EUROPEAN CHEMICALS AGENCY

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For decahydronaphthalene, CAS No 91-17-8 (EC No 202-046-9), registration number: [redacted]

Addressee: [redacted]**, registrant of decahydronaphthalene (concerned registrant)**

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph.

Registrants meeting the following criteria are not addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3)of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the Finnish Safety and Chemicals Agency as the Competent Authority of Finland (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registration of the concerned registrant after 5 September 2013, the date upon which the draft decision was circulated to the other Competent Authorities of the Member States and ECHA pursuant to Article 52(1) of the REACH Regulation.

This decision does not imply that the information provided by the concerned registrant in the registration is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier of the concerned registrants at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Finland has initiated substance evaluation for decahydronaphthalene, CAS No 91-17-8 (EC No 202-046-9) based on a registration dossier submitted by the concerned registrant and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to high tonnage and suspected PBT (persistent, bioaccumulative and toxic) properties, decahydronaphthalene was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be

evaluated in 2012. The Competent Authority of Finland was appointed to carry out the evaluation.

The evaluating MSCA (eMSCA) considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 28 February 2013.

On 20 March 2013 ECHA sent the draft decision to the concerned registrant and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 19 April 2013 ECHA received comments from concerned registrant of which it informed the eMSCA without delay.

The eMSCA considered the registrants' comments received. The comments were reflected in Section III of the draft decision (Statement of Reasons), whereas no amendments to the Information Required (Section II) were made.

In accordance with Article 52(1) of the REACH Regulation, on 1 August 2013 the eMSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

On 7 August 2013, the eMSCA contacted ECHA to indicate that through recent informal contact with the registrants, they had realised that they had not received all the registrants' comments. ECHA Secretariat reviewed the web-form process and confirmed that part of the registrants' comments on the draft decision was not completely downloaded to ECHA's internal document management system. Subsequently, all the comments had not been submitted to the eMSCA for consideration. Thus, the draft decision was withdrawn from the referral to the MSCAs on 12 August.

The eMSCA considered all the registrants' comments received. In addition, the evaluation was discussed with the registrant in a teleconference 29 August 2013. The comments were reflected in Section III of the draft decision (Statement of Reasons), and Section II (Information Required) was modified regarding ecotoxicity testing.

In accordance with Article 52(1) of the REACH Regulation, on 5 September 2013 the eMSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, one Competent Authority of the Member States submitted editorial proposalsfor amendment to the draft decision.

On 11 October 2013 ECHA notified the concerned registrant of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA has reviewed the proposals for amendment and amended Section III of the draft decision.

On 21 October 2013 ECHA referred the amended draft decision to the Member State Committee.

On 8 November 2013 the Registrant did not provide any comments on the proposal for amendment but only comments on the draft decision.

After discussion in the Member State Committee meeting on 10-13 December 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 10 December 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This decision does not imply that the information provided by the registrant in the concerned registration dossier is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier of the concerned registrant at a later stage, nor does it prevent reiteration of the substance evaluation process once the present substance evaluation has been completed.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the concerned registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Mysid Acute Toxicity Test; test method US EPA OPPTS 850.1035;

2. *Daphnia magna* acute immobilisation test; test method EU C.2/OECD 202;

3. Mysid Chronic Toxicity Test; test method US EPA OPPTS 850.1350 or *Daphnia magna* reproduction test; test method EU C.20/OECD 211; based on the results from the acute tests, the most sensitive species shall be tested; and

4. Aerobic mineralisation in surface water - simulation biodegradation test; test method EU C.25/OECD 309.

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit:

Full study reports and robust study summaries for the information required under points 1 - 4 of this Section II.

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrant shall submit to ECHA by 25 November 2015 an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on decahydronaphthalene and other relevant and available information, ECHA concludes that further information is required in order to enable the eMSCA to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

Regarding bioaccumulation, based on the available information, it was initially concluded by the evaluating Member State that decahydronaphthalene fulfils the B criterion, and the vB criterion. Two experimental fish bioaccumulation studies are available for decahydronaphthalene: an aqueous exposure flow-through bioaccumulation study with carp

(*Cyprinus caprio)* according to OECD 305 and a dietary exposure test similar to OECD 305 with rainbow trout (*Oncorhynchus mykiss)*. The measured bioconcentration factors (BCFs) range from 1627 - 2872 for the aqueous exposure study and 4343 - 6485 for the dietary study (all values corrected to 5 % lipid concentration). The experimental values from the aqueous study show BCF values predominantly above 2000 and below 5000 (average 2324 ± 362). The experimental values from the dietary exposure study show BCF values predominantly above 5000 (average 5356 ± 687). From the dietary exposure test a DT50-value of 4.4 days for depuration can be calculated. The biomagnification factor (BMF) derived from the test is below 1 (0.856) which indicates that the substance does not have the potential to biomagnify at successive trophic levels in the aquatic food chain.

The registrant in their comments agree that the B criterion is fulfilled. Regarding the dietary exposure test, the registrant points out that the dietary bioaccumulation study is recommended for substances with a very low water solubility (water solubility below 0.01 - 0.1 mg/l and log Kow above 5 according to the OECD 305 test guideline) and that decahydronaphthalene only marginally fulfils the criteria to perform a dietary bioaccumulation test (water solubility is 0.889 mg/L and mean log Kow 4.6). In addition, the registrants point out that BMF value is below 1 showing no potential of decahydronaphthalene to biomagnify in the food chain. Based on these considerations and acknowledging the discussion about the significant uncertainty of the conversion of BMFs to BCFs the registrants conclude that the BCF data from the aqueous bioaccumulation study have a better reliability and that the substance should be considered B but not vB.

In response to the registrants' comments, it is acknowledged that there is large uncertainty related to the BCF values derived from the dietary exposure bioaccumulation test data. The dietary exposure test gives information on feeding biomagnification potential (depuration rate constant and half-life, BMF-factor). In order to derive BCF values, up-take rate constants were estimated with several methods using fish weight and logKow values as input data (Spacie and Hamelink 1982; Tolls and Sijm 1995; Barber 2003 and Sijm et al. 1995 as reviewed in Crookes and Brooke (2011) and as cited in the OECD 305 test guideline Annex 8). These BCF values should be considered only tentative due to the large uncertainties related to the estimation methods. Nevertheless, the validity of the dietary exposure test has been evaluated and the test is considered reliable with restrictions. The "cut off" criteria for water solubility and log Kow given in the OECD guideline 305 are intended to be used when selecting the appropriate test (dietary vs. aqueous exposure). It is important to notice that although "cut off" criteria are given in the test guideline, the guideline also points out that " It is not possible to give exact prescriptive guidance on the method to be used based on water solubility and octanol-water partition coefficient "cut off" criteria, as other factors (analytical techniques, degradation, adsorption, etc.) can have a marked influence on method applicability for the reasons given above." As the substance is adsorptive, dietary exposure can be significant and the possibility of the substance fulfilling the vB criterion cannot be overruled. In conclusion, the substance fulfils the B criterion and might fulfil the vB criterion. In the decision no information is requested regarding bioaccumulation. Therefore, the decision (Section II Information required) has not been modified based on the registrants' comments on bioaccumulation. It is not foreseen that further testing on bioaccumulation is needed, as two valid bioaccumulation tests are already available.

Regarding persistence (P) and toxicity (T), the available information indicates that the P/vP and T criteria might be fulfilled. Nevertheless, due to uncertainties related to the information, no definitive conclusion can be made and further testing is deemed necessary in order to establish whether the suspected concern (PBT properties) may be realised or not.

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1. Short and long term toxicity testing on aquatic invertebrates (Points 1 - 3 of section II)

Information on long and short term toxicity on aquatic invertebrates is required in order to enable the eMSCA to assess the properties of the substance and to decide whether it is toxic (T) in accordance with Annex XIII of the REACH Regulation. This information is thus needed to establish whether the suspected concern (PBT properties) may be realised or not. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures. In addition, the testing is needed in order to derive Predicted No Effect Concentration (PNEC) values and to refine the risk characterisation ratios of the risk assessment.

For the registered substance no valid experimental data on acute or chronic ecotoxicity are available. ECOSAR QSAR predictions (acute EC/LC50 values for green algae 0.668 mg/l, for Daphnid 0.455 mg/l, for Mysid shrimp 0.086 mg/l and for fish 0.549 mg/l) indicate that decahydronaphthalene fulfils the T screening criterion and can fulfil the T-criterion. However, no definitive decision on T properties can be done due to uncertainties related to the QSAR predictions. Therefore, long term aquatic toxicity testing is deemed necessary. Short-term (acute) toxicity testing is needed in addition as a range-finding test. On the basis of ECOSAR QSAR predictions on acute toxicity the most sensitive species is Mysid. Therefore, short term and long term toxicity testing was required on Mysid in the draft decision sent to the registrants for comments 20 March 2013. For comparison and in order to obtain information on acute and chronic effects with a standard OECD test, short-term and long-term toxicity testing with Daphnia magna was deemed necessary in addition.

The registrants agreed in their comments dated 18 April 2013 to conduct a long-term Daphnia magna reproduction test according to OECD 211. Regarding the acute testing, they suggested to perform a short term test within the scope of the reproduction study as a preliminary range finding test but not as a full separate test since the data are not needed for the environmental assessment.

In response to the registrants' comments, it is reminded that information on acute toxicity is needed in order to define appropriate test concentrations for long term testing. Conducting full acute toxicity tests (which include relevant amount of replicates) is the most reliable and cost-effective way of generating this information. In addition, the results from the proposed acute ecotoxicity tests can be used in reviewing the environmental hazard classification.

Regarding the request for the acute and chronic Mysid testing, the registrant considered that these tests do not add valuable information to the environmental assessment of decahydronaphtalene. The registrant questioned the QSAR results that indicate that Mysids are the most sensitive species. They pointed out, that if the test Mysids have been obtained from the field and transfered to laboratory conditions, a stress effect can affect the results. In addition, they pointed out that the guideline is of the US EPA and that they are not aware of testing laboratories performing Mysid testing in Europe.

Regarding the registrants' comments on Mysids, it is acknowledged that the data behind ECOSAR predictions for chronic hazards to Mysid shrimp are not extensive enough (only two data points) to allow considering the chronic model reliable. However, the data behind predictions for acute effects is based on more data (14 data points) and the results of the model are considered reliable with restrictions. Decahydronaphthalene is within the applicability domain of the model (ECOSAR neutral organics) and the results are considered adequate for the purpose (identifying the most sensitive species for further testing). Therefore, on the basis of acute ECOSAR QSAR predictions the most sensitive species is

Mysid.

It has been speculated that if the test Mysids have been obtained from the field and transfered to laboratory conditions, a stress effect can affect the results. There is, however, no indication that the data used for ECOSAR predictions would have been affected by such a field-to-laboratory stress. The studies collected for the training set chemicals in ECOSAR undergo an extensive data validation step to ensure appropriateness for inclusion in the model. When tests are conducted according to the guidelines (US EPA test guideline for Mysid), only laboratory strains are used, thus, no above mentioned stress effect exists.

Mysid testing has been used extensively in the USA and they are considered to be suitable test organisms in acute and chronic toxicity tests (Nimmo & Hamaker 1982, EPA 2002). The requested tests should be performed according to US EPA guidelines which are international test methods recognised as being appropriate for conducting ecotoxicity tests and acceptable alternatives to the OECD tests (ECHA guidance Chapter R7b, p. 86-87).

In a teleconference held with the registrant on 29 August 2013 the registrant indicated willingness to perform acute tests on Mysid and Daphnid; and to perform chronic testing on either Mysids or Daphnids depending on which is the most sensitive species. This step-wise testing strategy has been adopted in the draft decision and Section II has been modified accordingly. The registrant would nevertheless still prefer to do the testing on Daphnids.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrant is required to carry out the following studies using the registered substance subject to this decision: Short-term toxicity testing on invertebrates (test method: Mysid Acute Toxicity Test US EPA OPPTS 850.1035 and *Daphnia magna* Acute immobilisation test, EU C.2/OECD 202) and Long-term toxicity testing on aquatic invertebrates (test method: Mysid Chronic Toxicity Test US EPA OPPTS 850.1350 or *Daphnia magna* reproduction test, EU C.20/OECD 211). Based on the results from the acute tests the most sensitive species shall be tested for chronic effects.

Due to the intrinsic properties of the substance (such as poor water solubility, high adsorption potential and high volatility), the substance is difficult to test. Therefore, the OECD Guidance Document 23 on aquatic toxicity testing of difficult substances (ENV/JM/MONO(2000)6) shall be taken into account when conducting the tests and the test results shall be based on measured concentrations.

In setting the range of concentrations to be tested in the chronic test, the principles of the test guidelines referred to in points 1 - 3 of Section II shall be followed and the test concentrations shall bracket the T-criterion (10 µg/l) and the lowest of the used effect concentrations (EC_{10}), which means that this value is calculated by interpolation and not by extrapolation.

2. Simulation testing on ultimate degradation in surface water (Point 4 of section II)

Information on biodegradation is required in order to enable the eMSCA to assess the properties of the substance and to decide whether it is persistent (P/vP) in accordance with Annex XIII of the REACH Regulation. This information is thus needed to establish whether the suspected concern (PBT/vPvB properties) may be realised or not. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures.
There are only screening level biodegradation data available for the substance. Persistence assessment of decahydronaphthalene was conducted using percentage biodegradation

values observed in ready and inherent biodegradability tests and in studies with microbial cultures as well as primary biodegradation half-life values derived from experimental data and QSAR modeling (see table 1). Two experimental half-lives for decahydronaphthalene biodegradation were obtained from the study reports. No temperature conversion has been applied to the data. Most of the experiments were done at 20-22 °C.

The studies conducted with pure decahydronaphthalene included four ready biodegradability tests and two inherent biodegradability tests (Table 1). Based on the tests, it is concluded that decahydronaphthalene is not readily biodegradable (degradation of test substance 0, 0, 1 - 3 and 3 % during 28 days in the four ready biodegradation tests). One of the ready biodegradation tests, in which no biodegradation was detected within 28 days, was extended to 67 days and 11.6 % degradation was observed. In the two inherent biodegradability tests, both of which are non-standard mineralization tests, the inocula were pre-adapted to decahydronaphthalene in the laboratory for 14 or 67 days (Table 1). The [redacted] (2004) test was performed in general agreement with a ready biodegradability guideline (OECD 301 F) with the exception that pre-adapted inoculum was used. The inoculum for this test was obtained from the ready biodegradability test (included in the same report) after 67 days incubation. The percentage degradation in the two inherent tests was 5.5 % during 29 days and 52.9 % during 59 days, respectively (Table 1), which suggests that decahydronaphthalene fulfils at least the P criterion and that it may fulfil the vP criterion.

Half-lives (13.6 and 66 days) for primary degradation of decahydronaphthalene in hydrocarbon mixtures were obtained from two primary degradation studies (Prince et al. 2008; [redacted]. 2009); both of these studies used as inoculum water sampled from the environment (Table 1). In addition, in studies with microbial cultures, the primary degradation of decahydronaphthalene was relatively slow (McKenzie and Hughes 1976) and only some of the tested strains showed the ability to degrade decahydronaphthalene (Soli and Bens 1973) (Table 1). In all four primary degradation studies, the study mixtures included paraffinic hydrocarbons, which are known to affect the degradation of decahydronaphthalene due to cometabolism. Decahydronaphthalene biodegradation rates are expected to be higher when cometabolic substrates are present.

Table 1. Summary of available biodegradation test results

Method	**Micro-bial source**	**Test temp.**	**Initial conc. of deca-hydro-naphtha-lene**	**Half-life** [a]	**Results and remarks**	**Reference**
Four ready bio-degradability tests (methods: OECD 301 C, OECD 301 F, modified OECD 301 F, ISO draft BOD test)	Acti-vated sludge	22-25°C[b]	41-100 mg/l	n.a.	Pure decahydronaphthalene was used. Degradation of decahydro-naphthalene was in all tests 0 - 3 % after 28 d. One of the tests was continued for an extended period (67 days) and biodegradation of 11.6 % was observed	[redacted] (2010), CITI (1992), [redacted] (1997), [redacted]. (2004)

Inherent biodegradability test (extended OECD 301 F test)	Acti-vated sludge	22 (±1) °C	approx. 50 mg/l	n.a.	Pure decahydronaphthalene was used. Inoculum was pre-adapted for 67 days with decahydronaphthalene. Initial concentration during pre-adaptation was approx. 50 mg/l. Biodegradation was 15.7 % after 28 days and 52.9 % after 59 days (test duration 59 days)	[redacted] (2004)
Inherent biodegradability test (CO_2 evolution)	Sewage/ soil	room temp.	8.8 mg/l	n.a.	Pure decahydronaphthalene was used. Inoculum was adapted for 14 days with decahydronaphthalene with addition of the substance in water on days 0, 7 and 11 to water/soil seeded flasks. Deca-hydronaphthalene concentration during pre-adaptation was not reported. Biodegradation was 5.5% after 29 days (test duration 29 days).	[redacted] (1986)
Primary biodegradation study	Marine bacteria, (pure and mixed cultu-res)	26 °C	not reported	n.a.	Synthetic hydrocarbon mixture was used as decahydronaphthalene source. Cometabolic substrates were present. The bacterial cultures had been isolated using hydrocarbons as the sole source of carbon and energy from California coastal areas (cultivation procedures described in Soli and Bens 1972). It is not indicated whether they were pre-adapted with decahydronaphtha-lene. Degradation was determined by gas chromatography (GC). Test duration was 10-14 days. In one test, two strains of eight were able to degrade decahydro-naphthalene, with percentage degradation of 20 % and 25 %. In other tests, two more strains were observed to degrade deca-hydronaphthalene (percentage degradation 7 % and 17 %).	Soli and Bens (1973)
Primary biodegradation study	Kuwait crude oil enrich-ment culture	22 °C	60 mg/l (estimated) [c]	n.a.	Synthetic hydrocarbon mixture was used as decahydronaphthalene source. Cometabolic substrates were present. The duration or other details of enrichment procedure are not reported. It is not indicated whether the enrichment culture was pre-adapted with decahydro-naphthalene. Degradation was determined by gas chromatography (GC).	McKenzie and Hughes (1976)

					Test duration was 21 days and primary degradation of 13.6% was observed.	
Primary biodegradation study	Rain-water retention pond (New Jersey, U.S.)	21 °C	not reported but was below 88 µl/l which was the initial conc. of biodiesel B20	13.6 d	Biodiesel B20 was used as deca-hydronaphthalene source. Cometa-bolic substrates were present. Test duration was 31 days. No pre-adaptation was conducted. Degradation was determined by gas chromatography (GC). There were no detectable hydrocarbons in the water (detection limit ca. 2 ppb in 10 ml water).	Prince et al. (2008)
Primary biodegradation study	Sea-water (Atlantic Ocean, New Jersey, U.S.)	20 (±1) °C	not determined	66 d	Synthetic hydrocarbon mixture was used as decahydronaphthalene source. Cometabolic substrates were present. Test duration was 180 days; however, for decahydro-naphthalene the calculation of half-life was performed on the basis of a monitoring period of 35 days. The quantification of absolute concentrations was not performed. At each sampling interval, the poisoned controls served as the standards to which the responses of the test samples, determined by GC, were compared. Inoculum was not pre-adaptated. It is mentioned that the seawater was not expected to contain any contaminants at levels which would interfere with the studies.	[redacted] (2009)
QSAR primary biodegradation estimation (BIOHCWIN model)	not appli-cable			68.6 d		U.S. EPA EPI Suite v4.00, BioHCwin v1.01a

[a] No temperature conversion has been applied. (n.a. = not applicable)
[b] (for the ISO draft BOD test ([redacted], 1997), temperature was not reported)
[c] Estimated by the evaluator from the data presented in McKenzie and Hughes (1976) (0.1 ml of mixture containing an equal weight of 15 hydrocarbons was added to 100 ml of seawater medium. For the estimation, it was assumed that each of the 15 hydrocarbons has a density of 0.8804 g/ml.).

In conclusion, the data suggest that the P and vP criteria are fulfilled. However, due to uncertainties related to the data (there are no mineralisation half-life values available, the primary biodegradation half-lifes are obtained from studies where mixtures of hydrocarbons have been used, there are no standard simulation tests available), the data are not sufficient to allow a direct comparison with the Annex XIII criteria and no definite conclusion on the P property can be drawn based on the available data. Therefore, simulation biodegradation testing is deemed necessary. The surface water compartment is considered

the most relevant based on distribution modelling. According to Mackay level III model, assuming that all emissions are only to water, 50 - 93 % of decahydronaphahalene will be distributed to water compartment, < 0.02 % to soil, 2.3 - 47 % to sediment and 2.8 - 5.3 % to air. The ranges for each compartment represent the percentages obtained when degradation half-life values of 13.6 d and 1400 d were used for the modelling.

The registant in their comments dated April 2013 pointed out that decahydronaphthalene is solely used in industrial environments and that the possible arising emission would enter the aqueous environment via waste water and a waste water treatment plant. Due to high volatility and adsorption potential the intake via other routes is considered insignificant by the registrants. As the substance is poorly water soluble (water solubility below 0.889 mg/L at 25°C) concentrations above the water solubility limit would cause the substance to float on the surface and be removed from the water by mechanical measures e.g. oil/water separator. As the substance shows a high potential to adsorb to organic particles a major part of the dissolved material would be bound to the sewage sludge and be incinerated or disposed of afterwards. Additionally a significant fraction will be released to the atmosphere as indicated by the high Henry`s law constant of 7093 Pa*m3/mol. Thus the remaining concentration that is emitted to surface water would be low even if no biodegradation occured. The low concentrations in the environment are reflected by the study design of the OECD 309 test and imply that the test substance serves as a secondary substrate and may be degraded by "cometabolism". Compared to the total mass of biodegradable carbon substrates available in the natural water the concentration of the test substance will be very low (<100 µg/l). Despite these facts the registrants considered that the high volatility of decahydronaphtalene renders the OECD 309 unsuitable for decahydronaphtalene.

In response to the registrants' comments, it is clarified that OECD 309 has been requested in the decision because water is considered the most relevant compartment based on distribution modelling and because OECD 309 is considered the suitable choise of testing when the aim is to to determine mineralization kinetics and rates. Although the guideline indicates that the test is suitable for non-volatile or slightly volatile substances, it is considered that the test should be suitable for decahydronaphthalene provided that high volatility of decahydronaphthalene is carefully taken into account in the test design and documentation.

In a teleconference held with the registrants 29 August 2013, the registrants indicated willingness to conduct the requested OECD 309 with the use of closed bottles and radioactively labelled decahydronaphthalene. The registrants propose to use surface water containing humic substances (or added humic substances) in order to keep decahydronaphthalene in the water phase and to allow substrates for the possible cometabolism of decahydronaphthalene. Also minimizing/eliminating the headspace of the test bottles is considered as a modification to the guideline. The OECD 309 testing protocol (with possible modifications to the guideline) will be defined in detail later in cooperation with the eMSCA.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to carry out the following study using the registered substance subject to this decision: Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309).

In selecting sampling sites for the study, the history of possible agricultural, industrial or domestic inputs must be considered. If it is suspected that an aquatic environment has been contaminated with the test substance or other hydrocarbons, it should not be used for the collection of test water.

The main objective of OECD 309 test is the determination of the mineralization, whereas an optional secondary objective is to obtain information on the primary degradation and the formation of major transformation products. The obtained results must include mineralization degradation half-lives and allow a direct comparison to the P/vP criteria established in Annex XIII to the REACH Regulation. If information on primary degradation and transformation products is submitted in addition, this information will be taken into account in the P/vP assessment.

The intrinsic properties of the substance (such as poor water solubility, high adsorption potential and high volatility) shall be taken into account when designing the study.

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the required tests, the sample of substance used for the new studies shall have a composition that is within the specifications of the substance composition that are given by all concerned registrants. It is the responsibility of all the concerned registrants to agree on the tested materials to be subjected to the tests subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the eMSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the studies must be shared by the concerned registrants.

V. General requirements regarding Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Jukka Malm
Deputy Executive Director

Annex 1. References

Barber, M.C., 2003. A review and comparison of models for predicting dynamic chemical bioconcentration in fish. Environmental Toxicology and Chemistry, 22, 1963 - 1992.

[redacted] (1986). Establishment of chemical fate testing methods. [redacted]. Report date: 1983-11-14.

CITI 1992 (Chemicals Inspection and Testing Institute) (1992). Biodegradation and bioaccumulation data of existing chemicals based on the CSCL Japan. Japan Chemical Industry Ecology-Toxicology & Information Center (JETOC). Testing laboratory: [redacted] Report date: 1992-10-31.Crookes, M. and Brooke, D. 2011. Estimation of fish bioconcentration factor (BCF) from depuration data. Environment Agency, Bristol, UK. ISBN 978-1-84911-237-6.

EPA (2002). Draft detailed review paper on Mysid life cycle toxicity test. [redacted]

[redacted] 2010. Ready biodegradability - manometric respirometry test with the test substance decahydronaphthalene. [redacted]
Report date: 2010-07-13.

[redacted] (2004). Final report. Project Number [redacted]. Test substances: pure hydrocarbons. Ready biodegradability: "OECD 301F manometric respirometry test" performed for: [redacted]

[redacted] (2009). Primary degradation in seawater study. [redacted]

[redacted] (1997). Bestimmung der biologischen Abbaubarkeit von Dekahydronaphthalin im Blok-Test (BOD-Test for insoluble substances). [redacted]. Report date: 1997-06-30.

McKenzie, P. and Hughes, D. E. (1976). Microbial degradation of oil and petrochemicals in the sea. Microbiology in agriculture, fisheries and food. pp 91-108.
Nimmo, D.R. & Hamaker, T.L. (1982). Mysids in toxicity testin – a review. Hydrobiology 93, 171-178

Prince RC, Haitmanek C and Lee CC (2008). The primary aerobic biodegradation of biodiesel B20. Chemosphere 71, 1446-1451.

Sijm, D.T.H.M., Verberne, M.E., De Jonge, W.J., Pärt, P. and Opperhuizen, A. 1995 Allometry in the uptake of hydrophobic chemicals determined in vivo and in isolated perfused gills. Toxicology and Applied Pharmacology, 131, 130-135.

Soli G and Bens EM (1972) Soli, G. and Bens, E.B. 1972. Bacteria which attack petroleum hydrocarbons in a saline medium. Biotechnol. Bioeng. 14, 319-330

Soli G and Bens EM (1973). Selective substrate utilization by marine hydrocarbonoclastic bacteria. Biotechnol. Bioeng. 15, 285-297.

Spacie, A. and Hamelink, J.L. 1982. Alternative models for describing the bioconcentration of organics in fish. Environmental Toxicology and Chemistry, 1, 309 - 323.

Tolls, J. and Sijm, D.T.H.M. 1995. A preliminary evaluation of the relationship between bioconcentration and hydrophobicity for surfactants. Environmental Toxicology and Chemistry, 14, 1675 - 1685.