# Annex XV report

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

 $Substance\ Name:\ Benzo[k] fluoranthene$ 

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#### Foreword

Benzo[k]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. Benzo[k]fluoranthene belongs to the eight PAHs that have a harmonised classification, according to the CLP Regulation (EC 1272/2008) as a Class 1B carcinogen.

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

Benzo[k]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 benzo[k]fluoranthene fulfils the PBT and vPvB criteria of Annex XIII of the REACH Regulation (ECHA, 2009). However, benzo[k]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 which led to the conclusion that benzo[k]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 benzo[k]fluoranthene was performed in March 2018, but no relevant new information has been detected or included in this current dossier.

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

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

Substance Name: Benzo[k]fluoranthene

EC Number: 205-916-6 CAS number: 207-08-9

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1B<sup>1</sup>.
- It is proposed to identify the substance as persistent, bioaccumulative and toxic (PBT) according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).
- It is proposed to identify the substance as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

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

#### Carcinogenicity - Article 57 (a):

Benzo[k]fluoranthene is listed by index number 601-036-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for:

Carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

#### PBT/vPvB - Articles 57 (d) and (e):

An assessment of the PBT/vPvB properties of BkFA has already been carried out by the MSC in the context of the identification of CTPHT as SVHC, as documented in the MSC Support Document for identification of CTPHT as SVHC (ECHA, 2009). Additional information was assessed earlier in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and the Annex XV Transitional Dossier on CTPHT (The Netherlands, 2008). Both reports support the conclusions on the PBT and vPvB properties of BkFA already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009). The information leading to the identification of CTPHT as SVHC is still valid and allows a compact assessment of the substance properties with a focus on PBT/vPvB. An additional literature search on benzo[k]fluoranthene was performed in March 2018, but no relevant new information has been detected or included in this current dossier.

<sup>&</sup>lt;sup>1</sup> Classification in accordance with section 3 of Annex I to Regulation (EC) No 1272/2008.

#### Persistence

In the atmosphere, BkFA is mostly particle-associated. The degradation rate depends on the type of particle to which it is bound. The expected lifetime is in the range of several hours to several days (European Commission, 2008).

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

Mackay *et al.* (1992) predicted that BkFA persists in sediment with half-lives higher than 1250 days. For water degradation, Mackay *et al.* (1992) predicted long elimination half-lives between 42 and 125 days. BkFA consists of 5 aromatic rings and it is expected that standard tests for biodegradation in water would show slow biodegradation of BkFA in water.

Wild and Jones (1993) reported a dissipation half-live for BkFA up to 359 days in a laboratory soil microcosm study. For assessing the degradation of BkFA, half-lives obtained under realistic conditions, such as field conditions, are given higher weight. Under field conditions Wild *et al.* (1991) demonstrated a half-life of more than 8.7 years in soil for BkFA. These values correspond to the estimated data by Mackay *et al.* (1992).

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

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

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

#### Bioaccumulation

Limited data on the bioaccumulation potential of BkFA were reported in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

It was already concluded in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) that the study by Newsted & Giesy (1987) can be considered as the main study for several PAHs, including BkFA as the most reliable equilibrium study with BCF > 2 000 L/kg.

The obtained BCF value for *Daphnia magna* (Newsted & Giesy, 1987) was 13 225 L/kg for BkFA.

Thus, BkFA has a high bioaccumulation potential at lower trophic levels, which could contribute to a constant high exposure of BkFA to predators for which the effects are unpredictable due to the absence of sufficient data.

It is concluded that BkFA is a bioaccumulative and very bioaccumulative substance.

BkFA meets the criteria for B and vB, in accordance to Annex XIII of REACH since the experimentally obtained BCF value for *Daphnia magna* was above 5 000 L/kg. This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

#### Toxicity

In two long-term fish studies, the effect of BkFA was examined. In a 7-day reproduction study in aquatic invertebrates, no effects were observed and in a 72-h algae study, an EC<sub>10</sub> growth  $> 1~\mu g/L$  was determined.

A 42-day Early Life Stage study with *Brachydanio rerio* by Hooftman & Evers-de Ruiter (1992) was given the highest weight. It provided an  $EC_{10}$  value (weight) of 0.31  $\mu$ g/L and an  $EC_{10}$  value (length) of 0.17  $\mu$ g/L. Length was the most sensitive endpoint.

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

In addition, BkFA is classified in the hazard class Carc. category 1B according to EU Regulation 1272/2008. Thus, the T criterion according to Annex XIII 1.1.3 (b) of REACH is also fulfilled. This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

#### Conclusion

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

Registration dossiers submitted for the substance? No

## PART I

# Justification

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

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

Table 1: Substance identity

EC number:	205-916-6
EC name:	Benzo[k]fluoranthene
CAS number (in the EC inventory):	207-08-9
CAS number: Deleted CAS numbers:	
CAS name:	Benzo[k]fluoranthene
IUPAC name:	Benzo[k]fluoranthene  pentacyclo[10.7.1.0 <sup>2</sup> , <sup>11</sup> .0 <sup>4</sup> , <sup>9</sup> .0 <sup>16</sup> , <sup>20</sup> ]icosa- 1(20),2(11),3,5,7,9,12,14,16,18-decaene
Index number in Annex VI of the CLP Regulation	601-036-00-5
Molecular formula:	C <sub>20</sub> H <sub>12</sub>
Molecular weight range:	252.3 g/mol
Synonyms:	Benzo[k]fluoranthene BkFA

#### Structural formula:

#### 1.2 Composition of the substance

Name: Benzo[k]fluoranthene

Description: Benzo[k]fluoranthene (BkFA) belongs to a group of Polycyclic Aromatic Hydrocarbons (PAHs). BkFA is not produced, as such. However, it may occur as a constituent in UVCB<sup>2</sup>-substances that are derived from coal or in petroleum streams. The dossier addresses the substance as itself.

Substance type: mono-constituent

#### 1.3 Physicochemical properties

Table 2: Overview of physicochemical properties

Property	Description of key information	Value [Unit]	Reference/ source of information
Physical state at 20°C and 101.3 kPa		solid	GSBL <sup>3</sup> database, accessed on 05 March 2018
Melting/ freezing point		217°C	Mackay <i>et al.</i> , 2006
Boiling point		480°C	Mackay <i>et al.</i> , 2006
Vapour pressure	Reported vapour pressure values are within the range of the two indicated values.	Range of reported Vp values  1.28x10 <sup>-8</sup> Pa at 20°C  6.7x10 <sup>-5</sup> Pa at 20°C  Selection of Vp value  1.3x10 <sup>-7</sup> Pa at 25°C (Extrapolated, Antoine eq.)*	Mackay <i>et al.</i> , 2006
Water solubility	Reported water solubility values are within the range of the two indicated values.	Range of reported Ws values  0.8 µg/L at 25°C (Generator column-HPCL/UV)  1.1 µg/L at 25°C (Generator column-HPLC/fluorescence)  Selected Ws value  0.2 mg/L at 25°C (column method)*	Mackay <i>et al.</i> , 2006
Partition coefficient n- octanol/water (Log value)	A range of LogKow values are reported in Mackay et al. (2006). Temperatures are not reported.	Range of reported LogKow values 5.94 (Shake flask/slow stirring) 7.2 (HPLC/fluorescence) Selected Log Kow value 6.11 (temp not reported)*	Mackay <i>et al.</i> , 2006

<sup>\*</sup>This reported value was selected in the Support document for identification of CTPHT as SVHC (ECHA, 2009)

<sup>&</sup>lt;sup>2</sup> Substances of Unknown or Variable composition, Complex reaction products or Biological materials

<sup>&</sup>lt;sup>3</sup> Gemeinsamer Stoffdatenpool Bund/Länder

## 2. Harmonised classification and labelling

Benzo[k]fluoranthene is covered by Index number 601-036-00-5 in part 3 of Annex VI to the CLP Regulation as follows:

Table 3: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index	International	EC No	CAS No	Classification		Labelling				Note
No	Chemical I dentification			Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram , Signal Word Code(s)	statement	Suppl. Hazard statement code(s)	Conc. Limits, M- factors	S
	Benzo[k]fluor anthene	205- 916-6	207-08- 9	Carc.1B Aquatic Acute 1 Aquatic chronic 1	H350 H400 H410		H350 H410	GHS08 GHS09 Dgr		

## 3. Environmental fate properties

#### 3.1 Degradation

The data provided on degradation of BkFA 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).

BkFA has five aromatic rings and a reported vapour pressure of  $1.3 \times 10^{-7}$  Pa at 25° C. Therefore, it is considered that BkFA is mainly particle-associated and is degraded by photolysis instead of oxidation.

#### 3.1.1.3 Phototransformation/photolysis

#### 3.1.1.3.1 Phototransformation in air

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

Photolysis in the troposphere results in the formation of reactive hydroxyl and nitrate (NO3) radicals and ozone (O3), which reacts as oxidizing agent with organic compounds, like PAHs. These radical and ozone reactions comprise mainly degradation of gas-phase PAHs (Calvert et al., 2002). Particle-associated PAHs are expected to degrade in air predominantly via direct photolysis by light with a wavelength < 290 nm (Kamens et al., 1988), although reaction with ozone will also occur (Peters and Seifert, 1980; Grosjean et al., 1983; Pitts et al., 1986; Coutant et al., 1988).

As stated earlier, BkFA is mainly particle-associated. The degradation rate of PAHs, and therefore of BkFA, depends on the type of particle to which they are bound (Behymer & Hites, 1988, cited in The Netherlands, 2008). Data are not available for BkFA, but for another mainly particle-associated PAH, namely Chrysene, the representative lifetime was determined between 10 hours and 7.8 days under natural conditions (European Commission, 2008).

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.

#### 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 normally takes place only in the upper few centimetres of the water-column and is therefore not considered to have significant impact on the overall persistency of PAHs in the aquatic environment.

#### 3.1.1.3.3 Phototransformation in soil

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

#### 3.1.1.4 Summary on abiotic degradation

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

Moreover, it was concluded that *in the atmosphere, free PAHs degrade within minutes to hours by direct photolysis.* BkFA is however mostly particle-associated in the atmosphere. Depending on the type of associated particle, the lifetime of BkFA can differ. For another

mainly particle-associated PAH, namely chrysene, the lifetime was determined between 10 hours and 7.8 days (European Commission, 2008).

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.

#### 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 PAHs according to their persistence in water, soil and sediment in different classes which correspond to a specific half-live in these compartments. The calculated half-lives of BkFA in water are in the range of 42 to 125 days and for sediment longer than 1250 days.

#### 3.1.2.2 Biodegradation in water and sediment

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

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

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

#### 3.1.2.3 Biodegradation in soil

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

Biodegradation rates of PAHs in soil depend on several factors related to the soil type, including pH, moisture content, nutrients, oxygen, and the diversity of the soil microbial population. Various species (bacteria, fungi, yeasts and algae) are known to degrade PAHs in soil (The Netherlands, 2008). It has been shown that the number of PAH-degrading microorganisms and the degradation capacity is higher in PAH-contaminated soils than in pristine soils, something explained by the development of an adapted soil microbial community.

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

On the basis of a comparison between two studies (Wild et al., 1991 and Wild and Jones, 1993) it was illustrated that the half-lives observed under laboratory conditions can be much shorter than those obtained from long-term field studies. This was attributed by the authors to the more optimal conditions (temperature, moisture content, nutrient and oxygen supply) applied in the laboratory tests.

They determined a dissipation half-life for BkFA in the range of 143 to 359 days in laboratory soil microcosms and under field conditions a half-life of 8.7 years. Wild et al. (1991) summarized, that biodegradation is the key process in PAH losses from these soils. The laboratory study done by Wild and Jones (1993) was conducted at a temperature range between 20 and 30°C. The field study Wild et al. (1991) was conducted at Luddington and Lee Valley, in the UK.

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

"'Aging' is a phenomenon associated with increased residence time of PAHs in soil, which can further decrease the bioavailability of PAHs in the terrestrial environment. Freshly spiked PAHs are more readily desorbed and thus more bioavailable than PAHs that have been in soil or sediment for a longer period of time (The Netherlands, 2008). This means that studies involving artificially added PAHs (e.g. 14C-labelled) often result in biodegradation rates much higher than rates observed for the same substances present in soil as part of a contamination by coal tar."

#### 3.1.2.4 Summary and discussion on biodegradation

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

For water degradation, Mackay *et al.* (1992) predicted long elimination half-lives between 42 and 125 days. BkFA consists of 5 aromatic rings and therefore standard tests for biodegradation in water could confirm slow biodegradation of BkFA. However, no conclusion is drawn on the biodegradability in water (European Commission, 2008).

Biodegradation studies in laboratory soil microcosms show dissipation half-lives up to 359 days (Wild and Jones, 1993). Biodegradation studies on soil done by Wild *et al.* (1991) revealed a half-life of more than 8.7 years for BkFA under field conditions. These values correspond to the estimated data by Mackay *et al.* (1992).

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

#### 3.1.3 Summary and discussion of degradation

In the atmosphere, BkFA is mostly particle-associated. The degradation rate depends on the type of particle to which it is bound. The expected lifetime is in the range of several hours to several days (European Commission, 2008).

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

The predicted half-lives range between 42 and 125 days for water degradation and half-lives higher than 1250 days for sediment.

Wild and Jones (1993) reported a dissipation half-live for BkFA up to 359 days in a laboratory soil microcosm study. For assessing the degradation of BkFA, half-lives obtained under realistic conditions, such as field conditions, are given higher weight. Under field conditions Wild *et al.* (1991) demonstrated a half-life of more than 8.7 years in soil for BkFA.

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

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

#### 3.2 Environmental distribution

#### 3.2.1 Adsorption/desorption

In the Support Document for identification of CTPHT as SVHC (ECHA, 2009) the adsorption properties of PAHs are described as follows:

"A linear relationship between Kow and the organic carbon-water partitioning coefficient Koc has been demonstrated for PAHs in sediments and soil. The Log Kow 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)."

BkFA has a Log Kow value of 6.11. It is therefore concluded that BkFA has a high potential to adsorb to particles in the environment.

#### 3.2.2 Volatilisation

BkFA has a vapour pressure of  $1.3 \times 10^{-7}$  Pa at 25 °C (Mackay *et al.*, 2006). It is therefore expected that BkFA will volatilise very slowly.

Moreover, in the Annex XV Transitional Dossier on CTPHT it is concluded that under field conditions, volatilisation of predominantly particle-bound PAHs is insignificant (The Netherlands, 2008).

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

#### 3.2.3 Distribution modelling

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

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

Distribution to:	Mass amount (percent)
Air	0.0431
Water	2.47
Soil	37.7
Sediment	59.8

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

#### 3.2.4 Summary and discussion of environmental distribution

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

#### 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)

The data provided on bioaccumulation of BkFA in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) are limited to one study in *Daphnia magna*.

The bioaccumulation potential of BkFA was assessed in the EU Risk Assessment report on CTPHT (European Commission, 2008). Bioaccumulation in *Daphnia magna* has been studied by Newsted & Giesy (1987). The study by Newsted and Giesy (1987) is based on a single 24 hour exposure, resulting in equilibrium partitioning of BkFA between the organism and water. In the study by Newsted & Giesy (1987) the BCF was determined at steady state in a static system. A BCF value of 13 225 L/kg was determined in this study.

Table 5: Experimentally obtained BCF value for BkFA

Species	BCF	Temp.	Test	Calculatio	R <sup>c)</sup>	Reference
			type <sup>a)</sup>	n <sup>b)</sup>		
D. magna	13 225 L/kg	Not reported	SR	Equi	2	Newsted & Giesy, 1987

- a) Static renewal
- b) Equi: equilibrium
- c) Reliability score taken from Verbruggen and van Herwijnen (2011): 2 reliable with restrictions

In the study by Newsted & Giesy (1987) the BCF was determined for a range of PAHs with resulting BCFs above 2 000 for several PAHs, including BkFA.

For BkFA no experimental fish data were available in the Support Document for identification of CTPHT as SVHC (ECHA, 2009). Experimental data from studies on other aquatic organisms, i.e. crustaceans, were considered relevant for BkFA and other PAHs for which no studies were available with fish or molluscs.

# 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 value for BkFA in *Eisenia andrei* of 15 000 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

Limited data on the bioaccumulation potential of BkFA are available in the EU RAR on CTPHT (EC, 2008) and in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

It was already concluded in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) that the study by Newsted & Giesy (1987) can be considered as a key study for several PAHs, including BkFA as the most reliable equilibrium study with BCF > 2000.

The obtained BCF value for *Daphnia magna* (Newsted & Giesy, 1987) was 13 225 L/kg for BkFA.

Thus, BkFA has a high bioaccumulation potential at lower trophic levels, which could contribute to a constant high exposure of BkFA to predators for which the effects are unpredictable due to the absence of sufficient data.

Therefore, it is concluded that BkFA 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

Information on hazard to human health relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (c) of the REACH Regulation is provided in Section 2 of this report (see harmonised classification and labelling of BkFA in Section 2 as Carc. 1B, H350).

#### 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.

#### 5.1.1 Fish

#### 5.1.1.1 Short-term toxicity to fish

No data available.

#### 5.1.1.2 Long-term toxicity to fish

The EU Risk Assessment Report on CTPHT (European Commission, 2008) summarises the following on environmental hazard assessment for the aquatic compartment:

In two studies, the effects of benzo[k]fluoranthene in an ELS test with Brachydanio rerio was examined. In the first 28-d study one concentration of 0.58  $\mu$ g/l was tested. At this concentration 52% mortality occurred (Hooftman & Evers-de Ruiter, 1992). In a second 42-d study a dose-response relationship was examined. The mentioned concentrations here are based on measured concentrations per concentration and not on average recovery times the nominal concentration as given in the report. The LC<sub>50</sub> estimated from the presented data with a log-logistic relationship was 0.65  $\mu$ g/l. From the data for weight and length, EC<sub>10</sub> values are derived of 0.31 and 0.17  $\mu$ g/l. Due to the good fit of the log-logistic equation, these estimates have a low uncertainty. No data for marine species are available.

In the Support document for the identification of CTPHT as SVHC (ECHA, 2009) it is indicated that an early life stage study performed with Brachydanio rerio revealed length as the most sensitive endpoint, with an  $EC_{10}$  value of 0.17  $\mu$ g/l (Hooftman & Evers-de Ruiter, 1992). Due to the good fit of the log-logistic equation, this EC10 estimate has a low uncertainty. The study was chosen as the key study for T-assessment.

#### 5.1.2 Aquatic invertebrates

#### 5.1.2.1 Short-term toxicity to aquatic invertebrates

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

Acute toxicity data for benzo[k]fluoranthene are only available for Daphnia magna.

However, in the two available studies (Bisson et al., 2000; Verrhiest et al., 2001) no effects were observed. However, due to the low solubility of benzo[k]fluoranthene of about 0.8 µg/l (Pubchem), acute effects are not anticipated.

#### 5.1.2.2 Long-term toxicity to aquatic invertebrates

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

In the 7-d reproduction study with Ceriodaphnia dubia no effects were observed (Bisson et al., 2000).

#### 5.1.3 Algae and aquatic plants

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

For algae no  $EC_{50}$  is presented. However, in the 72-h study with Pseudokirchneriella subcapitata the  $EC_{10}$  for growth is larger than 1  $\mu$ g/l (Bisson et al., 2000) and hence the  $EC_{50}$  must also be higher than this value.

# 5.2 Summary and discussion of the environmental hazard assessment

The environmental hazard assessment for BkFA was previously done for the identification of CTPHT as SVHC (ECHA, 2009). It is reported that an early life stage study performed with Brachydanio rerio revealed length as the most sensitive endpoint, with an EC10 value of 0.17  $\mu$ g/l (Hooftman & Evers-de Ruiter, 1992). Due to the good fit of the log-logistic equation, this EC<sub>10</sub> estimate has a low uncertainty. The study was chosen as the key study for T-assessment.

## 6. Conclusions on the SVHC Properties

#### 6.1 CMR assessment

Benzo[k]fluoranthene is listed by index number 601-036-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, BkFA meets the criteria of REACH Article 57 (a).

#### 6.2 PBT and vPvB assessment

#### 6.2.1 Assessment of PBT/vPvB properties

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

#### 6.2.1.1 Persistence

BkFA 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 BkFA of more than 8.7 years of BkFA under field conditions. Additionally, biodegradation studies in laboratory soil microcosms showed dissipation half-lives up to 359 days (Wild and Jones, 1993).

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

#### 6.2.1.2 Bioaccumulation

An experimentally obtained BCF value above 5 000 is reported for BkFA in *Daphnia magna*. In accordance to Annex XIII of the REACH Regulation, the B and vB criteria are fulfilled for BkFA.

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  $EC_{10}$  (length) value observed for *Brachydanio rerio* was 0.17  $\mu$ g/L (42 day Early Life Stage (ELS) study). Therefore, the T criterion according to REACH Annex XIII 1.1.3 (a) is fulfilled for BkFA. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

In addition, BkFA is classified in the hazard class Carc. category 1B according to CLP Regulation (EU) No 1272/2008. Thus, the T criterion of REACH according to Annex XIII section 1.1.3 (b) is also fulfilled.

#### 6.2.2 Summary and overall conclusions on the PBT and vPvB properties

#### Art 57 (d) and (e):

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

#### <u>Persistence</u>

In the atmosphere, BkFA is mostly particle-associated. The degradation rate depends on the type of particle to which it is bound. The expected lifetime is in the range of several hours to several days (European Commission, 2008).

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

Mackay *et al.* (1992) predicted that BkFA persists in sediment with half-lives higher than 1250 days. For water degradation, Mackay *et al.* (1992) predicted long elimination half-

lives between 42 and 125 days. BkFA consists of 5 aromatic rings and it is expected that standard tests for biodegradation in water would show slow biodegradation of BkFA in water.

Wild and Jones (1993) reported a dissipation half-live for BkFA up to 359 days in a laboratory soil microcosm study. For assessing the degradation of BkFA, half-lives obtained under realistic conditions, such as field conditions, are given higher weight. Under field conditions Wild *et al.* (1991) demonstrated a half-life of more than 8.7 years in soil for BkFA. These values correspond to the estimated data by Mackay *et al.* (1992).

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

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

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

#### Bioaccumulation

Limited data on the bioaccumulation potential of BkFA were reported in the EU Risk Assessment Report on CTPHT (European Commission, 2008) and in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

It was already concluded in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) that the study by Newsted & Giesy (1987) can be considered as a key study for several PAHs, including BkFA as the most reliable equilibrium study with BCF > 2000 L/kg.

The obtained BCF value for *Daphnia magna* (Newsted & Giesy, 1987) was 13 225 L/kg for BkFA.

Thus, BkFA has a high bioaccumulation potential at lower trophic levels, which could contribute to a constant high exposure of BkFA to predators for which the effects are unpredictable due to the absence of sufficient data.

It is concluded that BkFA is a bioaccumulative and very bioaccumulative substance.

BkFA meets the criteria for B and vB, in accordance to Annex XIII of REACH since the experimentally obtained BCF value for *Daphnia magna* was above 5 000 L/kg. This conclusion was already drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

#### **Toxicity**

In two long-term fish studies, the effect of BkFA was examined. In a 7-day reproduction study in aquatic invertebrates, no effects were observed and in a 72-h algae study, an EC  $_{10}$  growth  $> 1~\mu g/L$  was determined.

A 42-day Early Life Stage study with *Brachydanio rerio* by Hooftman & Evers-de Ruiter (1992) was given the highest weight. It provided an  $EC_{10}$  value (weight) of 0.31  $\mu$ g/L and an  $EC_{10}$  value (length) of 0.17  $\mu$ g/L. Length was the most sensitive endpoint.

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

In addition, BkFA is classified in the hazard class Carc. category 1B according to EU Regulation 1272/2008. Thus, the T criterion according to Annex XIII 1.1.3 (b) of REACH is also fulfilled.

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

#### Overall conclusion

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

#### Part II

### 7. Registration and C&L notification status

#### 7.1 Registration status

Benzo[k]fluoranthene is not produced intentionally and is not registered as such in the scope of the REACH regulation.

#### 7.2 CLP notification status

Table 6: CLP notifications

	CLP Notifications <sup>4</sup>
Number of aggregated notifications	2
Total number of notifiers	371

### 8. Total tonnage of the substance

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

#### 9. Information on uses of the substance

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

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

## 10. Information on structure of the supply chain

The structure of the supply chain and downstream users is difficult to oversee. However, the knowledge of uses decreases with the increase in the level of downstream uses.

<sup>&</sup>lt;sup>4</sup> C&L Inventory database, <a href="http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database">http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database</a> (accessed 05 March 2018)

#### 11. Additional information

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

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

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

#### 11.2 Alternatives

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

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

#### 11.3 Existing EU legislation

BkFA has a harmonised classification as Carc. 1B (Regulation (EC) No 1272/2008, Annex VI, Table 3.1).

BkFA is restricted by entry 50 of Annex XVII of the REACH Regulation. Therefore, extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain more than 10 mg/kg (0.001% by weight) of the sum of following PAHs: Benz(a)pyrene (CAS 50-32-8, Benzo(e)pyrene (CAS 192-97-2), Benzo(a)anthracene (CAS 56-55-3), Chrysene (CAS 218-01-9), Benzo(b)fluoranthene (CAS 205-99-2), Benzo(j)fluoranthene (CAS 205-82-3), Benz[k]fluoranthene (CAS 207-08-9) and Dibenzo(a,h)anthracene (CAS 53-70-3).

Further, articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1mg/kg BkFA (0.0001% by weight of this component).

For toys the same applies but the limit of BkFA content is 0.5 mg/kg (0.00005% by weight of this component).

BkFA is listed in Annex II of EU Regulation 1223/2009 as a substance, which is prohibited in cosmetic products.

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

#### 11.4 Previous assessments by other authorities

BkFA belongs to the substance group of PAHs of which many are well-known to be hazardous for human health and the environment. Eight PAHs, including BkFA which is carcinogenic, are already classified as CMR substances. Until now, several Annex XV dossiers for the identification of PAHs as substances of very high concern were explicitly based on their intrinsic properties (anthracene, B[a]P, chrysene and benz(a)anthracene) or of their PAH constituents (Anthracene Oils, CTPHT).

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

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