

**Substance Name: Fluoranthene**

**EC Number: 205-912-4**

**CAS Number: 206-44-0**

**MEMBER STATE COMMITTEE**

**SUPPORT DOCUMENT FOR IDENTIFICATION OF  
FLUORANTHENE**

**AS A SUBSTANCE OF VERY HIGH CONCERN  
BECAUSE OF ITS PBT<sup>1</sup> (ARTICLE 57D) AND vPvB<sup>2</sup>  
(ARTICLE 57E) PROPERTIES**

**Adopted on 12 December 2018**

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<sup>1</sup> PBT means persistent, bioaccumulative and toxic

<sup>2</sup> vPvB means very persistent and very bioaccumulative

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## 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.

Therefore, the SVHC identification of fluoranthene in this current dossier is 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) and was further supplemented with information from newer studies that are presented as further evidence as they does not trigger a need to modify the conclusions taken by authorities earlier on.

## 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

- The substance is identified as persistent, bioaccumulative and toxic (PBT) according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).
- The substance is identified 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 and vPvB properties in the present dossier and the conclusion that fluoranthene fulfils the criteria in Articles 57 (d) and (e) were based mainly on the information in the MSC Support Document on CTPHT (ECHA, 2009<sup>3</sup>) and supplemented with information from newer studies that are presented as further evidence in a weight of evidence approach. The newly available information however do not trigger a need to modify the conclusions taken by authorities earlier on and therefore allows compact assessment of the substance properties with a focus on PBT/vPvB properties.

#### Persistence

The available experimental information shows that fluoranthene degrades very slowly in soil with half-life > 180 days. Study performed under field conditions demonstrated half-life of more than 7.8 years in soil.

It is assumed that fluoranthene meets the P and vP criterion in sediment, as in the available simulation study with phenanthrene the half-life obtained meets the P and vP criterion. Considering that the biodegradation rates decrease with increasing number of aromatic rings and the half-lives of PAHs in sediment are proportionally related to the octanol-water partition coefficient (Kow), the half-life of fluoranthene should meet the P and vP criterion in sediment as well.

Therefore, the P and vP criteria according to REACH Annex XIII are fulfilled for fluoranthene for soil and sediment.

#### Bioaccumulation

Data on the bioaccumulation potential of fluoranthene were reported in the EU Risk Assessment report on CTPHT (European Commission, 2008<sup>4</sup>). 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

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<sup>3</sup> ECHA (2009): Support Document for identification of Coal Tar Pitch, High Temperature as a SVHC because of its PBT and CMR properties. <http://echa.europa.eu/documents/10162/73d246d4-8c2a-4150-b656-c15948bf0e77>

<sup>4</sup> European Commission (2008): European Union Risk Assessment Report, Coal Tar Pitch High Temperature, CAS No: 65996-93-2, EINECS No: 266-028-2.

to metabolise PAHs (biotransformation).

High BCF values have been reported especially for fish (2772 L/kg) and molluscs (range of 4 120 - 5 920 L/kg).

Fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH Regulation since several of the experimentally obtained BCF values (in fish and molluscs) were above 2000 and 5 000 L/kg respectively.

#### 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<sub>50</sub> values of fluoranthene are comparable to the obtained chronic NOEC or L(E)C<sub>10</sub> values.

Numerous long term studies with a range of species representing various taxonomic groups (fish, aquatic invertebrates and algae) report NOEC or EC<sub>10</sub> values for fluoranthene below 10 µg/L.

A 31 day *Mysidopsis bahia* study 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 Regulation.

#### 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 Regulation, based on a weight-of-evidence approach.

**Registration dossiers submitted for the substance: No**

## Justification

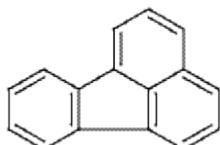
### 1. Identity of the substance and physical and chemical properties

#### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

|   |  |
|---|--|
| <b>EC number:</b>                                     | 205-912-4  |
| <b>EC name:</b>                                       | /  |
| <b>CAS number (in the EC inventory):</b>              | 206-44-0   |
| <b>CAS number:</b><br><b>Deleted CAS numbers:</b>     | /  |
| <b>CAS name:</b>                                      | Fluoranthene   |
| <b>IUPAC name:</b>                                    | Fluoranthene   |
| <b>Index number in Annex VI of the CLP Regulation</b> | /  |
| <b>Molecular formula:</b>                             | C <sub>16</sub> H <sub>10</sub>  |
| <b>Molecular weight range:</b>                        | 202.3 g/mol  |
| <b>Synonyms:</b>                                      | 1,2-(1,8-naphthalenediyl)benzene<br>1,2-Benzacenaphthene<br>1,2-(1,8-Naphthalene)benzene<br>1,2-(1,8-Naphthylene)benzene<br>Benzo[jk]fluorene<br>NSC 6803<br>Idryl<br>RCRA Waste Number U120<br>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<sup>5</sup>-

<sup>5</sup> Substances of Unknown or Variable composition, Complex reaction products or Biological materials

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                             |
|--|--|--|---|
| <b>Physical state at 20°C and 101.3 kPa</b>              |  | <i>Solid</i>   | <i>GSBL<sup>6</sup> database, accessed on 05 March 2018</i> |
| <b>Melting/freezing point</b>                            |  | 110.2 °C   | Mackay <i>et al.</i> (2006)                                 |
| <b>Boiling point</b>                                     |  | 384 °C   | Mackay <i>et al.</i> (2006)                                 |
| <b>Vapour pressure</b>                                   | Reported vapour pressure values are within the range of the two indicated values.<br><br>Note that most of the reported vapour pressure values at 25°C are < 0.01 Pa | <u>Range of reported Vp values</u><br>1.25x10 <sup>-4</sup> Pa at 25°C (extrapolated-Antoine eq.)<br>1.79 Pa at 25°C (supercooled liquid P <sub>L</sub> )<br><u>Selection of Vp value</u><br>1.2x10 <sup>-3</sup> Pa at 25°C (gas saturation)* | Mackay <i>et al.</i> (2006)                                 |
| <b>Water solubility</b>                                  | Reported water solubility values are within the range of the two indicated values.   | <u>Range of reported Ws values</u><br>0.120 mg/L at 25°C (shake-flask-nephelometry)<br>0.373 mg/L at 25°C (elution method)<br><u>Selected Ws value</u><br>0.2 mg/L at 25°C (column method)*  | Mackay <i>et al.</i> (2006)                                 |
| <b>Partition coefficient n-octanol/water (log value)</b> | A range of LogKow values are reported in Mackay <i>et al.</i> (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)

## 2. Harmonised classification and labelling

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

<sup>6</sup> Gemeinsamer Stoffdatenpool Bund/Länder

## 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  $1.2 \times 10^{-3}$  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 (NO<sub>3</sub>) radicals and ozone (O<sub>3</sub>), 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)            | $1.1 \times 10^1$                    | 0%                                  |                                     |                                     | 0%                                  |
| Acenaphthylene (3)         | $1.3 \times 10^{-1}$                 |                                     |                                     |                                     |                                     |
| Acenaphthene (3)           | $4.0 \times 10^{-1}$                 |                                     |                                     |                                     |                                     |
| Fluorene (3)               | $1.1 \times 10^{-1}$                 | 0%                                  |                                     |                                     |                                     |
| Anthracene (3)             | $8.7 \times 10^{-4}$                 | 3%                                  |                                     |                                     | 0.5%                                |
| Phenanthrene (3)           | $2.0 \times 10^{-2}$                 | 3%                                  | 12.4%                               | 1.9%                                | 0.4%                                |
| <b>Fluoranthene (4)</b>    | <b><math>6 \times 10^{-3}</math></b> | <b>54%</b>                          | <b>49.7%</b>                        | <b>19.1%</b>                        | <b>5.9%</b>                         |
| Pyrene (4)                 | $4.4 \times 10^{-4}$                 | 57%                                 | 61.4%                               | 29.6%                               | 7.5%                                |
| Benzo(a)anthracene (4)     | $2.1 \times 10^{-6}$                 | 97%                                 | 89.4%                               | 62.7%                               |                                     |
| Chrysene (4)               | $1.4 \times 10^{-6}$                 | 99%                                 |                                     |                                     |                                     |
| Benzo(b)fluoranthene (5)   | $1.0 \times 10^{-6}$                 | 100%                                | 92.2%                               | 92.3%                               |                                     |
| Benzo(a)pyrene             | $5.3 \times 10^{-8}$                 | 100%                                | 100%                                | 100%                                | 98.3%                               |
| Perylene (5)               | $1.8 \times 10^{-8}$                 | 100%                                |                                     |                                     | 90%                                 |
| Dibenzo[ac]anthracene (5)  | $5.7 \times 10^{-9}$                 | 100%                                |                                     |                                     |                                     |
| Dibenzo(a,h)anthracene (5) | $4.9 \times 10^{-9}$                 | 100%                                | 100%                                | 100%                                |                                     |
| Benzo(ghi)perylene (6)     | $1.0 \times 10^{-8}$                 | 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  $1 \times 10^6$  molecule/cm<sup>3</sup> and  $2 \times 10^5$  molecule/cm<sup>3</sup> 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.*

Xia et al. (2009) performed a study on photodegradation of polycyclic aromatic hydrocarbons in aqueous solution, and the effects of fulvic acid concentration. A blank sample (initial concentration of fluoranthene,  $46.0 \mu\text{g L}^{-1}$ ) resulted in a first-order kinetic rate constant ( $k$ ) of fluoranthene photodegradation of  $0.24 \pm 0.01 \text{ h}^{-1}$ . When combined with  $1.25 \text{ mg L}^{-1}$  BSFA, a  $k'$  for fluoranthene of  $0.36 \pm 0.02 \text{ h}^{-1}$  was derived.

Being a highly conjugated system it is not unusual (if not to say expected) that fluoranthene breaks down under the influence of UV radiation under controlled laboratory conditions and under very high radiation. These specific laboratory settings do not simulate/represent the normal environmental conditions. This is further explained in the ECHA R.11 Guidance:

*According to Castro-Jiménez and de Meent (2011), light absorption in natural water is significantly slower than measured in laboratory water with photo degradation occurring around 30 times more slowly for typical fresh water, 400 times more slowly for typical coastal sea water, and 500 times more slowly for ocean water. These authors also conclude that the "contribution of photodegradation in water to overall degradation is significant only for substances that reside in water to a considerable extent". They highlight that many substances reside in sediment and soil, rather than in water.*

### **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-life 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.*

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).

Smith et al. (2012) studied biodegradation kinetics of phenanthrene and fluoranthene by the bacterium *Sphingomonas paucimobilis* EPA505 using a dynamic passive dosing technique. Similar mineralization fluxes were observed for both substances, which increased by two orders of magnitude with increasing dissolved concentrations.

During the public consultation, references of seven studies related to the degradation of fluoranthene in water were provided (Birch et al., 2018, Concawe, 2012, Martin et al., 2017; Brakstad et al., 2018a, 2018b; Loftus et al., 2018; Ribicic et al., 2018). The studies have been assessed for their reliability and relevance according to OECD and ECHA guidelines (R11 and R7b). They have not been considered suitable for the P assessment as they present methodological limitations, as for example the addition of mineral media in the experiments, the origin of the samples that could be considered as pre-adapted to PAHs, absence of abiotic control and reference substance, the use of dispersant in the experiments, absence of information about the dissolved fluoranthene in the experiments, use of internal markers for the determination of half- life. In the case of the study of Martin et al. (2017) regarding ready biodegradation test, as fluoranthene was not tested, the information has not been further considered in the current assessment.

At present fluoranthene has not been tested in a sediment simulation study (OECD 308). However, during the public consultation a summary of such a study was provided in which the degradation of phenanthrene was studied (Meisterjahn et al. 2018). When converted to 12°C, the half-lives observed were higher than the vP criterion. Considering that the biodegradation rates decrease with increasing number of aromatic rings and the half-lives of PAHs in estuarine sediment are proportionally related to the octanol-water partition coefficient (Kow) (Durant et al. (1995) cited in the Annex XV transitional dossier for CTPHT (The Netherlands, 2008)), it can be assumed that fluoranthene also meets the P and vP criterion in sediment.

### 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.*

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."*

*Wild and Jones (1993) and Wild et al. (1991) 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 of Wild et al. (1991) was conducted at Luddington and Lee Valley, in the UK. When fluoranthene was spiked to soil the dissipation half-life was lower, i.e. 16 days. However, as the abiotic loss, due to e.g. volatilization, was high (34%), the reliability of this as a degradation half-life is questionable.*

Regarding the information provided in the studies by Wild and Jones (1993) and Wild et al. (1991), it should be noted that the MSC has already considered their use in the assessment of CTPHT as SVHC, and hence also for fluoranthene. In agreement with MSC conclusions made within the CTPHT assessment, the SVHC dossier submitter evaluated the study of Wild et al. (1991) as the most reliable evidence of persistency of CTPHT (thus also of fluoranthene), which is suitable for PBT assessment of pristine environment.

Harmsen and Rietra (2018) (reference provided during the public consultation) performed a long-term study on soil and sediment focusing on biodegradation of PAHs and total petroleum hydrocarbons (TPH), which has been monitored on seven experimental fields during periods up to 25 years. The study took place on experimental fields at Kreekraksluizen, situated in the Netherlands. Landfarms were initiated on a semi-field scale in 1990. About 50 cm of dredged sediment was applied and the layer thickness of the dewatered sediments was about 30 cm. The sediments were intensively treated to

stimulate biodegradation during the first years. Treatments used were cultivation, no cultivation, adding wood chips and adding sludge from a sewage system adapted to PAHs. In 1993, the sediment from the different experimental fields were combined into two new experimental fields containing sediments that originated from two harbors in a thicker layer. These sediments were further treated in a passive way (passive landfarming), only allowing vegetation to grow to create aerobic conditions and were followed for 20 years. The bioavailable fraction was measured using Tenax extraction. The study detailed the remaining concentration of every PAH measured and also of fluoranthene after 7.2 years and 22 years. The initial concentration of fluoranthene was 132 mg/kg, after 7.2 years, the remaining amount was estimated being 3.3 mg/kg and after 22 years, estimated of being 1.5 mg/kg. In other sediment from a harbour in Wemeldinge an initial concentration of fluoranthene of 15 mg/kg was estimated, after 7.2 years it remained 6.5 mg/kg and after 22 years 2.4 mg/kg. It is observed that degradation of fluoranthene may depend on the initial concentration and that certain fractions can remain for a long period of time in the environment (Harmsen and Rietra, 2018).

#### 3.1.2.4 Summary and discussion on biodegradation

For water degradation, Mackay *et al.* (1992) predicted half-lives between 300-1000h.

It is assumed that fluoranthene meets the P and vP criterion in sediment, as in the available simulation study with phenanthrene the half-life meets the P and vP criterion. Considering that the biodegradation rates decrease with increasing number of aromatic rings and the half-lives of PAHs in sediment are proportionally related to the octanol-water partition coefficient (Kow), the half life of fluoranthene should meet the P and vP criteria in sediment as well.

The half-life predicted by Mackay *et al.* (1992) supports the persistency of fluoranthene in sediments (half-life > 1250 days).

Biodegradation studies in laboratory soil microcosms, in which fluoranthene is applied via sludge, show dissipation half-lives up to 184 days (Wild and Jones, 1993). Biodegradation studies on soil in which fluoranthene is applied via sludge 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).

A study of Harmsen and Rietra, 2018, suggests that degradation rates of fluoranthene may depend on the initial concentration and that a certain fraction can remain for a long period of time in the environment.

Finally, biodegradation studies on soil done by Wild *et al.* (1991) demonstrated a fluoranthene half-life of more than 7.8 years under field conditions.

Hence, fluoranthene biodegrades very slowly in soil and field conditions, with different parameters impacting the biodegradation process. Data indicate that a low biodegradation of fluoranthene is observed in sediments, based on which fluoranthene meets the vP criteria for sediment.

Therefore, it is concluded that based on the available data, fluoranthene biodegrades very slowly in soil and sediment.

#### 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 a relevant degradation process in water, soil or sediment.

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

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

In view of the fact that phenanthrene meets the P and vP criterion in a sediment simulation study (Meisterjahn et al., 2018), it is assumed that fluoranthene will meet the P and vP criterion as well, considering that the biodegradation rates decrease with increasing number of aromatic rings and the half-lives of PAHs in sediment are proportionally related to the octanol-water partition coefficient ( $K_{ow}$ ) (Durant et al. (1995), cited in the Annex XV transitional dossier for CTPHT (The Netherlands, 2008)).

Wild and Jones (1993) reported a dissipation half-life for fluoranthene up to 184 days (corresponding to 643 days when converted to 12°C by using the Arrhenius equation) in a laboratory soil microcosm study when fluoranthene is applied via sewage sludge. Under field conditions, Wild *et al.* (1991) demonstrated a half-life of more than 7.8 years in soil for fluoranthene when applied via sewage sludge.

A study of Harmsen and Rietra (2018) suggests that the degradation rate of phenanthrene may depend on the initial concentration and that a certain fraction can remain for a long period of time in the environment.

Based on the sediment study of phenanthrene and field and microcosm studies in soil of fluoranthene, it is concluded that fluoranthene meets the P and vP criteria for soil and sediment.

The available information allows to conclude that fluoranthene meets the P and vP criteria for sediments and soil.

## 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  $1.2 \times 10^{-3}$  Pa at 25°C (ECHA, 2009). Compared to some other PAHs like chrysene ( $V_p = 5.7 \times 10^{-7}$  Pa at 25°C) and benz[a]anthracene ( $V_p = 7.6 \times 10^{-6}$  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 in March 2018 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 .

**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)                | Peer-reviewed BCF <sup>d)</sup> (L/Kg) | Test type <sup>a)</sup> | Calculation <sup>b)</sup> | R <sup>c)</sup> | Peer-reviewed R <sup>d)</sup>                           | References                           |
|---|---------------------------|--|-------------------------|---------------------------|-----------------|---|--------------------------------------|
| <b>Fish:</b>                              |                           |  |                         |                           |                 |   |                                      |
| <i>P. promelas</i>                        | 9 054                     |  | S                       | Equi (parent)             | 2               | 4 (BCF value based on dry weight)                       | Weinstein & Oris (1999)              |
| <b><i>P. promelas</i></b>                 | <b>3 388</b>              | <b>2772<sup>3)</sup></b>               | <b>S</b>                | <b>k1/k2 (parent)</b>     | <b>2</b>        | <b>2</b>  | <b>De Maagd (1996)</b>               |
| <i>P.promelas (larvae)</i>                | 14 836                    |  | CF                      | k1/k2 (parent)            | 1               | 4 (Short exposure; BCF value maybe based on dry weight) | Cho <i>et al.</i> (2003)             |
| <i>O. mykiss (juvenile)</i>               | 266-620                   |  | FT                      | k1/k2                     | unknown         |   | Lo <i>et al.</i> (2016)              |
| <i>P. promelas</i>                        | 2 439 <sup>6)</sup>       |  |                         |                           | unknown         |   | Carlson, (1979)                      |
| <i>P. yokohamae</i>                       | 1 341                     |  | FT                      | k1/k2                     | unknown         |   | Kobayashi <i>et al.</i> , 2013       |
| <i>C. auratus</i>                         | 666                       |  |                         |                           | unknown         |   | Ke <i>et al.</i> , 2007              |
| <i>D. rerio</i>                           | 1 376-2 827 <sup>5)</sup> |  |                         |                           | unknown         |   | Li <i>et al.</i> , 2018              |
| <i>D. rerio</i>                           | 901 <sup>2)</sup>         |  |                         |                           | unknown         |   | Xia <i>et al.</i> , 2015             |
| <i>Cichlid</i>                            | 1 665 <sup>2)</sup>       |  |                         |                           | unknown         |   | Xia <i>et al.</i> , 2015             |
| <b>Mollusca</b>                           |                           |  |                         |                           |                 |   |                                      |
| <b><i>M. edulis</i></b>                   | <b>5 920</b>              | <b>5 920</b>                           | <b>F</b>                | <b>k1/k2 (parent)</b>     | <b>1</b>        | <b>1</b>  | <b>McLeese &amp; Burridge (1987)</b> |
| <i>M.arenario</i>                         | 4 120                     | 4 120                                  | F                       | k1/k2 (parent)            | 1               | 1   | McLeese & Burridge (1987)            |
| <i>P. viridis</i>                         |                           | 12 250 <sup>3)</sup>                   | SR                      | Equi                      |                 | 2   | Richardson <i>et al.</i> (2005)      |
| <i>U. imbecillis (glochidia)</i>          |                           | 1735<br>1813                           | FT                      | Equi<br>Kin.              |                 | 2   | Weinstein, 2001                      |
| <i>Utterbackia imbecillis (glochidia)</i> | 2147                      |  | SR                      | Equi.                     |                 | 3   | Weinstein, 2002                      |
| <b>Polychaeta</b>                         |                           |  |                         |                           |                 |   |                                      |
| <i>N. virens</i>                          | 720                       | 720                                    | F                       | K1/k2 (parent)            | 1               | 1   | McLeese & Burridge (1987)            |
| <b>Crustacea</b>                          |                           |  |                         |                           |                 |   |                                      |
| <i>C. septemspinosa</i>                   | 180                       | 180                                    | F                       | K1/k2 (parent)            | 1               | 1   | McLeese & Burridge (1987)            |
| <i>D. magna*</i>                          | 1 742                     | 1 742                                  | SR                      | Equi                      | 2               | 2   | Newsted & Giesy (1987)               |
| <i>Diporeia spp.</i>                      |                           | 15 136-                                | SR                      | Kin.                      |                 | 2   | Schuler <i>et</i>                    |

|   |  |                              |    |       |  |   |                       |
|---|--|------------------------------|----|-------|--|---|-----------------------|
|   |  | 58<br>884 <sup>1)4)</sup>    |    |       |  |   | al. (2004)            |
| <i>Hyalella azteca</i>                        |  | 1 202-5<br>370 <sup>1)</sup> | SR | Kin.  |  | 2 | Schuler et al. (2004) |
| <b>Insecta</b>                                |  |                              |    |       |  |   |                       |
| <i>Chironomus tentans (3rd instar larvae)</i> |  | 891 –<br>2 512 <sup>1)</sup> | SR | Kin.  |  | 2 | Schuler et al. (2004) |
| <b>Amphibia</b>                               |  |                              |    |       |  |   |                       |
| <i>Rana pipiens</i>                           |  | 611 –<br>1659 <sup>1)</sup>  | FT | Equi. |  | 1 | Monson et al. (1999)  |

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/deuration rate, total: total compound concentration (including transformation products), parent: parent compound concentration

c) Reliability score: 1-reliable without restrictions, 2-reliable with restrictions, 4- not assignable

d) Peer reviewed by Bleeker & Verbruggen, 2009

1) Values represent (a range of) BCF values from (a range of) different exposure concentrations.

2) Lipid normalized BCF reported in this study

3) In this study BCF values are based on lipid weight, values given in this table are normalized to 5% lipid content

4) In this study no lipid content was given, but for a lipid normalized value to fall below the trigger value of 5000 the lipid content needs to be 59%, which seems to be unrealistically high

5) bioconcentration factors (range) with Dissolved organic matter (DOM) of various molecular weights at different concentrations and without DOM

6) Calculation method is unclear. Maximum concentration of fluoranthene 4.042 mg/kg bw at day 7, mass = 1.35 µg/L water

\*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 promelas*) 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 a 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, phenanthrene, 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  $9\,054 \pm 555$  L/kg. (Validity = 2)

McLeese and Burrige (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, 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. 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  $k_u$  and  $k_e$ , 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 CaCO<sub>3</sub>). 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)**

The study by Cho et al. (2003) has been reassessed by Bleeker and Verbruggen (2009) and was downgraded due to the short exposure and the fact that BCF value may have been based on dry weight (Validity = 4).

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. However according to the report by Bleeker and Verbruggen (2009) the reliability of this study is downgraded to 4 (not assignable). Nevertheless, other study in fish with reliability 2 (as assessed by Bleeker and Verbruggen (2009)) delivered a lipid normalized BCF of 2772 in *P. promelas* (De Maagd, 1996), what fulfils the B criterion.

Moreover, following the ECHA R.11 Guidance version 3.0 of June 2017 (page 69):... *Also use of other taxonomic groups than fish (e.g. mussel bioconcentration test, ASTM, 2003) is possible for measuring bioconcentration in the aquatic environment and the valid BCFs determined in other taxonomic groups can be used in assessing whether or not the B/vB criteria are met.* Therefore it is completely valid to use the most reliable data with invertebrate to conclude in the B/vB properties of fluoranthene. Hence, this substance fulfil B/vB criterion due to BCF of 5920 L/kg in *M. edulis* (reliability 1).

During public consultation experimental fish data became available (table 5). Reliability of these new data has not been assessed, but some BCF values obtained were above or close to the cut-off value of 2000 L/kg.

Concerning the available TMF values, it should be highlighted that TMF values on their own cannot be used as a basis to conclude that a substance is not bioaccumulative and are considered as supplementary information as stated in the ECHA R.11 Guidance. TMF and BMF-values provide an indication whether concentrations increase or decrease within the various members of a foodweb but they are only a relative indicator. The decisive elements that cause adverse effects and the hazard are the absolute concentrations in the various organisms. Compared to TMF or BMF, bioconcentration factor (BCF) is more directly related to the absolute concentrations in the organism. It has to be taken into account that if the organisms at the lower trophic level(s) experience substantial bioconcentration (what is certainly the case for mussels) the exposure via food for the higher organisms is also inevitably high. So, it is reasonable to foresee that rather high concentrations will build up that can easily cause adverse effects not only in the lower organisms but also in the higher ones. Unless substantial bioelution is observed the risk induced by the substance can propagate through the whole food web.

During Public Consultation 5 studies examining TMF-values from various locations were referred to (Wan et al., 2007, Nfon et al., 2008, Takeuchi et al., 2009, Khairy et al., 2014, and Wang et al., 2012). The presented TMF-values range from 0.11 to 1.2 gfood/gbw with an average value of 0.58 gfood/gbw. On the other hand TMF > 1 from Wang et al. (2012) supports also the decision on B criterion.

Many invertebrate species, contrary to fish, have a lower metabolic capacity which results in the highest BCF values. It is mentioned in the ECHA R.11 Guidance 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, ECHA R.11 Guidance 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.

Taking into account that the vB-criterion ( $BCF > 5000$  L/kgbw) is clearly met for mussels and that the concern is hardly mitigated for higher organisms, fluoranthene should be identified as very bioaccumulative.

### **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 (2772 L/kg) and molluscs (4 120-5 920 L/kg).

During the Public Consultation, the importance of trophic magnification factors and biomagnification factors in the assessment of bioaccumulation has been highlighted (Klečka et al., 2009; Matthies et al., 2016; McLachlan, 2018). Burkhard et al. (2012) stated that not only bioconcentration factors, but also bioaccumulation factors, biota-sediment accumulation factors, biomagnification factors, biota-suspended solids accumulation factors, and trophic magnification factors can be included in the evaluation.

However, if there is a concern for a specific trophic level, then that is enough reason to identify the substance as meeting the B criterion. Moreover, according to the ECHA R.11 Guidance, a substance can be considered as B or vB if results from a bioconcentration or bioaccumulation study in aquatic species allow to conclude on the B/vB property.

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<sub>50s</sub> of fluoranthene are comparable to the obtained chronic NOEC or L(E)C<sub>10</sub> 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 |
| <i>Freshwater organisms, acute</i> |          |          |       |         |            |

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|                                      |        |                                |           |  |  |
|--------------------------------------|--------|--------------------------------|-----------|--|--|
| <i>Scenedesmus vacuolatus</i>        | 24 - h | EC <sub>50</sub> (cell number) | 35 µg/L   |  | Walther et al., 2002, Altenburger et al., 2004 |
| <i>Rana catesbeiana</i>              | 96-h   | LC <sub>50</sub>               | 111 µg/L  |  |  |
| <i>Rana pipiens</i>                  | 48-h   | LC <sub>50</sub>               | 2.0 µg/L  | 48 hours exposure followed by 48 hours continuous irradiation with UV-A+B  | Walker et al., 1998<br>Monson et al., 1999     |
| <i>Xenopus laevis</i>                | 96-h   | LC <sub>50</sub>               | 193 µg/L  |  | Hatch & Burton Jr., 1998                       |
| <i>Lumbriculus variegatus</i>        | 96-h   | LC <sub>50</sub>               | 1.2 µg/L  | 12:12 h light:dark UV-A+B radiation  | Spehar et al., 1999                            |
| <i>Hydra americana</i>               | 96-h   | LC <sub>50</sub>               | 2.2 µg/L  | 12:12 h light:dark UV-A+B radiation  | Spehar et al., 1999                            |
| <i>Ceriodaphnia dubia</i>            | 48-h   | LC <sub>50</sub>               | 45 µg/L   |  | Oris et al., 1991                              |
| <i>Daphnia magna</i>                 | 48-h   | LC <sub>50</sub>               | 1.6 µg/L  | 12:12 h light dark UV-A+B radiation  | Spehar et al., 1999                            |
| <i>Gammarus pseudolimnaeus</i>       | 96-h   | LC <sub>50</sub>               | 108 µg/L  |  | Spehar et al., 1999                            |
| <i>Hyalella azteca</i>               | 5 d    | LC <sub>50</sub>               | 183 µg/L  | 12:12 h light:dark UV-A+B radiation or exposure under laboratory fluorescent light with UV radiation very similar to sunlight.   | Schuler et al., 2004                           |
| <i>Chironomus tentans</i>            | 2 d    | LC <sub>50</sub>               | 176 µg/L  |  | Schuler et al., 2004                           |
| <i>Utterbackia imbecilis</i>         | 24-h   | LC <sub>50</sub>               | 2.45 µg/L | UV-A radiation renewal every 8 hours; 4 hours pre-exposed under ambient laboratory lighting;   | Weinstein and Polk, 2001                       |
| <i>Physella virgata</i>              | 96-h   | LC <sub>50</sub>               | 82 µg/L   | 12:12 h light:dark UV-A+B radiation  | Spehar et al., 1999                            |
| <i>Lepomis macrochirus</i>           | 96-h   | LC <sub>50</sub>               | 12 µg/L   | 48 hours exposure followed by 48 hours continuous irradiation with UV-A+B  | Spehar et al., 1999                            |
| <i>Oncorhynchus mykiss</i>           | 96-h   | LC <sub>50</sub>               | 7.7 µg/L  | 48 hours exposure followed by 48 hours continuous irradiation with UV-A+B  | Spehar et al., 1999                            |
| <i>Pimephales promelas</i>           | 96-h   | LC <sub>50</sub>               | 9.2 µg/L  | Exposure under laboratory ultraviolet light with UV-A+B and a photoperiod of 12:12 hours light:dark or exposure under laboratory fluorescent light with UV radiation very similar to sunlight. | Spehar et al., 1999<br>Diamond et al., 1995    |
| <b>Freshwater organisms, chronic</b> |        |                                |           |  |  |

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|  |               |                                |                                      |  |                                  |
|--|---------------|--------------------------------|--------------------------------------|--|----------------------------------|
| <i>Pseudokirchneriella subcapitata</i> | 72 h          | EC <sub>10</sub> (growth)      | 8.6 µg/L                             |  | Bisson et al., 2000              |
| <i>Scenedesmus vacuolatus</i>          | 24 h          | EC <sub>10</sub> (cell number) | 14 µg/L                              |  | Altenburger et al., 2004         |
| <i>Ambystoma maculatum</i>             | 12 d          | NOEC (mortality)               | 125 µg/L                             |  | Hatch & Burton Jr., 1998         |
| <i>Rana pipiens</i> larvae             | 96 h          | NOEC hatching                  | >25 µg/L                             | Full sunlight  | Hatch & Burton Jr., 1998         |
| <i>Rana pipiens</i> larvae             | 96 h          |                                | 100% mortality at 5, 25 and 125 µg/L | Full sunlight  |                                  |
| <i>Xenopus laevis</i>                  | 96 h          | NOEC malformation              | 25 µg/L                              |  | Hatch & Burton Jr., 1998         |
| <i>Ceriodaphnia dubia</i>              | 7 d           | EC <sub>10</sub> reproduction  | 1.2 µg/L                             | Photoperiod 16:8 h light:dark at less than 500 lux   | Bisson et al., 2000              |
| <i>Daphnia magna</i>                   | 21 d          | NOEC growth                    | 1.4 µg/L                             | 12:12 h light:dark UV-A+B radiation  | Spehar et al., 1999              |
| <i>Diporeia</i> spp.                   | 28 d          | LC <sub>10</sub>               | 6.5 µg/L                             | Longest exposure duration of 28 days.  | Schuler et al., 2004             |
| <i>Hyalella azteca</i>                 | 10 d          | LC <sub>10</sub>               | 1.1 µg/L                             | 16:8 h light:dark UVA+B radiation  | Wilcoxon et al., 2003            |
| <i>Chironomus tentans</i>              | 10 d          | LC <sub>10</sub>               | 14 µg/L                              | Performed in the presence of a sand substrate, gold light was used (UV-A+B) with an intensity of 16:8 hours light:dark | Schuler et al., 2004             |
| <i>Lemna gibba</i>                     | 8 d           | EC <sub>10</sub> (growth rate) | 130 µg/L                             |  | Ren et al., 1994                 |
| <i>Danio rerio</i>                     | 41 d          | EC <sub>10</sub> (length)      | 18 µg/L                              |  | Hoofman & Evers-de Ruiter, 1992a |
| <i>Pimephales promelas</i>             | 32 d ELS test | NOEC growth                    | 1.4 µg/L                             | 12:12 h light:dark UV-A+B radiation  | Spehar et al., 1999              |
| <b>Marine organisms, acute</b>         |               |                                |                                      |  |                                  |
| <i>Neanthes arenaceodentata</i>        | 96 h          | LC <sub>50</sub>               | 258 µg/L                             |  | Rossi & Neff, 1978               |
| <i>Acartia tonsa</i>                   | 48 h          | LC <sub>50</sub> (survival)    | 120 µg/L                             |  | Bellas and Thor 2007             |
| <i>Ampelisca abdita</i>                | 96 h          | LC <sub>50</sub>               | 67 µg/L                              |  | Spehar et al., 1999              |
| <i>Callinectes sapidus</i>             | 1 h           | LC <sub>50</sub>               | 18 µg/L                              | After exposure for 1 hour, transferred to filtered sea water with exposure to  | Peachey 2005                     |

|                                |           |                             |          |   |                     |
|--------------------------------|-----------|-----------------------------|----------|---|---------------------|
|                                |           |                             |          | UV-A+B for 4 hours and 24 hours of recovery in filtered sea water for 24 hours in the dark  |                     |
| <i>Corophium insidiosum</i>    | 96 +1+1 h | EC <sub>50</sub> (reburial) | 20 µg/L  | After 96 hours exposure and 1 hour reburial, animals were transferred to uncontaminated seawater and irradiated for 1 hour with UV-A+B, reburial in sediment was measured for 1 hour after the 1 hour UV irradiation. | Boese et al., 1997  |
| <i>Emerita analoga</i>         | 96 +1+1 h | EC <sub>50</sub> (reburial) | 73 µg/L  | After 96 hours exposure and 1 hour reburial, animals were transferred to uncontaminated seawater and irradiated for 1 hour with UV-A+B, reburial in sediment was measured for 1 hour after the 1 hour UV irradiation. | Boese et al., 1997  |
| <i>Grandidierella japonica</i> | 96 +1+1 h | EC <sub>50</sub> (reburial) | 19 µg/L  | After 96 hours exposure and 1 hour reburial, animals were transferred to uncontaminated seawater and irradiated for 1 hour with UV-A+B, reburial in sediment was measured for 1 hour after the 1 hour UV irradiation. | Boese et al., 1997  |
| <i>Homarus americanus</i>      | 96 h      | LC <sub>50</sub>            | 317 µg/L |   | Spehar et al., 1999 |
| <i>Leptocheirus plumulosus</i> | 96 +1+1 h | EC <sub>50</sub> (reburial) | 20 µg/L  | After 96 hours exposure and 1 hour reburial, animals were transferred to uncontaminated seawater and irradiated for 1 hour with UV-A+B, reburial in sediment was measured for 1 hour after the 1 hour UV irradiation. | Boese et al., 1997  |

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|                                |        |                                       |           |   |                             |
|--------------------------------|--------|---------------------------------------|-----------|---|-----------------------------|
| <i>Libinia dubia</i>           | 1 h    | LC <sub>50</sub>                      | 17 µg/L   | After exposure for 1 hour, transferred to filtered sea water with exposure to UV-A+B for 4 hours and 24 hours of recovery in filtered sea water for 24 hours in the dark. | Peachey 2005                |
| <i>Menippe adina</i>           | 1 h    | LC <sub>50</sub>                      | 39 µg/L   | Laboratory ultraviolet light with UV-A+B and a photoperiod of 16:8 hours light:dark   | Peachey 2005                |
| <i>Mysidopsis bahia</i>        | 96 h   | LC <sub>50</sub>                      | 1.4 µg/L  | After exposure for 1 hour, transferred to filtered sea water with exposure to UV-A+B for 4 hours and 24 hours of recovery in filtered sea water for 24 hours in the dark. | Spehar <i>et al.</i> , 1999 |
| <i>Oithona davisae</i>         | 48 h   | EC <sub>50</sub> (immobility)         | 133 µg/L  |   | Barata <i>et al.</i> , 2005 |
| <i>Palaemonetes spec.</i>      | 96 h   | LC <sub>50</sub>                      | 142 µg/L  |   | Spehar <i>et al.</i> , 1999 |
| <i>Panopeus herbstii</i>       | 1 h    | LC <sub>50</sub>                      | 25.3 µg/L | After exposure for 1 hour, transferred to filtered sea water with exposure to UV-A+B for 4 hours and 24 hours of recovery in filtered sea water for 24 hours in the dark  | Peachey 2005                |
| <i>Rhepoxynius abronius</i>    | 96+1 h | EC <sub>50</sub> (reburial)           | 63 µg/L   | After exposure in water for 96 hours, transfer to sediment with overlying water to measure reburial EC50 after 1 hour.  | Boese <i>et al.</i> , 1997  |
| <i>Mytilus edulis</i>          | 48 h   | EC <sub>50</sub> (feeding filtration) | 80 µg/L   |   | Donkin <i>et al.</i> , 1989 |
| <i>Mulinia lateralis</i>       | 96 h   | LC <sub>50</sub>                      | 2.8 µg/L  | 16:8 hours light:dark, laboratory UV A and B light  | Spehar <i>et al.</i> , 1999 |
| <i>Arbacia punctulata</i>      | 96 h   | LC <sub>50</sub>                      | 3.9 µg/L  |   |                             |
| <i>Pleuronectes americanus</i> | 96 h   | LC <sub>50</sub>                      | 0.1 µg/L  | Laboratory ultraviolet light with UV-A+B and a photoperiod of   |                             |

|                                  |             |                                       |                 |  |                      |
|----------------------------------|-------------|---------------------------------------|-----------------|--|----------------------|
|                                  |             |                                       |                 | 16:8 hours<br>light:dark   |                      |
| <b>Marine organisms, chronic</b> |             |                                       |                 |  |                      |
| <i>Acartia tonsa</i>             | 72 h        | EC <sub>10</sub> (hatching)           | 41 µg/L         | Most sensitive parameter (hatching).   | Bellas and Thor 2007 |
| <i>Mysidopsis bahia</i>          | 31 d        | NOEC reproduction                     | 11.1 µg/L       | 16:8 hours light:dark, laboratory fluorescent light  | Spehar et al., 1999  |
| <b><i>Mysidopsis bahia</i></b>   | <b>31 d</b> | <b>NOEC reproduction</b>              | <b>0.6 µg/L</b> | <b>16:8 hours light:dark, laboratory UV A and B light</b>  |                      |
| <i>Paracentrotus lividus</i>     | 48 h        | EC <sub>10</sub> (larval development) | 21 µg/L         | Lighting by cool daylight lamps (380-780nm, PAR) with an intensity of 70 µE/m <sup>2</sup> /s and a photoperiod of 14:10 hours light:dark. | Bellas et al. 2008   |
| <i>Mytilus galloprovincialis</i> | 48 h        | EC <sub>10</sub> (larval development) | 34 µg/L         | Lighting by cool daylight lamps (380-780nm, PAR) with an intensity of 70 µE/m <sup>2</sup> /s and a photoperiod of 14:10 hours light:dark. | Bellas et al. 2008   |
| <i>Ciona intestinalis</i>        | 20 h        | EC <sub>10</sub> (larval development) | 242 µg/L        | Lighting by cool daylight lamps (380-780nm, PAR) with an intensity of 70 µE/m <sup>2</sup> /s and a photoperiod of 14:10 hours light:dark. | Bellas et al. 2008   |

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<sub>10</sub> are in between 1.0 and 1.5 µg/L. Bisson et al. (2000) found an EC<sub>10</sub> 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. Wilcoxon et al. (2003) reported a 10-d LC<sub>10</sub> 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<sup>2</sup> UV-B, 102.08 µW/cm<sup>2</sup> UV-A, and 289.24 µW/cm<sup>2</sup>. The LC<sub>10</sub> decreased strongly with UV-intensity. Under gold light (intensity of 0.17 µW/cm<sup>2</sup> UV-B, 0.09 µW/cm<sup>2</sup> UV-A, 167.72 µW/cm<sup>2</sup> visible) and fluorescent light (intensity of 1.32 µW/cm<sup>2</sup> UV-B, 13.65 µW/cm<sup>2</sup> UV-A, 424.69 µW/cm<sup>2</sup> visible) the LC<sub>10s</sub> were 56 and 8.0 µg/L, respectively. However, these values are comparable with the reported EC<sub>50s</sub>.***

***When exposed under laboratory ultraviolet light with 283 µW/cm<sup>2</sup> UV-A and 47 µW/cm<sup>2</sup> 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<sup>2</sup> UV-A, 7.5 µW/cm<sup>2</sup> UV-B, and***

**289  $\mu\text{W}/\text{cm}^2$  visible light and a photoperiod of 16:8 h light:dark, a 10-d  $\text{LC}_{10}$  for *Hyalella azteca* was found of 1.1  $\mu\text{g}/\text{L}$  (Wilcoxon et al., 2003). Under laboratory ultraviolet light with an intensity of 612  $\mu\text{W}/\text{cm}^2$  UV-A and 82  $\mu\text{W}/\text{cm}^2$  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  $\mu\text{g}/\text{L}$  (Spehar et al., 1999).**

**In all these experiments concentrations were experimentally determined. For the fresh water mollusc *Utterbackia imbecilis* the 24-h  $\text{LC}_{50}$  was 2.45  $\mu\text{g}/\text{L}$  with UV-A radiation (320-400 nm) at an intensity of 70  $\mu\text{W}/\text{cm}^2$  (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  $\text{LC}_{50}$ 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  $\text{LC}_{50}$ s for the freshwater oligochaete *Lumbriculus variegatus* and *Hydra americana* were 1.2  $\mu\text{g}/\text{L}$  and 2.2  $\mu\text{g}/\text{L}$ , respectively, with ultraviolet light with 359-587  $\mu\text{W}/\text{cm}^2$  UV-A and 63-80  $\mu\text{W}/\text{cm}^2$  UV-B and a photoperiod of 12:12 h light:dark. The 48-h  $\text{LC}_{50}$  for *Daphnia magna* was 1.6  $\mu\text{g}/\text{L}$ , with ultraviolet light with 783- 850  $\mu\text{W}/\text{cm}^2$  UV-A and 104  $\mu\text{W}/\text{cm}^2$  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  $\mu\text{W}/\text{cm}^2$  and UV-B intensity 2-5  $\mu\text{W}/\text{cm}^2$ ) no significant effects occurred at concentrations of 25  $\mu\text{g}/\text{L}$  or below (Hatch & Burton Jr., 1998). Even concentrations up to 25  $\mu\text{g}/\text{L}$  in combination with exposure in full sunlight with 200-1650  $\mu\text{W}/\text{cm}^2$  UV-A and 45-320  $\mu\text{W}/\text{cm}^2$  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  $\mu\text{g}/\text{L}$  all larvae died, while the controls were unaffected. The intensity of the sunlight was 200-1650  $\mu\text{W}/\text{cm}^2$  UV-A and 45-320  $\mu\text{W}/\text{cm}^2$  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  $\mu\text{g}/\text{L}$ . If instead UV-radiation was applied (465-724  $\mu\text{W}/\text{cm}^2$  UV-A and 68-109  $\mu\text{W}/\text{cm}^2$  UV-B), the NOEC dropped to 0.6  $\mu\text{g}/\text{L}$ .**

**Under the same UV-conditions conditions, also some  $\text{LC}_{50}$  values were found. The 48-h  $\text{LC}_{50}$  for the the marine mollusc *Mulinia lateralis* was 2.8  $\mu\text{g}/\text{L}$ , the 96-h  $\text{LC}_{50}$  for *Mysidopsis bahia* was 1.4  $\mu\text{g}/\text{L}$ , the 48-h  $\text{LC}_{50}$  for the urchin *Arbacia punctulata* was 3.9  $\mu\text{g}/\text{L}$  and the 96-h  $\text{LC}_{50}$  for *Pleuronectes americanus* was 0.1  $\mu\text{g}/\text{L}$  (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  $\text{LC}_{50}$  of 0.1  $\mu\text{g}/\text{L}$  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<sub>50</sub> value of 1.4µg/L for *Mysidopsis bahia* presents the lowest LC<sub>50</sub> 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 report by Verbruggen (2012) the lowest chronic value for algae was the 72-h EC<sub>10</sub> (growth) of 8.6 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/cm<sup>2</sup> and UV-B intensity 2-5 µW/cm<sup>2</sup>) 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<sup>2</sup> UV-A and 45-320 µW/cm<sup>2</sup> 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<sup>2</sup> UV-A and 45-320 µW/cm<sup>2</sup> 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<sub>50</sub>s of fluoranthene are comparable to the obtained chronic NOEC or L(E)C<sub>10</sub> values.*

Under normal laboratory conditions with gold or cool white fluorescent lighting or similar, such phototoxic effects will not occur (Bleeker and Verbruggen (2009)).

It is further reported that *"Numerous long term studies with a range of species representing various taxonomic groups report NOEC or EC<sub>10</sub> 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), which was also revised by Verbruggen (2012).

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) and was further supplemented with information from newer studies.

##### 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).

A study of Harmsen and Rietra (2018) suggests that degradation rates of fluoranthene may depend on the initial concentration and that a certain fraction can remain for a long period of time in the environment.

Furthermore, a very low degradation rate of fluoranthene is also expected for sediment compartments under anaerobic conditions. In view of the fact that phenanthrene meets the P and vP criterion in a sediment simulation study (Meisterjahn *et al.* 2018), it is assumed that fluoranthene will meet P and vP criterion as well considering that the biodegradation rates decrease with increasing number of aromatic rings and the half-lives of PAHs in sediment are proportionally related to the octanol-water partition coefficient (Kow) (Durant *et al.* (1995) cited in the Annex XV transitional dossier for CTPHT (The Netherlands, 2008)).

Therefore, it is concluded that the P and vP criteria according to REACH Annex XIII are fulfilled for fluoranthene in soil and sediment.

##### 6.2.1.2 Bioaccumulation

Experimentally obtained BCF values have been reported for fish (2772 kg/L) and molluscs (range of 4 120 - 5 920 L/kg). 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), which was also revised by Verbruggen (2012). 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

An assessment of the PBT and vPvB properties in the present dossier and the conclusion that fluoranthene fulfils the criteria in Articles 57 (d) and (e) were based mainly on the information in the MSC Support Document on CTPHT (ECHA, 2009<sup>7</sup>) and supplemented with information from newer studies that are presented as further evidence in a weight of evidence approach. The newly available information however do not trigger a need to modify the conclusions taken by authorities earlier on and therefore allows a compact assessment of the substance properties with a focus on PBT/vPvB properties.

#### Persistence

The available experimental information shows that fluoranthene degrades very slowly in soil with half-life > 180 days. Study performed under field conditions demonstrated a half-life of more than 7.8 years in soil.

It is assumed that fluoranthene meets the P and vP criterion in sediment, as in the available simulation study with phenanthrene the half-life meets the P and vP criterion. Considering that the biodegradation rates decrease with increasing number of aromatic rings and the half-lives of PAHs in sediment are proportionally related to the octanol-water partition coefficient (Kow), the half-life of fluoranthene meets the P and vP criterion in sediment as well.

Therefore, the P and vP criteria according to REACH Regulation Annex XIII are fulfilled for fluoranthene for soil and sediment.

#### 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 (2772 kg/L) and molluscs (range of 4 120-5 920 kg/L).

Fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH Regulation since several of the experimentally obtained BCF values (in fish and molluscs) were above 2 000 and 5 000 respectively.

#### 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<sub>50</sub> values of fluoranthene are comparable to the obtained chronic NOEC or L(E)C<sub>10</sub> values.

<sup>7</sup> ECHA (2009): Support Document for identification of Coal Tar Pitch, High Temperature as a SVHC because of its PBT and CMR properties. <http://echa.europa.eu/documents/10162/73d246d4-8c2a-4150-b656-c15948bf0e77>

Numerous long term studies with a range of species representing various taxonomic groups (fish, aquatic invertebrates and algae) report NOEC or EC<sub>10</sub> values for fluoranthene below 10 µg/L.

A 31 day *Mysidopsis bahia* study 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 Regulation.

Overall conclusion

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

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