EUROPEAN CHEMICALS AGENCY

Substance Name: Benzo[k]fluoranthene

EC Number: 205-916-6

CAS Number: 207-08-9

MEMBER STATE COMMITTEE

SUPPORT DOCUMENT FOR IDENTIFICATION OF

BENZO[K]FLUORANTHENE

AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS CARCINOGENIC (ARTICLE 57A), PBT[1] (ARTICLE 57D), vPvB[2] (ARTICLE 57E) PROPERTIES

Adopted on 12 December 2018

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[1] PBT means persistent, bioaccumulative and toxic

[2] vPvB means very persistent and very bioaccumulative

CONTENT

TABLES

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 for SVHC identification of 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.

Therefore, the SVHC identification of benzo[k]fluoranthene in this 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 the identification of CTPHT as SVHC (ECHA, 2009), and was further supplemented with information from newer studies that are presented as further evidence as they do not trigger a need to modify the conclusions taken by authorities earlier on.

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 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[3].
- 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

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 Regulation.

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

An assessment of the PBT and vPvB properties in the present dossier and the conclusion that benzo[k]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[4]) and supplemented with information from newer studies that are presented as further evidence in a weight of evidence approach. The newly available information however does 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 benzo[k]fluoranthene degrades very

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[3] Classification in accordance with section 3 of Annex I to Regulation (EC) No 1272/2008.

[4] 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

slowly in soil with half-life > 180 days. Study performed under field conditions demonstrated a half-life of more than 8.7 years in soil.

It is also assumed that benzo[k]fluoranthene meets the P and vP criterion in sediment, as in the available simulation study with phenanthrene the obtained 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 (K_{ow}), the half-life of benzo[k]fluoranthene will meet the P and vP criterion in sediment as well.

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

Bioaccumulation

Limited data on the bioaccumulation potential of benzo[k]fluoranthene were reported in the EU Risk Assessment Report on CTPHT (European Commission, 2008[5]) and in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

The obtained BCF value for *Daphnia magna* was 13 225 L/kg for benzo[k]fluoranthene.

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

Benzo[k]fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH Regulation since the experimentally obtained BCF value for *Daphnia magna* was above 5 000 L/kg.

Toxicity

A 42-day Early Life Stage study with *Brachydanio rerio* was given the highest weight. It provided an EC_{10} value (weight) of 0.31 µg/L and an EC_{10} value (length) of 0.17 µg/L. Length was the most sensitive endpoint.

Thus, benzo[k]fluoranthene fulfils the T criterion according to Annex XIII 1.1.3 (a) of REACH Regulation.

In addition, benzo[k]fluoranthene is classified in the hazard class Carcinogenic, category 1B according to Regulation (EC) 1272/2008[6]. Thus, the T-criterion according to Annex XIII 1.1.3 (b) of REACH Regulation is also fulfilled.

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

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[5] European Commission (2008): European Union Risk Assessment Report, Coal Tar Pitch High Temperature, CAS No: 65996-93-2, EINECS No: 266-028-2.

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Justification

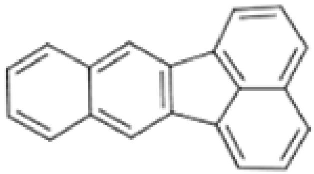
1. Identity of the substance and physical and chemical properties

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.$0^{2,11}$.$0^{4,9}$.$0^{16,20}$]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:	$C_{20}H_{12}$
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 belongs to a group of Polycyclic Aromatic Hydrocarbons (PAHs). Benzo[k]fluoranthene is not produced, as such. However, it may occur as a constituent in UVCB[7]-substances that are derived from coal or in petroleum streams. The dossier addresses the substance as itself.

Substance type: mono-constituent

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[7] Substances of Unknown or Variable composition, Complex reaction products or Biological materials

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[8] database, accessed on 05 March 2018
Melting/ freezing point		*217°C*	Mackay *et al.*, 2006
Boiling point		*480°C*	Mackay *et al.*, 2006
Vapour pressure	Reported vapour pressure values are within the range of the two indicated values.	*Range of reported Vp values* *$1.28x10^{-8}$ Pa at 20°C* *$6.7x10^{-5}$ Pa at 20°C* *Selection of Vp value* $1.3x10^{-7}$ Pa at 25°C (Extrapolated, Antoine eq.)*	Mackay *et al.*, 2006
Water solubility	Reported water solubility values are within the range of the two indicated values.	*Range of reported Ws values* *0.8 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 *et al.*, 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 *et al.*, 2006

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

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[8] 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 No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
601-036-00-5	Benzo[*k*]fluoranthene	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 benzo[k]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).

Benzo[k]fluoranthene has five aromatic rings and a reported vapour pressure of 1.3×10^{-7} Pa at 25° C. Therefore, it is considered that benzo[k]fluoranthene 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, benzo[k]fluoranthene is mainly particle-associated. The degradation rate of PAHs, and therefore of benzo[k]fluoranthene, depends on the type of particle to which they are bound (Behymer & Hites, 1988, cited in The Netherlands, 2008). Data are not available for benzo[k]fluoranthene, 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.*

Being a highly conjugated system it is not unusual (if not to say expected) that benzo[k]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.*

3.1.1.4 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.* Benzo[k]fluoranthene is however mostly particle-associated in the atmosphere. Depending on the type of associated particle, the lifetime of benzo[k]fluoranthene 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 benzo[k]fluoranthene 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

Benzo[k]fluoranthene was shown to biodegrade under aerobic conditions in water than PAHs containing up to four aromatic rings. Furthermore, degradation in aquatic anaerobic sediments is expected to be very slow, as assessed before 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.*

During the public consultation, references of three studies related to the degradation of benzo[k]fluoranthene in water were provided (Birch et al., 2018; Concawe, 2012; Martin et al., 2017). 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 benzo[k]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 testing, as benzo[k]fluoranthene was not tested, the information has not been further considered in the current assessment.

At present benzo[k]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 Netherlands, 2008), it can be assumed that benzo[k]fluoranthene will also meet 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.

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

"'Aging' is a phenomenon associated with increased residence time of PAHs in soil, which can further decrease the bioavailability of PAHs in the terrestrial environment. Freshly spiked PAHs are more readily desorbed and thus more bioavailable than PAHs that have been in soil or sediment for a longer period of time (The Netherlands, 2008). This means that studies involving artificially added PAHs (e.g. ^{14}C-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." Harmsen and Rietra (2018) also showed that the rapidly desorbed fraction of pyrene might degrade, whereas the slowly desorbed fraction is more persistent.

Wild and Jones (1993) and Wild et al. (1991) determined a dissipation half-life for benzo[k]fluoranthene 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 of Wild et al. (1991) was conducted at Luddington and Lee Valley, in the UK. When benzo[k]fluoranthene was spiked to soil the dissipation half-life was lower, i.e. 55 days. When this DT50 is converted to 12°C it will be higher than the P criterion.

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 benzo[k]fluoranthene. In agreement with MSC conclusions made within the CTPHT assessment, the SVHC dossier submitter evaluated the study Wild et al. (1991) as the most reliable evidence of persistency of CTPHT (thus also of benzo[k]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 PAHs measured and also of benzo[k]fluoranthene after 7.2 years and 22 years. The initial concentration of benzo[k]fluoranthene was 9 mg/kg, after 7.2 years, the remaining amount was estimated being 1.2 mg/kg and after 22 years, estimated of being 0.4 mg/kg. In other sediment from a harbour in Wemeldinge an initial concentration of benzo[k]fluoranthene of 2 mg/kg was estimated, after 7.2 years it remained 1.6 mg/kg and after 22 years 0.6 mg/kg. It is observed that degradation of benzo[k]fluoranthene may depend on the initial concentration and the certain fractions can remain for a long period of time in the environment. These data also reflected that benzo[k]fluoranthene 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 long elimination half-lives between 42 and 125 days. It is assumed that benzo[k]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 benzo[k]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 benzo[k]fluoranthene in sediments (half-life> 1250 days).

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

A study of Harmsen and Rietra (2018) suggests that degradation rates of benzo[k]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 benzo[k]fluoranthene half-life of more than 8.7 years under field conditions.

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

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

3.1.3 Summary and discussion of degradation

In the atmosphere, benzo[k]fluoranthene 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, benzo[k]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, benzo[k]fluoranthene is considered as hydrolytically stable.

Estimated half-lives for benzo[k]fluoranthene range between 42 and 125 days 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 benzo[k]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 Netherlands, 2008).

Wild and Jones (1993) reported a dissipation half-live for benzo[k]fluoranthene up to 359 days in a laboratory soil microcosm study when applied via sewage sludge. Under field conditions Wild *et al.* (1991) demonstrated a half-life of more than 8.7 years in soil for benzo[k]fluoranthene when applied via sewage sludge.

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

The available information allows to conclude that benzo[k]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 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)."

Benzo[k]fluoranthene has a Log Kow value of 6.11. It is therefore concluded that benzo[k]fluoranthene has a high potential to adsorb to particles in the environment.

3.2.2 Volatilisation

Benzo[k]fluoranthene has a vapour pressure of 1.3×10^{-7} Pa at 25 °C (Mackay *et al.*, 2006). It is therefore expected that benzo[k]fluoranthene 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 in March 2018 using EPI Suite (version 4.11) with default values of environmental emission rates (it is assumed that benzo[k]fluoranthene is released at equal rates to air, water, and soil) and default values of physicochemical properties.

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

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

The obtained results clearly indicate that benzo[k]fluoranthene mainly partitions to sediment and soil.

3.2.4 Summary and discussion of environmental distribution

Benzo[k]fluoranthene has a high potential to absorb to particles and volatilisation of benzo[k]fluoranthene is insignificant. Further fugacity modelling reveals that benzo[k]fluoranthene 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 benzo[k]fluoranthene in the Support Document for identification of CTPHT as SVHC (ECHA, 2009) are limited to one study in *Daphnia magna.*

The bioaccumulation potential of benzo[k]fluoranthene 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 benzo[k]fluoranthene 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 benzo[k]fluoranthene

Species	**BCF** L/kg	**Peer-reviewed BCFd)** **(L/Kg)**$^{d)}$	**Temp.**	**Test type**$^{a)}$	**Calculation** $^{b)}$	**R**$^{c)}$	**Peer-reviewed R**$^{d)}$	**Reference**
Fish:								
O. mykiss (juvenile)	199			FT	K1/K2			Lo et al. (2016)
C. auratus	2000					unknown		Ke et al., 2007
Crustacea								
D. magna	**13 225** $^{1)}$	**13 225**	**Not reported**	**SR**	**Equi**	**2**	**2**	**Newsted & Giesy, 1987**

a) Static renewal
b) Equi: equilibrium
c) Reliability score taken from Bleeker and Verbruggen (2009): 2 – reliable with restrictions
d) Peer reviewed by Bleeker & Verbruggen (2009)
1) 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 13%, which seems to be unrealistically high.

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 benzo[k]fluoranthene.

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 on the B/vB properties of benzo[k]fluoranthene. Hence, this substance fulfil B/vB criterion due to a BCF of 13 225 L/kg in D. magna (reliability 2).

During the public consultation experimental fish data became available (table 5). In the case of C. auratus BCF value of 2000 has been measured, which is very close to the cut-off value of B criterion. Nevertheless, experimental data from studies on other aquatic organisms, i.e. crustaceans, were considered relevant for benzo[k]fluoranthene and other PAHs for which no studies were available with fish or molluscs.

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 concentration 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, four studies examining TMF-values from various locations were referred to (Wan et al., 2007; Nfon, 2008; Takeuchi et al., 2009 and Wang et al., 2012). The presented TMF-values range from 0.27 to 0.91 g food/g bw. On the other hand TMF of 0.91 from Wang et al. (2012) is close to 1.

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 on PBT or vPvB indicates that the absence of a biomagnification potential cannot be used on its own to conclude that the B or vB criteria are not fulfilled.

It is noted that high BCFs in mussels have been reported for other PAHs, such as fluoranthene (BCF 4120-5920), pyrene (4430-77000) and benzo[a]pyrene (41000-142000) (ECHA, 2009). Therefore, despite the absence of measured bioaccumulation factors, mussels may be relevant target species for bioaccumulation of benzo[k]fluoranthene (Turja et al., (2013); Turja et al., (2014); Finish Environment Institute 2018 (open information)).

Taking into account that the vB-criterion (BCF > 5000 L/kg bw) is clearly met for crustacea, benzo[k]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 value for benzo[k]fluoranthene 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 benzo[k]fluoranthene 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 benzo[k]fluoranthene 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 benzo[k]fluoranthene.

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

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, that is sufficient 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.

Therefore, it is concluded that benzo[k]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

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 benzo[k]fluoranthene 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 µg/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_{50} *estimated from the presented data with a log-logistic relationship was 0.65 µg/l. From the data for weight and length,* EC_{10} *values are derived of 0.31 and 0.17 µg/l. Due to the good fit of the log-logistic equation, these estimates have a low uncertainty. No data for marine species are available.*

Table 6: Chronic toxicity data of benzo[k]fluoranthene in fish*:

Species	Test type	Exposure time	Criterion	Endpoint	Value [µg/L]	Reliability	Reference
Danio rerio	IF	42d	NOEC	Length, weight	< 0.58	2	Hooftman & Evers-de Ruiter, 1992b
Danio rerio	IF	42d	NOEC	Mortality	0.35	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	LC50	Mortality	0.65	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	LC10	Mortality	0.62	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	NOEC	Length	<0.19	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	EC50	Length	0.86	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	EC10	Length	0.17	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	NOEC	Weight	0.35	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	EC50	Weight	0.50	2	Hooftman & Evers-de Ruiter, 1992c
Danio rerio	IF	42d	EC10	Weight	0.31	2	Hooftman & Evers-de Ruiter, 1992c

* Verbruggen (2012)

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 µg/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. Due to the low solubility of benzo[k]fluoranthene of about 0.8 µg/l (Pubchem), acute effects are however not anticipated.

In the study by Verrhiest et al. (2001) also the effect of exposure to UV light was studied by placing the daphnids under UV-A (365 nm, 247 µW/cm2) for 2 hours., however this had no effect on the toxicity of benzo[k]fluoranthene (Verbruggen, 2012).

Verbruggen (2012) in his report indicated that an additional information is also available from one study performed with the marine bacterium species *Vibrio Fischeri* (Loibner et al., 2004) in which no effects were seen up to aqueous solubility of benzo[k]fluoranthene either.

5.1.2.2 Long-term toxicity to aquatic invertebrates

There is a number of reliable chronic studies with aquatic invertebrates available (Verbruggen, 2012):

Table 7: Chronic toxicity data of benzo[k]fluoranthene in aquatic invertebrates:

Species	Test type	Exposure time	Criterion	Endpoint	Value [µg/L]	Reliability	Reference
Crustacea							
Ceriodaphnia dubia	R	7 d	EC 10	reproduction	> 1.08	2	Bisson et al., 2000
Daphnia magna	R	21 d	NOEC	mortality, offspring intrinsic growth rate	≥2.2	2	AquaSense 2005
Daphnia magna	R	21 d	EC10	mortality, offspring intrinsic growth rate	>2.2	2	AquaSense 2005
Echinodermata							
Psammechinus miliaris	S	48 h	NOEC	larval development	≥ 2.6	2	AquaSense 2005
Psammechinus miliaris	S	48 h	EC10	larval development	> 2.6	2	AquaSense 2005
Mollusca							
Crassostrea gigas	S	48 h	NOEC	larval development	≥ 2.6	2	AquaSense 2005
Crassostrea gigas	S	48 h	EC10	larval development	> 2.6	2	AquaSense 2005

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 µg/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 benzo[k]fluoranthene 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 µg/l (Hooftman & Evers-de Ruiter, 1992). Due to the good fit of the log-logistic equation, this EC_{10} 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, benzo[k]fluoranthene 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) and was further supplemented with information from newer studies.

6.2.1.1 Persistence

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

A study of Harmsen and Rietra (2018) suggests that degradation rates of benzo[k]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 benzo[k]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 benzo[k]fluoranthene meets 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 (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 benzo[k]fluoranthene in soil and sediment.

6.2.1.2 Bioaccumulation

An experimentally obtained BCF value above 5 000 is reported for benzo[k]fluoranthene in *Daphnia magna*. In accordance to Annex XIII of the REACH Regulation, the B and vB criteria are fulfilled for benzo[k]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 EC_{10} (length) value observed for *Brachydanio rerio* was 0.17 µg/L (42 day Early Life Stage (ELS) study). Therefore, the T criterion according to REACH Annex XIII 1.1.3 (a) is fulfilled for benzo[k]fluoranthene. This conclusion was already drawn by the MSC in the context of the identification of CTPHT as SVHC (ECHA, 2009).

In addition, benzo[k]fluoranthene is classified in the hazard class Carcinogenic, category 1B according to CLP Regulation (EC) 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

An assessment of the PBT and vPvB properties in the present dossier and the conclusion that benzo[k]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[9]) 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 benzo[k]fluoranthene degrades very slowly in soil with half-life > 180 days. Study performed under field conditions demonstrated a half-life of more than 8.7 years in soil.

It is also assumed that benzo[k]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 benzo[k]fluoranthene will meet the P and vP criterion in sediment as well.

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

Bioaccumulation
Limited data on the bioaccumulation potential of benzo[k]fluoranthene 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).

The obtained BCF value for *Daphnia magna* was 13 225 L/kg for benzo[k]fluoranthene.

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[9] 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

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

Benzo[k]fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH Regulation since the experimentally obtained BCF value for *Daphnia magna* was above 5 000 L/kg.

Toxicity

A 42-day Early Life Stage study with *Brachydanio rerio* was given the highest weight. It provided an EC_{10} value (weight) of 0.31 µg/L and an EC_{10} value (length) of 0.17 µg/L. Length was the most sensitive endpoint.

Therefore, benzo[k]fluoranthene fulfils the T-criterion according to Annex XIII 1.1.3 (a) of REACH Regulation.

In addition, benzo[k]fluoranthene is classified in the hazard class Carcinogenic, category 1B according to Regulation (EC) 1272/2008. Thus, the T-criterion according to Annex XIII 1.1.3 (b) of REACH Regulation is also fulfilled.

Overall conclusion

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

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