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: Fluoranthene

EC Number: 205-912-4

CAS Number: 206-44-0

Submitted by: Belgium

Date: August 2018

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TABLES

Foreword

Fluoranthene 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. Fluoranthene has no 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).

Fluoranthene is a constituent, inter alia, in CTPHT. In the Support Document of Pitch, coal tar, high temp. (CTPHT) it has been concluded by the Member State Committee (MSC) that fluoranthene fulfils the PBT and vPvB criteria of Annex XIII to the REACH Regulation (ECHA, 2009). However, fluoranthene and some other 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.

The information which was available and led to the conclusion that fluoranthene is a SVHC is summarised in the support document for identification of CTPHT as SVHC (ECHA, 2009). This information is still valid and allows compact review of the substance properties with a focus on PBT/vPvB. An additional literature search on fluoranthene was performed in March 2018, but no relevant new information has been detected or included in this current dossier.

Therefore, the SVHC identification of fluoranthene in this current dossier is solely based on the information provided in the EU Risk Assessment Report on CTPHT (European Commission, 2008), the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008) and the support document for identification of CTPHT as SVHC (ECHA, 2009).

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

Substance Name: Fluoranthene

EC Number: 205-912-4

CAS number: 206-44-0

- 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

PBT/vPvB - Articles 57 (d) and (e):
An assessment of the PBT/vPvB properties of fluoranthene was carried out by the MSC in the context of the identification of CTPHT as SVHC, as documented in the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009). Additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008). Both reports support the conclusions on the PBT and vPvB properties of fluoranthene already drawn in the MSC Support Document on CTPHT. The information leading to the identification of CTPHT as SVHC is still valid and allows compact assessment of the substance properties with a focus on PBT/vPvB properties.

Persistence
In the atmosphere, fluoranthene is mostly gas phase-associated with lifetimes of 5.6 hours to 1.2 days. Depending on the type of associated particle, the lifetime of surface-adsorbed fluoranthene can increase from 7.7 hours up to 5.7 days (European Commission, 2008).

In water, fluoranthene is not hydrolysed and photo-degradation only appears at the upper few centimetres of a water-column. In soil, exposure to light is even more limited. Therefore, photo-degradation is not considered as relevant degradation process in water, soil or sediment.

Mackay *et al.* (1992) predicted that fluoranthene persists in sediment with half-lives higher than 1250 days. For water degradation, Mackay *et al.* (1992) predicted elimination half-lives between 300 and 1000 hours. Fluoranthene consists of 4 aromatic rings, so standard tests for biodegradation in water may reveal that fluoranthene is biodegradable under aerobic conditions (European Commission, 2008).

Wild and Jones (1993) reported a dissipation half-live for fluoranthene up to 184 days in a laboratory soil microcosm study. For assessing the degradation of fluoranthene, half-lives obtained under realistic conditions, such as field conditions are given higher weight. Under field conditions Wild *et al.* (1991) demonstrated a half-life of more than 7.8 years in soil for fluoranthene. These values correspond to the estimated data by Mackay *et al.* (1992).

For the sediment compartment, it is expected that fluoranthene degrades slowly, but no definite conclusion is drawn.

It is concluded that fluoranthene degrades very slowly in soil with half-lives > 180 days.

Therefore, based on a weight of evidence approach, the P and vP criteria according to REACH Annex XIII are fulfilled for fluoranthene. This conclusion was already drawn in the Support document for the identification of CTPHT as SVHC (ECHA, 2009).

Bioaccumulation
Data on the bioaccumulation potential of fluoranthene were reported in the EU Risk Assessment report on CTPHT (European Commission, 2008). The bioaccumulation factors in different species (fish, molluscs, polychaeta and crustacea) range from 180 L/kg (*C. septemspinosa*) to 14 836 L/kg (*P. promelas*).

Bioaccumulation potential of fluoranthene can differ between organisms due to their ability to metabolise PAHs (biotransformation).

High BCF values have been reported especially for fish (range of 3 388 - 14 836 L/kg) and molluscs (range of 4 120 - 5 920 L/kg).

In the Support document for the identification of CTPHT as SVHC (ECHA, 2009) the study by Weinstein and Oris (1999) with *P. promelas* was given the highest weight. In this study, juvenile fish (48 hours post-hatching) were exposed in a static system to four concentrations of fluoranthene in tap water in a dish containing 150 ml solution, prepared by a generator column. Apart from the four concentrations of fluoranthene in tap water, the accumulation was also determined at four different amounts of dissolved humic acid, each with four concentrations of fluoranthene. The concentration of the parent compound in water and fish were determined after one day of exposure using HPLC. The accumulation experiments showed a consistent picture of the bioaccumulation with the BCF decreasing exponentially with the concentrations of dissolved organic matter at all fluoranthene concentrations. At one dissolved humic matter concentration the BCF values were not significantly different. The BCF value in tap water without dissolved humic matter was 9 054 ± 555 L/kg.

It is concluded that fluoranthene is a bioaccumulative and very bioaccumulative substance. Fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH since several of the experimentally obtained BCF values (in fish and molluscs) were above 5 000 L/kg.

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

Toxicity
Fluoranthene appears to be extremely phototoxic when organisms are exposed in parallel to ultraviolet radiation, such as in sunlight. The acute $L(E)C_{50}$ values of fluoranthene are comparable to the obtained chronic NOEC or $L(E)C_{10}$ values.

Numerous long term studies with a range of species representing various taxonomic groups (fish, aquatic invertebrates and algae) report NOEC or EC_{10} values for fluoranthene below 10 µg/L. Spehar *et al.*, 1999 studied both acute and chronic effects of fluoranthene in the presence and absence of UV radiation with different species.

A 31 day *Mysidopsis bahia* study by Spehar *et al.* (1999) was given the highest weight, as it provided the lowest reliable NOEC (reproduction) value of 0.6 µg/L.

Therefore, fluoranthene fulfils the T criterion according to Annex XIII 1.1.3 a) of REACH.

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

Overall conclusion

In conclusion, fluoranthene meets the criteria for the identification of a PBT and vPvB substance according to Article 57 (d) and (e) of REACH, based on a weight-of-evidence approach.

Registration dossiers submitted for the substance? No

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:	205-912-4
EC name:	
CAS number (in the EC inventory):	206-44-0
CAS number: Deleted CAS numbers:	
CAS name:	Fluoranthene
IUPAC name:	Fluoranthene
Index number in Annex VI of the CLP Regulation	/
Molecular formula:	$C_{16}H_{10}$
Molecular weight range:	202.3 g/mol
Synonyms:	1,2-(1,8-naphthalenediyl)benzene 1,2-Benzacenaphthene 1,2-(1,8-Naphthalene)benzene 1,2-(1,8-Naphthylene)benzene Benzo[jk]fluorene NSC 6803 Idryl RCRA Waste Number U120 Fuoroanthene

Structural formula:
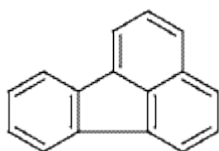
1.2 Composition of the substance

Name: Fluoranthene

Description: Fluoranthene belongs to a group of Polycyclic Aromatic Hydrocarbons (PAHs). It is not produced, as such. However, it may occur as a constituent in UVCB[1]-substances that are derived from coal or in petroleum streams. The dossier addresses the substance fluoranthene 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*	*GSBL[2] database, accessed on 05 March 2018*
Melting/freezing point		*110.2 °C*	Mackay *et al.* (2006)
Boiling point		*384 °C*	Mackay *et al.* (2006)
Vapour pressure	Reported vapour pressure values are within the range of the two indicated values. Note that most of the reported vapour pressure values at 25°C are < 0.01 Pa	*Range of reported Vp values* *1.25×10^{-4} Pa at 25°C (extrapolated-Antoine eq.)* *1.79 Pa at 25°C (supercooled liquid P_L)* *Selection of Vp value* 1.2×10^{-3} Pa at 25°C (gas saturation)*	Mackay *et al.* (2006)
Water solubility	Reported water solubility values are within the range of the two indicated values.	*Range of reported Ws values* *0.120 mg/L at 25°C (shake-flask-nephelometry)* *0.373 mg/L at 25°C (elution method)* *Selected Ws value* 0.2 mg/L at 25°C (column method)*	Mackay *et al.* (2006)
Partition coefficient n-octanol/water (log value)	A range of LogKow values are reported in Mackay *et al.* (2006). Values are within close range. Temperatures not reported.	*5.20**	ECHA, 2009

*This reported value was selected in the Support Document for identification of CTPHT as SVHC (ECHA, 2009)

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[1] Substances of Unknown or Variable composition, Complex reaction products or Biological materials
[2] Gemeinsamer Stoffdatenpool Bund/Länder

2. Harmonised classification and labelling

Fluoranthene has no harmonised classification in Annex VI of the CLP regulation.

3. Environmental fate properties

3.1 Degradation

The data on degradation of fluoranthene in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) are not assessed or discussed again in this dossier but included for convenience (flagged by *italic print*). Additional information available in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008) which was not discussed in the Support Document on CTPHT is included in this assessment.

3.1.1 Abiotic degradation

3.1.1.1 Hydrolysis

It is already recognised that *PAHs are hydrolytically stable in aqueous systems* (Support Document for identification of CTPHT as SVHC (ECHA, 2009)) and 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 oxidized 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).

Fluoranthene has 4 aromatic rings and a vapour pressure of 1.2×10^{-3} Pa at 25°C. Therefore, fluoranthene is considered more gas phase associated and will mainly be degraded by oxidation instead of photolysis. However, as indicated in table 3 below, fluoranthene is partitioned both to the gas phase and the particulate phase.

3.1.1.3 Phototransformation/photolysis

3.1.1.3.1 Phototransformation in air

Photolysis of PAHs in the atmosphere was assessed in the EU risk assessment report (European Commission, 2008) as following:

Photolysis in the troposphere results in the formation of reactive hydroxyl and nitrate (NO3) radicals and ozone (O3), 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 occurs (Peters and Seifert, 1980; Grosjean et al., 1983; Pitts et al., 1986; Coutant et al., 1988).

According to the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008), the photolysis of PAHs is as follows:

A two layer model has been proposed for the behaviour of naturally occurring PAH on airborne particulate matter, in which photo oxidation takes place in the outer layer, and much slower, 'dark' oxidation takes place in the inner layer (Valerio et al., 1987). This model is in line with the results of Kamens et al. (1991), who reported that PAH on highly loaded particles degrade more slowly than those on particles with low loads. As PAH occur mainly on particulate matter with a high carbon content, their degradation in the atmosphere is slower than that of PAH in the vapour phase under laboratory conditions or adsorbed on synthetic material like alumina and silica gel that have no or a low carbon content.

Table 3: In the atmosphere, PAHs are partitioned between the gas and particle phases (The Netherlands, 2008):

PAH (number of rings)	Vapour pressure (Pa) (a)	Observed % in particulate phase (b)	Observed % in particulate phase (c)	Observed % in particulate phase (d)	Observed % in particulate phase (e)
Naphthalene (2)	1.1×10^1	0%			0%
Acenaphthylene (3)	1.3×10^{-1}				
Acenaphthene (3)	4.0×10^{-1}				
Fluorene (3)	1.1×10^{-1}	0%			
Anthracene (3)	8.7×10^{-4}	3%			0.5%
Phenanthrene (3)	2.0×10^{-2}	3%	12.4%	1.9%	0.4%
Fluoranthene (4)	**6×10^{-3}**	**54%**	**49.7%**	**19.1%**	**5.9%**
Pyrene (4)	4.4×10^{-4}	57%	61.4%	29.6%	7.5%
Benzo(a)anthracene (4)	2.1×10^{-6}	97%	89.4%	62.7%	
Chrysene (4)	1.4×10^{-6}	99%			
Benzo(b)fluoranthene (5)	1.0×10^{-6}	100%	92.2%	92.3%	
Benzo(a)pyrene	5.3×10^{-8}	100%	100%	100%	98.3%
Perylene (5)	1.8×10^{-8}	100%			90%
Dibenzo[ac]anthracene (5)	5.7×10^{-9}	100%			
Dibenzo(a,h)anthracene (5)	4.9×10^{-9}	100%	100%	100%	
Benzo(ghi)perylene (6)	1.0×10^{-8}	100%	100%	100%	
Notes: (a) Vapour pressures taken from Neiderfellner *et al*. (1997) and Oja and Suuberg (1998). (b) Measurements made in Oslo, January/February 1979 (Thrane and Mikalsen, 1981). (c) Annual mean measurements made in Bayreuth, Germany, May 1995-April 1996 (Horstmann and McLachlan, 1998). (d) Summer mean measurements made in Bayreuth, Germany, May-October 1995 (Horstmann and McLachlan, 1998). (e) Measurements made in Torrance, California, February 1986 (Arey *et al*., 1987)					

Fluoranthene is overall mainly gas phase associated. Representative lifetimes of fluoranthene with respect to gas-phase reaction with hydroxyl (OH) radicals ranged from 5.6 hours (in summer) to 1.2 days (in winter). 24 hours-average summer and winter OH concentrations of 1×10^6 molecule/cm^3 and 2×10^5 molecule/cm^3 assumed for boundary layer UK (The Netherlands, 2008).

Representative lifetimes of surface-absorbed fluoranthene with respect to photolysis under conditions representative of a cloudless sky over southern UK ranged from 7.7 hours (in summer) to 5.7 days (in winter) (The Netherlands, 2008).

3.1.1.3.2 Phototransformation in water

As assessed before in the Support Document for identification of CTPHT as SVHC (ECHA, 2009), *photodegradation in natural waters takes normally place only in the upper few centimetres of the water-column and is therefore not considered to have significant impact on the overall persistency of PAHs in the aquatic environment*.

3.1.1.3.3 Phototransformation in soil

As assessed before in the Support Document for identification of CTPHT as SVHC (ECHA, 2009), *as exposure to light is even more limited in soils, photodegradation is as well not considered a relevant degradation process in terrestrial environments.*

3.1.1.4 Summary on abiotic degradation

It was already concluded in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) that *in general, PAHs are hydrolytically stable in aqueous systems. Under environmental conditions, therefore, hydrolysis does not contribute to the degradation of PAHs.*

Moreover, it was concluded that *in the atmosphere, free PAHs degrade within minutes to hours by direct photolysis.*

In addition, it was concluded that *photodegradation in natural waters normally takes place only in the upper few centimeters of the water-column and is therefore not considered to have significant impact on the overall persistency of PAHs in the aquatic environment. As exposure to light is even more limited in soils, photodegradation is as well not considered a relevant degradation process in terrestrial environments.*

In the atmosphere, fluoranthene is more gas phase-associated with lifetimes of 5.6 hours to 1.2 days. Depending on the type of associated particle, the lifetime of surface-adsorbed fluoranthene can increase from 7.7 hours up to 5.7 days (European Commission, 2008).

3.1.2 Biodegradation

3.1.2.1 Estimated data

As indicated in the Annex XV transitional dossier for CTPHT (The Netherlands, 2008), *Mackay et al. (1992) ranked 16 PAH according to their persistence in water, soil and sediment in different classes which correspond to a specific half-live in these compartments.* The calculated half-lives of fluoranthene in water are in the range of 300-1000 h and for sediment longer than 1250 days.

3.1.2.2 Biodegradation in water and sediment

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

Standard tests for biodegradation in water have demonstrated that PAHs with up to four aromatic rings are biodegradable under aerobic conditions, but that biodegradation rates of PAHs with more 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).

In general, PAHs are considered to be persistent under anaerobic conditions (Neff (1979); Volkering and Breure (2003) cited in The Netherlands, 2008). Aquatic sediments are often anaerobic with the exception of a few millimetre thick surface layer at the sediment-water interface, which may be dominated by aerobic conditions. The degradation of PAHs in aquatic sediments is therefore expected to be very slow.

3.1.2.3 Biodegradation in soil

Biodegradation in soil was 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.

Wild and Jones (1993) and Wild et al. (1991) studied the biodegradation of PAHs in soil amended with sewage sludge under laboratory and field conditions, respectively.

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.

They determined a dissipation half-life for fluoranthene in the range of 110 to 184 days in laboratory soil microcosm and under field condition a half-life of 7.8 years. Wild et al. (1991) summarized, that biodegradation is the key process in PAH losses from these soils. The laboratory study done by Wild and Jones (1993) was conducted at a temperature range between 20 and 30°C. The field study Wild et al. (1991) was conducted at Luddington and Lee Valley, in the UK.

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

"'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

The half-live predicted by Mackay *et al.* (1992) indicates that fluoranthene persists in sediment with half-lives higher than 1250 days. Therefore, it seems that fluoranthene biodegrades very slowly in sediment.

For water degradation, Mackay *et al.* (1992) predicted half-lives between 300-1000h. Fluoranthene consists of 4 aromatic rings, so standard tests for biodegradation in water may reveal that fluoranthene is biodegradable under aerobic conditions (European Commission, 2008).

Biodegradation studies in laboratory soil microcosms show dissipation half-lives up to 184 days (Wild and Jones, 1993). Biodegradation studies on soil done by Wild *et al.* (1991) revealed a half-life of more than 7.8 years for fluoranthene under field conditions. These values correspond to the half-lives predicted by Mackay *et al.* (1992).

Therefore, it is concluded that fluoranthene biodegrades very slowly in soil.

3.1.3 Summary and discussion on degradation

In the atmosphere, fluoranthene is mostly gas phase-associated with lifetimes of 5.6 hours to 1.2 days. Depending on the type of associated particle, the lifetime of surface-adsorbed fluoranthene can increase from 7.7 hours up to 5.7 days (European Commission, 2008).

In water, fluoranthene is not hydrolysed and photo-degradation only appears at the upper few centimetres of a water-column. In soil, exposure to light is even more limited. Therefore, photo-degradation is not considered as relevant degradation process in water, soil or sediment.

The predicted half-lives range between 300 and 1000 hours for water degradation and half-lives higher than 1250 days for sediment.

Wild and Jones (1993) reported a dissipation half-live for fluoranthene up to 184 days in a laboratory soil microcosm study. For assessing the degradation of fluoranthene, half-lives obtained under realistic conditions, such as field conditions are given higher weight. Under field conditions Wild *et al.* (1991) demonstrated a half-life of more than 7.8 years in soil for fluoranthene.

Based on the measured biodegradation results, it is concluded that fluoranthene degrades very slowly in soil.

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

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 sediment 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)."

Fluoranthene has a Log K_{ow} value of 5.20. It is therefore concluded that fluoranthene has a high potential to adsorb to particles in the environment.

3.2.2 Volatilisation

Fluoranthene has a vapour pressure value of $1.2x10^{-3}$ Pa at 25°C (ECHA, 2009). Compared to some other PAHs like chrysene (Vp = $5.7x10^{-7}$ Pa at 25°C) and benz[a]anthracene (Vp = $7.6x10^{-6}$ Pa at 25°C) (ECHA, 2009), the vapour pressure of fluoranthene is higher, but still considered to be low. It is therefore expected that fluoranthene will volatilise slowly.

In the Support document for the identification of CTPHT as SVHC (ECHA, 2009) it is indicated that: *"With their low vapour pressures in the range of $10^{-2} – 10^{-10}$ Pa, the PAHs contained in CTPHT are expected to volatilise very slowly."*

3.2.3 Distribution modelling

Mackay Level III fugacity modelling was carried out using EPI Suite (version 4.11) with default values of environmental emission rates (it is assumed that fluoranthene is released at equal rates to air, water and soil) and default values of physico-chemical properties (done in March 2018).

Table 4: Results of Mackay Level III fugacity modelling (EPI Suite, version 4.11) for fluoranthene

Distribution to:	Mass amount (percent)
Air	0.357
Water	7.75
Soil	60.5
Sediment	31.4

The obtained results clearly indicate that fluoranthene mainly partitions to soil and sediment.

3.2.4 Summary and discussion, of environmental distribution

Fluoranthene has a high potential to adsorb to particles and volatilisation of fluoranthene is insignificant. Further fugacity modelling reveals that fluoranthene is mainly distributed to soil and sediment.

3.3 Data indicating potential for long-range transport

Assessment of the potential for long-range transport is not considered in this dossier.

3.4 Bioaccumulation

3.4.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

Table 5 summarises different experimental results as reported in the EU Risk Assessment report on CTPHT (European Commission, 2008) with assigned reliability. The bioconcentration factors in different organisms range from 180 L/kg (*C. septemspinosa*) to 14 836 L/kg (*P. promelas*).

Table 5: Experimentally obtained BCF values for fluoranthene

Species	BCF (L/kg)	Test type[a]	Calculation[b]	R[c]	References
Fish:					
P. promelas	9 054	S	Equi (parent)	2	Weinstein & Oris (1999)
P. promelas	3 388	S	k1/k2 (parent)	2	De Maagd (1996)
P.promelas (larvae)	14 836	CF	k1/k2 (parent)	1	Cho *et al.* (2003)
Mollusca					
M. edulis	5 920	F	k1/k2 (parent)	1	McLeese & Burridge (1987)
M.arenario	4 120	F	k1/k2 (parent)	1	McLeese & Burridge (1987)
Polychaeta					
N. virens	720	F	K1/k2 (parent)	1	McLeese & Burridge (1987)
Crustacea					
C. septemspinosa	180	F	K1/k2 (parent)	1	McLeese & Burridge (1987)
D. magna*	1 742	SR	Equi	2	Newsted & Giesy (1987)

a) F: flow-through system, S: static exposure system, SR: static renewal, FD: organisms collected from the field; C: Continuous
b) k1/k2: kinetic: uptake rate/depuration rate, total: total compound concentration (including transformation products), parent: parent compound concentration
c) Reliability score: 1-reliable without restrictions, 2-reliable with restrictions
*Result from the support document for the identification of CTPHT as SVHC (ECHA, 2009).

The following analysis highlighted in *bold/italic* is cited from the European Union Risk Assessment Report on CTPHT (European Commission, 2008):

The bioaccumulation of 5 PAHs in fathead minnows (Pimephales promeals) was studied in a static experimental set-up according to the so-called 'adjusted Banerjee method' (De Maagd, 1996; chapter 4). This study was designed to quantify the role of biotransformation in the bioaccumulation process. PAHs were added to tap water by a generator column. Fish (7-11) of on average 0.52 g were added to an aquarium with 1.5 L of water. The concentrations of the parent compounds in both water and fish in the static systems were analyzed using HPLC during 48 hours on 7 to 11 points in time. Fish were fed daily until two days prior to the experiment. In the modelling of the concentrations, the amount of fish and the volume of the water were adjusted every time a sample was taken. The bioaccumulation with and without biotransformation was determined by running parallel tests with and without the addition of piperonyl butoxide (PBO), a known biotransformation inhibitor for substrates binding to the site of cytochrome P450-isoenzymes. To distinguish between loss due to abiotic processes and biotransformation controls without fish were used as well.

The uptake rate determined from the concentration in fish was not in accordance with the uptake rate determined from the decrease of concentration in the water phase. Therefore, the recovery of anthracene, fluoranthene, and benzo(a)anthracene from fish exposed via water had to be slightly adjusted downwards in comparison with homogenized fish spiked with the PAHs dissolved in hexane (18, 16, and 43% respectively). For benzo(a)anthracene this adjustment of the recovery did not result in an good fit of the data and therefore the uptake was also estimated on the concentration in the fish only. For phenanthrene the increase in fish and decrease in water concentration was in accordance with the recovery of phenanthrene determined from spiked fish homogenate (+3%). Only the estimated recovery of naphthalene appeared to be significantly higher from fish exposed via PAHs taken up from water than from homogenized fish spiked with naphthalene in hexane. In the latter case the recovery was only about 16%, which was attributed to volatilisation during the extraction process.

Estimated recovery of naphthalene to fit both the decrease in the aqueous concentration and increase in the concentration in fish was 35%. The calculated BCF values in the absence of PBO were 300 L/kg for naphthalene, 6 800 L/kg for phenanthrene and anthracene, 3 400 for fluoranthene and 200 L/kg for benzo(a)anthracene. Only for benzo(a)anthracene, biotransformation, which was not completely inhibited by PBO, significantly influenced the bioaccumulation process. No effect of biotransformation was observed for naphthalene, phenantrene, and anthracene, while the uptake of fluoranthene could be better modelled if biotransformation was taken into account. The amount of fish in the aquarium (more than 3 grams/L) is three times more than the upper limit of what is recommended in OECD guideline 305. However, in the modified Banerjee method this amount of fish is necessary to reduce the water concentration in such a way that the uptake can be modelled from the concentration in water (Validity = 2)

In another study with fathead minnows (Weinstein and Oris, 1999), juvenile fish (48 hours post-hatching) were exposed in a static system to four concentrations of fluoranthene in tap water in a dish containing 150 ml solution, prepared by a generator column. Apart from the four concentrations of fluoranthene in tap water, the accumulation was also determined at four different amounts of dissolved humic acid, each with four concentrations of fluoranthene. The concentration of the parent compound in water and fish were determined after one day of exposure using HPLC. The accumulation experiments showed a consistent picture of the bioaccumulation with the BCF decreasing exponentially with the concentrations of dissolved organic matter at all fluoranthene concentrations. At one dissolved humic matter concentration the BCF values were not significantly different. The BCF value in tap water without dissolved humic matter was 9 054 ± 555 L/kg. (Validity = 2)

McLeese and Burridge (1987) determined PAH accumulation in the clam Mya arenaria, 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, pyrenen, 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. Animals and water were sampled daily during the exposure period, and animals were sampled at days 1, 2, 4, 7 and 14 during the depuration period. Samples were analyzed using HPLC. Measured concentrations in water and animals were used to calculate ku and ke, which were subsequently used to calculate BCFs. For clam, mussel, shrimp and polychaete BCFs for fluoranthene were 4 120, 5 920, 180, and 720 respectively. The study is very well documented. (Validity = 1)

*Cho et al. (2003) exposed larvae of the fathead minnow (Pimephales promelas) to fluoranthene with and without methyl tert-butyl ether (MTBE) to determine if MTBE enhances bioaccumulation and toxicity of fluoranthene. Larvae (4 days post-hatching) were exposed to 20 **µg/L** fluoranthene and 0 or 40 **µg/L** MTBE under simulated sunlight for 24 hours in flow-through systems with dechlorinated and carbon-filtered tapwater (22 °C; pH 7.6, hardness 248 mg/L CaCO₃). After 24 hours of exposure, the fish were moved to clean water for the elimination phase. Fish were provided with a small amount of food (brine shrimp) for 30 minutes per day. Fish were removed for analysis at several time intervals during exposure and elimination. Concentrations of fluoranthene in fish and water were measured using reverse-phase HPLC. Toxicity was tested during 96 hours exposure in the same systems. BCFs were determined using rate constants. The presence of MTBE caused 37% higher uptake rates and 30% lower elimination rates, resulting in a BCF that was twice as high (29 208) as when no MTBE was present (BCF = 14 836). (Validity = 1)*

Bioaccumulation in *Daphnia magna* has been studied by Newsted & Giesy (1987). The study by Newsted & Giesy (1987) is based on a single 24 hours exposure, resulting in equilibrium partitioning of fluoranthene between the organism and water. In this study the BCF was determined at steady state in a static system. A BCF value of 1 742 L/kg was determined in this study. (Validity = 2)

In the Support document for the identification of CTPHT as SVHC (ECHA, 2009), the study by Weinstein and Oris (1999) was selected as having the highest weight (BCF value of 9 054 L/kg) as it reports a reliable equilibrium BCF for fluoranthene.

3.4.2 Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates

The European Union Risk Assessment Report on CTPHT (European Commission, 2008) reports a calculated BCF for fluoranthene in *Eisenia Andrei* of 1 900 and this value is considered to represent a reasonable worst case. The documentation of this QSAR result does not comply with REACH Annex XI and, thus, its reliability is limited.

3.4.3 Summary and discussion of bioaccumulation

In the Support Document for the identification of CTPHT as SVHC (ECHA, 2009) it is stated that:

Potential for biotransformation of substances in exposed species is also an important factor in assessing bioaccumulation. BCF values may be higher in early life stages of an organism than in the adult stage. Whereas fish, and to some extent also molluscs, have the ability to metabolise PAHs, no evidence of metabolism of PAHs has been observed in algae, or oligochaete.

Bioaccumulation potential of fluoranthene can therefore differ between the organisms due to their ability to metabolise PAHs (biotransformation).

High BCF values have been reported especially for fish (3 388-14 836 L/kg) and molluscs (4 120-5 920 L/kg).

Thus, it is concluded that fluoranthene is a bioaccumulative and very bioaccumulative substance. This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

4. Human health hazard assessment

Not relevant for the identification of fluoranthene as SVHC in accordance with article 57 (d) and (e) since the fulfillment of the T criterion is based solely on the environmental hazard assessment.

5. Environmental hazard assessment

5.1 Aquatic compartment (including sediment)

The Support Document for the identification of CTPHT as SVHC (ECHA, 2009) 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 & 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.

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

Numerous long term studies with a range of species representing various taxonomic groups report NOEC or EC10 values for fluoranthene below 10 µg/L. Spehar et al. (1999) studied both acute and chronic effects of fluoranthene in the presence and absence of UV radiation with different species.

Fluoranthene appears to be extremely phototoxic when organisms are exposed in parallel to ultraviolet radiation, such as in sunlight. The acute $L(E)C_{50}$s of fluoranthene are comparable to the obtained chronic NOEC or $L(E)C_{10}$ values as indicated in the table below:

Table 6: Overview of aquatic toxicity of fluoranthene

Aquatic Toxicity of Fluoranthene					
Species	Duration	Endpoint	Value	Comment	References
Freshwater organisms, acute					
Utterbackia imbecilis	24-h	LC$_{50}$	2.45 µg/L	UV-A radiation	Weinstein and Polk, 2001
Lumbriculus variegatus	96-h	LC$_{50}$	1.2 µg/L	12:12 h light:dark UV-A+B radiation	Spehar _et al._, 1999
Hydra americana	96-h	LC$_{50}$	2.2 µg/L	12:12 h light:dark UV-A+B radiation	Spehar _et al._, 1999
Daphnia magna	48-h	LC$_{50}$	1.6 µg/L	12:12 h light dark UV-A+B radiation	Spehar _et al._, 1999
Freshwater organisms, chronic					
Ceriodaphnia dubia	7-d	EC$_{10}$ reproduction	1.2 µg/L	Photoperiod 16:8 h light:dark at less than 500 lux	Bisson _et al._, 2000
Hyalella azteca	10-d	LC$_{10}$	1.1 µg/L	16:8 h light:dark UVA+ B radiation	Wilcoxen _et al._, 2003
Daphnia magna	21-d	NOEC growth	1.4 µg/L	12:12 h light:dark UV-A+B radiation	Spehar _et al._, 1999
Pimephales promelas	32-d ELS test	NOEC growth	1.4 µg/L	12:12 h light:dark UV-A+B radiation	Spehar _et al._, 1999
Rana pipiens larvae		NOEC hatching	>25 µg/L	Full sunlight	Hatch & Burton Jr., 1998
Rana pipiens larvae			100% mortality at 5, 25 and 125 µg/L	Full sunlight	
Marine organisms, acute					
Mulinia	96-h	LC$_{50}$	2.8 µg/L	16:8 hours light:dark,	

				laboratory UV A and B light	
lateralis					
Mysidopsis bahia	96-h	LC_{50}	1.4 µg/L		Spehar *et al.*, 1999
Arbacia punctulata	96-h	LC_{50}	3.9 µg/L		
Pleuronectes americanus	96-h	LC_{50}	0.1 µg/L		
Marine organisms, chronic					
Mysidopsis bahia	31-d	NOEC reproduction	11.1 µg/L	16:8 hours light:dark, laboratory fluorescent light	Spehar *et al.*, 1999
Mysidopsis bahia	31-d	NOEC reproduction	0.6 µg/L	16:8 hours light:dark, laboratory UV A and B light	

The following analysis of the data provide in table 6 highlighted in *bold/italic* is cited from the European Union Risk Assessment Report on CTPHT (European Commission, 2008):

*The lowest chronic NOECs or EC_{10} are in between 1.0 and 1.5 **µg/L.** Bisson et al. (2000) found an EC_{10} of 1.2 **µg/L** for the reproduction of Ceriodaphnia dubia exposed to fluoranthene for 7 days under laboratory light with an intensity less than 500 lux. Wilcoxen et al. (2003) reported a 10-d LC10 for the amphipod Hyalella azteca of 1.1 **µg/L.** This test was performed under UV-enhanced light with a photoperiod of 16:8 hours light:dark and an intensity of 7.54 **$µW/cm^2$** UV-B, 102.08 **$µW/cm^2$** UV-A, and 289.24 **$µW/cm^2$**. The LC_{10} decreased strongly with UV-intensity. Under gold light (intensity of 0.17 **$µW/cm^2$** UV-B, 0.09 **$µW/cm^2$** UV-A, 167.72 **$µW/cm^2$** visible) and fluorescent light (intensity of 1.32 **$µW/cm^2$** UV-B, 13.65 **$µW/cm^2$** UV-A, 424.69 **$µW/cm^2$** visible) the LC_{10}s were 56 and 8.0 **µg/L,** respectively. However, these values are comparable with the reported EC_{50}s.*

*When exposed under laboratory ultraviolet light with 283 **$µW/cm^2$** UV-A and 47 **$µW/cm^2$** UV-B and a photoperiod of 12:12 h light:dark, Spehar et al. (1999) found a NOEC of 1.4 **µg/L** for growth of Daphnia magna, exposed for 21 days. With UV-enhanced light with an intensity of 102 **$µW/cm^2$** UV-A, 7.5 **$µW/cm^2$** UV-B, and 289 **$µW/cm^2$** visible light and a photoperiod of 16:8 h light:dark, a 10-d LC_{10} for Hyalella azteca was found of 1.1 **µg/L** (Wilcoxen et al., 2003). Under laboratory ultraviolet light with an intensity of 612 **$µW/cm^2$** UV-A and 82 **$µW/cm^2$** UV-B and a photoperiod of 12:12 h light:dark the NOEC for growth of Pimephales promelas exposed for 32 days in an ELS test was 1.4 **µg/L** (Spehar et al., 1999).*
*In all these experiments concentrations were experimentally determined. For the fresh water mollusc Utterbackia imbecilis the 24-h LC_{50} was 2.45 **µg/L** with UV-A radiation (320-400 nm) at an intensity of 70 **$µW/cm^2$** (Weinstein and Polk, 2001).*

*However, the same effect that was observed for anthracene is also observed for fluoranthene. Fluoranthene appears to be extremely phototoxic when some organisms are exposed in combination with ultraviolet radiation, such as sunlight. The acute LC_{50}s of fluoranthene for fresh water species exposed under laboratory lighting with are comparable or even lower than the chronic NOEC. Evidence is The 96-h LC_{50}s for the freshwater oligochaete Lumbriculus variegatus and Hydra americana were 1.2 **µg/L** and 2.2 **µg/L,** respectively, with ultraviolet light with 359-587 **µW/cm**^{2} UV-A and 63-80 **µW/cm**^{2} UV-B and a photoperiod of 12:12 h light:dark. The 48-h LC50 for Daphnia magna was 1.6 **µg/L,** with ultraviolet light with 783- 850 **µW/cm**^{2} UV-A and 104 **µW/cm**^{2} UV-B and a photoperiod of 12:12 h light:dark (Spehar et al., 1999).*

*The study with embryos of four species of amphibians exposed to fluoranthene shows that under laboratory lighting with a limited intensity of radiation (visible light:UV-A:UVB= 100:10:1; UV-A intensity 62-68 **µW/cm**^{2} and UV-B intensity 2-5 **µW/cm**^{2}) no significant effects occurred at concentrations of 25 **µg/L** or below (Hatch & Burton Jr., 1998). Even concentrations up to 25 **µg/L** in combination with exposure in full sunlight with 200-1650 **µW/cm**^{2} UV-A and 45-320 **µW/cm**^{2} UV-B had no effect on the hatching of the frog Rana pipiens. However, just as for other organisms mortality appeared to be severe. At 5, 25, and 125 **µg/L** all larvae died, while the controls were unaffected. The intensity of the sunlight was 200-1650 **µW/cm**^{2} UV-A and 45-320 **µW/cm**^{2} UV-B. The test was performed early in April at 18-22 °C.*

Marine environment:
*In the study by Spehar et al. (1999) a 31-d chronic NOEC for the reproduction of the Mysid shrimp Mysidopsis bahia are reported. With a photoperiod of 16:8 hours light:dark in fluorescent light the NOEC was reported to be 11.1 **µg/L.** If instead UV-radiation was applied (465-724 **µW/cm**^{2} UV-A and 68-109 **µW/cm**^{2} UV-B), the NOEC dropped to 0.6 **µg/L.***

*Under the same UV-conditions conditions, also some LC_{50} values were found. The 48-h LC_{50} for the the marine mollusc Mulinia lateralis was 2.8 **µg/L,** the 96-h LC_{50} for Mysidopsis bahia was 1.4 **µg/L,** the 48-h LC_{50} for the urchin Arbacia punctulata was 3.9 **µg/L** and the 96-h LC_{50} for Pleuronectes americanus was 0.1 **µg/L** (Spehar et al., 1999).*

5.1.1 Fish

5.1.1.1 Short-term toxicity to fish and aquatic invertebrates

The 96h acute fish test with *Pleuronectes americanus* presents the lowest LC_{50} of 0.1 µg/L for fish (Spehar *et al.*, 1999).

5.1.1.2 Long-term toxicity to fish

The 32-d ELS study with *Pimephales promelas* provides the lowest NOEC (growth) of 1.4 µg/L for fish (Spehar *et al.*, 1999*).*

5.1.2 Aquatic invertebrates

5.1.2.1 Short-term toxicity to aquatic invertebrates

The 96h LC_{50} value of 1.4µg/L for *Mysidopsis bahia* presents the lowest LC_{50} for aquatic

invertebrates (Spehar *et al.*, 1999).

5.1.2.2 Long-term toxicity to aquatic invertebrates

The 31 day study with *Mysidopsis bahia* provides the lowest NOEC (reproduction) of 0.6 µg/L for aquatic invertebrates (Spehar *et al.*, 1999).

5.1.3 Algae and aquatic plants

In the EU Risk Assessment Report on CTPHT (The Netherlands, 2008), it is stated that:

The lowest chronic value for algae is the 72-h EC_{10} (growth) of 1.2 µg/L for Pseudokirchneriella subcapitata (Bisson et al., 2000).

5.1.4 Other aquatic organisms

In the EU Risk Assessment Report on CTPHT (European Commission, 2008) the long term toxicity to other aquatic organisms is summarised:

The study with embryos of four species of amphibians exposed to fluoranthene shows that under laboratory lighting with a limited intensity of radiation (visible light:UV-A:UVB= 100:10:1; UV-A intensity 62-68 µW/cm² and UV-B intensity 2-5 µW/cm²) no significant effects occurred at concentrations of 25 µg/L or below (Hatch & Burton Jr., 1998). Even concentrations up to 25 µg/L in combination with exposure in full sunlight with 200-1650 µW/cm² UV-A and 45-320 µW/cm² UV-B had no effect on the hatching of the frog Rana pipiens. However, just as for other organisms mortality appeared to be severe. At 5, 25, and 125 µg/L all larvae died, while the controls were unaffected. The intensity of the sunlight was 200-1650 µW/cm² UV-A and 45-320 µW/cm² UV-B. The test was performed early in April at 18-22 °C.

5.2 Summary and discussion of the environmental hazard assessment

In the support document for the identification of CTPHT as SVHC (ECHA, 2009) it is indicated that *fluoranthene appears to be extremely phototoxic when organisms are exposed in parallel to ultraviolet radiation, such as in sunlight. The acute $L(E)C_{50}s$ of fluoranthene are comparable to the obtained chronic NOEC or $L(E)C_{10}$ values.*

It is further reported that *"Numerous long term studies with a range of species representing various taxonomic groups report NOEC or EC_{10} values for fluoranthene below 10 µg/L. Spehar et al., 1999 studied both acute and chronic effects of fluoranthene in the presence and absence of UV radiation with different species. The 31 day Mysidopsis bahia study by Spehar et al. (1999) was chosen as key study, as it provided the lowest reliable NOEC (0.6 µg/L)''.*

Indeed, the lowest chronic effect concentration of fluoranthene was determined for *Mysidopsis bahia* with an NOEC reproduction value of 0.6 µg/L (Spehar *et al.*, 1999). This study is chosen as having the highest weight.

6. Conclusions on the SVHC properties

6.1 CMR assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (d) to (e) of REACH since the fulfillment of the T criterion is based solely on the environmental hazard assessment.

6.2 PBT and vPvB assessment

6.2.1 Assessment of PBT/vPvB properties

The PBT/vPvB assessment is based on information provided in the support document for the identification of CTPHT as SVHC (ECHA, 2009).

6.2.1.1 Persistence

Fluoranthene has a low water solubility and shows a high potential to adsorb to (organic) particles in the environment. The resulting low bioavailability is one of the limiting factors of its biodegradation.

Biodegradation studies on soil done by Wild *et al.* (1991) revealed a half-life of fluoranthene of more than 7.8 years under field conditions. Additionally, biodegradation studies in laboratory soil microcosms showed dissipation half-lives up to 184 days (Wild & Jones, 1993).

Therefore, it is concluded that the P and vP criteria for soil according to REACH Annex XIII are fulfilled for fluoranthene. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

6.2.1.2 Bioaccumulation

Experimentally obtained BCF values have been reported for fish (range of 3 388 - 14 836) and molluscs (range of 4 120 - 5 920). In accordance with Annex XIII of the REACH Regulation, the B and vB criteria are fulfilled for fluoranthene.

This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

6.2.1.3 Toxicity

The lowest NOEC (reproduction) value observed for *Mysidopsis bahia* was 0.6 µg/L (31 day study). Therefore, the T criterion according to REACH Annex XIII 1.1.3 (a) is fulfilled for fluoranthene. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

6.2.2 Summary and overall conclusions on the PBT and vPvB properties

Art 57 (d) and (e):
An assessment of the PBT/vPvB properties of fluoranthene has already been carried out by the MSC in the context of the identification of CTPHT as SVHC as documented in the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009). Additional

information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008). Both reports support the conclusions on the PBT and vPvB properties of fluoranthene already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009). The information leading to the identification of CTPHT as SVHC is still valid and allows a compact assessment of the substance properties with a focus on PBT/vPvB.

Persistence

In the atmosphere, fluoranthene is mostly gas phase-associated with lifetimes of 5.6 hours to 1.2 days. Depending on the type of associated particle, the lifetime of surface-adsorbed fluoranthene can increase from 7.7 hours up to 5.7 days (European Commission, 2008).

In water, fluoranthene is not hydrolysed and photo-degradation only appears at the upper few centimetres of a water-column. In soil, exposure to light is even more limited. Therefore, photo-degradation is not considered as relevant degradation process in water, soil or sediment.

Mackay et al. (1992) predicted that fluoranthene persists in sediment with half-lives higher than 1250 days. For water degradation, Mackay et al. (1992) predicted elimination half-lives between 300 and 1000 hours. Fluoranthene consists of 4 aromatic rings, so standard tests for biodegradation in water may reveal that fluoranthene is biodegradable under aerobic conditions (European Commission, 2008).

Wild and Jones (1993) reported a dissipation half-live for fluoranthene up to 184 days in a laboratory soil microcosm study. For assessing the degradation of fluoranthene, half-lives obtained under realistic conditions, such as field conditions are given higher weight. Under field conditions Wild et al. (1991) demonstrated a half-life of more than 7.8 years in soil for fluoranthene. These values correspond to the estimated data by Mackay *et al.* (1992).

For the sediment compartment, it is expected that fluoranthene degrades slowly, but no definite conclusion is drawn.

It is concluded that fluoranthene degrades very slowly in soil with half-lives > 180 days.

Therefore, based on a weight of evidence approach, the P and vP criteria according to REACH Annex XIII are fulfilled for fluoranthene. This conclusion was already drawn in the Support document for the identification of CTPHT as SVHC (ECHA, 2009).

Bioaccumulation

Data on the bioaccumulation potential of fluoranthene were reported in the EU Risk Assessment report on CTPHT (European Commission, 2008). The bioaccumulation factors in different species (fish, molluscs, polychaeta and crustacea) range from 180 L/kg (*C. septemspinosa*) to 14 836 L/kg (*P. promelas*).

Bioaccumulation potential of fluoranthene can differ between organisms due to their ability to metabolise PAHs (biotransformation).

High BCF values have been reported especially for fish (range of 3 388-14 836) and molluscs (range of 4 120-5 920).

In the Support document for the identification of CTPHT as SVHC (ECHA, 2009) the study by Weinstein and Oris (1999) with *P. promelas* was given the highest weight. In this study, juvenile fish (48 hours post-hatching) were exposed in a static system to four concentrations of fluoranthene in tap water in a dish containing 150 ml solution, prepared by a generator column. Apart from the four concentrations of fluoranthene in tap water,

the accumulation was also determined at four different amounts of dissolved humic acid, each with four concentrations of fluoranthene. The concentration of the parent compound in water and fish were determined after one day of exposure using HPLC. The accumulation experiments showed a consistent picture of the bioaccumulation with the BCF decreasing exponentially with the concentrations of dissolved organic matter at all fluoranthene concentrations. At one dissolved humic matter concentration the BCF values were not significantly different. The BCF value in tap water without dissolved humic matter was 9 054 ± 555 L/kg. (Validity = 2)

It is concluded that fluoranthene is a bioaccumulative and very bioaccumulative substance. Fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH since several of the experimentally obtained BCF values (in fish and molluscs) were above 5 000. This conclusion was already drawn in the Support document for the identification of CTPHT as SVHC (ECHA, 2009).

Toxicity
Fluoranthene appears to be extremely phototoxic when organisms are exposed in parallel to ultraviolet radiation, such as in sunlight. The acute $L(E)C_{50}$ values of fluoranthene are comparable to the obtained chronic NOEC or $L(E)C_{10}$ values.

Numerous long term studies with a range of species representing various taxonomic groups (fish, aquatic invertebrates and algae) report NOEC or EC_{10} values for fluoranthene below 10 µg/L. Spehar et al., 1999 studied both acute and chronic effects of fluoranthene in the presence and absence of UV radiation with different species.

A 31 day Mysidopsis bahia study by Spehar et al. (1999) was given the highest weight, as it provided the lowest reliable NOEC (reproduction) value of 0.6 µg/L.

Therefore, fluoranthene fulfils the T criterion according to Annex XIII 1.1.3 a) of REACH.

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

Overall conclusion
In conclusion, fluoranthene meets the criteria for a PBT and vPvB substance according to Art. 57(d) and (e) of REACH, based on a weight of evidence approach.

Part II

7. Registration and C&L notification status

7.1   Registration status

Fluoranthene is not produced intentionally and is not registered as such in the scope of the REACH Regulation.

7.2 CLP notification status

Table 7: CLP notifications

	CLP Notifications[3]
Number of aggregated notifications	8
Total number of notifiers	60

8. Total tonnage of the substance

Fluoranthene is not produced, as such and is not registered in the scope of the REACH Regulation. However, it may occur as a constituent in UVCB-substances that are derived from coal or in several petroleum streams. There is a broad range of different uses, e.g. production of other chemicals and rubber, uses in road construction and as lubricants.

9. Information on uses of the substance

There are numerous UVCB substances that contain fluoranthene. A wide range of uses are likely to have significant release to the environment. Some of those uses include coatings, adhesives, road and construction application and cleaning agents.

Information on tonnages per identified use for the substance are 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 CTPHT (European Commission, 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 difficult to oversee. However, the knowledge of uses decreases with the increase in the level of downstream uses.

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[3] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 05 March 2018)

11. Additional information

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

Fluoranthene is not produced as such, but it may occur together with other PAHs as constituent in UVCB substances that are derived from coal or in several petroleum streams. Among the PAHs benzo[a]pyrene (B[a]P, EC number: 200-028-5), anthracene (EC number: 204-371-1), chrysene (EC number: 205-923-4) and benz[a]anthracene (EC number 200-280-6) are already included into the Candidate List due to PBT and vPvB properties.

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 their PAH constituents. Fluoranthene was one of these constituents, which lead to the inclusion of CTPHT into the Candidate List based on PBT and vPvB properties.

11.2 Alternatives

It is possible to considerably decrease the PAH content of articles derived from coal or mineral oil (see, for example, use of low aromatic oils in tyres, (KEMI, 2003)). Alternative feedstocks of Petroleum substances with similar physical-chemical properties that never contained PAHs can be used to substitute critical feedstocks.

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

11.3 Existing EU legislation

Fluoranthene is listed in Annex X (List of priority substances in the field of water policy) of Directive 2000/60/EC of the European Parliament and of the Council.

11.4 Previous assessments by other authorities

Fluoranthene belongs to the substance group of PAHs of which many are well-known to be hazardous for human health and the environment. 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, chrysene, benz(a)anthracene) or of their PAH constituents (Anthracene Oils, CTPHT).

According to the Support Document for identification of CTPHT as SVHC (ECHA, 2009), fluoranthene fulfils the criteria of Article 57 d) and e) of the REACH Regulation. Thus, the MSC has already concluded on the PBT/vPvB criteria of fluoranthene and has confirmed its SVHC properties in 2009. However, fluoranthene and some other PAHs with SVHC properties already agreed on by the MSC have not yet been included in the Candidate List.

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