

Annex XV report

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: Pyrene

EC Number: 204-927-3

CAS Number: 129-00-0

Submitted by: FR-MSCA

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FOREWORD

Pyrene belongs to the substance group of Polycyclic Aromatic Hydrocarbons (PAHs) of which many are well-known to be hazardous for human health and the environment. Pyrene does not possess a harmonised classification according to the CLP Regulation (EC 1272/2008).

Until now, several Annex XV dossiers for the identification of substances of very high concern (SVHC) were explicitly based on the properties of PAHs as constituents of concern in the identified substances, such as Anthracene, Anthracene Oils, Coal Tar Pitch High Temperature (CTPHT), Benzo[a]pyrene, Benz[a]anthracene and Chrysene.

Pyrene is a constituent of coal-tar pitch, high temperature (CTPHT). In the Support Document of CTPHT, it has been concluded by the Member State Committee (MSC) that pyrene fulfills the PBT and vPvB criteria of Annex XIII to REACH Regulation (ECHA, 2009). However, pyrene and further PAHs whose properties have already been agreed on by the MSC in the CTPHT SVHC identification process have not yet been proposed for formal SVHC identification and inclusion in the Candidate List.

Pyrene was assessed with respect to PBT/vPvB properties based on the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009). For the purpose of the present SVHC proposal for pyrene, a supplementary literature search was made. The search identified only few studies not included in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008). Thus, the assessment of the PBT/vPvB properties in the present dossier and the conclusion that pyrene fulfils the criteria in Article 57 (d) and (e) was based mainly on the information in the Support Document on CTPHT (ECHA, 2009) and supplemented with information from newer studies that are presented as further evidence as they do not trigger a need to modify the conclusions taken by authorities earlier on.

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: Pyrene

EC Number: 204-927-3

CAS number: 129-00-0

- It is proposed to identify the substance as persistent, bioaccumulative and toxic (PBT) according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).
- It is proposed to identify the substance as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

The assessment of the PBT/vPvB properties in the present dossier and the conclusion that pyrene fulfils the criteria in Article 57 (d) and (e) were based mainly on the information in the MSC Support Document on CTPHT (ECHA, 2009) and supplemented with information from newer studies. This information was considered together in a weight-of-evidence approach.

Persistence

The available experimental information shows that pyrene degrades very slowly in soils exhibiting half-lives between 127 to 320 days, higher than 180 days (vP criteria according REACH Annex XIII). The soil experimental study conducted under field conditions and the predicted half-life support the low degradation in soils.

Thus, pyrene fulfils the criteria for P and vP of REACH Annex XIII.

Bioaccumulation

BCF values higher than 5 000 (vB criteria according REACH Annex XIII) have been measured in four studies with molluscs (6 430 to 77 000 L/kg), two studies with crustacean (12 300 to 166 000 L/kg) and one study with an oligochaete species (6 688 L/kg).

Thus, pyrene fulfils the B and vB criteria of REACH Annex XIII.

Toxicity

Based on the available information from long-term studies with aquatic organisms, the lowest EC₁₀ value was reported for the mollusc *Crassostrea gigas* exposed to UV radiation. The resulting EC₁₀ of 0.5 µg/L shows that pyrene fulfils the T criteria (NOEC or EC₁₀ for marine or freshwater organisms is less than 0.01 mg/L) of REACH Annex XIII.

Overall conclusion

In conclusion, pyrene meets the criteria for a PBT and vPvB substance according to Article 57 (d) and (e) of REACH by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

Registration dossiers submitted for the substance? Yes

PART I

Justification

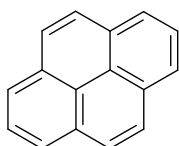
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	204-927-3
EC name:	Pyrene
CAS number (in the EC inventory):	129-00-0
CAS number: Deleted CAS numbers:	-
CAS name:	-
IUPAC name:	Pyrene
Index number in Annex VI of the CLP Regulation	No harmonised classification
Molecular formula:	C ₁₆ H ₁₀
Molecular weight range:	202.2506 g.mol ⁻¹
Synonyms:	pyren benzo[d,e,f]phenanthrene, beta-pyrene, benzophenantrene

Structural formula:



1.2 Composition of the substance

Name: Pyrene

Description: Pyrene belongs to the group of Polycyclic Aromatic Hydrocarbons (PAHs). Pyrene is not produced intentionally but does occur as a constituent in UVCBs¹ – often together with other PAHs - mainly derived from the coal and petroleum stream. The dossier addresses the substance pyrene as a substance itself.

Substance type: mono-constituent

1.3 Physicochemical properties

Table 2: Overview of physicochemical properties

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20°C and 101.3 kPa		Solid	Yaws, 2015
Melting/freezing point		145.3°C	ECHA dissemination site
Boiling point		360°C	ECHA, 2009
Vapour pressure		1.0 · 10 ⁻³ Pa at 25°C	ECHA, 2009
Density		1.209 Kg.L ⁻¹ at 20°C	ECHA dissemination site
Water solubility		0.134 mg.l ⁻¹ at 25°C	ECHA dissemination site
Partition coefficient n-octanol/water (Log value)		5.17 at 25°C	ECHA, 2009
		5.43 at 30°C	ECHA dissemination site
Flash point	According to CSN EN ISO 2592/2002	224.0°C at 101.325 kPa	ECHA dissemination site
Viscosity	According to OECD Test Guideline 114 (Viscosity of Liquids)	1.8 mm ² .s ⁻¹ at 150 °C	ECHA dissemination site
Henry's constant		1.4 Pa m ³ /mol at 25 °C	ECHA, 2009

2. Harmonised classification and labelling

No harmonised classification for pyrene.

¹ Substances of Unknown or Variable composition, Complex reaction products or Biological materials

3. Environmental fate properties

3.1 Degradation

The data provided on the degradation of pyrene in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) are not assessed or discussed again in this dossier but included in order to have access to the full dataset for assessment (flagged by *italic print*). Additional information is available in the EU risk assessment report on CTPHT (EC, 2008) and the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008).

3.1.1 Abiotic degradation

3.1.1.1 Hydrolysis

The stability to hydrolysis of PAHs has been already assessed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

Considering that pyrene does not present functional groups that result in hydrolysis, the substance is expected to be *hydrolytically stable in aquatic systems*. The Support Document furthermore states as a result that *hydrolysis does not contribute to the degradation of PAHs under environmental conditions*.

3.1.1.2 Oxidation

The oxidation of PAHs was summarised and discussed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) as follows:

In the atmosphere, the PAHs are either gas phase or particle-associated. It has been shown that the 2-4 ring PAHs with vapour pressure higher than or equal to 10^{-4} Pa are mostly gas phase-related and PAHs of 4 rings or more with vapour pressure below 10^{-4} Pa are particle-associated. In the gas phase PAHs are oxidised by atmospheric hydroxyl (OH) and nitrate radicals and ozone, whereas the particle-associated PAHs are expected to be degraded by direct photolysis and by reaction with ozone (The Netherlands, 2008).

In the atmosphere, pyrene can be partitioned in the gas phase and also adsorbed to the particle phase. In the gas phase, pyrene can undergo oxidation in the presence of OH radicals exhibiting low lifetimes between a few hours to less than one day (The Netherlands, 2008). Pyrene can be also adsorbed to the particle phase. Indeed, up to 61.4% of atmospheric pyrene has been observed to appear in particle phase (The Netherlands, 2008).

3.1.1.3 Phototransformation/photolysis

3.1.1.3.1 Phototransformation in air

The photolysis of PAHs in the atmosphere was already assessed in the EU risk assessment report (EC, 2008) and also discussed in the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008). The Support Document for identification of CTPHT as SVHC (ECHA, 2009) summarises the previous assessments as follows:

Photolysis in the troposphere results in the formation of reactive hydroxyl (OH) and nitrate (NO_3) radicals and ozone (O_3), which reacts as oxidizing agent with organic compounds, like PAHs. These radical and ozone reactions comprise mainly degradation of gas-phase PAHs (Calvert et al., 2002). Particle-associated PAHs are expected to degrade in air predominantly via direct photolysis by light with a wavelength < 290 nm (Kamens et al.,

1988), although reaction with ozone will also occur (Peters and Seifert, 1980; Grosjean et al., 1983; Pitts et al., 1986; Coutant et al., 1988).

As stated earlier, assuming that pyrene can also be associated to the particle phase in the atmosphere, it is expected that it degrades in air predominantly via direct photolysis, although reaction with ozone will also occur (the Netherlands, 2008). Furthermore, it is also mentioned from the study of Behymer and Hites, 1988, cited in the Netherlands, 2008, that degradation rate of PAHs, is related to the type of particle to which they are adsorbed. The Annex XV transitional dossier (The Netherlands, 2008) showed representative lifetimes of some surface-adsorbed PAHs with respect to photolysis. For pyrene, representative lifetimes between 3.7 hours and 4.8 days are found under representative conditions of a cloudless sky.

3.1.1.3.2 Phototransformation in water

Following the conclusions regarding PAHs in the Support Document for identification of CTPHT as SVHC (ECHA, 2008), an aquatic phototransformation of pyrene in the first few centimeters layer of the water column is expected. Therefore, aquatic photodegradation is not considered to have a significant impact on the overall persistency of pyrene in the environment.

3.1.1.3.3 Phototransformation in soil

Following the conclusion regarding phototransformation of PAHs in the Support Document for identification of CTPHT as SVHC (ECHA, 2008), a significant phototransformation of pyrene in soils is not expected, due to the limited exposition to light. Thus, photodegradation is not considered a relevant degradation process in soils.

3.1.1.4 Summary on abiotic degradation

In the atmosphere, degradation of pyrene by oxidation is expected when it is in the gas phase, as well as by direct photolysis when it is adsorbed to the particle phase. Furthermore, depending on the type of particles that the substance is bound to, the degradation of the substance by photolysis can vary between a few hours to days. In water, the substance is expected to be hydrolytically stable as the substance does not present functional groups that result in hydrolysis. Photodegradation of pyrene in water is not expected to be a relevant removal pathway because it only occurs in the first few centimeters layer of the water column. This degradation process is also not relevant in soils due to the limited exposure to light.

This conclusion was already drawn in the support document for identification of CTPHT as SVHC (ECHA, 2009).

3.1.2 Biodegradation

3.1.2.1 Biodegradation in water and sediments

The biodegradation in water was already assessed in the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008) and summarised in the Support Document for identification of CTPHT as SVHC (ECHA, 2009), thus this section will not be assessed again within this dossier.

Experimental information for biodegradation in water has demonstrated that PAH substances with up to four aromatic rings are biodegradable under aerobic conditions, but that biodegradation rates of PAHs with more than four aromatic rings, are very low (The Netherlands, 2008).

In general, the biodegradation rates decrease with increasing number of aromatic rings. This correlation has been attributed to factors like the bacterial uptake rate and the bioavailability. The bacterial uptake rate has been shown to be lower for the higher molecular weight PAHs as compared to the PAHs of lower molecular weight. This may be due to the size of high molecular weight members, which limits their ability to cross cellular membranes. In addition, bioavailability is lower for higher molecular PAHs due to adsorption to organic matter in water and sediment. It has further been shown that half-lives of PAHs in estuarine sediment are proportionally related to the octanol-water partition coefficient (Kow) (Durant et al. (1995) cited in The Netherlands, 2008).

Regarding biodegradation in sediments, although there is evidence for anaerobic transformation of PAHs, they are usually considered to be persistent under anaerobic conditions (The Netherlands, 2008). Thus a very low biodegradation of pyrene in sediments is expected (ECHA, 2009).

Mackay et al. (1992) estimated half-lives in the different environmental compartments based on model calculations and literature research. The calculated half-lives of pyrene in water were in the range of 42 to 125 days, and were estimated to be longer than 1250 days for the sediment compartment (ECHA, 2009).

3.1.2.2 Biodegradation in soil

The biodegradation in soil was already assessed in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) as follows:

Biodegradation rates of PAHs in soil depend on several factors related to the soil type, including pH, moisture content, nutrients, oxygen, and the diversity of the soil microbial population. Various species (bacteria, fungi, yeasts and algae) are known to degrade PAHs in soil (The Netherlands, 2008). It has been shown that the number of PAH-degrading microorganisms and the degradation capacity is higher in PAH-contaminated soils than in pristine soils, something explained by the development of an adapted soil microbial community. Several studies have also been demonstrated enhanced PAH degradation rates when the soil had been enriched with isolated PAH-degrading microorganisms ([...] The Netherlands, 2008). On the basis of a comparison between two studies (Wild et al. 1991 and Wild and Jones, 1993) it was illustrated that the half-lives observed under laboratory conditions can be much shorter than those obtained from long-term field studies. This was attributed by the authors to the more optimal conditions (temperature, moisture content, nutrient and oxygen supply) applied in the laboratory tests.

The results of Wild et al. (1991) and Wild and Jones (1993) demonstrate the difference of tests conducted for several PAHs in field conditions compared to laboratory tests. In the case of pyrene, the study of Wild et al. (1991) measured a half-life of 8.5 years in a field experiment with soils enriched with PAH-contaminated sludge, whereas the study of Wild and Jones (1993) derived half-lives for pyrene of 127-320 days in their microcosm study with three soil types (sandy loams, forest soil, and roadside soil) conducted at a range of temperature between 20 and 30°C.

Mackay et al. (1992) in their calculations predicted half-life values of PAHs for the soil compartment. For pyrene, the calculated half-life was in the range of 420-1250 days.

Furthermore the Support Document for identification of CTPHT as SVHC (ECHA, 2009) discusses "aging" for PAHs as follows:

"Aging" is a phenomenon associated with increased residence time of PAHs in soil, which can further decrease the bioavailability of PAHs in the terrestrial environment. Freshly

spiked PAHs are more readily desorbed and thus more bioavailable than PAHs that have been in soil or sediment for a longer period of time (The Netherlands, 2008). This means that studies involving artificially added PAHs (e.g. ¹⁴C-labelled) often result in biodegradation rates much higher than rates observed for the same substances present in soil as part of a contamination by coal tar."

3.1.2.4 Summary and discussion on biodegradation

Regarding the aquatic compartment, Mackay *et al.* (1992) predicted long half-lives in the range of 42 to 125 days. However, it was observed, that PAHs containing up to four aromatic rings are biodegradable under aerobic conditions. Considering that pyrene has four rings in its structure, the substance may biodegrade under aerobic conditions. In the sediment compartment, PAHs are usually considered to be persistent under anaerobic conditions, thus a low biodegradation of pyrene is expected in sediments. The half-life predicted by Mackay *et al.* (1992) indicates that the substance is persistent in sediments (half-life > 1250 days).

Regarding the soil compartment, experimental data on microcosm and under field conditions are available from the studies of Wild and Jones (1993) and Wild *et al.* (1991). The results show dissipation half-life values for pyrene in the range of 127 to 320 days under microcosm conditions and a half-life of 8.5 years in the field experiment. These results confirm that the biodegradation of pyrene in soils is very low. Furthermore, Mackay *et al.* (1992) predicted half-life for pyrene on the soil compartment in the range of 420-1250 days.

It is concluded that pyrene degrades very slowly in soil. This very low degradation rate of pyrene is also expected for sediment compartments under anaerobic conditions. These conclusions were already drawn in the support document for identification of CTPHT as SVHC (ECHA, 2009).

3.1.4 Summary and discussion of degradation

In the atmosphere, pyrene can be partitioned in the gas phase and also adsorbed in the particle phase. Degradation in the gas phase by oxidation in the presence of OH radicals takes place between a few hours to less than one day. However, pyrene may be more stable in the particulate phase than in the gas phase. Pyrene degradation by photolysis (in the particulate phase) can vary between a few hours to less than 5 days.

In the water and soil compartments, photolysis is only relevant in the upper few centimeters of the water column and the upper few millimeters of the soil. Thus, photodegradation is not considered as a relevant degradation process in water and terrestrial environments.

In general, PAHs are considered as chemically stable substances, with no functional groups that result in hydrolysis in the water and soil compartments. Therefore, pyrene is considered as hydrolytically stable.

The biodegradation rates of PAHs in the environmental compartments are governed by several factors and particularly by their low water solubility and their tendency to adsorb to particles and organic matter. Their low bioavailability, especially for the PAHs of more than two rings is one of the limiting factors for their biodegradation.

Estimated half-lives for pyrene in the aquatic compartment is 42 - 125 days. However, considering that pyrene has four aromatic rings in its structure, the substance may biodegrade under aerobic conditions. In the sediment compartment, a low biodegradation

of pyrene is expected. The half-life predicted by Mackay *et al.* (1992) for the sediment compartment are longer than 1250 days.

The available experimental data show that pyrene exhibits a low biodegradation in the soil compartment. The study conducted under microcosm conditions by Wild and Jones (1993) reported half-life values of 127 to 320 days, and the experimental study on field conditions, (Wild *et al.*, 1991) support the very low degradation of pyrene in soils demonstrated a half-life of 8.5 years.

3.2 Environmental distribution

3.2.1 Adsorption/desorption

In the Support Document for identification of CTPHT as SVHC (ECHA, 2009) the adsorption properties of PAHs are described as follows: *“A linear relationship between K_{ow} and the organic carbon-water partitioning coefficient K_{oc} has been demonstrated for PAHs in sediments and soil. The Log K_{ow} values from 4.6 to 6.6 can be translated as a high potential for partitioning to soils and sediments. Partitioning processes like adsorption to airborne particulate matter, as well as accumulation in sludge during wastewater treatment, have been demonstrated especially for high molecular weight PAHs (The Netherlands, 2008).”*

Based on the Log K_{ow} of 4.98 for pyrene, reported in the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008), the coefficient of partitioning between organic carbon and water, Log K_{oc} , has been estimated at 4.77 (The Netherlands, 2008) and it is concluded that pyrene has a high potential to adsorb to particles in the environment.

In the registration dossier (ECHA, 2009) a range of 4.1-5.9 is reported for Log K_{oc} , but no details are provided in the methodology.

3.2.2 Volatilisation

Pyrene exhibits a vapour pressure of 1.0×10^{-3} Pa at 25°C and a Henry's law constant of 1.4 Pa m³/mol at 25°C (Mackay *et al.*, 2006, cited by The Netherlands, 2008). Thus, some volatilisation is expected from water or soil surfaces.

3.2.3 Distribution modelling

Mackay Level III fugacity modelling was done using EPI Suite (version 4.11) with default values of environmental emission rates (equal and continuous release to water, soil and air). Calculation revealed a distribution of pyrene mainly to the soil compartment followed by the sediment and water phase. The air compartment is not expected to be a relevant route of distribution.

Table 3: Fugacity Model Calculation (EPI Suite, version 4.11) of Pyrene.

Distribution to:	Mass amount (percent)
Air	0
Water	7.64
Soil	61.8
Sediment	30.5

3.2.4 Summary and discussion of environmental distribution

Pyrene exhibits a high potential to adsorb to organic matter and some volatilisation from water surfaces. Furthermore, according to fugacity modelling, pyrene is expected to be mainly distributed in the soil compartment followed by the sediment and water compartments. The air compartment is not expected to be a relevant route of distribution.

3.3 Bioaccumulation

3.3.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

Several studies on bioaccumulation in aquatic organisms have been assessed in the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008) and reliable selected studies were summarised in the Support Document for identification of CTPHT as SVHC (ECHA, 2009). Furthermore, the RIVM (Bleeker and Verbruggen, 2009) also evaluated available data on bioaccumulation of PAHs in aquatic organisms, including pyrene, and examined their reliability. The studies reported in both reports were not assessed again within this dossier. In addition, a review of literature was carried out in June 2018 and additional data are presented in this dossier.

The support document for identification of CTPHT as SVHC (ECHA, 2009) summarised the results of studies conducted with fish for pyrene as follows:

Jonsson et al., 2004 exposed the fish Cyprinodon variegatus for 36 days to pyrene in continuous flow system with seawater, followed by 8 days of depuration. The BCF values calculated by kinetic approach were 97 and 147 for the low (7.57 µg/L) and the high concentrations (72.31 µg/L) tested.

The study of De Voogt *et al.*, 1991 reported BCF values from two experiments conducted with *Poecilia reticulata*. In the first study, fish were exposed to pyrene during 48 hours on static conditions. The authors calculated a BCF of $4\,810 \pm 2\,860$ L/kg using the Barnejee method. In the RAR, a reliability of 3 was attributed for this study (EC 2008). Furthermore, the RAR of CTPHT (EC, 2008) determined a mass balance for pyrene from the results of the static experiments and derived another BCF of 2 700 L/kg and they attributed a reliability of 2 for this study. For comparison the authors conducted a 7 days semi- static study and a BCF value of 11 300 L/kg was calculated. The BCF was determined by dividing the final concentration in fish by the average concentration in water during the last renewal period. For this experiment a reliability of 2 (valid with restrictions) was attributed (EC, 2008).

Nevertheless, the results of the experiments conducted by De Voogt *et al.*, 1991 were re-assessed in depth by RIVM (Bleeker and Verbruggen, 2009), and were considered as inconclusive (reliability 4).

RIVM (Bleeker and Verbruggen, 2009) calculated by kinetic approach a BCF of 1 474 L/kg (after lipid normalisation of 5%) for *Fathead minnows* from the results of the study of Carlson *et al.*, 1979 and attributed to the study a validity of 2. In the study, fish were exposed to a series of PAHs via flow through conditions for 28 days followed by 5 days of depuration.

Contrary to fish, the highest BCF values are reported specifically for molluscs. The support document for identification of CTPHT as SVHC (ECHA, 2009) summarised the studies as follows:

Bruner *et al.* (1994) exposed the zebra mussel *Dreissena polymorpha* in a static system to 3H-labelled benzo(a)pyrene and pyrene were. The BCF calculated using kinetic rate constants ranged from 13 000 to 35 000 L/kg for pyrene. Another study conducted also with *Dreissena polymorpha* is reported by Gossiaux *et al.*, 1996. In the study, organisms were exposed in a static system to radiolabelled benzo(a)pyrene in combination with pyrene. In total a number of 23 experiments with benzo(a)pyrene and 10 experiments with pyrene were conducted under either ambient field temperatures or laboratory temperatures. BCFs were calculated using kinetic rate constants and ranged from 37 000 to 43 000 for pyrene.

McLeese and Burridge (1987) determined PAH accumulation in the clam *Mya renaria*, the mussel *Mytilus edulis*, the shrimp *Crangon septemspinosa* and the polychaete worm *Nereis virens*. Groups of the invertebrates were exposed for 4 days in seawater containing a mixture of five PAHs (phenanthrene, fluoranthene, pyrene, triphenylene, and perylene) in continuous flow-systems. After 4 days, exposure was terminated, and the animals were maintained in flowing seawater at 10 °C for two weeks. Measured concentrations in water and animals were used to calculate k_u and k_e , which were subsequently used to calculate BCFs. For clam, mussel, shrimp and polychaete BCFs for pyrene were 6 430, 4 430, 225 and 700 L/kg respectively.

Richardson *et al.* (2005) exposed the green-lipped mussel (*Perna viridis*) to anthracene, fluoranthene, pyrene and benzo(a)pyrene in a renewal system for 20 days followed by a depuration period of 10 days. The BCF calculated by kinetic approach after lipid normalisation to 5% was 44 550 L/kg (Bleeker and Verbruggen, 2009).

In addition, the support document for identification of CTPHT as SVHC (ECHA, 2009) summarised also reliable studies conducted with crustacean organisms as follows:

Bioaccumulation in Daphnia magna was studied by Newsted and Giesy (1987), the study conducted in a static system allowed to calculate a BCF at steady state of 2702 L/kg. In a study by Southworth (1978) the potential for bioaccumulation in *Daphnia pulex* was studied for PAHs in a static system. The bioconcentration factor was determined at steady state conditions and as the ratio between the rates of uptake and elimination at non steady state conditions. The study indicated that the PAH content of *Daphnia* lipid was in equilibrium with the aqueous PAH concentration. The reported BCF was 2702 for pyrene.

Additional studies conducted with crustacean organisms have been assessed by RIVM (Bleeker and Verbruggen, 2009). The assessment included the study of Landrum *et al.*, 2003 with the amphipod *Diporeia* spp. In the study organisms were exposed to a range of concentrations of ¹⁴C PAHs during 28 days. The BCF values for pyrene by kinetic approach ranged from 12 300 to 36 333 L/kg for the concentrations tested (concentrations between 34 µg/L to 130.7 µg/L). A reliability of 2 was attributed for the study (Bleeker and Verbruggen, 2009). Landrum (1988), conducted experiments by flow-through systems with the amphipod *Pontoporeia hoyi* exposed to selected ¹⁴C radiolabelled PAHs during 6 hours followed by 14 days of depuration phase. The experiments allowed to calculate uptake and depuration rate constants for pyrene, resulting in a BCF of 166 000 L/kg (reliability of 1, Bleeker and Verbruggen, 2009). Another reliable BCF (reliability of 2) is reported with the estuarine copepod *Eurytemora affinis* from the study of Cailleau *et al.*, 2009. In the experiments, the organisms were exposed in a continuous flow-through system to dissolved PAH mixture for 86 hours. A low BCF by steady state for pyrene of 900 L/kg was determined.

RIVM (Bleeker and Verbruggen, 2009) also assessed studies conducted with insect, oligochaete and polychaeta species. In the study of Wild *et al.*, 1994, BCF values were determined for the larval midge *Chironomus riparius* for a range of pH tested. The BCF ranged between 713 to 1 227 L/kg. The study of Ankley *et al.*, 1997, calculated a BCF of 1 720 L/kg for *Lumbriculus variegatus* after 96h of exposition to pyrene. However, in the

experiments of Frank *et al.*, 1986 with the oligochaete *Stylodrilus heringianus* a high BCF of 6 688 L/kg was reported by kinetics approach. For these studies, a reliability of 2 was attributed (Bleeker and Verbruggen, 2009).

Additional studies on bioaccumulation of pyrene were identified in the recent literature search, especially on amphipods as follows:

Carrasco-Navarro *et al.*, 2015, showed the influence of temperature on the bioaccumulation, toxicokinetics, biotransformation and depuration of pyrene in the arctic marine amphipod *Gammarus setosus* at two temperatures, 2 and 8 °C. The experiments were conducted by water exposure of radiolabeled pyrene at concentrations of 1.96 ± 0.11 and 1.99 ± 0.15 mg/L for the 2 and 8°C treatments, respectively. The organisms were exposed to pyrene during 168 hours followed by 96 hours of depuration. The sampling times were 6, 24, 48, 96 and 168 h during the uptake phase and 6, 24, 48 and 96 h during the depuration phase. Analyses of the parent substance and total metabolites were conducted. Regarding the stability of the substance in water, the study mentions that the water concentrations decreased by 24 and 44% (average) after 6 and 24 h, respectively. The authors attributed the decrease to the uptake of pyrene by the organisms and to its sorption to the glass walls of the beakers. The average water concentration was used for the estimation of the toxicokinetics values. A two-compartment model was used to fix experimental values of total body burden, total metabolites and parent substance concentrations. The authors determined a BCF for the total body burdens of 13 913 L/kg (2 420 - 79 964) and 2 891 L/kg (1 540 - 5 425) for both temperature tested, respectively.

It is noted that no information is given in the paper about the physiological conditions of the organisms at the end of the experiments and whether they were fed during the experiments. It is noted also that the water concentrations were not reasonably constant over the entire exposure period. Furthermore, the BCF values reported in the paper should be treated also with caution because they were not calculated based on first order kinetics, one compartment as recommended by OCDE 305 and REACH guidelines.

Another study, Bustamante *et al.*, 2012, followed the kinetics of uptake and depuration of ^{14}C -pyrene in the organs and tissues (mantle, muscle, gills, digestive gland, and the remaining soft tissues) of *Crassostrea gigas* exposed via seawater. Oysters were exposed during 24 h to ^{14}C -pyrene then placed in depuration conditions for 15 days. Forty four oysters were placed in a 50 L glass aquarium containing natural seawater (closed circuit) spiked with ^{14}C -labelled pyrene. The initial pyrene concentration in the aquarium was $0.27 \mu\text{g L}^{-1}$ and every 30 min seawater radioactivity was measured and pyrene was added in order to keep its concentration constant during the whole uptake phase. Oysters were not fed during the exposure period and they were collected at 0, 2, 5, 9, 19 and 24 h during the uptake and at 0, 6, 18, 36, 96, 192 and 336 h during the depuration phase. It was possible to calculate uptake and depuration rates for every organ and tissues analysed. Considering whole body a BCF of $1\,560 \pm 630$ L/kg was reported.

It is noted that no information about the water concentrations during the time of exposition are reported in the paper. Furthermore, the authors indicated that the state of equilibrium was not reached during the time of exposition. Thus, considering these observations the BCF reported in the paper should be treated with caution.

3.3.2 Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

The European Union Risk Assessment Report on CTPHT (EC, 2008) estimated BCF values on earthworm for several PAHs according to the equilibrium partitioning approach (EP). For pyrene, it was estimated a BCF earthworm of 1 200 L/kg. This value represents a reasonable worst case (EC, 2008).

3.3.3 Field data

Bleeker and Verbruggen, 2009, reported a BAF for fish (*Acanthogobius flavimanus*) of 1 010 L/kg from the results of the study of Takeuchi *et al.* (2009).

Trophic magnification studies are available for pyrene in some food webs from different locations. In the study of Wan *et al.*, 2007, PAHs concentrations in phytoplankton, zooplankton, invertebrates, fishes, and one seabird species collected from Bohai Bay on the north of China were analysed. The TMF calculated for pyrene was 0.17. In another study, a TMF of 0.74 (0.66–0.82) was calculated from the analysis of PAHs on benthic and pelagic food chain from the Baltic Sea (Nfon *et al.*, 2008). The bioaccumulation and biomagnification of PAHs were investigated by Khairy *et al.*, 2014, from the analysis of 11 fish species and the blue crab, *Callinectes sapidus*, collected from the fresh-brackish portion of the Passaic River. The authors calculated a TMF of 0.24 for pyrene.

The study conducted by Wang *et al.*, 2012 reported estimated TMF values for PAHs, based on the analysis of several fishes with different feeding behaviors (herbivorous, omnivorous and carnivorous), collected on Taihu Lake in China. A TMF of 1.12 was calculated for pyrene, the authors suggested biomagnification of the chemical through a food chain.

It is mentioned in the chapter R.11 of the ECHA guidance on PBT or vPvB that the results from field studies should be considered as part of the overall evaluation of the bioaccumulation properties of a substance. However, currently there is no consensus about standard methodologies and guidelines for the interpretation of such results, generating uncertainties for the interpretation of those results. In particular, temporal and spatial variability or the inclusion/exclusion of a few or even a single species could affect the outcome of the TMFs. Thus, the data treatment could have a deep impact on the TMF values that were calculated. Ultimately, chapter R.11 of the ECHA guidance on PBT or vPvB indicates that the absence of a biomagnification potential cannot be used on its own to conclude that the B or vB criteria are not fulfilled.

3.3.4 Summary and discussion of bioaccumulation

The bioaccumulation potential of pyrene differs between organisms due to their capacity to metabolise (biotransform) PAHs. It is likely that pyrene is transformed in fish using enzymes belonging to the Cytochrome P450 enzymes (Cyt P450) and other mechanisms and subsequently excreted (Bleeker and Verbruggen, 2009), resulting in a low to moderate BCF. Regarding reliable data reported with fish, the BCF values range from 97 to 1 297 L/kg.

Contrary to fish, many invertebrate species have a lower metabolic capacity, resulting in highest BCF values. Indeed, very high BCFs are reported for some species of molluscs and range from 4 430 L/kg to 77 000 L/kg. Among crustaceans, the BCF vary considerably between the species ranging from 225 L/kg for *Crangon septemspinosa* to 166 000 L/kg for the amphipod *Pontoporeia hoyi*. In addition, a high BCF of 6 688 L/kg is reported with the oligochaete *Stylodrilus heringianus*.

4. Human health hazard assessment

The evaluation of the T criteria is based on the environmental toxicity of pyrene. Human health hazards were not assessed in this dossier.

5. Environmental hazard assessment

5.1 Aquatic compartment (including sediment)

Several environmental toxicity studies on aquatic organisms have been assessed in the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008) and summarised in the Support Document for identification of CTPHT as SVHC (ECHA, 2009). As the data presented in the following sections is mainly based on these documents, they will not be assessed and discussed again within this dossier. Additional relevant studies were retrieved in a bibliographic search up to June 2018 and have been included in the analysis hereafter.

The Support Document for the identification of CPHT as SVHC summarises the following on environmental hazard assessment for the aquatic compartment:

PAHs can be toxic via different modes of action, such as non-polar narcosis and phototoxicity. Phototoxicity is caused by the ability of PAHs to absorb UVA radiation, UVB radiation, and in some instances, visible light. It may occur as the result of the production of singlet oxygen, which is highly damaging to biological material, or as result of the formation of new, more toxic compounds from the photomodification (usually oxidation) of PAHs (Lampi et al., 2006). Phototoxic effects can be observed after a short period of exposure, which explains why for PAHs like anthracene, fluoranthene and pyrene, where phototoxicity is most evident, the acute toxicity values under simulated solar radiation may be lower than the chronic toxicity values determined under less harsh radiation.

The phototoxicity of PAHs is relevant where the PAHs are exposed to light and UV radiation, and considered to be most important for upper layers of aquatic and terrestrial environments. Although UV penetration depths may vary among PAH contaminated sites, it is not unlikely that significant portions of the aquatic community may be exposed to UV levels sufficient to induce phototoxicity, as UV levels occurring under normal sun light conditions have been shown to elicit these effects. There is growing evidence which suggests that phototoxic PAHs may be degrading aquatic habitats, particularly those in highly contaminated areas with shallow or clear water. Photo-induced chronic effects have been reported for anthracene at UV intensities occurring at depths of 10-12 m in Lake Michigan (Holst and Giesy, 1989). Phototoxicity of PAHs may also be initiated in aquatic organisms which have accumulated PAHs from the sediment and subsequently are exposed to sun light closer to the surface (The Netherlands, 2008).

Phototoxic effects of PAHs are therefore considered relevant in this hazard, respectively T-assessment.

5.1.1 Fish

5.1.1.1 Short-term toxicity to fish

No data are presented in the support document for identification of CTPHT as SVHC (ECHA, 2009).

Results from a short term study with fish are available in the literature. Oliveira *et al.*, 2012 conducted a standard bioassay (OECD 203) on juvenile fish of the specie *Pomatoschistus microps*. Organisms were exposed to 0.125, 0.25, 0.5 or 1 mg/L of pyrene during 96 hours. Mortality, swimming performance and several biomarkers were used as effect criteria. The study reported a LC₅₀ (96 h) for mortality of 0.871 mg/L. Furthermore, a significant decrease of swimming performance of fish was observed at all the concentrations tested. The study is considered as valid (reliability of 1).

5.1.1.2 Long-term toxicity to fish

No data are available on long term toxicity to fish.

5.1.2 Aquatic invertebrates

5.1.2.1 Short-term toxicity to aquatic invertebrates

Selected short term toxicity data with pyrene are summarised in the support document for identification of CTPHT as SVHC (ECHA, 2009). The selected studies are reported in the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008) as follow:

Regarding freshwater invertebrates, *the lowest value for Daphnia magna is reported in the study of Wernersson, 2003. In the experiments neonates were exposed for 24 h with 16:8 h of light: dark, then for 2 hours at an UV-intensity of $370 \pm 20 \mu\text{W}/\text{cm}^2$ (295-365 nm; peak 340 nm) and 1 hour of recovery in the test medium. The EC_{50} calculated for immobility was $1.38 \mu\text{g}/\text{L}$ for pyrene.*

Another study showed that when Daphnia magna neonates are exposed to UV-B radiation only (intensity $64 \mu\text{W}$) for four times two hours during 48 hours, the EC_{50} for immobility ranges from 2.7 to $20 \mu\text{g}/\text{L}$ at different hardness of the artificial test media and different concentrations of dissolved organic matter of natural waters (Nikkilä et al., 1999).

Also a low acute value is reported for the fresh water mollusc Utterbackia imbecillis, the LC_{50} (24h) was $2.63 \mu\text{g}/\text{L}$ when organisms are exposed to UV-A radiation (320-400 nm) at an intensity of $70 \mu\text{W}$ (Weinstein and Polk, 2001).

Acute data for marine species are also available and the lowest acute values are reported in the Annex XV transitional dossier (The Netherlands, 2008) as follows.

The lowest effect concentrations are similar to fresh water species in the presence of UV-radiation for embryos/larvae of molluscs and neonates/nauplii of crustaceans.

The study of Kagan et al., 1985, reported a LC_{50} for nauplii of Artemia salina of $8 \mu\text{g}/\text{l}$, when organisms are exposed for 2 hours in the dark followed by one hour with UV-radiation (320-400 nm; peak 350 nm) at an intensity of $1300 \mu\text{W}/\text{cm}^2$. When exposed for 2 hours in the dark followed by eight hours with UV-radiation (peak 312 nm) at an intensity of $975-1000 \mu\text{W}/\text{cm}^2$, the LC_{50} for nauplii of Artemia salina was estimated from the presented figure to be $36 \mu\text{g}/\text{L}$ (Peachey and Crosby, 1996). The same treatment with sunlight ($\lambda > 290 \text{ nm}$) at an intensity of $407-1429 \mu\text{W}/\text{cm}^2$ resulted in an EC_{50} of $3.4 \mu\text{g}/\text{l}$ (Peachy and Crosby, 1996). From these results it may be concluded that the maximum intensity of the radiation is more important than the time of irradiation.

The crustaceans Mysidopsis bahia was the most sensitive species, with a LC_{50} of $0.89 \mu\text{g}/\text{l}$ calculated in the experiment conducted by Pelletier et al., 1997. In the study, the organisms were exposed to concentrations of pyrene under ultraviolet light with an intensity of $397 \pm 35.1 \mu\text{W}/\text{cm}^2$ UV-A ($365 \pm 36 \text{ nm}$) and $134 \pm 22.8 \mu\text{W}/\text{cm}^2$ UV-B ($310 \pm 34 \text{ nm}$) with a photoperiod of 16:8 hour of light: dark.

Table 4: Overview of studies concerning the acute toxicity of pyrene to freshwater and marine invertebrates.

*Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009)

	Duration	Endpoint	Value	Comment	Reference
<i>Freshwater organisms, acute tests</i>					
<i>Daphnia magna</i>	27h	EC ₅₀ immobility	1.38 µg/L	Neonates 16:8 hours light: dark for 24 hours UV radiation for 2 hours and 1h recovery	Wernersson, 2003*
<i>Daphnia magna</i>	48 h	EC ₅₀ immobility	2.7 to 20 µg/L	Neonates UV-B radiation	Nikkilä <i>et al.</i> , 1999*
<i>Utterbackia imbecillis</i>	24h	LC ₅₀	2.63 µg/L	UV-A radiation	Weinstein and Polk 2001*
<i>Marine organisms, acute tests</i>					
<i>Artemia salinas</i>	3h	LC ₅₀	8 µg/L	2 hours in the dark UV radiation for one hour	Kagan <i>et al.</i> , 1985, 1987*
<i>Artemia salinas</i>	10 h	LC ₅₀	36 µg/L	2 hours in the dark followed by eight hours with UV radiation	Peachy and Crosby, 1996*
<i>Artemia salinas</i>	10 h	LC ₅₀	3.4 µg/L	2 hours in the dark followed	Peachy and Crosby, 1996*
<i>Mysidopsis bahia</i>	48 h	LC ₅₀	0.89 µg/L	16:8 hour light: dark UV- A B radiation	Pelletier <i>et al.</i> , 1997

5.1.2.2 Long-term toxicity to aquatic invertebrates

Chronic toxicity data are available for several aquatic invertebrates; the following studies were presented on the Support document for identification of CTPHT as SVHC (ECHA, 2009), as follows:

*Chronic toxicity data are reported for fresh water species with EC₁₀ values of 1.2 (algae, Bisson *et al.*, 2000) - 2.1 µg/L (Ceriodaphnia dubia, Bisson *et al.*, 2000) and for one marine oyster (Crassostrea) with a NOEC for shell development of 0.5 µg/l (Lyons *et al.*, 2002). As this latter NOEC value was the lowest one from a reliable study, it was chosen as the key study.*

Table 5: Overview of studies concerning the long term toxicity of pyrene to freshwater and marine invertebrates.

Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009)

Species	Duration	Endpoint	Value	Comment	Reference
<i>Freshwater organisms, long-term tests</i>					
Ceriodaphnia dubia	7 d	EC ₁₀ reproduction	2.1 µg/L	at less than 500 lux	Bisson <i>et al.</i> , 2000
<i>Marine organism, long-term tests</i>					
Crassostrea gigas	48 h	NOEC shell development	0.5 µg/L	Embryos/larvae 12:12 hour light: dark UV A B radiation	Lyons <i>et al.</i> , 2002

5.1.3 Algae and aquatic plants

For algae and aquatic plants, one study was considered in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

Bisson et al., 2000, reported an EC₁₀ value of 1.2 µg/L from a 72-h static study with Pseudokirchneriella subcapitata.

Table 6: Overview of the algae test with pyrene.

Source: Support Document for identification of CTPHT as SVHC (ECHA, 2009)

Species	Duration	Endpoint	Value	Comment	Reference
<i>Algae, long term test</i>					
Pseudokirchneriella subcapitata	72h	EC ₁₀ growth	1.2 µg/L	Light intensity 6000-8000 lux	Bisson <i>et al.</i> , 2000

5.1.4 Sediment organisms

Several toxicity studies of pyrene with living sediment organisms were assessed and reported in the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008). Furthermore, those studies were reassessed later by RIVM (Verbruggen, 2012), the results were reported as follows:

Toxicity studies with 2 freshwater oligochaetes are available. The lowest value for Limnodrilus hoffmeisteri is the EC₁₀ from a 28-d reproduction study (Lotufo and Fleeger, 1996). However, this value was extrapolated from concentrations showing more than 40% effect. Therefore, the EC₁₀ of 3.8 mg/kgdw (32 mg/kgdw, standard soil, recalculated to standard sediment with 10% organic matter) has a large uncertainty. Further, the reproduction falls rapidly with concentrations up to 210 mg/kgdw (1770 mg/kgdw,

standard soil), but remains almost constant from 210 to 841 mg/kg_{dw} (1770-7070 mg/kg_{dw}, standard soil). It is plausible that the bioavailability of pyrene in the sediment is limited at the higher concentrations by the solubility in the pore water of sediment. Possibly, pore water concentrations are already saturated around 400 mg/kg_{dw}, standard soil. If the 2 highest concentrations are omitted from the determination of EC₁₀, the resulting value of 26 mg/kg_{dw} (220 mg/kg_{dw}, standard soil) in standard sediment is much higher. Further, the reported EC₂₅ values determined by bootstrapping, are not in accordance with the log-logistic fit by which the EC₁₀ is derived. The EC₂₅ values reported by Lotufo and Fleeger (1996) for sediment egestion from a 10-d and a 5-d study and for reproduction from a 28-d study are 51.6, 58.9, and 59.1, respectively, for a sediment with 1.2% organic carbon. With the derived EC₅₀, which is rather certain because it is not an extrapolated value and the reported EC₂₅, EC_{10s} can be derived with a log-logistic model. For the endpoints mentioned above, these EC₁₀ values recalculated to sediment with 10% organic carbon are 222, 217, and 255 mg/kg_{dw}, respectively. These values probably are more realistic.

[...]

Some 10-d experiments with *Rhepoxynius abronius* were performed (Swartz et al., 1997). The LC_{10s} derived from the presented data are 45 and 154 mg/kg_{dw} standard sediment, the confidence limits of these values are rather small.

Table 7: Overview of the studies with sediments organisms

Species	Duration	Endpoint	Value	Comment	Reference
<i>Sediment organisms</i>					
<i>Limnodrilus hoffmeisteri</i>	10 d - 5 d	EC ₁₀ Sediment egestion	222-217 mg/kg _{dw}		Lotufo and Fleeger, 1996 Verbruggen, 2012
<i>Rhepoxynius abronius</i>	10 d	LC ₁₀ Mortality	45-154 mg/kg _{dw}	After 10 days, survivals were exposed to UV radiation for 1 h	Swartz et al., 1997

5.2 Terrestrial compartment

Several long term toxicity data are available regarding terrestrial organisms. The Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008) presents the results of the following studies.

The lowest value is the 28-day NOEC for reproduction of *Folsomia candida* reported by Bleeker et al., 2003. The NOEC recalculated to soil with an organic carbon content of 2% is 10 mg/kg_{dw}.

The EC₁₀/NOEC for reproduction *Folsomia fimetaria* and *F. candida* are very similar to this value, varying from 10 to 21 mg/kg_{dw} recalculated to a soil with 2% organic matter. Ageing of the compound for a period 120 days had little effect on the toxicity (Sverdrup et al., 2002c).

Experiments conducted with the annelid *Enchytraeus crypticus* shows from a 21-day reproduction study (Sverdrup et al. 2002b) a NOEC of 23 mg/kg_{dw} for standard soil (EC₁₀ of 14 mg/kg_{dw}). A similar 28-day reproduction study by Bleeker et al. (2002) results in a NOEC of 160 mg/kg_{dw} for standard soil. The NOEC for growth of *Eisenia veneta* from a 28-day study (Sverdrup et al., 2002d) was 37 mg/kg_{dw}, recalculated to 2% organic carbon (EC₁₀ of 48 mg/kg_{dw}). Droge et al. (2006) reported an EC₅₀ value of 52 mg/kg_{dw}.

Regarding terrestrial plants, the study conducted by Sverdrup et al., 2003, shows the fresh weight as the most sensitive endpoint in the experiments with *Sinapsis alba*, *Trifolium pratense* and *Lolium perenne*, with an exposure time of 19 to 21 days. From the reported EC₅₀ and EC₂₀ values, EC_{10s} can be derived with a log-logistic relationship. These EC₁₀ values for the three terrestrial plants are 34, 19, and 546 mg/kg_{dw} respectively for a soil with 2% organic carbon.

Finally, for nitrification, NOEC and EC₁₀ values of 99 and 160 mg/kg_{dw} (recalculated to a soil with 2% organic carbon) are reported from the study of Sverdrup et al., 2002a.

5.3 Summary and discussion of the environmental hazard assessment

Several short-term toxicity studies are available with freshwater and marine organisms. The lowest EC₅₀ values were those reported in *Daphnia magna* studies (1.38 µg/L and 2.7 µg/L) in presence of radiation. Concerning marine organisms, the lowest acute effect concentrations were reported for *Mysidopsis bahia* (0.89 µg/L) also in presence of UV radiation.

Regarding long-term toxicity, data are reported for two fresh water trophic levels (algae and crustacea) with EC₁₀ values of 1.2-2.1 µg/L and for one marine organism (mollusc) with a NOEC for shell development of 0.5 µg/L. This last study was chosen as key study for the assessment of T properties (ECHA, 2009).

6. Conclusions on the SVHC Properties

6.1 CMR assessment

No harmonised classification relevant for the PBT assessment is available for pyrene. The substance is identified in this report in accordance with Article 57(d) whereas for the toxicity only ecotoxicity is considered in the assessment. For Article 57(e) assessment of toxicity is not relevant.

6.2 PBT and vPvB assessment

An assessment of the PBT/vPvB properties of pyrene has been carried out by the MSC in the scope of the identification of CTPHT as SVHC. The PBT/vPvB assessment of this dossier is based on information provided in the support document for the identification of CTPHT as SVHC (ECHA, 2009).

Earlier assessments documented in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008) have been considered as additional information. Furthermore, additional relevant data retrieved from a literature search until June 2018 were incorporated as support information to the conclusion already established in the support document for the identification of CTPHT as SVHC (ECHA, 2009). They all confirm the information leading to the identification of pyrene as SVHC.

6.2.1 Assessment of PBT/vPvB properties

6.2.1.1 Persistence

Pyrene has a low water solubility and shows a high tendency to adsorb to particles and organic matter in the environment. The resulting low bioavailability is one of the limiting factors of its biodegradation.

Experimental data shows that pyrene exhibits a low biodegradation in the soil compartment. The study conducted under microcosm conditions by Wild and Jones (1993) reported half-life values of 127 to 320 days, and the experimental study in field conditions (Wild *et al.*, 1991) supports the very low degradation of pyrene in soils, the authors demonstrated a half-life of 8.5 years.

Furthermore, a very low degradation rate of pyrene is also expected for sediment compartments under anaerobic conditions.

Model calculations done by Mackay *et al.* (1992) support the high half-life values measured in the previous studies cited. In addition, the models predicted that P and vP criteria are fulfilled also for the compartments water and sediment.

Therefore, it is concluded that pyrene fulfils the P and vP criteria for soil according to REACH Annex XIII as the degradation half-life observed in soil exceed the cut value of 180 days. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009). The literature search done in June 2018 did not retrieve any new relevant data that would challenge this conclusion.

6.2.1.2 Bioaccumulation

Reliable experimental BCF values higher than 5 000 are reported for some species of molluscs (6 430 to 77 000 L/kg), crustacean (12 300 to 166 000 L/kg) and one species of oligochaete (6 688 L/kg).

Considering that the BCF values measured are above the B and vB criteria according to REACH Annex XIII, it is concluded that pyrene is a bioaccumulative and very bioaccumulative substance.

This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009). New data retrieved in the literature search done in June 2018 have been included in the current report and did not challenge the previous conclusion.

6.2.1.3 Toxicity

Regarding long-term results, the highest toxicity of pyrene for aquatic organisms observed has been in the mollusc *Crassostrea gigas* under UV radiation exposition and the EC₁₀ value reported for shell development was 0.5 µg/L (Lyons *et al.* 2002).

Furthermore, EC₁₀ values lower than 0.01 mg/L from long-term studies have been also reported for pyrene for the algae *Pseudokirchneriella subcapitata* (EC₁₀ growth inhibition of 1.2 µg/L) and for *Ceriodaphnia dubia* (EC₁₀ reproduction of 2.1 µg/L) (Bisson *et al.*, 2000).

Based on the available experimental aquatic long-term data, pyrene fulfils the T criteria according to REACH Annex XIII (NOEC/EC₁₀ for aquatic organisms less than 0.01 mg/L).

This conclusion was already drawn by the MSC in the context of the identification of CTPHT

as SVHC (ECHA, 2009). New data retrieved in the literature search done in June 2018 have been included in the current report and did not challenge the previous conclusion.

6.2.2 Summary and overall conclusions on the PBT and vPvB properties

The assessment of the PBT/vPvB properties in the present dossier and the conclusion that pyrene fulfils the criteria in Article 57 (d) and (e) were based mainly on the information in the MSC Support Document on CTPHT (ECHA, 2009) and supplemented with information from newer studies. This information was considered together in a weight-of-evidence approach.

Persistence

The available experimental information shows that pyrene degrades very slowly in soils exhibiting half-lives between 127 to 320 days, higher than 180 days (vP criteria according REACH Annex XIII). The soil experimental study conducted under field conditions and the predicted half-life support the low degradation in soils.

Thus, pyrene fulfils the criteria for P and vP of REACH Annex XIII.

Bioaccumulation

BCF values higher than 5 000 (vB criteria according REACH Annex XIII) have been measured in four studies with molluscs (6 430 to 77 000 L/kg), two studies with crustacean (12 300 to 166 000 L/kg) and one study with an oligochaete species (6 688 L/kg).

Thus, pyrene fulfils the B and vB criteria of REACH Annex XIII.

Toxicity

Based on the available information from long-term studies with aquatic organisms, the lowest EC₁₀ value was reported for the mollusc *Crassostrea gigas* exposed to UV radiation. The resulting EC₁₀ of 0.5 µg/L shows that pyrene fulfils the T criteria (NOEC or EC₁₀ for marine or freshwater organisms is less than 0.01 mg/L) of REACH Annex XIII.

Overall conclusion

In conclusion, pyrene meets the criteria for a PBT and vPvB substance according to Article 57 (d) and (e) of REACH by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

6.3 Assessment under Article 57(f)

This section is not relevant for the identification of the substance as SVHC in accordance with Article 57 points (d) and (e) of REACH.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 8: Registration status

From the ECHA dissemination site	
Registrations	<input type="checkbox"/> Full registration(s) (Art. 10) <input checked="" type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 9: CLP notifications

	CLP Notifications ²
Number of aggregated notifications	7
Total number of notifiers	128

8. Total tonnage of the substance

Table 10: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)	Intermediate Use Only (09/07/18)
Tonnage information from public sources other than registration dossiers (if available)	No data

Pyrene is registered as an intermediate under REACH. However, pyrene is generally not produced intentionally. In general, PAHs occur as constituents in substances from the coal and petroleum stream. Such substances are mostly well-defined Multi-Constituent Substances (MCSs) or Substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB substances).

² C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 09 July 2018). The following hazard classes are listed in the different notifications: Skin irritation, Eye irritation, Respiratory irritation, Acute toxicity and/or Aquatic Acute and Chronic toxicity.

9. Information on uses of the substance

Table 11: Uses

	Use(s)	Registered use	Use in the scope of Authorisation
Uses as intermediate	Use as Transported Intermediate for manufacture of fine chemicals PC 19: Intermediate Substance used as such or in a mixture	Yes	No
Formulation or repacking	\		
Uses at industrial sites	\		
Uses by professional workers	\		
Consumer uses	\		
Article service life	\		

There are numerous UVCB petroleum and coal stream substances that contain PAHs in variable concentrations, including pyrene. Among petroleum substances some have wide dispersive uses. Among the reported uses are: Uses in Coatings, uses in road and construction applications, in binders or agents, cleaning agents (BAUA, 2017). Those uses can lead to significant environmental releases.

Information on tonnage per identified use for the substance is limited. The use pattern of "Pitch, coal tar, high-temp" (CAS: 65996-93-2) was analysed and discussed in detail in the Risk Assessment Report of CTHPH (EC, 2008). It is reported that CTPHT is mainly used as a binding agent for anodes and electrodes. Taking the use as binding agent for refractory materials into account, these applications covered 94 % of the sales in the EU in 2003.

10. Information on structure of the supply chain

The structure of the supply chain and downstream users is complex. The primary producers of UVCBs containing pyrene are organised in industry consortia like CONCAWE³, Cefic⁴, LOA⁵ and others. According to information from an industry sector organisation the knowledge of uses decreases with the increase in the level of downstream uses.

³ ConcaWE is a division of the European Petroleum Refiners Association and supports members in implementation of the REACH regulation

⁴ European Chemical Industry Council

⁵ Lower Olefins and Aromatics Reach Consortium

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

Pyrene is not produced intentionally but occurs together with other PAHs as constituent of coal and petroleum stream UVCB substances. Among the PAHs benzo[a]pyrene (B[a]P, EC number: 200-028-5), chrysene (EC number 205-923-4), benz[a]anthracene (B[a]A, EC number 200-280-6) and anthracene (EC number: 204-371-1) are included in the Candidate List due to PBT and vPvB properties already.

Further UVCBs like CTPHT (EC number: 266-028-2) and five anthracene oil-derivatives (EC numbers: 292-604-8, 295-278-5, 295-275-9, 292-603-2, and 292-602-7) are listed in the Candidate List due to assessment of the intrinsic properties of its' PAH constituents. Pyrene was one of the constituents which lead to the inclusion of CTPH into the Candidate List based on its PBT and vPvB properties.

11.2 Alternatives

It is possible to considerably decrease the PAH content of UVCB substances derived from coal or mineral oil (see for example use of low aromatic oils in tyres, KEMI, 2003). Furthermore, there seems to be no unique, essential technical function of PAHs in PAH-containing UVCB substances in most cases. Currently, in most of the cases, alternatives to PAH-containing substances seem to be available, e.g. for binding material used in certain electrodes in the aluminium production.

It is important to stress that the complete picture of uses of pyrene-containing UVCB substances remains unclear as it is not possible to identify all of these substances themselves. Further regulatory actions on these substances might be warranted in the future.

11.3 Existing EU legislation

Pyrene has no harmonised classification and is not subject to specific regulatory measures.

11.4 Previous assessments by other authorities

Pyrene belongs to the substance group of PAHs of which many are well-known to be hazardous for human health and the environment. Several PAHs, including Benz(a)-anthracene, Chrysene, Benzo(a)pyrene, Benzo(b)fluoranthene, Benzo(j)-fluoranthene, Benzo(k)-fluoranthene, Benzo(e)pyrene, Dibenzo(a,h)anthracene, but not pyrene, are already classified as CMR substances. Until now, several Annex XV dossiers for the identification of PAHs as substances of very high concern were explicitly based on their intrinsic properties (anthracene, B[a]P, B[a]A, chrysene) or on their PAH constituents (Anthracene Oils, CTPHT).

In the Support Document of Pitch, coal tar, high temp. (CTPHT) it has been concluded by the Member State Committee (MSC) that pyrene fulfils the PBT and vPvB criteria of Annex XIII to the REACH Regulation (ECHA, 2009). However, pyrene and further PAHs whose properties have already been agreed on by the MSC in the CTPHT SVHC identification process have not been proposed (before the submission of the current Annex XV report) so far for formal SVHC identification and inclusion in the Candidate List.

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