EUROPEAN CHEMICALS AGENCY

Draft decision notified to the registrant(s) under Article 50(1) of REACH for comments

Helsinki, 10 September 2020

Addressees
Registrants of 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane listed in the last Appendix of this decision (registrant(s)[1])

Decision/annotation number
Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane
EC number: 435-790-1
CAS number: 297730-93-9

DECISION ON SUBSTANCE EVALUATION

Based on Article 46(1) of Regulation (EC) No 1907/2006 (REACH), ECHA requests you to submit the following information on 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane (referred to as "the Substance" or "HFE-7500" in this decision)[2]:

Environment

Request 1

1. Aerobic and Anaerobic Transformation in Aquatic Sediment Systems; test method OECD TG 308, as further specified in section A.6 "Specifications of the study";

The test has to be performed at a temperature of 12°C.

The test duration must be prolonged to 120 or even 160 days unless it can be justified that reliable results and identification of all degradation products relevant for the PBT assessment can be obtained within the normal duration of 100 days indicated in the OECD TG 308.

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[1] The terms registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

[2] Testing on vertebrate animals can only be started or performed after the decision has been adopted according to Article 52 of REACH.

Monitoring of the Substance concentrations in sediment, water and air is required.

A mass-balance calculation must be included in the test.

You must minimise any losses of the test substance due to volatilisation.

Relevant transformation and/or degradation products (including perfluorobutyric acid (PFBA, EC 206-786-3) must be identified and quantified at a concentration of ≥ 0.1 % w/w, unless demonstrated as technically not feasible.

Sterile water-sediment controls must be included in the test. In addition, if non-radiolabelled test material is used, sterile purified water controls must also be included.

If radiolabelled test substance is used, the total amount of non-extractable residues (NER) must be quantified and the reporting of results must include a scientific justification of the used extraction procedures and solvents.

Deadline to submit the requested information

Appendix 1: Section B.1 provides further details of how the deadlines were derived.

You have to provide an update of the registration dossier(s) containing the requested information, including robust study summaries and, where relevant, an update of the chemical safety report by the deadline (s) indicated below.

In addition to the robust study summary, you must submit the full study report for the request 1 by the same deadline, by attaching it to the relevant endpoint study record in IUCLID.

Request 1: The information required must be generated and provided **by 17 April 2023**.

Appendices

The reasons of this decision and any further test specifications of the requirements are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has a suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

ECHA
EUROPEAN CHEMICALS AGENCY

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Authorised[3] by Christel Schilliger-Musset, Director of Hazard Assessment

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[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane and other relevant available information, ECHA concludes that further information is required to enable the evaluating Member State competent authority (MSCA) to complete the evaluation of whether the Substance constitutes a risk to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in another decision to clarify the concern, according to Article 46(3) of REACH.

A.1 The potential risk – environment

The identification of a potential risk is based on a combination of exposure and hazard information.

According to information in the registration dossier the Substance is used as a functional fluid at industrial sites and by professional workers. Furthermore, article service-life in vehicles covered by the End of Life Vehicles (ELV) directive and in machinery, mechanical appliances, electrical/electronic articles covered by the Waste Electrical and Electronic Equipment (WEEE) directive is reported. Significant exposure to the environment cannot be excluded. In your comments, you indicate that the Substance is used in enclosed systems with no access by consumer users and limited release during servicing by professional workers. You expect that most of the release during the equipment lifetime will be evaporative losses through seals. You expect that electric [redacted] systems will be drained in a responsible manner and the high costs of the product will encourage re-processing and re-use rather than disposal as waste. However, this information does not change ECHA's conclusion that exposure of the environment can occur.

Based on information in the registration dossier, QSAR information and information from the published literature as detailed below, there is a concern that the Substance may be a PBT or vPvB substance as defined in REACH Annex XIII.

Based on this exposure and hazard information, there is a potential risk for the environment. As the available information is not sufficient to conclude on potential PBT/vPvB properties, further information is needed, as explained below.

A.2 The possible risk management measures – environment

If the obtained data from Request 1 is sufficient to confirm the suspected PBT/vPvB properties as defined in REACH Annex XIII, the evaluating MSCA will assess the need for further regulatory risk management in the form of identification as a substance of very high concern (SVHC) under Article 57 of REACH and subsequent authorisation or restriction of the Substance.

A.3 Explanation of the testing strategy – environment

The information requested constitutes the first tier in a testing strategy to clarify the concerns for suspected PBT/vPvB properties. Hence, the evaluating MSCA will review the information submitted by you as an outcome of tier 1 of the testing strategy, and evaluate if further information should be requested to clarify the concern for suspected PBT/vPvB properties.

A.4 REQUEST 1 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems): The concern(s) identified

3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane (referred to as "the Substance" or "HFE-7500" in this appendix) is a highly fluorinated substance and negligible degradation was observed in the ready biodegradation screening test available in the registration dossier. Hence, the Substance screens as potentially persistent according to ECHA Guidance R11 (ECHA, 2017).

Based on the measured log Kow values in the range of 5.75-6 reported in the registration dossier, the Substance fulfils the screening criteria for B/vB as defined in ECHA Guidance R11 (ECHA, 2017). Two experimental fish bioconcentration studies with the Substance are included in the registration dossier (ECHA dissemination website[4]). The BCF values determined in the Unnamed (2000) study are 3150- 8530 and in the Unnamed (2002) study 5200. Based on the weight of evidence, the evaluating Member State Competent Authority (eMSCA) considers that the B and vB criteria in Annex XIII of REACH appear to be met.

The available information does not allow concluding on whether the Substance fulfils the T criteria in Annex XIII of REACH.

In conclusion, there is a concern that the Substance may have PBT or vPvB properties according to Annex XIII of REACH. Further information requested in this decision is needed to clarify the PBT/vPvB concern.

A.5 Aerobic and Anaerobic Transformation in Aquatic Sediment Systems: Why new information is needed

There is no experimental data on hydrolysis due to the low water solubility of the Substance. EPISuite HYDROWIN (v2.00) predictions were not performed as the Substance

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[4] https://echa.europa.eu/registration-dossier/-/registered-dossier/21902/5/4/2/?documentUUID=05675650-2f6b-4034-8cf3-c736af32ed78

falls outside the application domain of the model. HFE-7500 includes an ether bond, which is usually considered to be relatively resistant to hydrolysis. The other functional groups of the Substance are not expected to be susceptible to hydrolysis.

Regarding phototransformation in air, two published scientific articles addressing the degradation of HFE-7500 by indirect phototransformation using hydroxyl radical and/or atomic chlorine in laboratory experiments are included in the registration dossier. In the study by Goto et al (2002), an atmospheric lifetime of 2.2 years is estimated, which can be converted to an atmospheric half-life[5] of 1.5 years. Diaz-de-Mera et al (2009) estimated an atmospheric lifetime of 2.9 years. An additional study by Rodriguez et al (2014) was found by the eMSCA where the atmospheric degradation of HFE-7500 with OH radicals at atmospheric pressure as a function of temperature (271-333 K) was studied in a reaction chamber using GC/FID and GC/MS techniques for the analysis. The authors estimated a local atmospheric lifetime of 0.30 years (at 275 K and ~760 torr) for HFE-7500, which can be converted to a half-life of 0.21 years.

Fluorinated acetate ester $n\text{-}C_3F_7CF(OC(O)CH_3)CF(CF_3)_2$ and formate ester $n\text{-}C_3F_7CF(OC(O)H)CF(CF_3)_2$ were detected as transformation products in the Goto et al (2002) and Rodriguez et al (2014) studies. Wang et al (2014) propose that the atmospheric transformation of HFE-7500 may ultimately lead to formation of perfluorobutyric acid (PFBA, EC 206-786-3). However, it is noted that this is partly based on theoretical assumptions on the degradation pathway and there is no experimental information indicating that PFBA is formed at relevant quantities in the environment.

Regarding biodegradation, a ready biodegradation screening test following OECD TG 301D is available for HFE-7500. After 28 days the degradation of the Substance was 1 % based on O_2 consumption and 0-1 % based on test material analysis. Hence, the Substance screens as potentially P/vP according to ECHA Guidance R11 (ECHA, 2017). There are no simulation biodegradation studies available for HFE-7500.

Degradation QSAR models were performed by the eMSCA as supporting information for the assessment. According to the EPISuite BIOWIN (v4.10) QSAR models, the Substance is not readily biodegradable and the BIOWIN 3 and 4 models predict very slow ultimate and primary degradation, respectively. The CATALOGIC model was used to get information on potential degradation pathways. Based on the model results, the degradation is initiated by the hydroxylation of the ethyl group. However, the model predicts HFE-7500 to be stable as both the probabilities for the first predicted transformation steps as well as the quantities of the predicted transformation products are very low ($P < 0.05$ and $Q < 0.04$).

HFE-7500 is a segregated hydrofluoroether that includes a perfluorinated region and a hydrocarbon region which are connected via an ether bond. The stability of organic fluorine compounds has been described in detail by Siegemund et al (2000). When all valences of a carbon chain are satisfied by fluorine, the zig-zag- shaped carbon skeleton is twisted out

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[5] half-life= 0.693 x lifetime, if first-order kinetics apply

of its plane in the form of a helix. This situation allows the electronegative fluorine substituents to envelope the carbon skeleton completely and shield it from chemical attack. Also the polarisability and high bond energies, which increase with increasing substitution by fluorine, of the carbon- fluorine bond contribute to the high stability of fluorinated compounds. The influence of fluorine is greatest in highly fluorinated and perfluorinated compounds. According to Wang et al (2015), under environmentally relevant conditions, perfluoroether chains are similarly resistant to abiotic (photolysis, reactions with OH radicals, and hydrolysis) and biotic degradation as the perfluoroalkyl chains.

The ether bond in HFE-7500 is not located between two per- or polyfluorinated fragments, but instead it connects the perfluorinated and the hydrocarbon fragments of the substance. Therefore, primary degradation of the Substance cannot be excluded. However, it is noted that if primary degradation occurs, persistent transformation products are expected to be formed, e.g. short chained perfluorinated carboxylic acids such as perfluorobutanoic acid (PFBA). At least three other hydrofluoroethers (ECs 484-450-7, 422-270-2 and 484-410-9), which are similar to HFE-7500, are registered under REACH but also for these substances only screening level biodegradation data, showing that they are not readily biodegradable, exist.

In conclusion, based on the available screening and QSAR information and considering that HFE-7500 is a highly fluorinated substance, there is a concern on its potential persistence. Further information on the degradation of HFE-7500 is needed to be able to firmly conclude on whether the parent Substance itself fulfils the criteria for P/vP in Annex XIII of REACH or whether it degrades to other persistent substances.

A.6 Aerobic and Anaerobic Transformation in Aquatic Sediment Systems: Considerations on the test method

Aims of the study

The simulation test is requested in order to obtain degradation half-lives of the Substance and to identify relevant transformation products, including PFBA.

Testing in sediment is considered appropriate for the following reasons:

HFE-7500 has low water solubility (0.021 mg/L) and high volatility (Henry's Law Constant 4.7×10^7 Pa·m^3/mol). Therefore, the Substance may disappear rapidly from surface water and soil via volatilisation. However, based on the high log Koc value (4.88), part of the Substance may adsorb to suspended material and end up in the sediment. Based on Level III distribution modelling in EPISUITE, air and sediment are the most relevant compartments for the Substance. Therefore, further information on the persistence of the substance in sediment is needed.

In your comments to the original draft decision, you argued that only emissions to air are expected from the registered uses of the Substance and that the Substance is not expect to be present in or remain in aquatic sediments. You also provided new environmental distribution modelling results. Furthermore, you commented that the OECD 308 guideline indicates that it is not appropriate for volatile test materials, which suggests that the method will not provide data relevant to real environmental/aquatic systems.

According to the ECHA Guidance Section R.11.4.1.1.1, page 44 (ECHA, 2017), a conclusion needs to be derived for all environmental compartments. The specific concern for persistency is normally present for the environmental compartment for which the P/vP criteria are most likely to be exceeded. There is a preference to test first in the water compartment. Exclusion of certain environmental compartments from the P/vP assessment based on absence of exposure may be acceptable only in very exceptional cases and upon justification. In this case, sufficient justification to exclude the sediment-water compartment has not been provided.

ECHA shares your view that based on the information on uses, most of the emissions of the Substance are likely to go to the atmosphere, and due to the high volatility and low water solubility, wet deposition from the atmosphere is not likely to be significant. However, considering the high adsorption potential of the Substance, adsorption into aerosols and particulate material and consequently dry deposition could occur to some extent. Hence, most of the Substance emitted to the atmosphere is expected to stay there until degraded, but it is not possible to know how much can be deposited to surface media. As indicated in the draft decision and in your comment, the atmospheric lifetime of HFE-7500 is estimated to be in the range of years, and thus, even though the deposition rate would be low, the emissions to air constitute a potential source of exposure for a long timespan. Furthermore, direct emissions of the Substance to water cannot be completely excluded either. Therefore, it is not possible to conclude that there is a complete absence of exposure of other environmental compartments than air.

ECHA highlights that the distribution models, including the NewEQC model that you refer to in your comments, can contribute to a hazard assessment and provide insights into the fate processes and important compartments to consider in an assessment, but they are not intended to be predictive of actual concentrations. Hence, the distributions estimated by the models can help to select the most relevant environmental compartment for the degradation simulation testing in the context of the persistency assessment of HFE-7500.

ECHA agrees with you that due to the high volatility, the Substance is not expected to remain in surface waters or soils for long periods. However, based on the high log Koc (4.88), the Substance may adsorb to particulate matter in water and end up in the sediment. This is supported by the environmental distribution modelling performed by the eMSCA as well as by you, which indicate that air and sediment are expected to be the most relevant compartments for the Substance, depending on the emission scenario applied in the modelling. Therefore, ECHA considers that simulation testing in water-sediment system is the most relevant option for persistence testing.

Finally, ECHA considers that, although the OECD 308 guideline indicates that it is applicable to non-volatile and slightly volatile substances, it can be performed for HFE-7500 if proper care and some modifications to the guideline are made in order to minimise possible loss of the Substance from the test system via volatilisation. OECD 308 tests have been performed for other highly volatile substances, e.g. decamethylcyclopentasiloxane (EC 208-764-9) (Unnamed, 2010), and the results have been suitable for persistence assessment (ECHA, 2018).

As to your comment suggesting that the OECD 308 study will not provide data relevant to real environmental/aquatic systems, ECHA highlights that according to the fourth introductory paragraph to Annex XIII, the PBT assessment of substances must be based on data obtained under 'relevant conditions'. 'Real environmental conditions' can vary widely across the European Union, depending on where and when a substance is being used and the use(s) in question. 'Relevant conditions' means conditions that allow for an objective assessment of the PBT/vPvB properties of a substance instead of the PBT/vPvB properties of a substance in particular environmental conditions (see Case A-013-2014, BASF, Decision of the Board of Appeal of 7 December 2016, paragraph 113; and Case A-004-2017, 3v Sigma S.p.A., Decision of the Board of Appeal of 15 January 2019, paragraph 57).

The requested sediment simulation test OECD TG 308, including identification of degradation products, is a standard information requirement at Annex IX and Annex X, Section 9.2.1.3 and 9.2.3 of REACH. It could also be a requirement for concluding your PBT assessment according to Annex XIII, Section 2.1 of REACH and could be requested in compliance check under Article 41 of REACH. However, since the information request is based on a potential risk identified and since the requested test deviates from the standard test design, the substance evaluation is an appropriate process in the present case. In addition, as you are the only addressee of this decision, your rights and obligations are not prejudiced by the choice of the process.

Specifications of the requested study

The simulation biodegradation study must be conducted following the OECD TG 308 guideline. Determination of degradation half-lives, identification and quantification of all potential degradation products relevant for the PBT/vPvB assessment (at a concentration of ≥ 0.1 % w/w unless it can be demonstrated that this is technically not feasible) and mass balance are required to be included in the study.

Test temperature

The test has to be performed at a temperature of 12 °C to represent the average environmental temperature for the EU.

Test duration

Based on the available information, mineralisation of the Substance is unlikely but some primary degradation leading to persistent degradation products cannot be excluded.

However, the primary degradation may be slow, especially at the low test temperature of 12°C. Therefore, in order to increase the possibility to detect degradation products as well as to facilitate comparison of data with the persistency trigger values, the test duration must be prolonged to 120 or even 160 days unless it can be justified that reliable results and identification of all degradation products relevant for the PBT assessment can be obtained within the normal duration of 100 days indicated in the OECD TG 308. Experience shows that an extension of the test duration is possible without significantly reducing the microbial activity, even though the OECD 308 test guideline states that the test duration should not normally exceed 100 days. A research project tested three substances and prolonged the OECD 308 test duration for 300 days (UBA, 2012 and 2013).

Analytical monitoring and mass balance

In the original draft decision sent for your commenting ECHA requested use of a radio-labelled test material in the OECD 308 test. However, you claimed that manufacturing of radio-labelled HFE-7500 is highly impractical and cost prohibitive, and hence, you proposed to perform the test with unlabelled test material and instead to monitor the concentrations of the Substance in water, sediment and air using purge and trap gas chromatography/mass spectrometry with evaluation of mass balance at each time point.

ECHA notes that radiolabelling is recommended in the OECD 308 guideline as it allows the measurement of non-extractable residues (NER) and $^{14}CO_2$ and consequently the determination of full mass balance. For the Substance, mineralisation is expected to be very low or negligible, and hence, the inability to measure the evolved CO_2 due to lack of radiolabelling is not likely to be a problem. Due to the high log Koc value of the substance (4.88), formation of NER could be significant and lack of data on its amount could potentially lead to difficulties in interpretation of the results of the study. Therefore, radio-labelling of the test material (at the most stable part of the molecule) is recommended by ECHA.

However, since you claim this to be technically and economically not feasible ECHA agrees that the test can also be conducted with non-labelled test substance using a suitable analytical method. Regarding the purge and trap gas chromatography/mass spectrometry method proposed by you, it should be kept in mind that based on the public information found by ECHA on this method, it seems that it may be applicable for volatile substances but it is not clear whether the adsorption of the Substance on sediment may prevent recovery, and whether potential less volatile transformation/degradation products can be reliably measured with this method.

ECHA emphasises that it is your responsibility to prove the adequacy of the method according to the requirements of the OECD 308 guideline and to ensure that the test performed meets the quality criteria (regarding recovery and repeatability and mass balance) of the guideline and provides results suitable for comparison with the Annex XIII criteria for P/vP of REACH.

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Consideration of low water solubility and high volatility

The low water solubility and high volatility of the Substance must be taken into account in the study design. You must minimise losses of the test substance by volatilisation. This could include for instance use of closed vessels with limited headspace and spiking the sediment directly (rather than the overlying water) with the test substance. Any modification to the guideline has to be well documented and justified. Overall, the test performed should meet the quality criteria of the OECD test guideline, and provide results suitable for comparison with the REACH Annex XIII criteria for P/vP.

In your comments to the draft decision, you stated that you prefer to follow the OECD 308 guideline as closely as possible. You disagreed especially with the suggestion to spike the sediment because starting with the Substance in the water better mimics the transport scenario expected in the environment and ensures that the Substance will be present in the aerobic layer of the sediment instead of having the bulk of the Substance in the anaerobic parts of the sediment. You also pointed out that the headspace should not be completely eliminated in order to maintain aerobic conditions.

ECHA agrees that the OECD 308 guideline should be followed as much as possible and modifications necessary to address the high volatility of the Substance should be made. Minimisation of headspace and spiking the sediment are mentioned as potential modifications as they have been used for other volatile substances, e.g. decamethylcyclopentasiloxane (EC 208-764-9) (Unnamed, 2010; ECHA, 2018).

ECHA agrees that normally the test substance should be introduced to the water phase. However, for highly volatile substances this may not be feasible because the substance may be lost by volatilisation.

The purpose of the requested test is to assess the degradation of the Substance in the sediment compartment and not the dissipation/transfer behaviour in a water-sediment system. Therefore, it is important that the Substance is present at a sufficient concentration in the sediment phase. In order to ensure this, spiking the sediment instead of the water column may be necessary. The Substance can be spiked to multiple positions in the surface layer of the sediment and in that way most of the Substance is expected to be in the aerobic part of the sediment and not in the anaerobic layers as suggested by you in your comments to the draft decision. It is reminded that the OECD TG 308 assesses both the aerobic and anaerobic transformations in aquatic sediment systems.

The test can be performed without these possible modifications or using some other modifications to the guideline if you can demonstrate that results suitable for comparison with the REACH Annex XIII criteria for P/vP are obtained and clear documentation and justification for any modification is provided. Further information on possible modifications and test conditions of OECD 308 tests for volatile substances can be found for example in Shrestha et al (2020). ECHA agrees with your proposal to perform a pilot study before the definitive test in order to see what modifications to the guideline are necessary and feasible.

In your comments on the Proposals for amendment (PfAs), you referred to the difficulties observed by Shrestha et al (2020) in maintaining aerobic conditions in the water phase when using closed set-up and co-solvent. ECHA notes that the authors of the study mentioned different measures that could be applied to enhance the aeration of the water phase, e.g. overhead stirring of the water surface which is considered as a promising option. OECD 308 recommends for ventilation either gentle bubbling or passing air over the water surface with gentle stirring of the water surface, at the same time avoiding as far as possible any disturbance of the sediment phase. The test guideline further indicates that slightly volatile chemicals should be tested in a biometer-type system with gentle stirring of the water surface, or in closed vessels with a headspace of either atmospheric air or nitrogen and with regular exchange of the headspace gas in the aerobic test in order to compensate for the oxygen consumption by the biomass. In the OECD 308 study with the highly volatile decamethylcyclopentasiloxane (Unnamed, 2010; ECHA, 2018), closed test vessels were used and for each air-exchange, headspace gas was withdrawn through two types of traps while concurrent bubbling of fresh air into the water was carried out.

ECHA notes that due to the high volatility of the Substance, if gentle stirring or bubbling of the water surface is done continuously, it may result in increased losses of the Substance by volatilisation. However, aeration of the water phase (if needed to compensate for oxygen consumption) can be done concurrently with the exchange of the headspace gas in a closed test vessel.

It is important to quantify the amount of parent substance and relevant transformation products removed from the test system in the outlet gas during the aeration events. This quantification is needed for the determination of the half-life of the Substance and formation of the transformation products.

Furthermore, since in the Shrestha et al (2020) study the depletion of oxygen in the headspace and water phase seemed to be due to degradation of the co-solvent, it is important to avoid or minimise as much as possible the use of co-solvent and choose a solvent with slow degradation.

Analytical monitoring and Identification of transformation/degradation products at a concentration of ≥ 0.1 % w/w

Monitoring of the test substance concentrations in the three phases - sediment, water and air (i.e. volatile fraction) – must be carried out during the study in order to determine the mass balance.

It must be ensured that the extraction of the test substance in the three phases is as exhaustive as possible in all samplings. According to the OECD TG 308, the number of sampling times should be at least six (including zero time). Due to its low water solubility and high volatility, the Substance is expected to adsorb rapidly to sediment and may volatilise from the water phase, and therefore, additional sampling points during the initial period of the study are needed in order to determine the rate of distribution between the three phases. This is a necessary provision for a successful kinetic modelling when performing the data evaluation because it may be necessary to re-calculate the test concentration and to adequately identify the point in time to use as the starting point for calculation of the half-life. To do this, three samples must be taken on the first day, after 3, 6 and 12 hours; another sample must be taken after 24 hours followed by sampling times at day 7, 14 and day 28. The following sampling times must be nearly evenly distributed over a 4 weeks interval. Hence, depending on the total duration of the study, a total of at least 11 sampling time points for a test duration of 160 days must be included in the study.

The requirement for the additional exact sampling points was not included in the draft decision that was sent for your commenting, but provided during the decision-making, through a proposal for amendements. In your comments you argued that the sampling points are too prescriptive, particularly the timepoints on the first day. You argued that the degradation is expected to be slow and the sample preparation is expected to take some time, making the 1 hour sampling point not practical. You proposed to do the sampling at 0, 1, 3, 7, 14, 28 days and every 4 weeks after that. ECHA agrees that the degradation is expected to be slow and points out that the additional sampling on the first day is to determine the distribution of the Substance in the three phases (water, sediment, air) as this will help to obtain more accurate kinetic modelling and half-lives as indicated above. Based on the additional distribution data exploring the maintenance of the Substance in water, soil and sediment samples included in the registration dossier, significant volatilisation of the Substance may occur from water-sediment systems within hours. Furthermore, based on the high log Koc, the Substance may also adsorb rapidly to sediment and form non-extractable residues. Therefore, ECHA disagreed with your proposal to remove the three additional sampling points on the first day but decided to change the 1 hour sampling point to 3 hours sampling point in order to have more time for sample preparation between the zero hour sampling and the first sampling after that.

Furthermore, as indicated above, mineralisation of the Substance is unlikely due to the perfluorinated structure but some primary degradation leading to persistent degradation products cannot be excluded. Therefore, identification and quantification of all potential degradation products relevant for the PBT/vPvB assessment (at a concentration of ≥ 0.1 % w/w unless it can be demonstrated that this is technically not feasible) is required. "Technically feasible" means that you have demonstrated within allocation of reasonable efforts to develop suitable analytical methods and other test procedures to accomplish testing in sediment, water and air so that reliable results can be generated. In your comments you indicated that you aim to have analytical methods with a limit of detection (LOD) of <0.01 mg/kg or 1% of the initial dose (whichever is lower), as specified in OECD TG 308 (paragraph 15). However, ECHA requests identification and quantification of the relevant transformation/degradation products at a concentration of ≥ 0.1 % w/w. This is justified based on the expected low primary degradation rate of the Substance, especially when considering the low test temperature of 12 °C, and the relevance of the expected degradation products to the PBT assessment. Based on the structure of the Substance, and as indicated also in your comments to the draft decision, PFBA is expected to be one of the possible degradation products and will be monitored during the test. It belongs to the group of perfluorinated carboxylic acids which are known to be highly persistent. Therefore, the potential formation of PFBA (at a concentration of ≥ 0.1 % w/w) especially must be monitored in the requested simulation study.

In the draft decision sent for your commenting the concentration threshold of ≥ 0.1 % w/w was not specified as a requirement for the identification and quantification of the relevant transformation/degradation products. Therefore, ECHA made a PfA in order to give you a possibility to comment it. In your comments, you proposed to analyse only 1,1,1,2,3,3,3- heptafluoropropane and perfluorobutyric acid as degradation products, unless monitoring of additional transformation/degradation products would be needed in order to obtain a sufficiently high mass balance. You argue that these two final degradation products are stable whereas based on the available data on toxicokinetics, phototransformation and hydrolysis with HFE-7500 and similar substances, the expected intermediate transformation products will be further degraded more rapidly. ECHA agrees that 1,1,1,2,3,3,3- heptafluoropropane and perfluorobutyric acid are expected to be the final stable degradation products. However, based on the available information it cannot be excluded that some of the other possible transformation/degradation products could also be relevant for the PBT assessment. Furthermore, if the test substance is not radiolabelled (as you proposed in your comments to the draft decision), monitoring only the two final degradation products may not be sufficient for an adequate mass balance calculation. Therefore, ECHA maintained the requirement to identify and quantify all relevant transformation/degradation products at a concentration of ≥ 0.1 % w/w (unless it can be demonstrated that this is technically not feasible).

Furthermore, a mass balance calculation must be included. It is noted that a full mass balance calculation is only possible if radiolabelled test material is used. If the requested test is performed with non-labelled test material (as you proposed in your comments to the draft decision), the mass balance calculation must be determined based on the measured quantities of the parent substance and of the relevant degradation/transformation products in all compartments (sediment, water and air). In that case it will not be a comprehensive mass balance calculation as it is not possible to directly quantify the amount of non-extractable residues (NER) or evolved CO_2.

Sterile controls

Sterile water-sediment controls must be included in the test to determine to what extent the test substance decrease is due to biotransformation or to potential abiotic losses (e.g. volatilization, formation of non-extractable residues (NER)).

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If the test substance is not radiolabelled, it will not be possible to differentiate whether the observed losses in a sterile water-sediment control are due to leakage of the volatile fraction or due to formation of NER. In that case, including also a sterile control containing only purified water, without sediment addition, will further help the interpretation of the results as the NER formation is minimized, and hence, any potential losses are assumed to be due to leakage of the test substance. If in a sterile purified water control the test substance is maintained in the test bottles then it can be assumed that negligible leakages are occurring in the water-sediment test bottles. Therefore, if non-labelled test material is used, sterile purified water controls must also be included in the test.

ECHA notes that it is important to ensure that test conditions in the sterile controls and the active test bottles are as identical as possible. A precondition for conclusion on degradation is that other removal processes are not assessed as degradation. With this aim it is necessary to compare processes observed in sterile controls with those observed in the active test bottles under comparable test conditions.

Therefore, other test specifications of the sterile control bottles, such as the headspace volume, sampling times, analytical measurements as well as any potential causes of disturbance (such as aeration events) that might affect the distribution of the test substance or that could cause leakage, must be the same as in the active water-sediment test bottles, to ensure comparability. However, it is noted that if in the active water-sediment bottles the test substance is spiked into the sediment, as recommended in the decision, the addition of the test substance into the sterile water control will differ as the substance has to be added to the water phase.

OECD TG 308 does not include instructions for a sterile control. However, OECD TG 309 gives guidance on the preparation of sterile water controls as well as sterile controls containing water with sediment added in large amounts. Furthermore, ECHA notes that the OECD TG 308 test (Unnamed, 2010; ECHA, 2018) for decamethylcyclopentasiloxane (EC 208-764-9), as well as other published water-sediment degradation simulation studies (e.g. Liu et al, 2013; Shrestha et al 2016, 2020) included sterile controls and can provide guidance on the preparation of sterile controls. In these studies the sterilisation was done either by the addition of sodium azide, autoclaving or both. In addition, in another publication (Otte et al, 2018) different methods for sterilisation of marine sediment were compared.

The selection of the sterilisation method and time to perform the sterilisation in the sterile water-sediment controls, e.g. before or after the acclimation period specified in the paragraph 31 of OECD TG 308, may have an effect on the sediment properties. Based on Otte et al (2018), thermal sterilization, gamma radiation and chemical sterilisation have all advantages and disadvantages. Considering the importance of the integrity of the sediment phase to produce meaningful results for comparison to unsterilised conditions, ECHA recommends to use methods that have the least impact on the mineral phases and the geochemistry of the sediment. OECD TG 309 indicates that the sorption characteristics of the sediment may be altered by autoclaving. According to Otte et al (2018) autoclaving and gamma radiation lead to a large increase in dissolved organic carbon and have impacts on the mineral phase, while chemical sterilisation seems to be the method that would likely have the least impact on the geochemistry of the sediment phase. However, it should be noted that chemical sterilisation may also affect some sediment properties, e.g. triggering changes in pH.

In conclusion, you must explain and justify the methods and procedure used for establishing the sterile controls in the study report, and determine the efficiency of the sterilisation by measurements of microbial biomass. OECD TG 308 indicates that the microbial biomass of both water and sediment must be measured at post-handling, test start and test end, and mentions methods for that. Furthermore, ECHA recommends that the method of sterilisation should be the same for the sterile water-sediment controls and the sterile purified water controls to ensure better comparability between the two different controls. Finally, ECHA notes that communication with the eMSCA is possible in case you wish to have a mutual discussion on the preparation of the sterile controls.

Consider quantification of NER

Quantification of non-extractable residues (NER) must be carried out if radiolabelled test substance is used. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA, 2017). The Background note on 'Options to address NER in regulatory P assessment', published on the ECHA website, provides some suggestions on the further refinement[6].

Request for the full study report

You must submit the full study report for Request 1. Considering the complexity of the simulation study and the possible modifications needed to the standard method requested, a complete rationale of test design and interpretation of results and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess all the provided information, including the statistical analysis, and to efficiently clarify the concern for potential persistence.

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[6] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

A.7 Aerobic and Anaerobic Transformation in Aquatic Sediment Systems: Alternative approaches and proportionality of the request

The request for OECD TG 308 study is suitable and necessary to clarify the concern on potential persistence of the Substance. There is no equally suitable alternative way available of obtaining this information.

A.8 REQUEST 1: Notes for consideration

Fluoride ion analysis

As already explained above, if the test substance is not radiolabelled, possibilities for obtaining a comprehensive mass balance are limited. The determination of defluorination could provide additional information on biotransformation and mass balance, compared to the measurement of parent substance and transformation products only. Fluoride analysis has been conducted in some published degradation studies on poly- or perfluorinated substances and used as indication of defluorination/degradation (e.g. Li et al 2018, Liou et al 2010, Quinete et al 2010, Schröder 2003, Wang et al 2005). Therefore, if radiolabelled test substance is not used, ECHA recommends including the analysis of fluoride ions in the test, both in the active tests bottles and in the sterile controls.

For a meaningful analysis of fluoride, an analytical method would be needed which is sufficiently sensitive to detect and quantify the amount of fluoride that could be formed during the potential degradation of the Substance. The expected amount of fluoride released (at different assumed degrees of defluorination) and the study conditions (such as initial test substance concentration and background concentration of fluoride) may help to conclude on whether the fluoride analysis is technically feasible in the study.

B.1 Consideration of the time needed to perform the requested studies

The deadline for provision of the requested data takes into account the time that you may need to agree on which of the registrant(s) will perform the required tests (3 months is allocated for this) and include the time required for developing an analytical method, conduct of the study according to the test guideline, preparation of the study report and reporting in IUCLID.

In the draft decision communicated to you, the time indicated to provide the requested information was 21 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 27 months. You sought to justify this request by the need of an extensive amount of initial analytical method development (estimated to take 3-6 months) and the need to conduct a pilot study before the definitive study in order to define the experimental design to prevent volatilisation of the test substance. You claimed that since the degradation is expected to be slow, the durations of both the pilot study and the definitive study are likely to be the maximum 100 days indicated in the OECD 308 guideline. Therefore, you estimated that 10-12 months are needed in total for the pilot study and 6-8 months for the definitive study (including data analysis and reporting).

ECHA notes that analytical method development is already included in the usual deadline of 18 months for degradation simulation studies, and hence, no additional time is justified based on that. However, ECHA agrees that due to the likely need to make some modifications to the OECD 308 guideline in order to prevent volatilisation of the Substance, a pilot study may need to be conducted. As you indicated that it would need to be 100 days long, ECHA agrees to extend the deadline by 4 months. Furthermore, since ECHA requests prolongation of the OECD 308 study from the usual 100 days indicated in the guideline up to 160 days, 2 months are added to the usual deadline of 18 months given to simulation studies.

In your comments to the proposals for amendements you requested to further extend the 27 months timeline by an additional 4-5 months. You were still of the opinion that due to the poor water solubility and volatility of the Substance, a significant amount of method development is needed, and hence, 2-3 extra months should be given for that. Furthermore, you claimed that 1-2 extra months are needed if the study must be performed under good laboratory practice (GLP), and additional 1-2 months are necessary to synthesize standards and characterize their purity for the analysis of the relevant transformation/degradation products. Finally, in addition to the technical challenges, you requested to extend the deadline by 3-6 months in case of a new contingency for the Covid-19 situation.

Regarding your request for additional time needed for method development due to low solubility and high volatility of the Substance, ECHA reminds that the deadline of 27 months already included 4 extra months for conducting a pilot study (as indicated above). However, ECHA agrees with your comment that due to the potential challenges related to maintaining aerobic conditions in closed systems as observed in Shrestha et al (2020), further time for method development may be needed. Thus, ECHA decided to extend the timeline with additional 2 months based on this reason. You also commented that the OECD 308 study with decamethylcyclopentasiloxane (Unnamed, 2010; ECHA, 2018) mentioned in the decision is not publicly available, and hence, it may not be possible for you to obtain information on the study that would be useful for the method development. ECHA clarifies that the study with decamethylcyclopentasiloxane was simply used as an example to show that successful testing has been possible with other highly volatile substances. There is no need to consult the study authors. As to your request for later applying a further extension of the deadline if significant challenges arise after the initial pilot study, ECHA highlights that once the final decision is adopted, ECHA is not in a position to extend the deadlines.

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ECHA points out that when generating new information, according to Article 13 (4) of REACH ecotoxicological and toxicological tests and analyses must be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or ECHA. This includes also degradation simulation studies as they are considered under the section on ecotoxicological information in the REACH Annexes VIII-X. Therefore, ECHA interprets that the requested degradation simulation study must be performed in compliance with GLP, and the time needed for that is already included in the usual deadline of 18 months for degradation simulation studies.

Regarding your comment on the additional time needed for synthesis of standards for the analysis of transformation/degradation products, ECHA agrees with your proposal to extend the timeline by 2 months. This is because in the final decision the identification and quantification of all transformation/degradation products relevant for the PBT assessment at a concentration of ≥ 0.1 % w/w is requested, which is lower than the limit of detection of 0.01 mg·kg^{-1} or 1% of the initial amount applied to a test system which is mentioned in the OECD TG 308 and which you planned to use according to your comments to the draft decision.

Finally, regarding the uncertainties related to the current Covid-19 situation, it is difficult to foresee in advance how much time would be needed in such a case, as the situation may differ between countries and will depend on the severity of the potential new outbreak. As indicated above, neither ECHA nor the eMSCA have the competence to extend the deadline given in the final Decision once it is adopted. However, should you face delays in testing and providing the requested data due to the Covid-19 situation, you can contact the eMSCA explaining your situation for their consideration.

In conclusion, after considering your comments on the PfAs, ECHA decided to set the timeline to 31 months.

B.2 References

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Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the end of the 12-month evaluation period i.e. after 20 March 2019.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected PBT/vPvB, exposure of environment and wide dispersive use, 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane CAS No 297730-93-9 (EC No 435-790-1) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2018. The updated CoRAP was published on the ECHA website on 20 March 2018. The competent authority of Spain (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 45(4) of the REACH Regulation, the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the following concerns: suspected PBT/vPvB properties. Therefore, it prepared a draft decision under Article 46(1) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 20 March 2019.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation as described below.

ECHA notified you of the draft decision and invited you to provide comments.

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took the comments from you, which were sent within the commenting period, into account and they are reflected in the reasons (Appendix 1). The request and the deadline were amended.

Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the evaluating MSCA received proposal(s) for amendment to the draft decision and modified the draft decision. They are reflected in the reasons (Appendix 1)

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ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendment(s).

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

MSC agreement seeking stage

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-70 written procedure and ECHA took the decision according to Article 52(2) and Article 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to otherwise fulfil the information request (s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the required experimental study/ies, the sample of the substance to be used ('test material') has to have a composition that is within the specifications of the substance composition that are given by all registrant(s). It is the responsibility of all the registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on the composition of the test material. The substance identity information of the Substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.