

Member State Committee (MSC)

Opinion

on persistency and bioaccumulation of

Octamethylcyclotetrasiloxane (D4)

EC Number: 209-136-7

CAS Number: 556-67-2

and

Decamethylcyclopentasiloxane (D5)

EC Number: 208-764-9

CAS Number: 541-02-6

according to a MSC mandate¹

Adopted on 22 April 2015

¹Annex 1: Request to the Member State Committee for an opinion on the persistence and bioaccumulation of the substances D4 and D5 against the criteria in Annex XIII of REACH; I(2014)0295 of 14 October 2014

OPINION OF THE MEMBER STATE COMMITTEE
ON PERSISTENCY AND BIOACCUMULATION
OF OCTAMETHYLCYCLOTETRASILOXANE (D4)
AND DECAMETHYLCYCLOPENTASILOXANE (D5)

At the request of the Executive Director of ECHA, pursuant to Article 77(3)(c) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), the Member State Committee (MSC) has adopted an opinion on persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5).

I PROCESS FOR ADOPTION OF THE OPINION

In his letter of 14 October 2014, attached as Annex 1, ECHA's Executive Director (ED) asked MSC to draw up an opinion on whether the relevant properties of D4 and D5 meet the criteria in Annex XIII of REACH for being persistent or very persistent or bioaccumulative or very bioaccumulative, based on the information prepared by the Member State Competent Authority of the United Kingdom (UK CA) and submitted to ECHA on the 1st of October 2014, and the comments and responses which were received in the 45-day public consultation. MSC is to submit its opinion to the Risk Assessment Committee (RAC) and its Rapporteurs for RAC's deliberations on the Restriction proposal for D4 and D5.

The request followed the indication from the UK-CA through an entry on the Registry of Intentions that they will submit in April 2015 a proposal to restrict the substances Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5) from being placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products which are washed off in normal use conditions (<http://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance/6318/search/+term>).

The request from ECHA's ED is not a request for identification of these substances as substances of very high concern (SVHC) and therefore this opinion of MSC will not lead to the Candidate List listing of these substances.

On 1 October 2014, the UK-CA submitted to ECHA the relevant parts of their Annex XV restriction report related to the PBT/vPvB properties of D4 and D5.

A public call for evidence on documents submitted by the UK CA was launched on 15 October 2014 on ECHA website. Parties concerned and MSCAs were invited to submit comments and contributions by 29 November 2014.

Following the public call for evidence, the compiled comments and contributions were sent to the UK CA for consideration and response in response to comment documents and, where relevant, in the updated updated PBT reports that have been used as a basis for this opinion development.

Following the receipt of the ED's request, MSC agreed on Terms of reference for the MSC rapporteur and on the indicative timeframe for the development of this opinion. Based on the mandate received by MSC at the MSC-38 plenary meeting, on 7 November 2014, the MSC Chairman appointed a volunteering member as Rapporteur for the opinion preparation on D4 and D5.

II ADOPTION OF THE OPINION OF THE MSC

Rapporteur, appointed by MSC: **Jan Wijmenga**

The MSC opinion was adopted on 22 April 2015.

The MSC opinion was adopted by consensus.

III OPINION OF MSC

MSC has formulated its opinion on:

- a) whether the information provided in the UK-CA's report on the identification of PBT and vPvB substances, is sufficient and adequate to develop an opinion of a similar robustness to an SVHC agreement,
- b) whether the information provided, taking into account the comments received in the call for information and responses to them, shows that the substances fulfil the criteria of Annex XIII of REACH for a Persistent and Bioaccumulative (PBT) and/or very Persistent and very Bioaccumulative (vPvB) substances.

After examination of the information provided by the UK-CA and the comments related to the persistence and bioaccumulation of D4 and D5 raised during the call for evidence, MSC agreed that a scientifically robust conclusion can be drawn, similar to an SVHC agreement. The available information shows that the substances D4 and D5 meet the criteria for vB and for vP as defined in the REACH Regulation (EC) No 1907/2006.

IV SCIENTIFIC GROUNDS FOR THE OPINION

IV.1 Summary of the Dossier submitter's proposal

IV.1.1 Octamethylcyclotetrasiloxane (D4)

The dossier submitter (DS, UK Competent Authority) proposed that D4 meets the REACH Annex XIII criteria for both a PBT and vPvB substance. D4 is registered under REACH. The MSC mandate only includes assessing the bioaccumulation and persistence criteria, hence the findings of the DS with regard to the toxicity part of the PBT/vPvB assessment will not be reflected here.

Persistence

D4 is poorly soluble in water, volatile and also adsorbs strongly to soil and sediment. D4 is not readily biodegradable. Although it can hydrolyse in pure water with a relatively short half-life (e.g. 16.7 days at pH 7 and 12 °C), it is highly adsorptive to organic matter in suspended solids, sediment and soils, and this adsorption may limit the rate of hydrolysis in natural waters. A conclusion about overall persistence in natural waters cannot be drawn in the absence of definitive data. The available data do not allow a reliable soil degradation half-life to be derived.

Based on OECD TG 308 sediment simulation studies (Xu, 2009a & 2009b), D4 has an estimated degradation half-life of 365 days in anaerobic sediment and 242

days in aerobic sediment at 24 °C, expected to be longer at lower environmental temperatures. Persistence in sediment is also supported by sediment core data from Lake Pepin, USA (Powell, 2009 & 2010).

The DS concluded that D4 meets the Annex XIII criteria for a very persistent (vP) substance in sediment which is in agreement with the registrants own conclusions (updated submission of 14 October 2014).

Bioaccumulation

Several reliable studies have been performed that indicate that D4 meets the criteria for very bioaccumulative (vB) substances:

- A steady-state BCF of 12,400 L/kg based on total ¹⁴C measurements was measured for Fathead Minnow *Pimephales promelas* (Fackler *et al.*, 1995).
- A steady state BCF was reported for Common Carp *Cyprinus carpio* in the range of 3,000 – 4,000 L/kg (based on parent compound analysis) (CERI, 2007 and 2010a). The kinetic BCF in one of the studies was in the range 4,100 - 5,500 L/kg (without growth correction; it is higher if growth is taken into account).
- Whole body concentrations achieved during laboratory bioconcentration studies were up to around 2.6 mg/kg ww for Fathead Minnow *P. promelas* (Fackler *et al.*, 1995) and 10 mg/kg ww for Common Carp *C. carpio* (CERI, 2007). Higher concentrations have been observed in feeding studies, i.e. 100 mg/kg ww (not including liver) immediately after 35 days of uptake in *P. promelas* (Dow Corning, 2007) and 27.4 mg/kg ww after 13 days of uptake in *C. carpio* (CERI, 2011). The analysis shows that D4 can achieve whole fish concentrations similar to a range of substances that are widely accepted as being very bioaccumulative (e.g. UV-328 and UV-320, long chain perfluorocarboxylic acids, musk xylene, hexaBDE and HBCDD).

Fish dietary bioaccumulation studies are available that permit calculating a biomagnification factor (BMF):

- A dietary BMF between 0.47- 4.6 was measured in Rainbow Trout *Oncorhynchus mykiss* (Dow Corning, 2007). The growth-corrected depuration rate constant calculated from this study was 0.00659 day⁻¹.
- A growth-corrected and lipid-normalised BMF of 0.51 and 0.7 has been measured in *C. carpio* (CERI, 2011). The growth-corrected depuration rate constant calculated from this study was ~0.058 day⁻¹.

The rate of depuration seen in the feeding studies is consistent with the BCF for D4 being >5,000 L/kg (EA, 2012). A BMF (growth-corrected and lipid-normalised) above 0.31 corresponds to a BCF (lipid normalised) over 5,000 L/kg, based on the regression by Inoue *et al.* (2012).

Several field studies are available. The DS considers that different conclusions can be drawn from some studies depending on the food chain configuration that is assumed. Most field studies typically show that trophic magnification is not occurring in aquatic food webs. However, BSAF values above one have been measured for benthic invertebrates and fish in both laboratory and field studies, and BMFs above one have been measured for some fish feeding relationships in field studies.

There is also unequivocal evidence that D4 can be found in a wide range of organisms (particularly fish and aquatic invertebrates but also birds and mammals) throughout aquatic food chains, including top predatory fish such as

Lake Trout and Cod, as well as Grey Seal *Halichoerus grypus*. Concentrations are generally relatively low, but have been reported to be up to 900 µg/kg wet weight for some wild fish species at locations with significant local sources. This is within an order of magnitude of contamination levels of other substances (HBCDD and pentaBDE) that are considered to meet the vB criteria (and maximum concentrations achieved in fish bioconcentration tests are similar to a range of substances that are considered to meet the vB criterion).

D4 is present in biota in remote regions, including fish (e.g. Atlantic Cod *Gadus morhua* and Polar Cod *Boreogadus saida*) and birds (e.g. Black-legged Kittiwake *Rissa tridactyla* and Glaucous Gull *Larus hyperboreus*) in the European Arctic (Campbell, 2010). The levels are generally low (often close to the limit of detection, and frequently not detectable) but higher levels (up to 9.2 µg/kg wet weight in cod liver and 6.5 µg/kg wet weight in Glaucous Gull liver) have also been reported. Although some of the high levels might be linked to local sources (i.e. WWTP discharge points), D4 is detectable in some of the samples from more remote locations.

Based on the high fish BCF values, supported by other available data in a weight-of-evidence approach, the DS concluded that D4 meets the Annex XIII criteria for vB based on the fish BCF.

IV.1.2 Decamethylcyclopentasiloxane (D5)

The DS proposed that D5 meets the REACH Annex XIII criteria for a vPvB substance. D5 is registered under REACH.

Persistence

D5 is poorly soluble in water, volatile and also adsorbs strongly to soil and sediment. D5 has a hydrolysis half-life of 365 days at pH 7 and 12°C (freshwater), and 64 days at pH 8 and 9°C (marine water), and is not readily biodegradable. Based on OECD TG 308 sediment simulation studies (Xu, 2010), it has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24°C, expected to be longer at lower environmental temperatures. Persistence in sediment is supported by sediment core data from Lake Pepin, USA (Powell, 2009 & 2010). The available data do not allow a reliable soil degradation half-life to be derived.

The DS concluded that D5 meets the Annex XIII criteria for a very persistent (vP) substance in water and sediment.

Bioaccumulation

Several reliable studies have been performed that indicate that D5 meets the criteria for very bioaccumulative (vB) substances:

- A steady-state BCF of 7,060 L/kg based on total ¹⁴C measurements was measured for Fathead Minnow *Pimephales promelas* (Drottar, 2005).
- The steady state BCF for Common Carp *Cyprinus carpio* was reported to be in the range 12,049 – 12,617 L/kg (based on parent compound analysis) or 10,550 – 11,048 L/kg when normalised to a 5 per cent lipid content. The kinetic lipid-normalised BCF is higher still) (CERI, 2010b)
- Whole body concentrations achieved during laboratory bioconcentration studies were up to around 20 mg/kg ww or more for Fathead Minnow *P. promelas* (Drottar, 2005) and 17 mg/kg ww for Common Carp *C. carpio* (CERI, 2010). The analysis shows that D4 can achieve whole fish concentrations similar to a range of substances that are widely accepted as being very

bioaccumulative (e.g. UV-328 and UV-320, long chain perfluorocarboxylic acids, musk xylene, hexaBDE and HBCDD).

Fish dietary bioaccumulation studies are available that permit the derivation of a biomagnification factor (BMF):

- A dietary BMF between 0.63 – 3.9 (depending on normalisation) was measured in Rainbow Trout *Oncorhynchus mykiss* (Dow Corning, 2006). The growth-corrected depuration rate constant calculated from this study was 0.00939 day⁻¹.
- A dietary BMF of 0.96-1.21 (growth-corrected and lipid-normalised) has been measured in *C. carpio* (CERI, 2011). The growth-corrected depuration rate constant calculated from this study was ~0.023 day⁻¹.

Thus the low rate of depuration seen in the feeding studies with *O. mykiss* and *C. carpio* is consistent with the BCF for D5 being >5,000 L/kg (EA, 2012). A BMF (growth-corrected and lipid-normalised) above 0.31 corresponds to a BCF (lipid normalised) over 5,000 L/kg, based on the tentative regression by Inoue *et al.* (2012).

Various field studies are available. The DS considers that different conclusions can be drawn from some studies depending on the food chain configuration that is assumed. The DS considers that trophic magnification may occur in some food webs whereas trophic dilution occurs in others. Other explanations may include variable exposure and food web dynamics.

There is unequivocal evidence that D5 can be found in a wide range of organisms (particularly fish and aquatic invertebrates but also birds and mammals) throughout aquatic food chains, including top predators such as American Mink *Mustela vison*, Grey Seal *Halichoerus grypus* and Pilot Whale *Globicephala* sp. Concentrations have been reported up to 1-3 mg/kg ww for some wild fish species at locations with significant local sources.

D5 is also found in fish, birds and marine mammals sampled from remote regions with low background levels in abiotic media (e.g. Svalbard in the European Arctic). Levels are generally very low (often close to the analytical detection limit, and frequently not detectable). Nevertheless, higher levels (e.g. up to 60 µg/kg lipid in Kittiwake liver and 128 µg/kg lipid in samples of Polar Cod) have also been reported.

The DS concluded that D5 meets the Annex XIII criteria for vB based on the fish BCF, and supported by the other available data, particularly trophic magnification and the detection of D5 in wildlife at high concentrations.

IV.2.1 Summary of comments received during public consultation

During the public consultation, comments were received for D4 from 21 parties and for D5 from 35 parties. One Member State (DE) has indicated its support to the assessments of the UK on both substances. In the following the key aspects of the comments, provided by industry associations, manufacturers and importers, individual scientists and consultants, are presented. The comments and the dossier submitter's responses to them are provided in the Response to comments documents (RCOMs). The main focus of the comments was the assessment of bioaccumulation, but also comments related to the opinion making process, the uses of the substance and economic consequences, and comments related to persistence assessment and (eco)toxicity assessment were made. Essentially the same comments were made for D4 and D5, therefore the summary covers both substances.

Persistence

In the comments on the persistence assessment the conclusion "P" and/or "vP" for the sediment compartment was generally agreed to be fulfilled. Detailed comments were made on the presentation and calculation of hydrolysis half-lives of both substances.

It was pointed out that for the interpretation of information on the long-range transport potential it should be considered, amongst others, that atmospheric deposition is an unlikely route of distribution for these substances and that the presented field data from remote locations may not be considered to provide evidence of long-range transport or of persistence due to potential contamination during sampling and analysis and due to likelihood of local releases.

D4 and D5 were commented to have a low overall persistence (Pov) due to their volatility and consequently a relatively high partitioning to air followed by abiotic degradation in the atmosphere (estimated half-lives > 10 days for both) and by hydrolysis in most natural waters. Pov was stated to provide a better representation of the hazard associated with "P" as the approach accounts for the partitioning properties in relation to the reactivity of the substances.

Bioaccumulation

BCF in general and the numeric (v)B-criteria of Annex XIII in particular were considered by commenters as a screening method for bioaccumulation, not as ultimate evidence. Bioconcentration was deemed in some comments as a minor mechanism of bioaccumulation which may be relevant for lower trophic levels but not for the overall assessment in the presence of field data on bioaccumulation, in particular on trophic magnification. The perception was frequently presented that a (very) bioaccumulative substance is a substance which elicits systematic trophic magnification and for which the fugacity ratios are > 1.

Several comments suggested the UK to improve its weight-of-evidence approach, and in particular make it more robust and transparent by considering all available evidence and applying a weighting system. A weight-of-evidence assessment should be possible to conclude either way, for refuting or for confirming the concern.

According to some comments, the frequently observed lack of field trophic magnification for D4 and D5 should receive more weight in the weight-of-evidence assessment than the high experimental BCFs compared to what the UK suggests in its assessments. The reliability of the reported BCF-values was not questioned but it was considered that, when taking into account all lines of evidence, D4 and D5 could not be considered to behave like bioaccumulative substances.

In particular, several parties provided comments that due to the high adsorption potential, with higher bonding to oxygen than to carbon atoms, the thermodynamic limitation and high volatility, the numeric Annex XIII criteria are not suitable for assessing the real life behaviour of the unique silicon chemistry but overpredict their bioaccumulation potential. The validity of the numeric Annex XIII criteria for such data rich cases as D4 and D5 was questioned. However, it was generally expressed, that the current Annex XIII allows the robust dataset on D4 and D5 to be taken into account in a weight-of-evidence assessment and that the dataset clearly shows that the substances are not bioaccumulative.

The following aspects were considered to provide lines of evidence of that D4 and D5 are not bioaccumulative: they are biodiluted towards the top of some food webs based on field data and the substances are biotransformed/metabolised efficiently in fish, mammals and some invertebrates. Experimental depuration rates of D4 and D5 are higher than what is in science often referred to as a limit

for highly bioaccumulative substances. Furthermore, biota can absorb D4 and D5 only to a certain limit concentration based on its thermodynamic properties and the water-biota and sediment-biota fugacities of D4 and D5 are < 1 . Based on recent studies comparing the field data of the benchmark substance PCB-180, after normalising the data with regard to concentration gradients and home ranges of measured species, D4 and D5 would not seem to exhibit same level of bioaccumulation as PCB-180. Furthermore, the BCF-values and other available bioaccumulation data showed that the bioaccumulation behaviour of D4 and D5 does not follow the same pattern as the traditional hydrophobic contaminants, e.g. PCBs and PAHs. It would not be possible to accurately predict the actual bioaccumulation behaviour of D4 and D5 with K_{ow} values.

In addition to this, some commenters noted that D4 and D5 were quickly eliminated from rats and humans by exhalation and that mammal studies demonstrated that the fraction that would be taken up in the blood could be oxidized/hydrolysed and excreted, so there would be no biomagnification potential in air-breathing organisms and in terrestrial food webs.

IV.2.2 Comments which are considered to be out of scope for comparison with Annex XIII criteria

Several comments not directly related to the assessment of the data against the (v)P and (v)B criteria of Annex XIII to REACH were provided during the public consultation. These are summarised below. The UK-CA has responded to these comments and they are to be considered in the preparation of the restriction proposal and the subsequent RAC opinion making. Since they do not relate to the PBT/vPvB assessment, they are not taken into account under the mandate of the MSC.

The concern was expressed frequently that if D4 and D5 would be inappropriately identified as PBT/vPvB, this would set a precedent for all silicon chemistry.

Concerns about the transparency/suitability of the process of forming the MSC-opinion were expressed. Additionally, a major concern described in several comments was the anticipation that if the MSC opinion would conclude that the substances are PBT/vPvB, this alone and in combination of a potential subsequent restriction would deteriorate the reputation of other siloxanes as well and would have a major impact to the European silicone industry and to the European economy. Information on uses and confidential estimates of economic impacts of an unjustified restriction of D4 and D5 as PBT/vPvB were provided. Also concerns about global ramification of the substances as a consequence of MSC opinion making were expressed.

It was commented that use of (and products containing) D4 and D5 are not of concern to the environment and that the current environmental levels do not cause a quantifiable risk to the environment or human health. Fulfilling the PBT/vPvB criteria should not alone be of concern but in order to trigger regulatory risk management, there should be corroborative evidence to suggest that the accumulation would be expected to result in adversity. A reference was made in this context to the review of D5 by the Canadian Ministers of Environment and Health. Furthermore, a newly published probabilistic risk assessment (Woodburn and Powell, 2014) would show that there is no risk for the benthic organisms.

Several comments were also made to the toxicity and ecotoxicity assessment.

IV.3 MSC assessment of the submitted information

IV.3.1 PERSISTENCE

According to Annex XIII of REACH, a substance fulfils the criterion for being persistent (P) or very persistent (vP) when the degradation half-life exceeds a certain number of days, which is specific for each environmental compartment, in any of the compartments. An overview of the criteria is given in Table 1.

Table 1: REACH Persistence criteria (Annex XIII), based on half-lives for environmental compartments

Compartment	Persistent (P)	Very Persistent (vP)
Marine water	$t_{1/2} > 60$ days	$t_{1/2} > 60$ days
Fresh or estuarine water	$t_{1/2} > 40$ days	$t_{1/2} > 60$ days
Marine sediment	$t_{1/2} > 180$ days	$t_{1/2} > 180$ days
Fresh or estuarine water sediment	$t_{1/2} > 120$ days	$t_{1/2} > 180$ days
Soil	$t_{1/2} > 120$ days	$t_{1/2} > 180$ days

The majority of the comments that were submitted in the public consultation on the P/vP behavior of D4 and D5 indicate that although degradation half-lives in sediment are meeting the vP criterion, the substance should not necessarily be considered P (or vP), as the properties of D4 and D5 (high volatility, poor water solubility, relatively rapid transformation (hydrolysis) in the water column) would mean that the removal time for the sediment compartment is fast. The MSC has evaluated the significance of the alleged fast removal time in the sediment compartment and evaluated the information on which the DS based its conclusion that D4 and D5 can be considered vP.

Water

The PBT report for D4 concluded that hydrolysis half-life of D4 in the environment is estimated to be (EA, 2009) 16.7 days (freshwater) and 2.9 days (marine water). Nevertheless, standard tests suggest that D4 is not readily biodegradable (3.7% mineralisation after 29 days) (Springborn Smithers Laboratories, 2005). Interpretation is complicated by the high volatility of the substance meaning that it was present in the headspace of the test vessels. Additional studies suggest that D4 might be susceptible to biodegradation, particularly with adapted microorganisms. However, mineralisation has not been confirmed, and MSC agrees with the DS that the results cannot be used to predict the extent or time-frame for biodegradation in the environment.

In the supporting PBT report for D5 (Annex 3), the DS states that D5 meets the Annex XIII criteria for vP. Hydrolysis half-lives were reported:

Hydrolysis half-life at pH 7 and 12°C (freshwater) = 315 days.
Hydrolysis half-life at pH 8 and 9°C (marine water) = 64 days.

The available enhanced biodegradation experiments (using PDMS tubing or discs) do not allow to derive rates of degradation in aqueous compartments, but indicate that microbial degradation is very limited at best. Adaptation to improve/ensure bioavailability of D5 was performed using PDMS tubing on which D5 was sorbed. Biofilm formation was observed and degradation seemed to occur (after adaptation). In order to confirm that D5 was being degraded in the test system, a final series of experiments was carried out in a batch study using ¹⁴C-labelled D5. In this study the D5 was administered to the test system adsorbed onto PDMS discs (approximately 27.9 µg ¹⁴C-D5 per disc) and mineralisation was determined by measuring the ¹⁴CO₂ evolved. The inoculum used in this study was the adapted inoculum (containing a biofilm). No significant differences were observed in the ¹⁴CO₂ evolved from the test system compared with controls (<1

per cent of the total radioactivity in both case). At the end of the experiment, over 95 per cent of the ^{14}C -D5 was found to remain on the PDMS discs and minimal amounts were present in the aqueous phase. Van Egmond and Finnegan (2010) suggested that transfer of D5 to the active biofilm may have been too limited in this test system to allow measurable biodegradation to be seen.

Overall, these results are suggestive that some biodegradation (mineralisation) of D5 could occur, particularly with adapted microorganisms, where availability of the substance to the microorganisms is enhanced. However, the extent or time-frame for biodegradation in the environment is difficult to estimate from the results of this study. In addition, the experiments with ^{14}C -labelled substance did not confirm that mineralisation of D5 was occurring. In combination with the hydrolysis data, MSC sees this as support for D5 being persistent in the water column.

MSC is of the opinion that a definitive conclusion on the P, or vP properties of D5 in water does not need to be drawn in the context of this opinion since sufficient information is available to conclude on persistence of D4 and D5 in sediment.

Sediment

In OECD 308 simulation studies (XU 2009a, 2009b), D4 has an estimated degradation half-life of 365 days in anaerobic sediment and 242 days in aerobic sediment at 24°C. For D5, a half-life was found of 1,200-2,700 days in aerobic and 800-3,100 days in anaerobic sediments, at 24°C.

The average fraction of D4 in the sediment compartment (taken from lake Pepin, organic carbon content=3.7%, pre-exposed to D4/D5) was found to be 97% (anaerobic) and >98% (aerobic) throughout the study.

In another simulation study sediment (Sanford lake, Xu and Miller, 2008) a lower carbon content was used (~2.9%) and still > 95% of D4 was found to be sorbed to the sediment throughout the experiment. Especially in the aerobic simulation study, one would expect the amount of D4 sorbed to the sediment to gradually diminish as the dissipation in the aqueous phase lowers the dissolved concentration of D4 over time and desorption (and resuspension) of the sorbed fraction from the sediment could occur to some extent. However, sediment concentrations do not significantly decrease, despite the (relative) high volatility of D4/D5 (as demonstrated in this study and the next subsection).

Monitoring data (Lake Pepin, Powell 2009, 2010) show that D4/D5 is detectable in the lake sediment in amounts one or two orders of magnitude higher than expected based on detailed fate modelling for lake Pepin (Whelan 2009). Also in other locations such concentrations of ~3.7-4.1 ug D4/kg wet weight were encountered in sediment (Inner Oslofjord, Powell et al., 2009a).

Both the simulation studies and monitoring data indicate that the fraction present, and the half-life of D4/D5 in sediment (both aerobic and anaerobic) are high, and experimental data actually shows much higher fractions/concentrations present than predicted based on location specific fate modelling.

MSC concludes that this discrepancy between the experimental data and fate model prediction invalidates the argument that the overall persistence (P_{ov}) as estimated in global environmental fate modelling would be low.

Other aspects related to fate and removal rates

Although overall persistence (P_{ov}) does not play a role in direct numeric comparison to the criteria of Annex XIII of REACH, it was suggested in the public consultation that it can be part of a weight-of-evidence assessment. The DS concluded that the P_{ov} has no direct relation to the persistence criteria of REACH.

Nevertheless, if a substance possesses such specific fate properties that the removal from the sediment compartment would be very significant, then this might suggest that sediment would not be a relevant compartment for the assessment of persistence.

The overall persistence in the environment represents the estimated average residence time of a substance in all environmental compartments, and can therefore not be compared quantitatively to the REACH Annex XIII criteria. The Pov does not give information on the residence times of individual compartments. Therefore, instead of using the (modelled) overall persistence in the environment to compare to the P/vP criteria as a number of the commenters suggest, half-lives of removal for individual environmental compartments, or the compartment of concern (sediment) are much more illustrative. A high removal rate from sediment (as the main compartment of concern for P in this case) would be a more solid reason to question the relevance of the sediment compartment.

The individual compartment half-lives of removal (as derived by SimpleBox 3.0 modelling (Den Hollander et al., 2004) using input estimates from QSAR (EpiSuite) for degradation half-lives in atmosphere=13 days, water=19 days, soil=38 days, sediment=170 days, all at 25°C) and values from the PBT report for D4 and D5 for input and estimations of the compartment removal half-lives, including volatilization, resuspension, burial and advection processes, on the regional scale (at environmental temperatures; 12°C fresh and marine water) are shown for D4 and D5 in table 1 and 2 (see Annex 5).

Fresh water sediment removal rates were calculated (188 and 253 days) that are still above the degradation half-life vP criterion for sediment in Annex XIII (180 days). The specific chemistry of D4 and D5 (high volatility, low water solubility, strong sorption behavior) does apparently not lead to rapid removal from the sediment compartment. Modelled air and water compartment removal half-lives are well below the degradation half-lives used as input, as volatilization (from water) and advection (from regional to continental scale) give large contributions to the compartments removal half-lives. However, the removal half-life for sediment is not determined strongly by non-degradation removal contributions for this compartment.

The argument provided in several comments in the call for evidence that the specific silicone chemistry would lead to rapid removal from sediment, and therefore in a weight-of-evidence approach would allow to overrule the degradation half life criteria in REACH Annex XIII, is therefore seen by MSC to be invalid. Furthermore the monitoring data showing high fractions of D4/D5 in the sediment compartment (> 95%) also invalidate the argument that rapid removal rates from sediment would lead to low overall persistence in the environment, despite long degradation half-lives that show that the substances are persistent according to Annex XIII criteria.

MSC Conclusion

The observations in experimental simulation studies and monitoring studies, lead to the conclusion that D4 and D5 have to be considered as very persistent (vP) in sediment for both D4 and D5. MSC has considered the key studies selected by the DS and agrees on the reliability evaluation of the DS.

MSC has evaluated non-degradation processes and concluded that these do not have a large impact on the sediment removal half-life, and thus cannot be used to refute the relevance of the sediment compartment in the assessment of persistence.

IV.3.2 BIOACCUMULATION

IV.3.2.1 Aqueous bioconcentration tests

According to Annex XIII of REACH, a substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2000, and a substance fulfils the "very bioaccumulative" criterion (vB) when the bioconcentration factor in aquatic species is higher than 5000. These are the criteria set out in section 1 of Annex XIII. These criteria should thus be considered as definitive criteria, although in some comments made during the public consultation they are referred to as screening criteria.

Annex XIII states that a weight-of-evidence approach for assessing the PBT/vPvB properties is in particular relevant where the criteria set out in Section 1 cannot be applied directly to the available information. In a weight-of-evidence assessment for bioaccumulation, all data on bioaccumulation are considered together, and not only the results of the bioconcentration tests. In this section the validity and most important findings from the bioconcentration tests with D4 and D5, as presented by the DS, are summarized and assessed by MSC and it is assessed whether the criteria for bioaccumulation can be directly applied to the results of these tests.

D4

A study with fathead minnows is available that included a preliminary test with 6 days exposure followed by 14 days of depuration and a definitive test with 28 days of exposure and 14 days of depuration (Fackler, Dionne et al. 1995). Fish of comparable size and weight (0.48 g) were used in both phases of the test. The DS reported BCF from this study as a kinetic BCF of 7400 L/kg from the preliminary experiment and a steady-state BCF of 12400 L/kg after 28 days and a kinetic BCF of 13400 L/kg from the definitive study. The DS also mentioned a re-analysis of the data (Smit, Posthuma-Doodeman et al. 2012), taking into account the variable exposure concentrations during both phases of the test (both test were performed at concentration in the range of 0.2 to 0.5 µg/l). The best fit of Smit et al. (2012) to all combined data from the preliminary and definitive test yielded a kinetic BCF of 19000 L/kg.

The lipid content of the fish was 6.4% and a BCF normalized to 5% lipids of 14900 L/kg is calculated from these data. Growth was not reported and growth correction could not be applied. However, MSC considers this less relevant for this species, because all fish were 3.5 cm and 0.48 g, and though still immature, had already an age of about half a year. The analysis was done on total radioactivity and 7.3% of total radioactivity was unextractable. For this part it could not be investigated whether it still included parent compound. For the extractable part (92.7%) all radioactivity could be attributed to parent D4. Thus, MSC concludes that the BCF for D4 in fathead minnows is at least 13800 L/kg based on parent compound.

Two bioconcentration studies with carp (*Cyprinus carpio*) are available (CERI, 2007, 2010), that were evaluated by the DS. Both studies had an exposure period of 60 days followed by a depuration period of 15 days in the first study and 12 days in the second. The growth corrected BCF values reported for the first study (CERI, 2007) are 4120 to 4560 L/kg for the nominal concentration of 2.5 µg/L. For the lower concentration of 0.25 µg/L the growth corrected values are 4610 to 4890 L/kg. For the second study (CERI, 2010a), the growth corrected BCF values are 4705 to 4898 L/kg in the concentration of 2.39 µg/L and 6530 to 6930 L/kg for the 0.235 µg/L concentration.

The ranges reflect two growth rates employed by the DS. The highest BCF values reflect only the growth rate during the uptake phase. The lower BCF values are based on lower growth rates. The DS determined these values by including the

weights over both the uptake and the depuration phase. In all four series the weight of fish increases exponentially with a growth rate of 0.016 to 0.017 d⁻¹ in the uptake phase, but suddenly does not increase anymore in the depuration phase.

MSC is of the opinion that the weight of the fish in the depuration phase probably reflects the amount of homogenate used for analysis. It seems that this is kept constant from the end of the uptake phase at 20 g. A possible explanation for this is mentioned in the test report itself (CERI, 2007): 'The 50mL-sample was diluted to a suitable concentration, because the concentration of the test item in the fish sample exceeded the range of the calibration curve.'

Therefore, the upper values are considered more plausible by MSC.

The lipid content in the test fish was variable as analysed by the DS. In the first study (CERI, 2007) the lipid content at the start of the test is 3.18%, at the first day of depuration 5.36% in the higher concentration and 6.56% in the lower concentration, and 4.22% at the end of the test. Although variable, if average lipid contents are taken into account, the growth corrected BCF values normalized to 5% lipids are 5360 and 5260 for the higher and lower concentration in the first study. In the second study, the lipid content at the start of the test is 4.89%, at day 47 of the uptake phase 6.43% in the higher concentration and 5.84% in the lower concentration, and 4.15% at the end of the test. Although variable, if average lipid contents are taken into account, the growth corrected BCF values normalized to 5% lipids are 4900 and 6930 for the higher and lower concentration in the first study. These values are considered by MSC to be the more plausible upper values as explained above.

D5

For D5 a bioconcentration test with fathead minnows (*Pimephales promelas*) has been performed as well (Drottar, 2005). The exposure period was 35 days and the depuration period 70 days. Exposure concentrations were 1.1 and 15 µg/L, the latter being almost equal to the water solubility of 17 µg/L. Steady-state BCF values were reported, because concentrations differed non-significantly on days 14, 21, 28 and 35 of exposure. These steady-state BCF values were 7060 L/kg at 1.1 µg/L and 1950 L/kg at 15 µg/L. However, with up to 50% difference between the different time points the requirement for steady-state from the OECD 305 test guideline is clearly not fulfilled, which states that fish concentrations should be within 20% of each other. Indeed, kinetic BCF values were much higher, with 13300 L/kg at 1.1 µg/L and 5250 L/kg at 15 µg/L.

The percentage of parent compound in fish was 83%. This means that the kinetic BCF values corrected for parent compound are 11000 L/kg at 1.1 µg/L and 4360 L/kg at 15 µg/L. It is not mentioned by the DS if this was the percentage of extractable radioactivity, as was the case for the similar BCF study with D4, or if 17% metabolites were found in the extract. The lipid content ranges from 2.9% at the beginning of the test to 4.1% at the end of the uptake phase to 5.2% at the end of the depuration phase. Taking the average lipid contents, the kinetic BCF values normalized to 5% lipids based on parent compound are thus 13600 and 5360 L/kg.

It is stated by the DS that due to the scatter in the depuration data, the kinetic BCF data could be less certain. However when reviewed by MSC, the uptake phase itself as well as the kinetics indicate that steady-state is certainly not reached in the 35 days of the uptake period. Despite the fact that the depuration data show some scatter, depuration rate constants are rather similar for both concentrations (0.0179 d⁻¹ at 15 µg/L and 0.0294 d⁻¹ at 1.1 µg/L). This indicates that only half of steady-state has been reached after 35 days. Further, the uptake rate constant at the higher concentration is quite low (93.8 L/kg/d versus 390.9

L/kg/d at 1.1µg/L). This could be because the test was run at a concentration near the water solubility, and bioavailability might have been reduced. This would make all results of the higher concentration less reliable.

A bioconcentration study for D5 was performed with carp (*Cyprinus carpio*) with an uptake phase of 60 days and a depuration phase of 41 days (CERI, 2010b). On the last three sampling points (35, 49, and 60 days) concentration in fish differed less than 20%. Steady-state BCF values were 12600 L/kg at 1.03 µg/L and 12000 L/kg at 0.0981 µg/L. Kinetic BCF values were slightly higher, being 16000 L/kg and 14350 L/kg, respectively. The lipid content of the fish was 5.96% at the start of the test to 5.45% at the end of the test. Normalized to 5% lipids, the kinetic BCF values reduce to 14000 and 12600 L/kg. Growth was not reported in the study, but the DS remarked that the growth rate in a similar study with D4 (see above) was 0.016 to 0.017 d⁻¹. Because this is about half the depuration rate constants observed, a similar growth rate would increase the growth corrected BCF values by a factor of approximately 2.

MSC conclusion

MSC has considered and discussed the key bioconcentration studies selected by the DS and concludes that these are valid studies. Kinetic BCF values for D4, normalized to 5% lipids and corrected for growth rate, are almost 14000 for fathead minnows and around 5000 to 7000 for carp. Kinetic BCF values for D5, normalized to 5% lipids and corrected for growth rate, are around 5000 to more than 13000 for fathead minnows and higher values of 13000 to 14000 are observed in carp. Growth rate was not measured in fathead minnows, but was assumed to be negligible. If not, it would further increase the BCF values. The lower value for D5 in fathead minnows is possibly affected by solubility constraints, leading to reduced bioavailability and thus a possible underestimation of the real BCF value. In the test for D5 in carp, growth rate was also not determined, and growth dilution possibly leading to lower BCF values is probably a significant process. Therefore, no exact estimates could be made, but the derived BCF values for D5 in carp should be considered as minimum values.

A direct comparison with the bioaccumulation criteria of section 1 of Annex XIII is thus possible, and shows that both D4 and D5 meet the vB criterion of a BCF value higher than 5000 L/kg.

IV.3.2.2 Dietary bioaccumulation tests

The comments made during the public consultation on the interpretation of the dietary test according to the OECD 305 guideline were focusing on the fact that no biomagnification occurs. This is used to suggest that these substances should not be considered as bioaccumulative in a weight-of-evidence approach.

In the revision from the OECD 305 test guideline from 2012 a new dietary test has been introduced. For D4 and D5 several tests have been performed with this dietary exposure, with carp and with rainbow trout. The principle of the dietary test is that fish are exposed during an uptake phase via the diet only. During this uptake phase, fish are kept in a flow-through system with clean water, so exposure through the aqueous phase is negligible. A depuration phase similar to the aqueous bioconcentration study follows the uptake phase, i.e. fish are fed clean food and are kept under clean water conditions.

The result of the dietary exposure test is twofold as discussed by the DS: the biomagnification factor (BMF) and the depuration rate constant (see sections IV.1.1 and IV.3.2.3).

MSC is of the opinion that the biomagnification factor from this test can however not be directly compared with biomagnification under field conditions. The uptake

in the field situation at similar food concentrations is higher, because exposure in the field is via water and food simultaneously. The concentration in a fish is determined by the sum of two terms, one governed by uptake from water (BCF * concentration in water) and the other by uptake from food (dietary BMF * average concentration in food); see e.g. Hendriks et al., 2001.

Because the water concentration is maintained as low as possible by flow-through with clean water, exposure in a dietary test in the laboratory is not directly comparable to total exposure of both water and diet in the field situation. When a substance in the field shows biomagnification relative to its food sources (i.e., BMF >1), the water uptake term has implicitly been taken into account as well. In the laboratory dietary BMF study, this process is only represented by the food term and water uptake is absent or negligible.

Therefore, MSC considers the criterion BMF > 1 not appropriate, if BMF is derived following the OECD test guideline 305 for the dietary bioaccumulation test.

For carp it was shown that a BCF value of 5000 L/kg, normalized to a lipid content of 5%, corresponds to a lipid normalized BMF from the dietary test of only 0.31 kg food/kg fish, based on a regression between both parameters for nine compounds (Inoue, Hashizume et al. 2012). Of the five substances that had a BCF value higher than 5000 L/kg, only two of them had a BMF value in excess of 1 (hexachlorobenzene and Binox m), while three others (pentachlorobenzene, musk xylene and solvent blue 36) had BMF values between 0.32 and 0.41 (musk xylene is an SVHC substance under REACH based on its vPvB properties).

More information on biomagnification in carp comes from a study in which accumulation of polychlorinated biphenyls (PCBs) and polybrominated diphenyl ethers (PBDEs) was studied (Stapleton, Letcher et al. 2004). Although not lipid normalized and growth corrected, BMF values were below 1 for PCB52, PCB153, PCB180, BDE28, and BDE153. Only the BMF for BDE47 was higher than 1 (1.36), predominantly due to the high assimilation efficiency of 93%. This indicates that in carp, well-known (v)B chemicals such as BDE and PCB congeners can have BMF values below one in laboratory dietary accumulation studies.

Several dietary bioaccumulation studies were performed with rainbow trout (*Oncorhynchus mykiss*). In a study examining the accumulation of fipronil in a mixture, the following lipid normalized and growth corrected kinetic BMF values were obtained: fipronil 0.02, fipronil sulfone 7.2, α -hexachlorocyclohexane 0.24, heptachlor epoxide 2.6, *o,p'*-DDT 6.9, *o,p'*-DDD 2.4, *p,p'*-DDT 9.9, *p,p'*-DDD 4.0, PCB84 3.2, PCB132 5.5, and PCB174 6.4.

The assimilation efficiency of the two DDT compounds amply exceeded 100%, which might have led to erroneously high BMF values for DDT (Konwick, Garrison et al. 2006). Kinetic BMF values of about 3.5 to 4 for D4 and D5 have been determined, comparable to known (v)B chemicals such as heptachlor epoxide, sum PCBs and sum DDT.

MSC concludes that these studies support the findings of the DS that even if the BMF from a dietary test is below 1, the BCF of such a substance could still meet the (v)B criterion. This was observed for e.g. Musk xylene, Solvent blue 36, and several PCB congeners.

D4

The DS considered two dietary bioaccumulation studies to be valid. A dietary bioaccumulation study for D4 was performed with carp (*Cyprinus carpio*, CERI 2011). The uptake period was 13 days and the depuration period 28 days. The lipid normalized and growth corrected kinetic BMF value for D4 was 0.728 with an assimilation efficiency of 49,8%, determined by the DS by fitting the data of the uptake phase with the equations from the OECD 305 test guideline.

A dietary study for D4 has also been performed with rainbow trout (*Oncorhynchus mykiss*) with an exposure period of 35 days and a depuration period of 42 days. The lipid normalized and growth corrected kinetic BMF for D4 from this study was 4.0 with an assimilation efficiency of 0.40 (Woodburn, Drottter et al. 2013).

D5

From the same valid dietary bioaccumulation study as described above with carp (*Cyprinus carpio*, CERI 2011), the lipid normalized and growth corrected kinetic BMF value for D5 was 1.191 with an assimilation efficiency of 0.320, determined by the DS by fitting the data of the uptake phase with the equations from the OECD 305 test guideline.

The same valid dietary study for with rainbow trout (*Oncorhynchus mykiss*) as described above was also performed for D5. The lipid normalized and growth corrected kinetic BMF for D5 from this study was 3.4 with an assimilation efficiency of 0.44 (Woodburn, Drottter et al. 2013).

Conclusion

MSC has considered and discussed the key dietary biomagnification studies selected by the DS and concludes that these are valid studies. The BMF values from the dietary studies performed with D4 and D5 are comparable with other substances that have BCF values above 5000 and are considered to be PBT and/or vPvB substances, as summarized above. MSC supports the conclusion of the DS on this subject.

IV.3.2.3 Elimination half-lives

Role of metabolism for half-lives of D4 and D5

It has been commented in the public consultation that D4 and D5 are metabolized fast enough to take away the concern for bioaccumulation. However, the DS has argued that both D4 and D5 exhibit low rates of overall depuration in fish feeding studies (including metabolism), consistent with the BCF being >5,000 L/kg (EA, 2012). MSC has therefore looked into this issue in more detail.

Metabolism is claimed to be an important factor in the observed bioaccumulative behaviour in the field. It is suggested that this fast elimination is the reason for the negative trophic magnification factors that are often observed (i.e. biodilution instead of biomagnification, see also sections IV.1.1. and IV.3.2.4). Reference is made to the half-life of 70 days as criterion for the half-life (see below).

A new study on metabolism was recently provided (Domoradzki, Sushynski et al. submitted). To study the kinetics in fish, mature rainbow trout (*Oncorhynchus mykiss*) were dosed orally with labelled D4 and D5 and followed for 96 hours. Analysis of the parent compound and metabolites was performed in urine, bile, liver, digestive tract, and fat, and additionally in milt for D4 and in eggs for D5. The fact that metabolites are present clearly shows that both D4 and D5 are metabolised in fish.

The elimination half-lives in blood based on total radioactivity were 39 hours for D4 and 70 hours for D5. From the parent and metabolite concentrations in blood, metabolism half-lives were calculated by fitting to a model. This yielded half-lives for metabolism of 6.7 days for D4 and 4.2 days for D5, corresponding to metabolism rate constants of 0.10 d⁻¹ for D4 and 0.17 d⁻¹ for D5. However, the validity of the estimated rate constants for metabolism based on whole body concentrations could be argued. Both D4 and D5 partition strongly into fat. In fat no metabolites were present. Besides that after 96 h, 2% of D4 and 14% of D5

were recovered as metabolites. Because metabolites were not determined in the remainder of the carcass, metabolism could be higher. The metabolism rates based on these figures were at least 0.005 d^{-1} for D4 and 0.037 d^{-1} for D5.

Also the samples for the dietary bioaccumulation studies were discussed. After 5 days exposure to radiolabelled D4, 5% of radioactivity in whole-body homogenate of fish was present as metabolites. For D5, metabolites accounted for 31%. This corresponds to rates of 0.010 d^{-1} for D4 and 0.062 d^{-1} for D5. If excretion of metabolites would be significant in 5 days this rate constant might be an underestimation as well. However, most informative are the overall elimination rate constants for prolonged exposure, including internal redistribution within the organisms after uptake. In the end, the rate for metabolism cannot be higher than the overall elimination rate.

Half-lives as a metric for bioaccumulation potential

Bioaccumulation processes are directly dependent on the elimination half-life. Upon prolonged exposure and after internal redistribution of a compound, the rate of elimination is independent of the uptake route. Besides that, uptake rates are rather similar for different compounds and strongly dependent on e.g. ventilation rates of gills for aqueous and feeding rate for dietary exposure. So, the elimination rate is a discriminating factor in the bioaccumulation potential of compounds.

This principle has recently been applied in a publication to come up with a value for the maximum elimination half-life for bioaccumulative substances (Goss, Brown et al. 2013). The authors themselves state that the exact value is primarily a policy decision. As an example they present a half-life of 70 days, which corresponds to an elimination rate constant of 0.01 d^{-1} . This value was derived by taking a daily feeding rate of $0.01 \text{ kg}_{\text{food}}/\text{kg}_{\text{organism}}/\text{d}$. If the assimilation efficiency is 100%, the biomagnification factor will exceed 1 if the elimination rate is lower than 0.01 d^{-1} .

MSC considers that this value is a rather strict value and does not distinguish between the difference in elimination rates for different size of organisms. It however depends on the species studied, lipid content and metabolism. In addition, growth and reproductive activity can influence and complicate determining the relevant rate.

By taking the feeding rate as the only uptake rate, the contribution of uptake via passive diffusion via the water phase is neglected. This is an accurate description for the dietary bioaccumulation test according to the OECD 305 test guideline, in which water concentrations are maintained at negligible level due to flow through with clean water. The total uptake in the field situation will be higher at equal food concentrations, because exposure is via water and food simultaneously. As a result, with equal food consumption, higher elimination rates than 0.01 d^{-1} will in the field situation still result in biomagnification factors above 1 (see also section IV.2.3.4).

Moreover, the feeding rate of $0.01 \text{ kg}_{\text{food}}/\text{kg}_{\text{organism}}/\text{d}$ is not representative of the dietary bioaccumulation test from the OECD 305 test guideline. More often, fish are fed at a feeding rate of $0.03 \text{ kg}_{\text{food}}/\text{kg}_{\text{organism}}/\text{d}$ (3% of their body weight each day). This would increase the elimination half-life to 0.03 d^{-1} , corresponding to a half-life of 23 days, still assuming an assimilation efficiency of 100%. Next to that, the lipid content of the food is around 15%, thrice as high as the default value for fish of 5%, which means that the lipid normalized BMF (considered as best measure for an increase in fugacity, see also section IV.2.3.5) exceeds one if the elimination half-life is below 0.09, corresponding to a half-life of 7.7 days.

Further, the kinetic processes of especially bioconcentration from water, which are the uptake and elimination rate constants, are dependent on the size of a fish as well (e.g. Barber 2008, Brooke, Crookes et al. 2012). This implies that setting one value for the depuration rate constant for different organisms is not appropriate. If aqueous bioconcentration is considered, an uptake rate constant of 520 l/kg/h could be estimated for fish with a weight of 1 g (REACH guidance, R7c). The elimination half-lives that lead to bioconcentration factors of 2000 and 5000 could thus be estimated to be 0.26 d⁻¹ and 0.10 d⁻¹. For fish weighing ten grams these values would be approximately half of these values. A similar limit of 0.065 d⁻¹, and 0.085 d⁻¹ when lipid normalized, for the depuration rate corresponding with a BCF a 5000 was reported by the DS (Brooke and Crookes 2012).

Observed depuration for D4 and D5

The overall depuration rate constants from relevant aqueous bioconcentration and dietary bioaccumulation studies are summarized here by MSC. Where possible these constants were corrected for growth and normalized to default lipid content of 5% by MSC.

D4

In the bioconcentration study for D4 with fathead minnows the reported depuration rate constant was 0.12 d⁻¹ (Fackler, Dionne et al. 1995). However, MSC considers this is as a clear overestimation of the depuration, as visible from the presented data as well as the reported time for 50% depuration of between 7 and 12 days in the definitive study and more than 14 days in the preliminary experiment. Based on a re-evaluation of all the presented data in the study, the overall depuration rate constant for the bioconcentration study for D4 with fathead minnows was 0.061 d⁻¹. Weight of the fish was reported, but growth is not mentioned. Because the fish used were non-juvenile fathead minnows, a correction for growth rate is not deemed necessary. The reported lipid content was 6.4%, the depuration rate constant normalized to 5% lipids then becomes 0.078 d⁻¹.

Two aqueous bioconcentration tests for D4 were performed with carp (*Cyprinus carpio*, CERI 2007, 2010a). Both studies were performed at two concentrations (nominal concentrations of 2.5 and 0.25 µg/L). The depuration rate constants were obtained from regression of the natural logarithm of the concentrations in the depuration phase versus time. These values were 0.0789 and 0.107 d⁻¹ in one study, and 0.0991 and 0.843 d⁻¹ in the other. The corresponding growth rates determined over the uptake only period were 0.0166, 0.0165, 0.0160 and 0.0169 d⁻¹, respectively. The growth in the depuration phase was probably not measured (see section IV.3.2.1). The growth corrected depuration rate constants were thus 0.0623, 0.0905, 0.0831 and 0.0674 d⁻¹, respectively. The lipid content varied over time in the first study being 3.18% at the start, 4.22% at the end, 5.36% in the higher concentration and 6.56% at the lower concentration at day 1 of depuration. Similarly in the second study the lipid content was 4.89% at the start, 4.15% at the end, 6.43% in the higher concentration and 5.84% at the lower concentration at day 1 of depuration. The lipid normalized and growth corrected depuration rate constants are estimated to be 0.0530, 0.0842, 0.0857, 0.0669 d⁻¹, respectively.

From the dietary bioaccumulation study for D4 with carp (*Cyprinus carpio*, CERI 2011), the overall depuration rate was 0.0797 d⁻¹, obtained by the DS from regression of the natural logarithm of the concentrations in the depuration phase versus time. The growth rate during the depuration phase was 0.0224 d⁻¹. Thus, the growth corrected depuration rate constant was 0.0573 d⁻¹. An almost identical value of 0.0582 d⁻¹ was obtained by the DS, if the natural logarithms of the

amount per fish were regressed against time instead. The average lipid content of the fish over the whole study was 5.77%. If only the values at the beginning, the middle and the end of the depuration phase are taken, the average lipid content is 6.3%. With this value the depuration rate constant normalized to 5% lipids is 0.072 d^{-1} .

A dietary study for D4 has also been performed with rainbow trout (*Oncorhynchus mykiss*). The growth corrected depuration rate from this study was reported to be 0.0070 d^{-1} . This was based on a growth rate of 0.0279 d^{-1} , and an overall depuration rate of 0.035 d^{-1} , similar to the one determined from a regression of the *ln*-transformed concentrations in fish during the first week of the depuration phase versus time (Woodburn, Drottar et al. 2013). The difference between the overall depuration rate and the growth rate is thus very small. The time weighted-average lipid content over the whole experiment is reported to be 6.32%. With this, the growth corrected depuration rate constant normalized to 5% lipids becomes 0.0088 d^{-1} . The lipid content during the depuration phase might have been slightly higher, which would increase the normalized depuration rate a bit.

Calculating the overall depuration rate constant from the original data, cited as Dow Corning (2007) by the DS, shows that other ways of determining the total depuration rate constants, by including all data, whether or not *ln*-transformed yields similar results of 0.036 to 0.037 d^{-1} . If the mass per fish is used instead of the concentrations, the growth corrected depuration rate constant obtained from the depuration is in the order of 0.010 to 0.011 d^{-1} . It can thus be concluded that the overall depuration rate is very low, which is surprising because this is the dietary study that is cited in the metabolism study mentioned above (Domoradzki, Sushynski et al. submitted). This is a clear indication that the presence of metabolites after short-term exposure cannot be translated one-to-one to depuration rates after prolonged exposure.

MSC concludes that for D4 the growth corrected depuration rates normalized to 5% lipids from the three valid studies with carp (5 values) are very consistent. Also the value for fathead minnows lies in the same range. It appears however that the value for rainbow trout from the dietary study is much lower than this. In all cases the growth corrected depuration rate constant normalized to 5% lipids is at most 0.09 d^{-1} . MSC can therefore agree to the conclusion of the DS that the elimination half life of D4 is consistent with the the suggested elimination half-life that leads to bioconcentration factors above 5000, estimated to be 0.067 d^{-1} (EA, 2012) as cited by the DS.

D5

For D5 similar studies are performed as for D4. An aqueous dietary study for D5 with fathead minnows (Drottar, 2005) was also performed at two concentrations (1.1 and $15 \mu\text{g/L}$). The reported depuration rate constants by the DS were 0.0179 d^{-1} in the high concentration and 0.0294 d^{-1} in the low concentration. The reported lipid contents by the DS are 4.1% at the end of the uptake phase and 5.2% at the end of the depuration phase. With an average lipid content over the depuration phase the depuration rates normalized to 5% lipids are 0.017 and 0.027 d^{-1} , respectively.

From the same dietary bioaccumulation study with carp (*Cyprinus carpio*) as described above for D4, the overall depuration rate for D5 was 0.0449 d^{-1} , obtained from regression of the natural logarithm of the concentrations in the depuration phase versus time. The growth corrected depuration rate constant was 0.0225 d^{-1} . As for D4, an almost identical value of 0.0234 d^{-1} was obtained by the DS for D5, if the natural logarithms of the amount per fish were regressed against time instead. The average lipid content of the fish over the whole study was

5.77%. With an average lipid content of 6.3% during the depuration phase, the depuration rate constant normalized to 5% lipids is 0.028 d^{-1} .

A dietary study for D5 has also been performed with rainbow trout (*Oncorhynchus mykiss*). The growth corrected depuration rate from this study was reported to be 0.010 d^{-1} . This was based on a growth rate of 0.0264 d^{-1} (Woodburn, Drottar et al. 2013). The time weighted-average lipid content over the whole experiment is reported to be 5.64%. With this, the growth corrected depuration rate constant normalized to 5% lipids becomes 0.011 d^{-1} . The lipid content during the depuration phase might have been slightly higher, which would increase the normalized depuration rate a bit.

An aqueous bioconcentration test for D5 was performed with carp (*Cyprinus carpio*, CERI 2010b) at two concentrations (nominal concentrations of 1 and $0.1\text{ }\mu\text{g/L}$). The depuration rate constants were obtained by the DS from regression of the natural logarithm of the concentrations in the depuration phase versus time. These values were 0.0315 and 0.0362 d^{-1} for the high and low concentration, respectively. Growth rates were not determined in this study, but from equivalent studies with D4 (see above) these are probably significant, being in the range of 0.016 - 0.017 d^{-1} . This would result in growth corrected depuration rates of 0.015 and 0.020 d^{-1} . With a mean lipid content of 5.71% as reported by the DS, the growth corrected depuration rate constants normalized to 5% lipid become 0.017 and 0.022 d^{-1} .

Similar to D4, MSC concludes that for D5 the growth corrected depuration rates normalized to 5% lipids from the two studies with carp (5 values) are very consistent. Also the value for fathead minnows lies in the same range. As for D4, the value for rainbow trout from the dietary study is the lowest one for D5, but the difference is much less than for D4. The depuration rate constants are all low and vary from 0.011 to 0.027 d^{-1} .

MSC can therefore agree to the conclusion of the DS that the elimination half life of D5 is consistent with the suggested elimination half-life that leads to bioconcentration factors above 5000, estimated to be 0.067 d^{-1} (Brooke et al. 2012a) as cited by the DS.

Conclusion on half-lives and metabolism

MSC concludes that overall half-lives in whole body of fish, including the contribution of metabolism are all below 0.1 d^{-1} for D4 and at least a factor of 3 lower than 0.1 d^{-1} for D5.

As shown above, in aqueous bioconcentration studies this could result in BCF values above 5000. In a dietary OECD 305 feeding study such low rate constants could already result in lipid normalized kinetic BMF values above 1, depending on the feeding rate and on the assimilation efficiency. This is consistent with the observed dietary BMF values (section IV.3.2.2). So far, there is no regulatory criterion for the BMF, neither from the dietary OECD 305 study nor from field studies. This concern for bioaccumulative behavior of substances with a BMF even below one is also confirmed by benchmarking with other chemicals (see also section IV.3.2.2). Thus, even lower depuration rate constants than those leading to a BMF of 1 in this test set-up could still be considered as of concern.

Therefore, the MSC concludes that the observed half-lives in fish for D4 and D5 are consistent with the potential to bioconcentrate to high levels in aqueous bioconcentration studies and the potential to biomagnify in a dietary bioaccumulation study. The observed half-lives for D4 and D5 thus support the concern for bioaccumulation (B and vB) that arises from the aqueous and dietary laboratory bioaccumulation studies. Given the importance of the depuration half-

lives for all bioaccumulation processes, including those under field conditions, this is a very important finding.

IV.3.2.4 Biota to sediment accumulation factors

The DS discusses Bioaccumulation Factors (BAFs) and biota-sediment accumulation factors (BSAFs) in one section. Given the limited attention and weight given to the BAF factors, MSC does not consider these in the opinion. BSAFs are discussed in somewhat more detail and are evaluated here by MSC. According to the REACH guidance, for a substance exceeding a Log Kow value of 5.5, a BSAF value in the order of 0.5 or more indicates high bioaccumulation potential (ECHA, 2014).

For D4, a laboratory accumulation study with the sediment worm *Lumbriculus variegatus* (Krueger et al., 2008a) allowed normalized BSAF values of 19 to 28 to be derived (Annex 2). A laboratory study with the insect *Chironomus tentans* gave BSAF values of 0.6-2.6 (Kent et al., 1994).

Field studies on fish in Japanese rivers (SIAJ, 2011) also gave BSAF values above one. Concentrations in sediment were generally low (often close to or below the limit of quantification), D4 was still detectable in the biota samples from the area, particularly flathead mullet and Japanese seabass.

For D5, a laboratory study (Krueger et al., 2008b) with *Lumbriculus variegatus* gave normalized BSAFs of 0.96 – 8.65 (EA, 2013). BSAF values above one have also been determined in some studies, e.g. in fish (SIAJ, 2011) invertebrates, (Powell et al., 2009b). MSC regards other available BSAF studies, reported in the PBT summary for D5 as not reliable.

Overall conclusion on BSAFs

MSC agrees with the DS the laboratory and field studies for D4 and D5 discussed above have interpretation difficulties and limitations, and thus cannot be given much weight in the overall assessment. However, MSC agrees with the DS that they do show that D4 and D5 can in some cases accumulate from sediments into biota to a degree that is indicative of bioaccumulating substances.

IV.3.2.5 Field data on presence of D4 and D5 in the environment

D4

The DS has shown that D4 can be found in a wide range of organisms (particularly fish and aquatic invertebrates but also birds and mammals) throughout various aquatic food chains, including top predatory fish and mammals such as the Grey Seal. Concentrations are generally relatively low, but the DS concludes that they are in a comparable range with other vB substances for some wild fish species at locations with significant local sources.

D4 is present in biota in remote regions, including fish and birds in the European Arctic (Campbell, 2010). The levels are generally low and frequently not detectable but higher levels do occur. Although some of the high levels might be linked to local sources (i.e. WWTP discharge points), D4 is detectable in some of the samples from more remote locations.

D5

The DS has shown that that D5 is found particularly in fish and aquatic invertebrates but also birds and mammals throughout various aquatic food chains, including top predators such as American Mink Grey Seal and Pilot Whale.

D5 is also found in fish, birds and marine mammals sampled from remote regions with low abiotic background levels, e.g. Svalbard in the European Arctic. Levels are generally shown to be very low, and frequently not detectable. Nevertheless, higher levels have also been reported.

MSC conclusion

MSC considers the fact that D4 and D5 are found in a wide range of organisms, in a wide range of food chains and in remote areas as reliable supportive evidence for the very bioaccumulative behavior of D4 and D5. This is in agreement with the DS conclusions. The finding that concentrations of D4 and D5 in remote areas are low or not always detectable is shared with many other PBT/vPvB substances, and cannot be used on its own to disqualify the vPvB properties of D4 and D5.

IV.3.2.6 Field data on biomagnification and trophic magnification factors

Use of field data in the bioaccumulation assessment

It was mentioned in the comments submitted during the public consultation that laboratory studies are not a good metric for siloxanes, but that most weight should be given to field studies. Many field studies have been performed for D4 and D5, in particular trophic magnification studies in which the biomagnification over a whole food chain is assessed. It was brought forward in the public consultation that these food chain studies show that trophic magnification factors are usually below 1. On the basis of this fact it was argued that both D4 and D5 should not be considered as bioaccumulative.

In response to this the DS remarked that if a substance is not biomagnifying but or even shows biodilution, i.e. trophic magnification factors are ≤ 1 , this does not automatically lead to the conclusion that the substance is not bioaccumulative. In the response to the comments made during the public consultation the DS has quoted the REACH Guidance, Chapter R.11 on PBT assessment:

"In principle, BMF values are not directly related to the BCF values in a way that they can be directly calculated from each other, unless certain assumptions and recalculations are made as in the case of the fish dietary accumulation test (Anon. 2004a, 2004b and Section R.7.10). However, because food chain transfer and secondary poisoning are basic concerns in relation to PBT and vPvB substances, an indication of a biomagnification potential can on its own right be considered to conclude that a substance meets the B or vB criteria but absence of such a biomagnification potential cannot be used to conclude that these criteria are not fulfilled. The same applies for bioaccumulation factors (BAF) calculated from field data (i.e. by relating concentrations in field sampled aquatic organisms to the concentration in their habitat). If such BAF values are above the criteria for B or vB it should be considered whether this information is sufficient to conclude that the substance meets the B or vB criteria."

The reason is stated here as well. Field data may be variable, which prevents to extrapolate a conclusion drawn from some ecosystems to all ecosystems. This seems especially the case for D4 and D5, for which rather variable results were found. This is reflected by the fact that several trophic magnification factors are below one, but some are above one, as indicated by the DS.

Discussion of trophic magnification studies for D4 and D5

Without any further data treatment, biomagnification and/or trophic magnification for D4 reported by the DS is lower than one for Lake Pepin, inner and outer Oslofjord, Lake Erie, Lake Mjøsa and Lake Randsfjorden, 1 for Lake Ontario and higher than one for Lake Opeongo and Tokyo Bay.

Similarly, reported biomagnification and/or trophic magnification for D5 is lower than one for Lake Pepin, inner and outer Oslofjord and Lake Erie, 1 for Tokyo Bay and higher than one for Lake Opeongo, Lake Mjøsa, Lake Randsfjorden, Lake Champlain and Lake Ontario. This would still lead to contradictory conclusions on the bioaccumulative behavior of D4 and D5, not a priori the conclusion that the substances are not bioaccumulative.

Several data treatments have been applied. A re-analysis, which has been extensively summarized by the DS, was made of all the studies for D4 and D5, except for Lake Ontario, Lake Opeongo, and Lake Champlain. By applying a probabilistic method, a value for each species was drawn from a statistical distribution for that species. This generally lowered the values of the TMF substantially, resulting in the TMF for D4 in Lake Mjøsa only, and for D5 in Lake Mjøsa, Lake Randsfjorden to be higher than one. This also indicates that the conclusion on whether the substance biodilutes or biomagnifies could change as well by applying this probabilistic method. E.g. the TMF for D4 in Tokyo Bay changed from 1.3 to 0.6 after application of the probabilistic method.

Another data treatment was done by adjusting biota concentrations for differences in exposure due to spatial differences in their home range. This has been done for the studies in Tokyo Bay, Lake Ontario, and Lake Champlain. For this purpose, sediment samples were taken to obtain a concentration profile of the substances in the study areas. Concentrations in biota are then adjusted to the exposure that is representative for their home range (i.e. on basis of BSAF). This adjustment had a major influence on the outcome. The TMF for D5 in Lake Champlain for example changed from 2.0 without treatment to 0.5 after adjustment for spatial differences.

The DS remarked that this is dependent on the assumption made in the analysis, in which the home range increases with the size of the fish. Another assumption is that sediment concentrations are representative of the exposure concentrations for the biota to which the adjustment is applied. Given the fact that the food chains from both Tokyo Bay and Lake Champlain are described as pelagic and not benthic, MSC argues whether such an adjustment is applicable. Water concentrations were not determined in the study.

Another data treatment is the scaling of the TMF values to that of known POPs such as PCB153. This process is referred to as benchmarking. Although this could have an impact on the magnitude of the TMF, the DS noted that it will not change the sign of the TMF, i.e. whether the substance will biodilute or biomagnify.

From the above, MSC concludes that the way in which the TMF values are calculated has a great impact on the outcome of the TMF value. Not only the magnitude of the TMF value can be impacted, but also the sign of it. In addition, the setup of the field study could have its influence on the resulting TMF values as well. These aspects cover both spatial and temporal variability in sampling, but also the selection of species belonging to the ecosystem.

Spatial variability can lead to different organisms exposed to different environmental concentrations. This is the reason why some of the recalculations are performed as described above. However, temporal differences could have a strong impact on trophic magnification as well. The DS remarked that for the Lake Pepin food chain study, fish, occupying the higher end of the sampled food chain, were sampled in September 2007, and sediment and invertebrates, occupying the lower end of the food chain, were sampled in May 2008. This lake (which is characterized by inflow and outflow of a river) has a rather strong variation in hydraulic residence times varying from 6 to 47 days, which probably will have an impact on exposure concentrations. Such temporal variability further complicates the interpretation of the observed TMF values.

Further it appears that TMF values could be strongly dependent on the inclusion or exclusion of certain species. A good example is given in the study performed in Lake Erie (McGoldrick, Chan et al. 2014). If plankton and walleye are excluded from the regression, the TMF values for D4 and D5 increase from 0.74 and 0.75 to 1.1 and 1.2, respectively. However, at the same time, the TMF value for PCB180 decreases from 1.2 to 0.58.

The DS also mentions the re-analysis of the Oslofjord study for D4 by (Smit, Posthuma-Doodeman et al. 2012). This analysis is extended by MSC for D5 and presented here as a further example of how the inclusion of certain species could affect the resulting TMF values. A main criticism of Smit et al. (2012) on the Oslofjord study is the division in several food chains. Most of the species are assigned to the dominant food chain A. This assignment was based on all species that have a stable carbon isotope ($\delta^{13}\text{C}$), which is not significantly lower than that of Atlantic cod, which form the top of the food chain. This is based on the fact that the higher the carbon isotope ratio is, the more benthic the food sources of the species are.

However, zooplankton was also added to this dominant benthopelagic food chain, although zooplankton appeared to be fully pelagic. The effect on the data is shown in Figure 1. Trophic dilution occurs in the benthopelagic part of the food web. However, for the whole Oslofjord ecosystem no trend is observed. For the pelagic part of the food chain seems to be opposite to this, but it should be noted that except for D5 in the benthopelagic (dominant) and the smaller benthic food chain none of the regression slopes is significant.

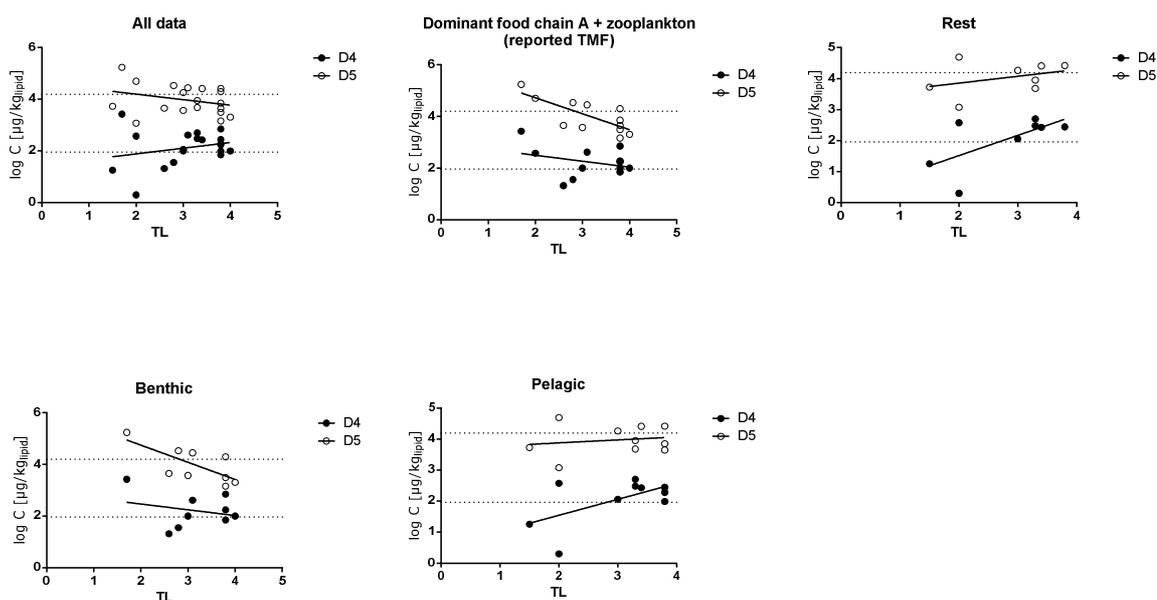


Figure 1: Trophic magnification in the inner Oslofjord. 'All data' refers to all species mentioned in the study. The dominant food chain A (which is benthopelagic) plus zooplankton corresponds to the trophic magnification factors that are presented in the study report. The data that were not included in this regression are shown as 'Rest'. The food chains assigned by Smit et al. (2012) as 'benthic' and 'pelagic' are shown at the bottom row.

The DS remarked that trophic dilution is observed for benthic and benthopelagic food chains, but that trophic magnification could occur in pelagic food chains. The re-analysis of the Oslofjord data as shown above indeed show the same pattern. A possible explanation is that in a benthopelagic food chain the lower trophic levels (e.g. worms) are more benthic and the higher trophic levels (e.g. fish) are more pelagic. Given the high persistence in sediment, but some hydrolysis in the

water column and volatilization from water, a deviation from thermodynamic equilibrium is possible. Such an effect might lead to differences in exposure levels between lower and higher trophic levels (Smit, Posthuma-Doodeman et al. 2012).

MSC Conclusion

Field data for D4 and D5 show highly variable results. Although biodilution occurs in most benthopelagic ecosystems, biomagnification is observed for some pelagic systems. Which part of the ecosystem is considered, seems decisive for the outcome of the TMF value for D4 and D5. Further, the inclusion or exclusion of a few or even a single species could already affect the outcome of the TMF for D4 and D5. Temporal and spatial variability are aspects that add further uncertainty to the interpretation of the results. Last, the data treatment is an important factor on the TMF values that are calculated. Especially the probabilistic method and the adjustment for differences in spatial exposure could have a major influence on the calculation of the TMF.

Field data for biomagnification of D4 and D5 are inconclusive, but some of the trophic magnification studies support the fact that D4 and D5 are bioaccumulative. Next to that, the PBT guidance of ECHA clearly states that the absence of such biomagnification should not be used to conclude that the substances do not meet the B or vB criterion.

IV.3.2.7 Use of a fugacity approach in the bioaccumulation assessment

In the comments submitted during the public consultation the use of fugacity ratios has been mentioned several times. It is suggested that fugacity ratios are a suitable tool to assess the bioaccumulation potential: The low fugacity ratios between biota and its surrounding environment (e.g. sediment) should be considered as an indication of the lack of bioaccumulation potential. In the PBT assessment for D5 the DS had indicated that the calculation of the fugacity ratio is an approximation that is based on certain assumptions. In addition, it is noted that there is a lack of scientific agreement about how to interpret fugacity ratios.

One of the assumptions made is that the partitioning to lipids is equal to the octanol-water partitioning. It is indicated by the DS that K_{ow} might be a strong overestimation of the lipid-water partition coefficient. As a consequence, fugacity ratios are calculated that are probably erroneously low. MSC is of the opinion that the comments from the public consultation about the special chemistry of these substances could be equally well applicable to the assumption that lipid-water partitioning for D4 and D5 is similar to that of hydrophobic organic chemicals.

As an example presented here by MSC, BSAF values are calculated that correspond to a fugacity ratio of 1 (Annex 4). The experimental organic carbon partition coefficient is taken (K_{oc}) for partitioning to soil in combination with K_{ow} for lipid-water partitioning. With the values as proposed by the DS for risk assessment, these BSAF values would be 180 and 710 L_{lip}/kg_{oc} , for D4 and D5 respectively. BSAF values of this magnitude are unrealistically high, indicating that the fugacity ratio concept is not necessarily applicable here.

MSC Conclusion

In summary, the fugacity approach has not been accepted for regulatory decision-making worldwide and not validated for D4 and D5. In his response to the comments made during the public consultation, the DS also remarks that such an approach should also be validated with confirmed PBT and vPvB substances before any conclusions can be drawn from such an assessment. Therefore, MSC supports the conclusion of the DS that this approach is not suitable to conclude that D4 and D5 are not bioaccumulative.

V. Assessment and comparison with the Annex XIII criteria

Persistence

Based on the information presented by the DS and careful consideration of the comments received in the public consultation, MSC supports the opinion of the DS that D4 and D5 both meet the vPvB criteria in Annex XIII of REACH.

With regard to the assessment of persistence, MSC concludes that the experimental observations in simulation and monitoring studies lead to the conclusion that both D4 and D5 meet the vP criterion as specified in REACH Annex XIII.

MSC has evaluated non-degradation processes and concluded that these do not have a large impact on the sediment removal half-life, and thus cannot be used to refute the relevance of the sediment compartment in the assessment of persistence.

Based on OECD TG 308 sediment simulation studies (Xu, 2009a & 2009b), D4 has an estimated degradation half-life of 365 days in anaerobic sediment and 242 days in aerobic sediment at 24°C, MSC concludes that D4 meets the Annex XIII criteria for a very persistent (vP) substance in sediment according to Regulation (EC) No 1907/2006.

Based on OECD TG 308 sediment simulation studies (Xu, 2010), D5 has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24°C. MSC concludes that D5 meets the Annex XIII criteria for a very persistent (vP) substance in sediment according to Regulation (EC) No 1907/2006.

Bioaccumulation

With regard to the assessment of bioaccumulation, MSC concludes that D4 and D5 are very bioaccumulative based on high fish BCF values, supported by multiple lines of evidence on biomagnification in dietary studies, and elimination half lives. In addition, the available field data provides evidence that bioaccumulation and trophic magnification have been shown to occur in certain food webs in the environment. The available information on biomagnification and trophic magnification factors (BMF/TMF) in the field, indicating that biodilution occurs in some food chains or in parts of some food chains, does not invalidate the other lines of evidence.

D4 meets the Annex XIII criteria for a very bioaccumulative (vB) substance according to Regulation (EC) No 1907/2006 based on the following studies:

- A steady-state BCF of 12,400 L/kg for Fathead Minnow *Pimephales promelas* (Fackler et al., 1995) based on total 14C measurements.

- A steady state BCF for Common Carp *Cyprinus carpio* in the range of 3,000 – 4,000 L/kg (based on parent compound analysis) (CERI, 2007 and 2010a). The kinetic BCF in one of the studies was in the range 4,100 - 5,500 L/kg.

D5 meets the Annex XIII criteria for a very bioaccumulative (vB) substance according to Regulation (EC) No 1907/2006 based on the following studies:

- A steady-state BCF of 7,060 L/kg for Fathead Minnow *Pimephales promelas* (Drottar, 2005), based on total ¹⁴C measurements.
- The steady state BCF for Common Carp *Cyprinus carpio* in the range 12,049 – 12,617 L/kg (based on parent compound analysis) or 10,550 – 11,048 L/kg when normalised to a 5 per cent lipid content (CERI, 2010b).

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ANNEXES

- Annex 1 Request from the Executive Director of ECHA to the MSC of 14 October 2014 I(2014)0295 – ‘the mandate’.
- Annex 2 UK-CA’s report on the identification of PBT and vPvB substance results of evaluation of PBT/vPvB properties of D4
- Annex 3 UK-CA’s report on the identification of PBT and vPvB substance results of evaluation of PBT/vPvB properties of D5
- Annex 4 Calculation of fugacity ratios
- Annex 5 Calculations on fate and removal rates