beverage, other sectors. Information on emissions is not available at the granularity level of specific articles such as clay targets.

⁵⁸ Besluit van de Vlaamse regering van 1 juni 1995 houdende algemene en sectorale bepalingen inzake milieuhygiëne, Subafdeling 5.32.7bis.2. Kleischieten, Artikel 5.32.7bis.2.1. Algemene bepalingen.

⁵⁹ https://wetten.overheid.nl/BWBR0017601/2008-06-01

 $^{^{60}}$ PAHs as the sum of naphthalene, phenanthrene, anthracene, fluoranthene, chrysene , benzo(a)anthracene , benzo(a)pyrene, benzo(k)fluoranthene, ideno(1,2,3-cd)pyrene, benzo(ghi)perylene

⁶¹ https://zoek.officielebekendmakingen.nl/stcrt-2016-65496.html

^{62 &}lt;u>https://wetten.overheid.nl/BWBR0022830/2021-08-01</u>

⁶³ https://industry.eea.europa.eu/.

B.2.2. Manufacturing of clay targets

B.2.2.1. Occupational exposure

As occupational exposure is not a main driver for the restriction proposal the exposure and risk characterisation for workers during the manufacturing of clay targets is discussed only qualitatively.

Because RAC and SEAC were not supportive to grant authorisations for use of CTPHT in clay targets, this restriction proposal is based on the assumption that authorisations won't be granted and therefore CTPHT would not be allowed to be used as a binder in clay targets in the EU. However, as the processes to produce clay targets is regarded as generally the same regardless of the exact nature of the binder used, the Dossier Submitter considers that the exposure assessment is also relevant for the other PAH-containing binders subject to the proposed restriction. It qualitatively shows at which levels workers may be exposed to the PAHs contained in the binders used for clay target production.

A strong relationship between occupational exposure and the PAH-concentration in the binder may be assumed in this respect, however, the relationship may not simply be a proportionate one (as occupational exposure is determined by other aspects as well such as the number of production lines and the OCs and RMMs in place). 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[def]chrysene as a marker. Inhalation exposure has been modelled with ART 1.5 using the predicted 90th percentile full-shift exposure. In the application of DEZA for CTPHT, the exposure estimates (8h-TWA) per worker at sites using solid or liquid CTPHT is 30.93 and 1.4 ng BaP/m³, respectively (8h-TWA, adjusted for frequency of tasks and personal protective equipment). In the application of Bilbaina for CTPHT, five worker types were distinguished with exposure estimates ranging from 0.188 to 14.78 ng BaP/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[def]chrysene 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.

B.2.2.2. Environmental release

The applications for authorisation of CTPHT in clay targets (ECHA, 2020) considered that the only release to the environment from clay target production is by emission to the air. Further, RAC considered that there may be (indirect) release to waste water and soil (e.g. via working clothes washing, rainwater run-off, etc) but RAC expects this release to be lower than the release to air.

Three releases points were identified by the applicant:

- Release from holding tanks and mixer units (passive ventilation); the other binders subjected to the proposed restriction.
- Forced ventilation from the moulding machines;

- Release via the general room ventilation at the production sites.

There is no treatment of the air releases. The evaporation rate is estimated for the 12 indicators PAHs of CTPHT, based on the vapour pressure, the air speed and the surface area of the liquid phase. In addition, releases from mixer units are estimated from the concentration of solid particles (which PAHs adhere to) in air and the mixing ratio of limestone and binder. Releases to air from the manufacturing of clay targets with CTPHT are estimated to be respectively 3.92 and 3.99 kg/year of 12 PAHs in Bilbaina and Deza applications. Since the sum of the 12 indicator PAHs represents only about 7% of the mass of CTPHT, RAC considered that the environmental releases from the manufacture of clay targets is underestimated in the applications for authorisation for CTPHT.

For the purpose of this report, the Dossier Submitter observes that even if the releases during manufacture of clay targets are underestimated, it is orders of magnitude lower than the releases during the service life of the clay targets, which are used as the basis for the impact assessment. This consideration for CTPHT is also valid for the other binders subjected to the proposed restriction.

B.2.3. End-use of clay targets (article service life)

B.2.3.1. Consumer exposure

In the applications for authorisation (ECHA, 2020), the applicants assumed no dermal exposure for consumers, and estimated exposure in air for benzo[def]chrysene of 0.17 ng/m³ (back-calculated from concentration in one soil sample). RAC considered the exposure estimate of 0.17 ng BaP/m³ for the handling and shooting of clay targets highly uncertain, especially due to the methodology 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.

As exposure of consumers from handling and shooting of clay targets is not a main driver for the restriction proposal and considering the challenges to reliably estimate this exposure, the exposure of consumers from handling and shooting of clay targets is considered qualitatively as supporting evidence to justify the need for a restriction and for the impact assessment.

B.2.3.2. Environmental release

See section 0.

B.3. Risk characterisation

As stated in section 1.2.7, occupational exposure is not the main driver for the restriction proposal the exposure 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.

Some qualitative discussion is provided here in addition.

For workers involved in the production of clay targets, RAC concluded that the operational conditions and risk management measures were not appropriate and effective in limiting the risk for workers⁶⁴.

Although the baseline assumption is that CTPHT would not be allowed to be used as a binder in clay targets in the EU, the processes to produce clay targets is regarded as generally the same regardless of the exact nature of the binder used, and thus the Dossier Submitter considers that the risk characterisation is also relevant for the other PAH-containing binders subject to the proposed restriction. It qualitatively shows the cancer risk levels for workers in the clay target production. Risk from dermal exposure could not usefully be illustrated with quantitative data.

A strong relationship between occupational exposure and the PAH-concentration in the binder may be assumed in this respect, however, the relationship may not simply be a proportionate one (as occupational exposure is determined by other aspects as well such as the number of production lines and the OCs and RMMs in place). It can be assumed that the worker risks will generally be lower when using other binders than CTPHT.

Bilbaina -Inhalation route

The exposure values calculated as 8h-TWA are multiplied by the excess cancer risk and the resulting lifetime excess risks are listed in Table 40.

Table 40. Combined exposure and risk characterisation for production workers

Worker type	Exposure	Lifetime excess risk		
	ng BaP/m³	Lung cancer	Bladder cancer	
1a Outdoor unloading of both solid and liquid CTPHT and transfer of solid pitch into the holding tank	14.78	8.2 × 10 ⁻⁵	5.91 × 10 ⁻⁵	
1b Indoor unloading and transfer of solid CTPHT pellets into the holding tank	30.97	1.7 × 10 ⁻⁴	1.24 × 10 ⁻⁴	
2a Operators of the moulding machines and work within the near field of the hot mixture	0.49	2.7 × 10 ⁻⁶	1.98 × 10 ⁻⁶	
2b Operators involved in stacking and packaging of the finished product	0.19	1.05 × 10 ⁻⁶	7.5 × 10 ⁻⁷	
2c Operators performing all tasks related to the production line	0.37	2.08 × 10 ⁻⁶	1.49 × 10 ⁻⁶	

DEZA Inhalation route

The exposure values calculated as 8h-TWA are multiplied by the excess cancer risk and the resulting lifetime excess risks are listed in Table 41.

⁶⁴ The reason for the conclusion was that the applicants had not demonstrated that the hierarchy of control is respected for the transfer stations for solids as they do not prevent worker exposure, and the efficiency of the general ventilation could not be demonstrated.

Table 41. Combined exposure and risk characterisation for production workers

Worker group* and type of handled CTPHT	Lifetime excess risk				
	Lung cancer	Bladder cancer			
Group 1 and 3 -Solid CTPHT	1.73 × 10 ⁻⁴	1.24 × 10 ⁻⁴			
Group 2 -Liquid CTPHT	8.12 × 10 ⁻⁶	5.8 × 10 ⁻⁶			

^{*}The grouping refers to the different production sites covered by the application.



Annex E: Impact Assessment

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

Only information additional to the information presented in section 2.2.2 is given below. In this table, the names that are not associated to an EC number correspond to the names "as reported" in the registration dossiers submitted to ECHA.



Table 42. Substances of the "rosins" group registered with uses as binder/binding agents

EC number	CAS number	Name	Total tonnage ⁶⁵	Classification ⁶⁶	PBT assessment ⁶⁷
232-304- 6	8002-26- 4	Tall oil	Registered 100 000-1 000 000 tpa	In registrations: not classified Additional notifications: Skin Sens. 1, Skin Corr. 1C, Eye Dam. 1, Eye Irrit. 2, Muta. 2, Repr. 1B H360 FD, STOT SE 1, STOT RE 1, Aquatic Acute 1, Aquatic Chronic 1, Aquatic Chronic 3	
232-414- 4	8016-81- 7	Tall-oil pitch	Registered 100 000-1 000 000 tpa	In registrations: not classified Additional notifications: not classified	
232-475- 7	8050-09- 7	Rosin	Registered 100 000-1 000 000 tpa	Harmonised classification: Skin Sens. 1 Additional notifications: Resp. Sens. 1, Acute tox 4 H312 H332, Skin Irrit. 2, Skin Mild Irrit. 3, Eye Irrit. 2, Eye Irrit. 2B, Aquatic Chronic 1, Aquatic Chronic 2, Flam. Sol. 2, Skin Sens. 1A	PBT assessment concluded by Finland ⁶⁸ Not PBT Not vPvB
232-476- 2	8050-15- 5	Resin acids and Rosin acids, hydrogenated, Me esters	Registered 100- 1000 tpa	In registrations: Aquatic Chronic 3 Additional notifications: Skin Sens. 1, Aquatic Chronic 4	
232-478- 3	8050-25- 7	Resin acids and Rosin acids, esters with triethylene glycol	Registered 1000- 10 000 tpa	In registrations: not classified Additional notifications: Aquatic Chronic 3	
232-479- 9	8050-26- 8	Resin acids and Rosin acids, esters with pentaerythritol	Registered 10 000- 100 000 tpa	In registrations: not classified Additional notifications: Eye Irrit. 2, Skin Sens. 1	

⁶⁵ Registrations accessed 21/06/2021

⁶⁶ C&L inventory accessed 03/2021

⁶⁷ PACT accessed 26/08/2021.

⁶⁸ Conclusion available at: https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff94d.

EC number	CAS number	Name	Total tonnage ⁶⁵	Classification ⁶⁶	PBT assessment ⁶⁷
232-480- 4	8050-28- 0	Rosin, maleated	Registered 1000- 10 000 tpa	In registrations: Skin Sens. 1, Eye Dam. 1, Aquatic Chronic 2 Additional notifications: Skin Irrit. 2, Skin Mild Irrit. 3, Skin Sens. 1B, Eye Irrit. 2, Eye Irrit. 2B, Aquatic Chronic 3, Flam. Sol. 2, Acute Tox. 4 H332	PBT assessment concluded by Finland ⁶⁹ Not PBT Not vPvB
232-482- 5	8050-31- 5	Resin acids and Rosin acids, esters with glycerol	Registered 10 000- 100 000 tpa	In registrations: not classified Additional notifications: Eye Irrit. 2, Acute Tox. 4 H302 H312 H332	
232-694- 8	9007-13-	Resin acids and Rosin acids, calcium salts	Registered 10 000- 100 000 tpa	In registrations: not classified Additional notifications: Flam. Sol. 2, Flam. Sol. 1, Skin Irrit. 2, Skin Mild Irrit. 3, Eye Irrit. 2, Eye Irrit. 2B, Skin Sens. 1, Acute Tox. 4 H332	
263-142- 4	61790- 50-9	Resin acids and Rosin acids, potassium salts			
263-144- 5	61790- 51-0	Resin acids and Rosin acids, sodium salts Registered 10 000- 100 000 tpa In registrations: Eye Irrit. 2 Additional notifications: Skin Sens. 1, Residue Sens. 1, Skin Irrit. 2		Additional notifications: Skin Sens. 1, Resp.	PBT assessment concluded by Finland ⁷⁰ . Not PBT Not vPvB
264-848- 5	64365- 17-9	Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol	Registered 100- 1000 tpa	In registrations: not classified	Substance evaluation ongoing (data requested) by Finland ⁷¹ No conclusion on PBT/vPvB concern yet
266-037- 1	65997- 01-5	Tall oil, sodium salt	Registered 100 000-1 000 000 tpa	In registrations: Skin Corr. 1B, Skin Sens. 1B, Skin Irrit. 2, Eye Dam. 1 Additional notifications: Skin Corr. 1A, Skin Sens. 1, Eye Irrit. 2	

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 $^{^{69} \} Conclusion \ available \ at: \ \underline{https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ffa41}.$

⁷⁰ Conclusion available at: https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff8fb.

⁷¹ Related documents available at: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e981e.

EC number	CAS number	Name	Total tonnage ⁶⁵	Classification ⁶⁶	PBT assessment ⁶⁷
266-040- 8	65997- 04-8	Rosin, fumarated	Registered 10 000- 100 000 tpa	In registrations: Skin Sens. 1, Eye Dam. 1, Aquatic Chronic 4 Additional notifications: Skin Sens. 1B, Aquatic Chronic 3	
266-041- 3	65997- 06-0	Rosin, hydrogenated	Registered 1000- 10000 tpa	In registrations: not classified Additional notifications: Eye Irrit. 2, Eye Irrit. 2B, Aquatic Chronic 2, Flam. Sol. 2, Skin Mild Irrit. 3, Skin Sens. 1, Acute Tox. 4 H332	PBT assessment concluded by Finland ⁷² . Not PBT Not vPvB
266-042- 9	65997- 13-9	Resin acids and Rosin acids, hydrogenated, esters with glycerol	Registered 1000- 10000 tpa	In registrations: not classified Additional notifications: Aquatic Chronic 4	Substance evaluation concluded by Finland ⁷³ No conclusion on PBT/vPvB concern yet
268-884- 2	68153- 38-8	Resin acids and Rosin acids, esters with diethylene glycol	Registered 100- 1000 tpa	In registrations: not classified Additional notifications: Aquatic Chronic 4	
269-035- 9	68186- 14-1	Resin acids and Rosin acids, Me esters	Registered 10-100 tpa	In registrations: Aquatic Chronic 3	
269-825- 3	68334- 35-0	Resin acids and Rosin acids, calcium zinc salts	Registered 100 to 1000 tpa	In registrations: not classified	
270-461- 2	68440- 56-2	Resin acids and Rosin acids, magnesium salts	Registered 1000- 10000 tpa	In registrations: not classified	
271-996- 4	68648- 53-3	Resin acids and Rosin acids, hydrogenated, esters with triethylene glycol	Registered 10-100 tpa	In registrations: not classified	
273-574- 5	68990- 02-3	Resin acids and Rosin acids, hydrogenated, sodium salts	Registered 10 to 100 tpa	In registrations: Eye Irrit. 2	

⁷² Conclusion available at: https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809ff9a4.

⁷³ Conclusion available at: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9747.

EC number	CAS number	Name	Total tonnage ⁶⁵	Classification ⁶⁶	PBT assessment ⁶⁷
284-009- 7	84776- 83-0	Resin acids and Rosin acids, esters with trimethylolpropane	Registered 100 to 1000 tpa	In registrations: not classified	
293-631- 8	91081- 28-6	Resin acids and Rosin acids, reaction products with formaldehyde, sodium salts	Registered 100 to 1000 tpa	In registrations: Eye Irrit. 2	
293-659- 0	91081- 53-7	Rosin, reaction products with formaldehyde	Registered 1000- 10000 tpa	In registrations: not classified	
295-855- 1	92129- 53-8	Resin acids and Rosin acids, reaction products with formaldehyde, potassium salt	Registered 100- 1000 tpa	In registrations: Eye Irrit. 2	
296-047- 1	92202- 14-7	Rosin, fumarated, reaction products with glycerol and pentaerythritol	Registered 1000- 10000 tpa	In registrations: Skin Sens. 1, Eye Irrit. 2, Aquatic Chronic 4	
305-514- 1	94581- 15-4	Resin acids and Rosin acids, fumarated, esters with pentaerythritol	Registered 10 000- 100 000 tpa	In registrations: Skin Sens. 1, Eye Irrit. 2, Aquatic Chronic 4 Additional notifications: Skin Sens. 1B	
305-515- 7	94581- 16-5	Resin acids and Rosin acids, maleated, esters with glycerol	Registered 100- 1000 tpa	In registrations: Skin Sens. 1, Eye Irrit. 2, Aquatic Chronic 4 Additional notifications: Skin Sens. 1B	
305-516- 2	94581- 17-6	Resin acids and Rosin acids, maleated, esters with pentaerythritol	Registered 1000- 10000 tpa	In registrations: Skin Sens. 1, Eye Irrit. 2, Aquatic Chronic 4 Additional notifications: Skin Sens. 1B	
307-051- 0	97489- 11-7	Resin acids and Rosin acids, fumarated, esters with glycerol	Registered 1000- 10000 tpa	In registrations: Skin Sens. 1, Eye Irrit. 2, Aquatic Chronic 4 Additional notifications: Skin Sens. 1B	
500-163- 2	65997- 05-9	Rosin, oligomers	Registered 1000- 10000 tpa	In registrations: not classified Additional notifications: Skin Sens. 1, Resp. Sens. 1, Skin Irrit. 2, Skin Mild Irrit. 3, Eye Irrit. 2, Eye Irrit. 2B, STOT SE 3, Flam. Sol. 2, Acute Tox. 4 H332	

EC number	CAS number	Name	Total tonnage ⁶⁵	Classification ⁶⁶	PBT assessment ⁶⁷
500-451- 8	160901- 14-4	Fatty acids, tall-oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts	Registered 100- 1000 tpa	In registrations: Skin Sens. 1, Eye Dam. 1	
		Resin acids and Rosin acids, polymd., esters with pentaerythritol	Registered 100- 1000 tpa	In registrations: not classified	
	Resin acids and Rosin acids, polymd., esters with glycerol Registered 100-1000 tpa In registrations: not classified		In registrations: not classified		
	2156595- 41-2	Hydrogenated rosin alcohols (abitol)	Registered 10-100 tpa	In registrations: Skin Sens. 1, Aquatic Chronic 4	Substance evaluation for the concerns: suspected PBT/vPvB, exposure of environment, high RCR, wide dispersive use has been withdrawn on 22/03/2022 ⁷⁴
	68425- 02-5	Hydrogenated rosin, zinc salt	Registered 1-10 tpa	In registrations: not classified Additional notifications: Skin Sens. 1, Acute Tox. 4 H332	
	-	Reaction mass of Rosin, hydrogenated and [1 <i>R</i> -(1 <i>a</i> ,4 <i>aβ</i> ,10 <i>aa</i>)]-1,2,3,4,4 <i>a</i> ,9,10,10 <i>a</i> -octahydro-7-isopropyl-1,4 <i>a</i> -dimethylphenanthren-1-carboxylic acid	Registered 1000- 10000 tpa	In registrations: not classified	
	-	Calcium zinc salts of oligomers of rosin	Registered 10 to 100 tpa	In registrations: not classified	

⁷⁴. Documents available at: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180b9176d.

Patents were searched to identify additional alternatives. No precise identification of substances (except substance CAS No. 68131-77-1) is available.

Table 43. Patents⁷⁵

Publication number	Publication date	Alternative substances and/or technologies
Alternative substances (combination of bi	nders and fillers)
CN112028590 (A)	2020-12-04	60-65 parts (by weight) of clay, 15-20 parts of stone powder, 8-10 parts of pregelatinized starch, 0.5-1 part of sodium carboxymethyl starch, 0.3-0.6 part of aerosil (pyrogenic silica), 1-3 parts of talcum powder, 0.4-0.6 part of magnesium stearate and a wetting amount of water
CN111960802 (A)	2020-11-20	60-70wt% of Jingdezhen Zisha raw ores, 10-15wt% of potassium feldspar, 15-20wt% of kaolin, 3-5wt% of gypsum and 1-5wt% of barium carbonate
CN106867265 (A)	2017-06-20	10-20 parts resin acid (rosin), 38-60 parts heavy calcium carbonate, 8-15 parts low-molecular-weight polypropylene and 5-8 parts binder (CAS No. 68131-77-1)
CN104649612 (A)	2015-05-27	8-14 % of resin acid (rosin), 1-2 % of polypropylene wax and 85-90 % of calcite powder
CN103497502 (A)	2014-01-08	20-23 parts of BPS (brominated polystyrene), 1-5 parts of magnesium hypophosphite, 11-25 parts of talcum powder, 2-6 parts of PA (polyamide), 3-9 parts of PB (polybutadiene), 1-8 parts of maleic anhydride, 2-9 parts of triphenyl phosphate, 3-8 parts of calcium stearate, 1-5 parts of polyether glycol, 25 parts of toluene diisocyanate, 2-5 parts of chlorobenzoate, 2-3 parts of silica white, 2 parts of kaolin, 2 parts of pigment, 3 parts of thickener and 9 parts of dispersant
CN103497416 (A)	2014-01-08	34-46 parts of BPS (brominated polystyrene), 18-24 parts of magnesium hypophosphite, 2-9 parts of maleic anhydride, 3-4 parts of zinc borate, 2-6 parts of polyvinyl ester, 1-8 parts of tin isooctyl dimethyl dimercaptoacetate, 31-46 parts of resin matrix PPH and PPB, 2-6 parts of defoaming agent, 1.5-3.5 parts of preservative, 3-8 parts of stearic acid, 3-4 parts of zinc borate and 1-2 parts of modified ethylene double fatty acid amide
CN103497409 (A)	2014-01-08	15-25 parts of BPS (brominated polystyrene), 5-20 parts of magnesium hypophosphite, 11-25 parts of talcum powder, 2-6 parts of PA (polyamide), 3-9 parts of PB (polybutadiene), 1-8 parts of maleic anhydride, 2-9 parts of triphenyl phosphate, 3-8 parts of calcium stearate, 2-7 parts of stearic acid, 10-16 parts of paraffin oil, 14-16 parts of calcium carbonate, 10-14 parts of polypropylene, 2-5 parts of nano calcium sulfate, 10-30 parts of linear low-density polyethylene, 5-9 parts of white oil and 1-8 parts of nucleating agent
CN103497393 (A)	2014-01-08	34-46 parts of BPS (brominated polystyrene), 18-24 parts of magnesium hypophosphite, 9-13 parts of talcum powder, 1-4 parts of modifier, 11-18 parts of PE (polyethylene), 5-14 parts of PVC (polyvinyl chloride), 2-6 parts of stibium-base nano composite environment-friendly flame retardant, 4-8 parts of poly-4-methyl-1-pentylene, 1-3 parts of active calcium, 3-8 parts of stearic acid, 3-4 parts of zinc borate and 1-2 parts of modified ethylene double fatty acid amide
CN103351544 (A)	2013-10-16	34 to 46 parts of BPS, 18 to 24 parts of magnesium hypophosphite, 9 to 13 parts of powdered steatite, 7 to 13 parts of polypropylene ester, 3 to 8 parts of high-density polyethylene, 2 to 6 parts of powdered steatile, 2 to 9 parts of liquid paraffin, 1 to 9 parts of antistatic agent, 5 to 10 parts of plasticized starch, 5 to 8 parts of halogen-free expanding fire retardant, 1 to 6 parts of crystallization II ammonium polyphosphate, and 3 to 8 parts of smoke suppressor
CN102452812 (A)	2012-05-16	8-14 percent by weight of a resin acid (rosin), 1-2 percent by weight of polypropylene wax and 85-90 percent by weight of calcite powder
CN101654353 (A)	2010-02-24	18 to 45 portions of gypsum powder, 25 to 65 portions of mountain flour or metal mineral powder and 12 to 40 portions of water;

⁷⁵ http://worldwide.espacenet.com, with key word "clay target*", accessed 21/06/2021

Publication number	Publication date	Alternative substances and/or technologies
JP2009174749 (A)	2009-08-06	75-89 % inorganic filler, 5-10 % polystyrene, 2-4 % aliphatic aromatic hydrocarbon resin, 2-5 % amorphous olefin resin, 2-7 % stabilizer/lubricant
CN101493303 (A)	2009-07-29	press forming of mineral mixed powder (variety of raw materials like kaolin, white clay, red clay, feldspar powder, light calcium carbonate, mud, horse trace mud, purple sand mud, talcum powder, quartz, etc.) that is processed by soft burning
CN101413771 (A); CN101413771 (B)	2009-04-22	80-85 parts of skeletal stone dust material, 8-10 parts of binder (several binder suggested, like mixture of modified starch and PVA polyvinyl alcohol, or modified starch and sodium alginate), 2-3 parts of dispersant, 2-5 parts of stabilizer, 1-3 parts of demoulding powder
KR20070106343 (A)	2007-11-01	48-98wt% of a pozzolana-based inorganic material with 15-60wt% of lime(Ca(OH)2), 0.5-5wt% boric acid or potassium hydroxide
WO2007104319 (A1)	2007-09-20	only clay, low-temperature firing so that silicate compounds are formed in the clay, cold pressing and low temperature firing
CN1403503 (A)	2003-03-19	IVGP-20, resin acid and polypropylene and heavy CaCO3
ES2180389 (A1); ES2180389 (B1)	2003-02-01	only clay; with adequate firing and without reaching the vitrification of the clay, resistance to casting is achieved with traditional machines
ES2180388 (A1); ES2180388 (B1)	2003-02-01	only clay; with adequate firing and without reaching the vitrification of the clay, resistance to casting is achieved with traditional machines
<u>US6394457 (B2)</u>	2002-05-28	binder: sulfur, various resins, waxes, glycosides, sugars, ureas and thermoplastic materials. Sulfur is preferably included as about 30-45 %, more preferably about 40-42 % of a mix using calcium (carbonate as a filter, for example. If a filler such as fly ash powder is used, sulfur is preferably included as 30-40 %, more preferably about 34-36 % of the mix).
<u>US5947475 (A)</u>	1999-09-07	binder: sulfur, various resins, waxes, glycosides, sugars, ureas and thermoplastic materials. Sulfur is preferably included as about 30-45 %, more preferably about 40-42 % of a mix using calcium (carbonate as a filter, for example. If a filler such as fly ash powder is used, sulfur is preferably included as 30-40 %, more preferably about 34-36 % of the mix).
US5389142 (A)	1995-02-14	uniformly blending together clay, water and binder wherein the binder consists of about 1-2 percent of sodium silicate and about 0-1 percent of dextrin, by weight of the mixture, the total concentration of binder not exceeding about 2 percent,
US5316313 (A)	1994-05-31	uniformly blending together clay, water and binder wherein the binder consists of about 1-2 percent of sodium silicate and about 0-1 percent of dextrin, by weight of the mixture, the total concentration of binder not exceeding about 2 percent,
<u>JPS5248300 (A);</u> <u>JPS568960 (B2)</u>	1977-04-16	100 parts of resin (60 to 98 wt% of a low molecular weight thermoplastic resin and 2 to 40 wt% of a high molecular weight thermoplastic resin), 100 to 900 parts by weight of an inorganic powder filler and, if necessary, a small amount of processing aid, pigment, and antioxidant
Alternative technologies		
CN209131513 (U)	2019-07-19	reusable plastic flying saucer provided with a laser receiving sensor, with laser flying saucer gun
<u>US2015198420 (A1)</u>	2015-07-16	target system simulating moving real life targets for gun shooting training including in combination a laser transmitter device attached to an oscillator device
US2015097338 (A1)	2015-04-09	target game having a stationary display that provides the capabilities to mimic moving targets
US2014335478 (A1); US9267762 (B2)	2014-11-13	set of modified video images including a moving clay target image and a phantom clay target image adjacent the moving clay target image

E.7. Practicality, enforceability and monitorability

Enforcement of the restriction and monitoring of the results of the implementation of the restriction are performed by measuring the concentration of indicator PAHs in the clay targets. This involves:

- sampling of clay targets (eg buying articles available in the market);
- preparing samples (crushing of targets and extraction of PAHs from crushed targets);
- necessary availability of standard for calibration for each PAH;
- analytical methods.

The sampling of clay targets and preparation of samples is not believed to lead to any particular issue, as the matrix is rather simple (binder and filler composed of limestone) and homogeneous.

For the enforcement of the existing national restriction in a Member State (targeting 16 PAHs), the samples are prepared as follows: "the clays were crushed to 2 - 3 mm pieces; to 0,5 g of the grounded material a deuterated surrogate for internal standard for each PAH analysed was added and the mixture extracted with 10 ml of toluene for 1 hr at 60 °C. For analysis 1 ml was injected in a GC-MS equipment. The result is related to the dry mass which was determined after a national standard". Furthermore, "the detection limit for the sum of the 16 PAHs is within the range of 0.1 to 0.4 mg/kg (dry mass)".

Information on the extraction and analytical method used to verify compliance with the ISSF rule has been provided by ISSF (direct exchange with Dossier Submitter) and by a company in the third parties consultation (#3576). Companies rely on method of commercial laboratory (e.g. Bureau Veritas) with the following method: "AfPS GS 2019:01, ultrasound extraction with Toluene, determination with GC/MS, reporting limit: 0.2 mg/kg".

As the targeted 18 PAHs include the 16 EPA PAHs (which are routinely measured in the environment) and 2 additional PAHs already in the scope of entries 28 and 50 of Annex XVII, the Dossier Submitter considers that calibration standards and analytical methods are readily available (Wenzl et al., 2006; Wise et al., 2015; Andersson and Achten, 2015; Lund and Liu, 2015). Existing analytical methods have been described extensively in the Background Document supporting the restriction on PAHs in granules or mulches used as infill material (update of entry 50)⁷⁶ and is not discussed again in this report. The Forum Compendium of Analytical Methods recommended by the Forum to check compliance of REACH Annex XVII restrictions⁷⁷ provides information on available methods for solid matrices.

In conclusion, as the method AfPS-GS-2014:01 PAK (targeting the same 18 PAHs than this restriction proposal) or its updated version AfPS-GS-2019:01 PAK (targeting 15 PAHs⁷⁸) have

 $\frac{\text{https://echa.europa.eu/documents/10162/17088/compendium of analytical methods en+\%281\%29}{.pdf/4c730fb9-1b48-2e14-6ee3-7a36391b7322?t=1626370365832}$

⁷⁶ https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181d5746d

⁷⁷ June 2021, 2nd edition, accessible at

⁷⁸ Acenaphthene, acenaphthylene and fluorene have been removed compared to the AfPS-GS-2014:01 PAK.

been or are used in the Member State to enforce their national restriction and by companies to verify compliance with the ISSF rule, the Dossier Submitter believes that a harmonised method based on these can be developed for the enforcement and monitoring of the proposed restriction by the time it enters into force.

In its advice, the Forum concludes that the restriction proposed will be enforceable provided that a specific state-of-the art analytical method is developed defining the necessary harmonised testing approach before the entry into force of the restriction.

RAC box

PAHs targeted under entry 50 of Annex XVII, national restriction and existing analytical methods for PAHs in various matrices are reported in the table below.

		Annex XVII entry 50 in rubber and plastic	Austrian restriction in clay pigeons	German method in rubber, plastics, cosmetics etc (AfPs 2014:01 PAK)	German method in rubber, plastics, cosmetics etc (AfPs 2019:01 PAK)	Forum's compendium of analytical methods in solid matrices
	Acenaphthylene		×	×		
	Acenaphthene		×	×		
Ē	Fluorene		×	×		
nit	Anthracene		×	×	×	
Igns	Phenanthrene		×	×	×	
ie	Fluoranthene		×	×	×	
ssoc	Pyrene		×	×	×	
he [Benzo[a]anthracene	×	×	×	×	×
by t	Chrysene	×	×	×	×	×
pes	Benzo[a]pyrene	×	×	×	×	×
öda	Benzo[b]fluoranthene	×	×	×	×	×
s pr	Benzo[e]pyrene	×		×	×	×
Indicator PAHs proposed by the Dossier Submitter	Benzo[j]fluoranthene	×		×	×	×
tor	Benzo[k]fluoranthene	×	×	×	×	×
dica	Benzo[ghi]perylene		×	×	×	×
뒫	Indeno[1,2,3cd]pyrene		×	×	×	×
	Dibenzo[a,h]anthracene	×	×	×	×	×
	Naphtalene		×	×	×	
	Dibenzo(a,e)pyrene					×
ë s	Dibenzo(a,h)pyrene					×
New classifie d PAHs as Carc.1B	Dibenzo[a,i]pyrene					×
d da d	Dibenzo[a,l]pyrene					×

SEAC box

The following note is intended to provide transparency in the SEAC rapporteurs' evaluation of Forum's comments.

Note phone call at 2022-04-08 with Bundesanstalt für Materialforschung und -prüfung (BAM) in Berlin (DE) section 1.7 "Organic Trace and Food Analysis"

Participants:

Klaus URBAN SEAC Rapporteur Michael BÜCKER SEAC Advisor Matthias KOCH BAM-1.7

Background/motivation:

ECHA's Forum for Exchange of Information on Enforcement (Forum) submitted an opinion on ECHA's Annex XV dossier. In Forums' view no ISO or CEN methods for these 18 PAHs have been suggested. Forum is promoting a German method, AfPs 2014:01 PAK, that has often been used to analyze these 18 PAHs in compliance with the requirements of the Product Safety Act for the award of the GS mark. Since 10 April 2020 AfPs 2014:01 PAK is reworked and published as AfPs 2019:01 PAK only contains 15 of the PAHs proposed in this restriction. At that time, BAM-1.7 has participated in the method validation interlaboratory test within the framework of the BVL⁷⁹ working group "Consumer Goods". This BVL method is in principle identical to AfPs. The SEAC rapporteurs found it appropriate to consult the experience in BAM-1.7 in front of the evaluation of Forum proposal.

Phone call note:

Rapporteur:

AfPs 2014:01 PAK resp. AfPs 2019:01 PAK is intended to be used for plastics and rubber according REACH Annex XVII Entry 50 and not for this type of matrix in clay targets. Could the method also be used for chemical analysis of PAHs in clay targets?

BAM-1.7:

The method incl. CRM originally developed for REACH Annex XVII entry 50 could possibly also be applied to the matrix PAH-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.

Rapporteur:

In the AfPs 2019:01 PAH guideline, the sum of the PAHs from individual contents are more of 0.2 mg/kg. For the analysis of PAHs in clay targets (planned sum value limit 0.005 mg/kg) a validation of the method seems appropriate.

BAM-1.7:

It must be ensured that the limit of quantification of each individual PAH component can

⁷⁹ The Federal Office of Consumer Protection and Food Safety (BVL) fulfils many tasks in the area of food safety in Germany.

actually be achieved with the test method. An effective method could be, 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 extract could also be concentrated. Another possibility would be a so-called "large volume injection" in the GC-MS measurement.

Rapporteur:

For the case Forum/RAC see a need for a specific CRM based on ground clay targets, what effort must be expected?

BAM-1.7:

From the experience with AfPs 2014:01 PAK/AfPs 2019:01 PAK we estimate the cost to be about € 100,000-200,000 for CRM/method development. This is the experience from the production of the CRM for REACH Annex XVII entry 50 (here BAM-B001⁸⁰). 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/milled 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

Rapporteurs:

Are there any general remarks from the point of view of practitioners in organic chemical analysis?

BAM-1.7:

A comparison of the AfPs 2014:01 PAH and AfPs 2019:01 PAH methods shows only differences in the list of PAHs. While AfPs 2014:01 PAK still contains 18 PAHs, the version AfPs 2019:01 PAK has only 15 PAHs listed as analytes. The reduction from 18 to 15 is due to the omission of acenaphthene CAS No 83-32-9, acenaphthylene CAS No 208-96-8 and fluorene CAS No 86-73-7.

The methods are well established and used since 2014. In practice, 500 mg of sample material is weighed in and 20 ml of toluene is added. For internal calibration, at least three different PAH deuterium standards are added to the toluene before. These are PAH with exchanged hydrogen atoms (hydrogen-1) against hydrogen isotope deuterium (hydrogen-2). The sample material is extracted with toluene for one hour at 60°C in an ultrasonic bath. After cooling down to room temperature, an aliquot (subsample) is taken from the extract. In the case of polymers (entry 50 e. g. plastic or rubber products), matrix problems may occur during the analysis. In this case, a column chromatographic purification step would also have to be carried out before the gas chromatographic analysis.

Quantification is carried out on the gas chromatograph with mass-specific detector (GC-MSD) using the SIM method (SIM: single/selected ion monitoring). During SIM, the mass

⁸⁰ 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.

spectrometric detector only "looks" at specific, selected masses, namely precisely at the molecular masses typical for the respective PAHs. This form of measurement is much more sensitive than the MS scan over a large mass range. A normal single quadrupole mass spectrometer is used for SIM-mode measurements.



Annex G: Stakeholder information

Two applications for authorisation were submitted for the use of CTPHT as a binder in clay targets. Applications were submitted by substance manufacturers, who sell the substance for the clay target manufacturers to be used as a binder. The information provided by the substance manufacturers and their downstream users in the applications, the information from the public consultation, and the information to the questions raised by the SEAC and RAC Committees were used to prepare this dossier. To complement the information from the applications, Dossier Submitter contacted:

- Other European manufacturers of clay targets (out of which 1 agreed to an interview)
- Organisations representing the clay target shooters (including the International Sport Shooting Federation (ISSF)) and the Finnish Sport Shooting Association (FSSA)
- Other manufacturers of substances (both manufacturers of those substances that are under the scope of the restriction proposal and those of alternative substances)

The aim was to gather information regarding different binder materials that can be used as a binder in clay targets, on their technical characteristics from the point of view of both the manufacturers of clay targets and the shooters and market information regarding the quantities and prices of different type of clay targets.

A total of six rounds of e-mail exchanges was done with the ISSF, who provided most of the information regarding different types of clay targets in the market, the quantities produced and used in EU, price information regarding different types of clay targets, information about the technical characteristics of different types of clay targets, and about the clay target specific rules that are applied in the competitions under the ISSF.

A shooting club was visited in Finland, with the environmental manager of the Finnish Sport Shooting Association. The visit was to gather information on the experience of shooters with different types of clay targets and to find out how the clay target fragments are handled once they land on the shooting ground.

One of the contacted EU manufacturers of clay targets agreed to an interview. The manufacturer asked about the types of clay targets that they manufacture. Manufacturer confirmed that the so-called eco-friendly clay targets perform equally compared to the traditional clay targets in terms of the technical characteristics. They also confirmed the price information that was received from the ISSF. They raised the issue of the availability of some of the alternative substances.

Registrants of Pitch, petroleum, arom. (EC No. 269-110-6) have been contacted by email between April 2021 and July 2021 to clarify the identity and composition of the registered substances and identify alternatives to this substance in clay targets.