EUROPEAN CHEMICALS AGENCY

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

For N,N-dicyclohexylbenzothiazole-2-sulphenamide, CAS No 4979-32-2 (EC No 225-625-8)

Addressees: Registrant(s) of N,N-dicyclohexylbenzothiazole-2-sulphenamide

This decision is addressed to all Registrant(s) 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. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrant(s) meeting the following criteria are *not* addressees of this decision: i) Registrant(s) who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrant(s) 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 Federal Institute for Occupational Safety and Health (BAuA) as the Competent Authority of Germany (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 is based on the registration dossiers on 29 April 2014, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the Registrant(s) 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 Germany has initiated substance evaluation for N,N-dicyclohexylbenzothiazole-2-sulphenamide, CAS No 4979-32-2 (EC No 225-625-8) based on registrations submitted by the Registrant(s) and other relevant and available information 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 Human health/Suspected CMR, Sensitiser, Environment/Suspected PBT/vPvB, Exposure/Wide dispersive use, Consumer use, Worker exposure, Aggregated

tonnage, N,N-dicyclohexylbenzothiazole-2-sulphenamide was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of Germany was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the following concerns: Environment/Suspected PBT/vPvB, Exposure/Wide dispersive use.

In the course of the evaluation, the evaluating MSCA noted an additional concern regarding the prenatal developmental toxicity in terms of an identified data gap.

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 20 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) 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.

Registrants' commenting phase

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant(s). On basis of this information, the Statement of Reasons (Section III) was amended accordingly.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 30 October 2014 the evaluating MSCA 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 of the receipt of the notification.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 5 December 2014 ECHA notified the Registrant(s) 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 reviewed the proposals for amendment received and amended the draft decision.

On 15 December 2014 ECHA referred the draft decision to the Member State Committee.

By 5 January 2015, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. The Member State Committee took into account the comments the Registrant(s) made on the proposals for amendment (PfAs).

After discussion in the Member State Committee meeting on 3-5 February 2015, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 5 February 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance N,N-dicyclohexylbenzothiazole-2-sulphenamide (DCBS) subject to the present decision:

1. Prenatal Developmental Toxicity Study in rabbits (EU B.31; OECD 414), oral route.

2. Tests on biodegradation to assess the PBT-/vPvB properties for DCBS including potential metabolites simulation

2. a) Test on biodegradation in soil (EU C.23; OECD 307);

2. b) In case the test under 2. a) does not allow to conclude that DCBS is very persistent (vP) according to Annex XIII, 1.2.1. of the REACH Regulation an additional test on biodegradation in sediment (EU C.24; OECD 308).

The tests shall include both the part concerning derivation of the degradation kinetics and the part concering identification of transformation products / pathways. Because of the high tendency of DCBS to adsorb, a high ratio of non extractable residues (NER) are expected. Consequently, particular effort investigating if NER are formed by DCBS or by degradation products is necessary.

Both studies shall contain investigations to cover the range of pH 5.5 to 8.0. The kinetic part of the tests shall be conducted at 12°C.
In respect to other testing details the respective OECD test guidelines shall be followed (e.g. concering the soil and sediment types investigated) without deviations.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information on the registered substance in a revised version of the chemical safety report:

3. Further information on environmental exposure assessment:

a) Assumptions underlying environmental exposure estimation;
b) Environmental exposure assessment for the sediment compartment for the manufacturing of DCBS;
c) Environmental exposure assessment for the production and use of tyres and general rubber products;
d) Environmental releases from the use of tyres.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit a full study report for the information required under point 1 and robust study summaries for the information required under point 2.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by 07 March 2017 an update of the registrations containing the information requests of 1. and 2.a) and 3. in this decision[1] and an update of the Chemical Safety Report.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by 05 September 2017 an update of the registrations containing the information request of 2.b) in this decision[2] and an update of the Chemical Safety Report, if this study is conducted.

III. Statement of reasons

1. Prenatal Developmental Toxicity Study in rabbits (EU B.31; OECD 414), oral route

No data are available for the prenatal developmental toxicity of N,N-dicyclohexylbenzothiazole-2-sulphenamide (DCBS). Therefore, the hazard characterization of the compound can not be concluded upon, raising a concern on the safe use of the compound.

Three studies in rats have been submitted by the Registrant(s) for reproductive toxicology: A non-guideline screening test (Ema et al., 2007a), an OECD 422 (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test) study (Ema et al., 2007b) and an OECD 416 (Two Generation Reproduction Toxicity Study) (Ema et al., 2008) study.

Whereas the available studies provide information on fertility and peri- and postnatal development, it is not possible to evaluate the potential prenatal developmental toxicity without the data of the appropriate study.

The Prenatal Developmental Toxicity Study in rabbits, oral route; EU B.31/OECD 414 is a guideline study and is the recommended study to elucidate the prenatal developmental toxicity. Additionally, it should be noted that prenatal developmental toxicity studies are a standard information requirement of the REACH Regulation.

The rabbit shall be used since all other studies in the reproductive toxicity testing of DCBS have been performed on rats and it would be usefull to generate the data on prenatal developmental toxicity in a second species (no- rat). The oral route was selected as default route.

The data of the Two Generation Reproduction Toxicity Study have been published in a scientific paper, thus, the evaluating MSCA was able to analyse the data independently. As a result the evaluating MSCA came to a different conclusion in regard of the no observed adverse effect level (NOAEL) derivation than the Registrant(s). Based on this experience ECHA requires not only the robust study summary but also a full study report of the Prenatal Developmental Toxicity Study to facilitate the independent evaluation of the data generated by the Registrant(s).

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are requested to

[1] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).
[2] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

submit the following study using the registered substance subject to this decision: Prenatal Developmental Toxicity Study in rabbits, oral route; test method: EU B.31; OECD 414.

2. Test on biodegradation in sediment (EU C.24; OECD 308) and on biodegradation in soil (EU C.23; OECD 307)

DCBS is a potential PBT-/vPvB-substance. The Registrant(s) screened the P and vP properties of DCBS according to Annex XIII 3.1.1. The results suggest that DCBS is persistent or very persistent under relevant environmental conditions. The substance has also been discussed in the PBT-Expert-Group of ECHA.

With the registration dossier, information on hydrolytical degradability of DCBS was submitted indicating that the substance is hydrolytically degradable to a certain degree. The hydrolytical transformation products of DCBS are MBT (CAS No 149-30-4) and Dicyclohexylamine (CAS No 101-83-7). However, hydrolysis rates are rather low and do not significantly influence the persistency of DCBS in the environment under relevant environmental conditions (temperature, pH, etc.).

In their comments on the draft decision, the Registrant(s) state that in 2008, the PBT Working Group (PBT List No. 66) concluded that N,N-dicyclohexylbenzothiazole-2-sulphenamide (DCBS) does not meet the P criterion due to a fast hydrolysis. ECHA points out the following:

The assessment of the PBT-properties of DCBS was discussed at the fourth meeting of the ECHA PBT expert group 28 - 29 May 2013. In the evaluation relevant environmental conditions (temperature, pH, etc.) were considered. In line with the approach agreed at the 32. meeting of ECHA's Member State Committee (MSC-32) relevant environmental conditions include 12°C temperature.

DCBS has a high tendency to adsorb to sediments and particles. Therefore, the presence of sediments and particles under relevant environmental conditions must be taken into account when interpreting the hydrolization rate measured according to the standard hydrolysis test employing clean water.

According to structure activity assessments, biological degradation of DCBS – if possible at all – might require several complex steps. Some of these include unlikely reaction steps (kinetically extremely slow reaction steps). It is also expected that the covalent bond between the dicyclohexylamine moiety and the MBT moiety is unlikely to be biologically degraded. This cleavage is only possible via abiotic degradation processes, most likely hydrolysis caused by acid catalysis. The degradation products observed in degradation studies might indicate whether abiotic or biotic degradation is taking place. If MBT (CAS No 149-30-4) and Dicyclohexylamine (CAS No 101-83-7) are identified as primary degradation products this is suggesting that degradation is dominated by abiotic processes, i.e. hydrolysis. If hydroxylated transformation products of DCBS were identified as primary degradation products this would be an indicator for a biotic transformation process.

In their comments on the draft decision the Registrant(s) state that degradation products have been observed in several studies. In the hydrolysis study 2-mercaptobenzothiazole (MBT) and Dicyclohexylamine (DCHA) have been identified as primary hydrolysis products. 2-methyl-Thiobenzo-Thiazole (MeSBT), benzothiazole (BT), 2-Benzothiazolone (BTon) and 2-Benzothiazolesulfonic acid (BTSOH3) as identified in the inherent tests can be formed by biotic and/or by abiotic processes. It is however obvious that DCHA, formed as an intermediate in the inherent study was consumed during the study which can only occur by

biodegradation. ECHA points out the following:
This comment supports the evaluation results that starting from DCBS the identified transformation and degradation products may only be explained following a metabolism pathway starting with the cleavage of the covalent bond between the dicyclohexylamine moiety and the MBT moiety. This cleavage is only possible via abiotic degradation processes, most likely hydrolysis caused by acid catalysis. The comment of the Registrant(s) is congurent with the evaluation by the evaluating MSCA that in the inherent study this was the primary degradation step. None of the identified metabolites prove a biological degradation of DCBS itself. If hydroxylated transformation products of DCBS might be identified this would be an indicator for a biotic primary degradation step.

DCBS was not readily biodegradable in screening tests. Moreover, screening tests on inherent biodegradability were submitted in an update to the registration. However, these tests are not reliable because purity was unclear, the mass balance at the start of the experiment is not confirmed, and pH values are partly implausible or missing. Nevertheless, MBT (CAS No 149-30-4) and Dicyclohexylamine (No CAS 101-83-7) were identified as primary degradation products suggesting that hydrolysis is the dominant degradation process in these tests and not biological degradation.

In their comments on the draft decision, the Registrant(s) state that the inherent biodegradability tests did not use a pre-adapted inoculum. The inoculum contained a mixture of activated sludge from municipal and industrial sewage treatment plants (Currenta, 2013a/b), which is in accordance with the OECD 302C guideline. A pre-adaptation process of the inoculum to DCBS prior to test start was not performed. It can be therefore concluded that DCBS is inherently biodegradable when considering the low water solubility and thus the low bioavailability. ECHA points out the following:

On the basis of this information the relevants section was amended and the reference to pre-adapted industrial inoculums was deleted. However, the inherent biodegradability tests (Currenta a/c) show experimental shortcomings. One test vessel with test substance in both studies has undesignedly and extremely higher pH value (both > pH 9.4) than all the other test vessels with test substance and those with blank tests (all < pH 7.1). These two test vessels show extremly high biochemical oxygen demand (BOD) values, which wrongly indicate a biodegradation of the test substance beyond 100%. This influences the calculated mean value, erroneously. Following the guideline, these two test vessels have to be removed from any further assessment and conclusion. The mean value of the degradation (%) of the remaining three test vessels for both studies was calculated following the procedure of calculation by the author of the studies. The mean degradation reached after 28 days is 3.3 % for Currenta 2013c and 28.7 % for Currenta 2013a. It can be therefore concluded that DCBS is NOT inherently biodegradable.

Two other screening tests on inherent biodegradability (Currenta, 2013b/d) are not reliable because purity was unclear, the mass balance at the start of the experiment is not confirmed, and pH values are partly implausible or not reported. Nevertheless, MBT (CAS 149-30-4) and Dicyclohexylamine (CAS 101-83-7) were identified as primary degradation products suggesting that hydrolysis, already before the start of the experiment, is the dominant degradation process in these tests and not biological degradation.

Annex XIII of the REACH Regulation distinguishes between screening of P and vP properties and the definitive assessment of P and vP properties – i.e. comparision with the numeric P, B, and T-criteria. In case screening information is indicating a substance might fulfil the PBT- or vPvB-criteria, the Registrant(s) need to provide further information according to Annex XIII 3.2 (see Annex XIII 2.1).

With regard to assessing the persistency of DCBS, the Registrant(s) provided only screening information. Also the studies submitted with an update of the registration belong to screening information. Due to experimental shortcomings, the information seems not to be reliable enough to allow an assessment of the persistency. A reassessment is suggesting that DCBS is not inherently biodegradable and the lack of degradation (< 20%) may provide sufficient information to confirm P according to Guidance R11.1.3.1.

In their comments on the draft decision, the Registrant(s) agree that a conclusive and definite assessment of the persistence of DCBS is not possible based on the available information. ECHA supports the assessment of the Registrant(s). This includes the available information on hydrolysis. However, the reassessment of Currenta 2013, a-c) is suggesting that DCBS is NOT inherent biodegradable and the lack of degradation (< 20%) may provide sufficient information to confirm the P criteria for DCBS according to Guidance R11.1.3.1. (Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment, version 2.0, November 2014).

Hence, it is concluded that simulation testing according to Annex XIII 3.2.1 needs to be provided including the fate and properties of potential transformation products of DCBS.

According to Mackay fugacity model level I based on the physico-chemical properties the main target compartments for DCBS are sediment with 49.72 % and soil with 49.17 % (Currenta, 2010e).

Consequently, the persistency of DCBS in the target compartments sediment and soil needs to be addressed by appropriate testing.

In their comments on the draft decision, the Registrant(s) state that Mackay modelling was provided but should be regarded only as an indication of the potential fate of a substance. The level I model does not consider via which compartment a substance enters the environment. The exposure assessment shows that exposure of soil is negligible. The risk characterisation ratios (RCR) for the environmental exposure scenarios do not indicate a risk for the soil compartment. Therefore, soil should not be regarded as the environmental compartment of primary concern. ECHA points out the following:

Considering the fate and behaviour of PBT/vPvB substances the target compartment may be different than the compartment into which a substance enters the environment. The risk characterisation ratios (RCR) do not represent the long term impact of PBT/vPvB substances. They have the ability to accumulate via the food chain and may dissipate from one compartment to another. Hence, a direct emission into a compartment is not necessary to assess it as the environmental compartment of primary concern. The available information and the inherent substance properties are suggesting that DCBS is persistent or very persistent under relevant environmental conditions in the soil compartment.

According to Annex XIII of REACH and the aspects mentioned before a simulation test on degradation in soil and a simulation test on degradation in sediment including the fate and properties of transformation products and metabolites need to be provided. The target compartments sediment and soil must be assessed under relevant environmental conditions like 12°C in line with the approach agreed at MSC-32 and must cover the full range of pH 5.5 to pH 8.0.

In their comments on the draft decision, the Registrant(s) agree that 12 °C is the relevant temperature for assessment of degradation processes under environmental conditions. The Registrant(s) prefer to conduct the simulation tests at 20 °C due to practical reasons.
In conclusion, the Registrant(s) do not agree to perform studies only under alkaline

conditions but within a range of 5.5 to 8.0 as described in OECD 307.

MSC-40 concluded based on the proposals for amendments (PfAs) and the respective comments by the Registrant(s), in line with the approach agreed at MSC-32, and according to PBT Guidance (p39, R.11.4.1.1 Persistence assessment) that the test temperature shall be 12°C for the kinetic part of the degradation tests for the following reasons: (1) For PBT/vPvB assessment it is considered more appropriate instead of using room temperature to use an environmentally relevant temperature in the EU generically set at 12°C. (2) Avoidance of temperature correction with the Arrhenius equation will allow obtaining more accurate results reducing uncertainties.

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are requested to submit the following study using the registered substance subject to this decision:

- Test Method: EU C.24 (OECD 308): simulation testing on biodegradation in sediment (Annex XIII 3.2.1 (c) and Annex X 9.2 and Annex IX 9.2.1.4) and identification of degradation products (Annex XIII and Annex X 9.3.4. and Annex IX 9.2.3);
- Test Method EU C.23 (OECD 307): simulation testing on biodegradation in soil (Annex XIII 3.2.1 (b) and Annex X 9.2 and Annex IX 9.2.1.3) and identification of degradation products (Annex XIII and Annex X 9.3.4. and Annex IX 9.2.3).

In their comments on the draft decision, the Registrant(s) agree to study the degradation of DCBS further in detail. However, the Registrant(s) do not agree with the proposed testing strategy. The Registrant(s) propose a tiered testing approach starting with an enhanced ready biodegradability test. If the enhanced ready biodegradability test fails, prior to initiating a full OECD 308 study, a reduced/modified OECD 308 study can be performed.

ECHA welcomes the decision by the Registrant(s) to study the degradation of DCBS further in detail. This includes generating a metabolism scheme. The available screening information prove that DCBS is not readily biodegradable and not inherently biodegradable. In these test systems the test conditions have been modified to achieve optimal conditions for degradation. Consequently, it is scientifically implausible that in another ready biodegradability test the pass level would be reached. Also, an additional screening test system would not allow the identification of biotic degradation products. The main concern is that DCBS is persistent or very persistent in the sediment or in the soil compartment. According to Annex XIII 1.1.1. and 1.2.1. of REACH there are standalone criteria for P and vP inside the compartment sediment and inside the compartment soil.

The Registrant(s) agrees in their comments from January 2015 that neither a "not-P" nor a "P" as result of testing only one of the two compartments would exclude the concern for "vP" in the other compartment. Consequently, if tested in a tiered approach the second test must be performed in any other case than "vP" as conclusion of the first test. The evaluating MSCA pointed out the following: Since in degradation studies no animal testing is involved it seems proportionate to perform both tests at the same time. Also the substance properties and the behaviour of DCBS are already well known and no new knowledge can be expected from the first test which would influence the set up of the second test. In view of the evaluating MSCA any unnecessary delay in the PBT-/vPvB-assessment would risk emissions of a potential substance of very high concern into the environment.

At the meeting of the Member State Committee (MSC-40) the PfAs concerning the order of the simulation studies and the respective comments were discussed. The Committee concluded in line with the considerations of the Registrant(s) that the test on biodegradation in soil shall be conducted prior to the test on biodegradation in sediment and a longer period of time for this second study shall be provided to allow tiered testing. In contrast to

the comments by the Registrant(s) the Committee concluded that the set up and design of both tests shall follow the respective OECD guidelines without deviations.

The OECD 308 test simulates a natural pond with a sediment compartment. Scientifically, this test system is well established to test the biodegradation inside the sediment compartment without any modification and deviation from the guideline necessary. The same applies to the OECD 307 which is well established to test the biodegradation inside the soil compartment. In addition, both would allow the scientifically proven identification of biotic degradation products.

Note regarding chronic toxicity on fish:
In the draft decision sent to the Registrant(s) a test on chronic toxicity on fish was requested. The reason was as follows:

DCBS is a potential PBT-substance. Therefore, further information on chronic ecotoxicity needs to be provided in order to definitely assess toxicity for aquatic organisms with regard to the T criterion.

With regard to chronic toxicity only a Daphnia test (TG OECD 211) and the NOErC for algae (TG OECD 201) are available for DCBS.

No conclusive assessment of the toxicity is possible since data regarding the chronic toxicity to fish are lacking. For confirmation that a substance is not toxic for the environment, all three trophic levels (see REACH Guidance R.11.1.3.3) need to be considered (if P and B criteria are fulfilled). Since DCBS is proven to be very bioaccumulative and screening information on biodegradability is suggesting that the substance is persistent or very persistent it seems to be appropriate to request additional information on chronic fish toxicity (Fish early-life stage toxicity test, OECD 210, Annex IX 9.1.6.1).

The Registrant(s) provided a test on chronic fish toxicity using MBT (Benzothiazole-2-thiol; CAS No 149-30-4) as read-across substance. This read-across is not reliable as MBT constitutes only a part of the DCBS molecule. The other moiety Dicyclohexylamine (CAS No 101-83-7) is considerably toxic in different ecotoxicity tests. In addition, also the physiochemical properties of MBT deviate significantly from DCBS. MBT is a well soluble substance (118mg/L) and DCBS has a very low solubility (1.9µg/L). A read-across for such different substances is not possible and therefore MBT cannot be used as read-across substance.

Furthermore, for poorly water-soluble substances the chronic toxicity cannot be predicted from acute tests. The acute tests conducted with DCBS did not show any effects or no effects at low concentrations. However, as no conclusion from acute tests to chronic toxicity is possible and the appearance of specific modes of actions or other chronic effects cannot be excluded, the chronic fish test is necessary to be conducted. Also the very high bioaccumulation factor should be considered in this case.

There is additional information relevant to human health available indicating that chronic toxicity may appear and showing that DCBS causes polyploidy and could activate the arylhydrocarbon receptor. However, this data does not allow further conclusions on toxicity.

The Registrant(s) commented that the test on chronic toxicity to fish is not necessary because:

1. If at all, the decision concerning a chronic fish test shall be switched until clarity has been achieved whether P/vP is fulfilled or not.

2. There is no scientific evidence that a chronic fish test would lead to a measurable effect.

The evaluating MSCA decided to await the results of the P/vP assessment of the substance. If the test on biodegradation in sediment and on biodegradation in soil shows that DCBS is P, the evaluating MSCA will evaluate the need for further testing on chronic toxicity in order to definitely assess toxicity for aquatic organisms with regard to the T criterion.

For this reason and the reason of animal welfare no test on chronic toxicity to fish is requested at this step of the process.

3. Further information on environmental exposure assessment

DCBS is a potential PBT-/vPvB-substance produced in amounts greater 1000 tonnes per year and is considered a substance with wide dispersive uses (production and use of tyres and rubber products).

Regarding environmental exposure assessment, sufficient information needs to be provided by the Registrant(s) to conclude on the concern for the environment. However, there are information gaps and imprecisions regarding the following aspects:

a) Assumptions underlying environmental exposure assessment

General assumptions underlying single exposure scenarios for DCBS are partly missing or not plausible. This concerns in particular the amounts of DCBS used and emission days per site, as well as operational conditions (OC) and risk management measures (RMM). For exposure assessment, the OC, RMM, and use(s) must be described in sufficient detail to understand for what purpose the substance is used, which processes are performed with the substance and how these processes are operated so that the release is limited to the release factor reported in the chemical safety report (CSR).

The amounts used per site in exposure scenarios (ES) 2 and 4 (manufacture of the substance, production of tyres and general rubber goods, and retreading) have not been specified. The number of emission days for ES 2 (production of tyres and general rubber products) is not conclusive. The Registrant(s) report emission days of up to 365 days. 365 emission days do not seem to be realistic for single downstream user sites. Therefore environmental releases might be higher than assumed in the CSR. No emission days per site are given for ES 4.

No information has been provided on efficiencies of existing RMM and OC in (ES) 2 and 4 (manufacture of the substance, production of tyres and general rubber goods, and retreading). This concerns especially the removal efficiency of waste water treatment plants since it is stated by the Registrant(s) that DCBS will be mainly released via the aquatic route. RMM addressing air emissions have not been specified in detail as well. However, in the EU risk assessment report (RAR) for N-Cyclohexylbenzothiazol-2-sulphenamide (CBS) (CAS No 95-33-0) annual releases of dust to air are reported. Since OC are stated to be the same for CBS and DCBS, releases to air cannot be excluded for DCBS.

ECHA does not agree with the Registrant(s) considering information on RMM and OC in the CSR to be sufficient as commented on the draft decision. The Registrant(s) intend to update the CSR considering further information on emissions to air. Although read-across to CBS (CAS No 95-33-0) is reasonable due to a similar chemical structure and physico-chemical properties and same operational conditions, it is not possible to estimate environmental releases of DCBS based on the data available in the exposure scenarios.

Therefore, pursuant to Article 46(1) of the REACH Regulation the Registrant(s) are requested to submit missing information and plausible data in terms of:

- tonnages;
- operational conditions of the processes;
- type and efficacy of risk management measures in place.

Furthermore, the Registrant(s) are requested to provide sufficient information why a derivation from the default values for emission days given in Chapter R.16 of ECHAs guidance on information and chemical safety assessment (version 2.1, 2012) is acceptable in an updated exposure assessment.

The amount used for environmental exposure estimation in ES 1 has been clarified by the Registrant(s). ECHA agrees that for ES 1 it is appropriate to use measured data for exposure assessment. For this scenario RMMs have been already considered in the calculation and the assumption of 365 emission days is therefore acceptable. However, the use of measured data, as applied in ES 1, is not applicable to downstream user scenarios ES 2 and ES 4. Information on environmental exposure needs to be specified in detail within the supply chain. If the Registrant(s) did not receive detailed information from downstream users, environmental exposure assessment needs to be performed according to Guidance R.16.
b) Environmental exposure assessment for the sediment compartment for the manufacturing of DCBS

In the exposure assessment provided, estimated concentrations of DCBS in sediments are missing for ES 1 (manufacturing of the substance). The Registrant(s)' argumentation that relevant accumulation of DCBS in sediments is not expected is not acceptable since it has been shown in screening tests that the substance is not readily biodegradable and will be mainly released via the aquatic route.

Therefore, pursuant to Article 46(1) of the REACH Regulation the Registrant(s) are requested to provide an exposure assessment for the sediment compartment for the manufacturing of DCBS. In their comment on the draft decision the Registrant(s) agreed to update the CSR considering information on exposure of sediment.

c) Environmental exposure assessment for the production and use of tyres and general rubber products

With regard to ES 2 (production of tyres and general rubber products), the article categories indicate uses in vehicles (AC 1), machinery, mechanical appliances, electrical/ electronic articles (AC 2), electrical batteries and accumulators (AC3) and rubber articles (AC 10). However, the Registrant(s) did not specify what products are exactly comprised by the term "general rubber products". Moreover, no differentiation has been made between the amount of DCBS used for tyre production and that for general rubber products. If the Registrant(s) had not followed a read-across approach transferring the PECs of CBS without adjusting input data to DCBS, this would have an impact on the estimation of environmental releases in exposure scenario 5 (use of tyres and general rubber products) which also combines tyres and general rubber products since different emission factors underlying environmental release categories (ERC) 10a, 10b, and 11a are assigned to that single scenario.

Although the Registrant(s) focused on the use of tyres due to low abrasion of general rubber goods compared to that of tyres which can be regarded as worst case, the amounts of DCBS used for the production and use in tyres must be further specified.

Therefore, pursuant to Article 46(1) of the REACH Regulation the Registrant(s) are requested to specify the term "general rubber products" and to report the amounts used for the production of tyres and that of general rubber goods separately, at this considering information request 3a.

In their comments, the Registrant(s) gave further information regarding production and use of tyres and general rubber products. ECHA agrees with the Registrant(s) that the scenario for the use of tyres for which most of the substance is used represents a worst case.
d) Environmental releases from the use of tyres

In exposure scenario 5 (use of tyres and general rubber products) the Registrant(s) assume the concentration of DCBS in articles to be [redacted]% due to complete consumption during vulcanization. However, a concentration of [redacted]% in tyres does not seem to be plausible when it is referred to a concentration of DCBS in preparations of up to [redacted]% in ES 2 and 4 (production of tyres and general rubber products, retreading), especially when process temperatures do not exceed 200 °C (as stated by the Registrants) but according to the registrations the decomposition temperature of DCBS accounts for ≥ 300°C at 1013 hPa. Therefore it is expected that residues of DCBS will be still contained in the product and will be potentially released to the environment via abrasion during use and the following processes in the environment (leaching, degradation of particles, etc.).

As already stated above, due to a read-across to CBS, the Registrant(s) did not perform exposure estimations for DCBS itself. However, the assumptions and (possible) input data need to be plausible. Moreover, a concentration of [redacted]% cannot be regarded as a worst case consideration and further reliable information is required.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) are requested to update the exposure scenario for the use of tyres on a (realistic) worst case basis.

In their comment on the draft decision, the Registrant(s) agreed to update the CSR considering further information on environmental releases from the use of tyres.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental studies, the sample of the substance to be used shall 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 composition of the test material. The substance identity information of the registered 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. Finally, the tests must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental studies the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:

https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrant(s) to perform the stud(y/ies) on behalf of all of them.

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://www.echa.europa.eu/regulations/appeals
The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
Director of Evaluation

Annex 1: List of registration numbers – This annex is confidential and not included in the public version of this decision