EUROPEAN CHEMICALS AGENCY

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

**For Phenol, styrenated CAS No 61788-44-1 (EC No 262-975-0) and Reaction mass of 2,4,6-tris(1-phenylethyl)phenol and 2,6-bis(1-phenylethyl)phenol CAS No not available (EC No 915-333-5)**

**Addressees: Registrant(s)[1] of Phenol, styrenated and Reaction mass of 2,4,6-tris(1-phenylethyl)phenol and 2,6-bis(1-phenylethyl)phenol (Registrant(s))**

This decision is addressed to the Registrant(s) of the above substance with active registrations pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.
Based on an evaluation by the Health & Safety Executive as the Competent Authority of the United Kingdom (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 dossier(s) on 7 May 2015, 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 dossier(s) of the Registrant(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.

## I. PROCEDURE

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of the United Kingdom has initiated substance evaluation for Phenol, styrenated, CAS No 61788-44-1 (EC No 262-975-0) and Reaction mass of 2,4,6-tris(1-phenylethyl)phenol and 2,6-bis(1-phenylethyl)phenol (EC No 915-333-5) based on registration(s) 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 the environment: PBT properties, endocrine disruption and

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of Registrants addressed by the decision.

cumulative exposure, Phenol, styrenated and Reaction mass of 2,4,6-tris(1-phenylethyl)phenol and 2,6-bis(1-phenylethyl)phenol were included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of the United Kingdom was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA noted additional concerns regarding cumulative exposure to sediment, terrestrial and marine compartments, and for terrestrial secondary poisoning.

The evaluating MSCA considered that further information was required to clarify the abovementioned environmental 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 25 March 2015

On 7 May 2015 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.

**Registrant(s) commenting phase**

By 15 June 2015 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, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

The draft decision sent to the Registrant(s) for commenting also included a number of other requests: a requirement for long-term aquatic invertebrate toxicity testing for monostyrenated phenol, long-term sediment and soil organism toxicity tests and a soil organism bioaccumulation test. These were intended to address environmental risk-driven concerns that were identified during the evaluation. However, the Registrant(s) raised concerns about the number of tests actually required due to the number of interdependencies between certain test requirements (e.g. the need for the tests to refine the environmental risk assessment depends on the outcome of the Persistent Bioaccumulative and Toxic (PBT) and Endocrine Disruption (ED) assessment). This made it difficult for the Registrant(s) to quantify the cost of the overall testing requirements.

Although the original proposal was clear that PBT and ED testing was to be completed prior to addressing concerns for the environmental risk assessment, for reasons of proportionality and to avoid unnecessary testing, given the views of the Registrant(s), ECHA amended the original draft decision to remove all testing to refine the environmental risk assessment. Further information may be requested in a follow-up decision.

**Commenting by other MSCAs and ECHA**

In accordance with Article 52(1) of the REACH Regulation, on 3 March 2016 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, one Competent Authority of the Member States and ECHA submitted proposals for amendment (PfAs) to the draft decision.

On 8 April 2016 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 accordingly.

**Referral to Member State Committee**

On 18 April 2016 ECHA referred the draft decision to the Member State Committee.

By 10 May 2016, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. In addition, the Registrant(s) provided comments on the draft decision. The Member State Committee took the comments on the proposal(s) for amendment of the Registrant(s) into account. The Member State Committee did not take into account the Registrant(s)' comments on the draft decision that were not related to the proposal(s) for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 6 – 9 June 2016, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 8 June 2016. ECHA took the decision pursuant to Article 52(2) and Article 51(6) of the REACH Regulation.

## II. INFORMATION REQUIRED

This decision is addressed to Registrant(s) of two different"substances" registered under REACH having different EC numbers. In the view of ECHA this is appropriate as the two substances have constituents in common; the registrations of the substance with EC number 262-975-0 cover the full range of styrenated phenol constituents: mono-, di- and tristyrenated phenol (different registrations having different amounts of each) and the registration of the substance with EC number 915-333-5 falls within that constituent range as the two constituent groups that it contains are di- and tristyrenated phenol.

According to Article 56 of REACH, the concentration limit for a Substance of Very High Concern is 0.1% w/w. This means that any Registrant whose registration contains the constituent of potential concern for PBT or ED at or above 0.1% w/w is considered a relevant addressee for all testing required by this decision relating to that concern (e.g. any Registrant whose substance contains ≥0.1% w/w monostyrenated phenol will need to respond to requirements 1, 2 and 5-7). ECHA highlights a relevant component is a constituent, an impurity, or an additive (article 3, paragraph 1 of REACH).

In Annex I of REACH, which describes the requirements for the Chemical Safety Report (CSR), paragraph 0.3 notes the need for the assessment to consider "any major impurities". To provide guidance on "major", ECHA refers the Registrant(s) to Regulation EC 1272/2008 on the classification, labelling and packaging of substances and mixtures. Table 1.1 in Annex I of the Regulation specifies a concentration limit relevant for environmental mixture classification of 0.1% w/w for classification as Aquatic Acute 1 and Aquatic Chronic 1, and a limit of 1% w/w for classification as Aquatic Chronic 2-4. Therefore for data requirement 7, which is not related to the PBT or ED concern, the same classification rules shall apply for deciding which constituents are "major". In the view of ECHA, the environmental classifications (excluding multiplication (M-) factors) of the constituents based on the currently available data are:

- Monostyrenated phenol (MSP): Aquatic Chronic 2 (N.B. this could change depending on the result of requirement 6)
- Distyrenated phenol (DSP): Aquatic Acute 1; Aquatic Chronic 2
- Tristyrenated phenol (TSP): Aquatic Chronic 1

For the purposes of this decision, the word "constituent" is used hereafter to refer to constituent, impurity or additive.

The requirements below are made on a constituent basis. As noted above ECHA considers that these requirements are equally applicable to both substances, for example a requirement for tristyrenated phenol applies to both substances with EC numbers 262-975-0 and 915-333-5.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions (in accordance with Article 13 (3) and (4) of the REACH Regulation) and specific constituents of the registered substances subject to the present decision:

**Information for PBT assessment**

1. **Partition coefficient n-octanol/water of the monostyrenated phenol constituent of the registered substance (test method: Partition coefficient (1-octanol/water): slow-Stirring method OECD 123 or HPLC method OECD 117 or shake-flask method OECD 107.**

2. **Surface tension of the monostyrenated phenol constituent of the registered substance (test method: EU A.5./OECD 115).**

3. **Persistence test of the tristyrenated phenol constituent of the registered substance as further specified in section III. The Registrant(s) shall perform one of the following tests at a temperature of 12 °C:**

   - Preferably: Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309)

   If OECD 309 is not feasible, either:

   - Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD 307) or
   - Sediment simulation testing (Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD 308)

4. **Long-term toxicity testing on fish using the tristyrenated phenol constituent of the registered substance (test method: Fish, early-life stage (FELS) toxicity test, OECD 210).**

Information requirement 4 depends on the outcome of requirement 3 as further specified in section III.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information regarding the registered substances subject to the present decision:

5. **Update the PBT assessments in the Chemical Safety Reports to take account of all relevant constituents present in the registered substance at quantities greater than or equal to 0.1% w/w.**

**Information for endocrine disruption**

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the following information using the indicated test method (in accordance with Article 13 (3) and (4) of the REACH Regulation) and a specific constituent of the registered substance subject to the present decision:

6. **Fish Sexual Development Test (FSDT) (test method: Fish Sexual Development test OECD 234) for the monostyrenated phenol constituent of the registered substance using five test concentrations and appropriate controls.**

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall also submit the following:

7. **Information on the endocrine disruption potential of their respective substance with respect to human health as further specified in section III.**

**Information for environmental risk assessment**

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall also submit the following information regarding the registered substances subject to the present decision:

8. **Update the environmental risk assessment to**:
    a. Account for all major constituents of the registered substance (mono-, di- and tristyrenated phenol).
    b. Justify the exclusion of environmental emissions arising from waste generation.
    c. Assess environmental emissions from the recycling of articles containing styrenated phenol.
    d. Provide information on direct marine emissions for each exposure scenario.

Once the results of the PBT and ED testing in this decision are available, and the risk assessment refined, ECHA will consider the need for a follow-up decision to address any remaining concerns.

**Addressees of this decision**

This decision is sent to all Registrants of both Phenol, styrenated CAS No 61788-44-1 (EC No 262-975-0) and Reaction mass of 2,4,6-tris(1-phenylethyl)phenol and 2,6-bis(1-phenylethyl)phenol CAS No not available (EC No 915-333-5). Some of the addressees have transported isolated intermediate (TII) or on site isolated intermediate (OSII) registrations where strictly controlled conditions (SCC) are indicated.

One PfA proposed that only Registrants who have full REACH registrations should be addressees of this decision. In their comments one Registrant supported this proposal whilst two did not, and another remained neutral. The following text clarifies why the decision is sent to all Registrants.

During the discussion at the Member State Committee (MSC) meeting of 6 June 2016, a representative for all of the Registrants stated that a common position had been agreed by the Registrants that they all wished to be addressed in the decision, regardless of whether they hold full registrations or TII/OSII registrations (where SCC is claimed). They explained

that they all wished to be included as addressees as the data requested in this decision would be used under other EU legislation, for example plant protection products. They explained that one use of the registered substances is to manufacture [redacted], which are used in the formulation of [redacted] products and that metabolites of [redacted] would need to be assessed for PBT and ED to permit authorisation under that legislation. Therefore the data requested in this decision would be relevant to cover the concern that [redacted] could degrade to styrenated phenols in the environment, particularly as [redacted] products are released directly to the environment.

**Deadline for submitting the required information**

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **4 November 2019** an update of the registration(s) containing the information required by this decision[2], including robust study summaries and, where relevant, an update of the Chemical Safety Report. However, if the requested fish, early-life stage (FELS) test (OECD 210) is not needed the deadline for the registrations(s) update shall be **2 November 2018**.

The timeline has been set to allow for sequential testing as appropriate.

## III. STATEMENT OF REASONS

**PBT assessment**

ECHA has taken an approach to substance evaluation that considers the main constituents of the registered substance individually for the purposes of the PBT assessment (assuming that all isomers have similar properties). This approach has been endorsed by relevant experts, and used to assess constituents of the registered substance under previous legislation. It is also an option described in section R11.4.2.2 of the Guidance on Information Requirements and Chemical Safety Assessment Chapter R11: PBT/vPvB assessment version 2.0 (November 2014).

The available data for each constituent group (i.e. mono-, di- and tristyrenated phenol) was compared against the REACH Annex XIII criteria. Where a definitive conclusion could not be drawn for a constituent, a test strategy has been set out below.

The distyrenated phenol constituents do not meet the Annex XIII criteria for both bioaccumulative (B) and very bioaccumulative (vB). The available data also suggest that the long-term NOECs will be >0.01 mg/L and so it is concluded that distyrenated phenol constituents do not meet the Annex XIII T-criterion. Given that these constituents are not B/vB or T there is no need to investigate persistence for PBT purposes.

### 1. Partition coefficient for monostyrenated phenol

Monostyrenated phenol does not meet the screening criteria for persistence, bioaccumulation or toxicity based on the currently available information. However, this conclusion is mostly based on non-test information, and there is some uncertainty over the log Kow value in particular (for example for di- and tristyrenated phenol, the experimental log Kow values exceed the predicted values by between 0.4 and 1.2 log units). As this is an important property for the screening assessment, ECHA considers that a reliable log Kow value is needed to verify the read-across of bioaccumulation data from cumylphenol to monostyrenated phenol. Depending on the outcome of the surface tension test (requirement

[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).

2 in this decision), the Registrant(s) shall, with justification, chose the most appropriate method of log Kow using ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R7a, version 4.1, October 2015, specifically table R.7.1-6 therein).

One Registrant queried the need for the test given that the analogue substance cumylphenol has a measured log Kow of 3.8. In particular they questioned why any further data was needed to support the read-across, especially if the distyrenated phenol constituent exhibited no bioaccumulation (in a fish study). In reply, ECHA notes that the predicted log Kow value of cumylphenol is 4.1 (KOWWIN v1.67), suggesting that the KOWWIN model over-predicts the measured value slightly. However, for di- and tristyrenated phenol, the experimental log Kow values exceed the predicted values by between 0.4 and 1.2 log units. ECHA is therefore concerned that the model prediction might also under-estimate the measured log Kow of monostyrenated phenol.
It is important to verify that the measured log Kow of monostyrenated phenol is not higher that the predicted value, otherwise the read-across of the cumylphenol bioaccumulation data to monostyrenated phenol becomes more uncertain. An accurate log Kow value for monostyrenated phenol is also important for the exposure assessment modelling in addition to the PBT assessment).

Another Registrant agreed to perform the test, but suggested to use the OECD 117 test guideline as monostyrenated phenol is likely to be within the validity range of the method (up to log Kow = 6). ECHA agrees this is a possibility, as well as the OECD 107 (shake flask), and the decision has been amended to state this. The Registrant(s) will need to judge which is the most appropriate method to use once the surface tension data are available.

A further Registrant queried which of the two possible monostyrenated phenol isomers should be tested. In reply, ECHA considers that the measurement should be representative of both isomers. The Registrant(s) should decide the most appropriate way to achieve this and justify their approach. This could either be via read-across or two separate measurements. ECHA agrees with the Registrant that either a specific synthesis or purification of the registered substance will be necessary to produce a suitable test material for this test (and others). ECHA notes that specific constituents have previously been synthesised to test distyrenated and tristyrenated phenols, which are included in the registration data.

This Registrant also questioned why the bioaccumulation potential of monostyrenated phenol needs to be further investigated. As stated above, there is some uncertainty over its bioaccumulation potential because of the reliance on non-test information (and there is particular uncertainty for the log Kow value). Therefore, while ECHA agrees that monostyrenated phenol appears to be of low concern for bioaccumulation in a PBT context, the uncertainty in a key physico-chemical parameter prevents a definitive conclusion from being made. ECHA notes that an accurate log Kow value is also needed for the environmental exposure and risk assessment. The same Registrant queried why this constituent is relevant for the composition of the substance that they have registered from a risk assessment perspective. ECHA has provided guidance above in this decision regarding the need for each Registrant to identify relevant constituents for risk assessment purposes. However, for PBT concerns, as is the case of this request, the 0.1% w/w threshold is more appropriate. The log Kow data are also important in the exposure assessment to inform risk management decisions if the constituent is determined to be a Substance of Very High Concern (SVHC) as a result of the PBT or ED assessment.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the monostyrenated phenol constituent of the registered substances subject to this decision:

- Partition coefficient n-octanol/water (test method: OECD 123 or HPLC method OECD 117 or shake-flask method OECD 107.

**2. Surface tension for monostyrenated phenol**

A measurement of surface tension for monostyrenated phenol is not available. It is important to be certain of this parameter before measuring the octanol-water partition coefficient, because surface activity can affect this measurement. Therefore the Registrant(s) is required to perform such a measurement before the log Kow test (requirement 1 in this decision).

In their comments one Registrant queried which of the two monostyrenated phenol isomers should be tested. They also queried the need for the test in a PBT context although agreed that it might be useful for risk assessment. ECHA considers that the measurement should be representative of both isomers. The Registrant(s) should decide the most appropriate way to achieve this and justify their approach. This could either be via read-across or two separate measurements. As stated above for the related log Kow measurement of monostyrenated phenol, ECHA considers that the data are necessary for both PBT and risk assessment.

A different Registrant agreed to perform the test.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the monostyrenated phenol constituent of the registered substance subject to this decision:

- Surface tension (test method: EU A.5./OECD 115)

**3. Environment simulation study for tristyrenated phenol**

Tristyrenated phenol is confirmed as meeting the Annex XIII criteria for being both bioaccumulative (B) and very bioaccumulative (vB). This is based on the results of an OECD 305 dietary accumulation study which have been extrapolated to give an equivalent Bioconcentration Factor (BCF) of 10,395 L/kg. The Biomagnification Factor (BMF) from the study is around 0.36 and the depuration half-life is around 18.4 days; these values are also consistent with a BCF >5,000 L/kg. This constituent also meets the screening criteria for persistence, and QSAR estimates suggest that the T-criterion could also be met based on the predicted long-term toxicity to fish. Therefore, it is concluded that further information on both persistence and toxicity is needed for the tristyrenated constituent of the registered substance in order to decide whether or not it meets the Annex XIII criteria for P, vP and/or T.

In their comments one of the Registrants disagreed with the conclusion that tristyrenated phenol is vB. They comment that the "primary outcome of a dietary bioaccumulation test is a BMF value on a non-steady state basis, whereas the Annex XIII criterion for bioaccumulation provides a threshold value for BCF based on a steady state basis". ECHA contends that Annex XIII includes no specification that a BCF value needs to be derived on a "steady-state basis". ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R11, November 2014) indicates that both a kinetic and a steady state BCF (or BMF) can be used in the B assessment. In some instances, the kinetic BCF (or BMF) may actually be more appropriate. For example, the guidance states "this [kinetic BCF] approach is especially useful in those cases where steady state was not reached during the uptake period". ECHA agrees that the dietary exposure method is designed principally to derive a kinetic BMF. However, if steady state does occur during the relatively short uptake period, a steady state BMF can also be derived. For tristyrenated

phenol, three measurements of test substance concentration were made, and these did not suggest that steady state was achieved during the test.

The Registrant also commented that there is currently no general agreement about how to extrapolate a BMF value to a BCF value that is suitable for comparison to the REACH Annex XIII criteria. ECHA recognises that there is no agreed (dietary) BMF threshold for concluding B or vB. However, weight of evidence approaches for the B assessment have been (and are being) used to interpret dietary studies with respect to the Annex XIII criteria. These include consideration of the depuration half-life and conversion of the BMF to BCF using different empirical equations. These options are explained in the draft OECD guidance for the OECD 305 fish bioaccumulation study. In the case of tristyrenated phenol, the calculated BCF values are in the range 8,607-36,320 L/kg (i.e. all significantly exceeding the vB threshold). The lipid-normalised, growth-corrected depuration rate constant (k2) value is 0.038 $d^{-1}$ (~18 days). A comparison of the depuration rate constant from fish bioconcentration tests to the measured fish BCF value is described in a report published by the Environment Agency[3], and cited in the draft OECD guidance for the OECD 305 Bioaccumulation test method. The analysis indicates that a (lipid-normalised) k2 value below 0.085 $d^{-1}$ (i.e. 8.2 days) is comparable to a BCF exceeding 5,000 L/kg. Therefore the k2 of 0.038 $d^{-1}$ calculated from the fish feeding study for tristyrenated phenol also suggests that the BCF >5,000 L/kg.

In addition to the dietary data, an independent BCF study for tristyrenated phenol has previously been attempted by one of the Registrants using aqueous exposure. The details of the study are confidential, and the study is not fully valid due to problems with the control group. However, the uptake seen in the early stages of the experiment is consistent with a BCF >5,000 L/kg for tristyrenated phenol. In a registration update, one Registrant has also included the results for two biotransformation tests performed with tristyrenated phenol using hepatic enzymes in rainbow trout liver S9 fractions and rainbow trout hepatocytes. These assays have yet to gain regulatory acceptance. However, despite this caveat, ECHA notes the results, which indicate no significant metabolism of tristyrenated phenol, do not contradict the findings of the dietary bioaccumulation study.

Therefore, these data provide additional support for the current vB conclusion.

In their comments, the Registrant(s) also proposed to perform an earthworm bioaccumulation study (OECD 317) to improve the bioaccumulation assessment. ECHA had initially proposed this test to refine the terrestrial secondary poisoning risk assessment, but this has been postponed pending receipt of data requests 1-7 (see the discussion above). ECHA does not consider that an earthworm bioaccumulation study would be a useful addition to the current "B" assessment of tristyrenated phenol. This is principally because a robust conclusion with respect to the Annex XIII criteria can already be made. A further concern is that there are no criteria with which to compare an earthworm Biota Sediment Accumulation Factor (BSAF) or BAF. Unlike the dietary fish BMF, there are no recognised ways to convert an earthworm BSAF or BAF to a value that can be compared with the Annex XIII criteria. Earthworms are metabolically and physiologically quite different to fish. Therefore in this case it is unclear how the weight of evidence would be improved with the additional data.

A different Registrant stated that they support the conclusion on bioaccumulation for tristyrenated phenol based on the experimental information, although they disagree with the P assessment.

[3] Depuration rate constant: growth correction and use as an indicator of bioaccumulation potential". Brooke, DN & Crookes MJ. 2012. Environment Agency, Bristol, UK. ISBN: 978-1-84911-283-3

Overall ECHA remains satisfied that tristyrenated phenol meets the vB criteria, and no further information is required for this aspect of the assessment.

In the interests of animal welfare and to follow the order of testing in ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R11, version 2.0, November 2014), to investigate the PBT concern, persistence shall be investigated first. To address persistence, the Registrant(s) is required to perform an OECD 309 aqueous simulation study for tristyrenated phenol, if technically feasible. This method is preferred as it avoids the problem of bound residues, which can confound the interpretation of the sediment and soil studies. If the aqueous test cannot be conducted, the Registrant(s) shall perform either the OECD 307 or 308 study, accepting that interpretation may be more challenging.

In their comments, one of the Registrants questioned the requirement to perform the study at 12°C. ECHA notes that this temperature reflects a decision made at MSC-32 that 12 °C represents an environmentally relevant temperature for the test to be performed at. The current ECHA Guidance R11, also highlights that this is the preferred temperature for new simulation studies. Since the MSC-32 decision, all simulation studies that have been requested by ECHA to measure environmental half-lives have been at 12°C.

The Registrant also questioned whether it was possible to perform the test at 20°C and extrapolate the result to 12°C using the Arrhenius equation. ECHA acknowledges that this is a possibility, but there is a strong preference to avoid this calculation because there are uncertainties in the activation energy ($E_a$) value used. The simulation test will not provide an $E_a$. Assessments for Plant Protection Products assume a generic value for $E_a$ that has been derived from a pesticide dataset, but it is uncertain how applicable such a value is for tristyrenated phenol. Therefore the test should be conducted at 12°C, but if the Registrant(s) can provide clear justification that it is not technically feasible to use this temperature, the study may be conducted at 20°C, and the result extrapolated to 12°C.

In their comments one Registrant noted a number of benefits of using a radio-labelled test item. ECHA agrees that there are advantages of using radio-labelled material, but leaves the choice of the need for the material, radiolabelled or not, to the Registrant(s).

In a further comment, one of the Registrants suggested measuring photodegradation as part of the PBT assessment of the registered substance. In response, ECHA notes that photodegradation is not generally considered to be an important fate process in the environmental assessment under REACH (see for example ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R7b, version 3.0, February 2016, section R7.9.5 therein). This is because of the considerable local variability of light intensity in the aquatic environment, due for example to water depth and turbidity, as well as the presence of quenching agents. Therefore a photodegradation test is not required for the PBT assessment, or the environmental risk assessment.

A different Registrant questioned the approach of using simulation testing to investigate persistence of this type of substance. They also expressed concerns about the formation of bound residues in the sediment or soil tests, and how this should be interpreted. They considered that these studies are more likely to be appropriate compared to the aquatic test as in their view sediment and soil are the target compartments. They proposed, without being specific, simpler laboratory pre-testing without radio-labelled substances, first focussing on primary degradation along with use-related monitoring. In reply, ECHA notes that the proposed simulation studies will measure primary degradation. Monitoring, while useful for the exposure assessment, is very unlikely to be directly suitable for persistence assessment. This is because of the need to be able to accurately establish the degradation kinetics from the measured substance (and possibly metabolite) concentrations. It also

seems likely that the same problems highlighted by the Registrant for bound residue would occur, but potentially be further confounded by the presence of other organic substances.

ECHA acknowledges the complexity of simulation testing, particularly if sediment or soil testing is the only option, and non-extractable residues occur in significant quantities. However, equally a PBT assessment should not be avoided simply because it is complex, particularly if there are significant concerns such as the vB criteria being already met. The OECD 309 test has been proposed in the first instance as a way of avoiding the issue of bound residues.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out one of the following studies using the tristyrenated phenol constituent of the registered substance subject to this decision:

Preferably:

- Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309)

If this is not feasible, either:

- Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD 307) or
- Sediment simulation testing (Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD 308)

### 4. Fish Early Life Stage toxicity test

A long-term fish toxicity study test is required to investigate whether the T criterion is met for tristyrenated phenol. In the absence of any specific evidence of ED potential, a fish early life stage (FELS) test is required given the log Kow value of this constituent. The test is not required if the requested degradation simulation testing shows that either a) this constituent does not meet the Annex XIII criteria for P (in which case it can be concluded that the constituent is not PBT and not vPvB) or b) the constituent meets the Annex XIII criteria for vP (in which case it can be concluded that the constituent is vPvB). However, in this scenario, the Registrant(s) should also consider whether the long-term fish test is required to refine the aquatic Predicted No Effect Concentrations (PNEC) in the event that there are environmental risks following requirement 7 of this decision. In the interests of animal welfare, the Registrant(s) shall attempt to refine environmental exposure before performing the fish test. The Registrant(s) are referred to ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R7b, version 3.0, February 2016), figure R7.8-4, which states that "long-term fish testing [is] not necessary if Predicted Environmental Concentration/Predicted No Effect Concentration (PEC/PNEC) <1 based on Daphnia long-term result and AF of 50".

In their comments, one of the Registrants argued that the FELS test should be performed even if tristyrenated phenol is determined to be vP. ECHA disagrees. This is contrary to the principle of vertebrate testing being the last resort. If it is possible to conclude the PBT assessment without performing the FELS test this should be done. As described above, ECHA considers that tristyrenated phenol meets the vB criteria of REACH Annex XIII. Therefore, if the simulation study shows that this constituent is vP, the PBT assessment can be concluded (the constituent being vPvB).

ECHA's view is that performing the FELS test if tristyrenated phenol is vP would be an unnecessary vertebrate study.

In a further comment, the same Registrant indicated that the physicochemical properties of the test substance (tristyrenated phenol) mean that the study is not straightforward, requiring radio-labelling, and will also be time-consuming to conduct. They also point out that there is no alert for tristyrenated phenol for any toxicity to fish with the available information.

In reply, ECHA appreciates the potential complexity of the study. It is noted that a 21-day Daphnia study was previously performed using tristyrenated phenol, so ECHA would anticipate that experience from that aquatic test can be used. Radio-labelled material will also be required for the persistence test, so ECHA anticipates that additional time for this aspect of the FELS test is not required. The decision does already provide 12 months for the performance of the FELS test if the study is required. ECHA has not seen the structural alert analysis performed by the Registrant. Nevertheless, the very significant uptake observed in the fish bioaccumulation test shows that the tristyrenated phenol is highly bioavailable, and so adverse toxic effects cannot be discounted if there is adequate exposure and resulting body burden.

Another Registrant indicates that there are data available from an OECD 204 prolonged fish toxicity study which they propose to obtain (and update their registration with accordingly) to fulfil this requirement. In reply, ECHA advises that the OECD 204 test guideline is not recognised as providing a measure of chronic toxicity in fish (for example, it is not included in the options in the ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R7b, version 3.0, February 2016) for aquatic toxicity). In addition the OECD Fish Toxicity Testing Framework highlighted a number of limitations of the OECD 204 test guideline and this test guideline has also now been deleted from the OECD test method library. It is also unclear whether these data relate specifically to tristyrenated phenol or to a test of a mixture of constituents. The decision specifically requires tristyrenated phenol to be tested to provide an unambiguous result for this constituent. Therefore, ECHA considers that updating the registration with the information for the 'existing' OECD 204 data is insufficient to address the endpoint.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the tristyrenated phenol constituent of the registered substances subject to this decision:

- Long-term toxicity testing on fish (test method: Fish, early-life stage (FELS) toxicity test, OECD 210)

## 5. PBT Assessment

The registered substance contains a number of impurities and the Registrant(s) should update their PBT assessments to ensure that all relevant impurities in their substance are considered in their CSR where these are present at 0.1% w/w or above.

In their comments, one Registrant agreed to revise the whole PBT assessment, including impurities.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to:

- Update their PBT assessments in order to take account of all relevant impurities of the registered substances.

**Endocrine disruption**

### 6. Fish sexual development test

Screening data suggest that some constituents of the registered substance, particularly monostyrenated phenols have potential for impacting the endocrine system. Information comes from two sets of experiments:

a. Screening tests carried out by Ogawa[4] *et al.* (2006) using a yeast two-hybrid assay with three different compositions of styrenated phenol showed signs of estrogenic activity. The strongest activity was found with a mixture consisting of 74% mono- and 26% distyrenated phenol, which showed a similar level of activity to that seen for nonylphenol and bisphenol-A. A mixture consisting of mono-, di- and tristyrenated phenol (of unknown composition) showed a lower activity and a mixture consisting of 93% distyrenated phenol and 7% tristyrenated phenol showed no activity unless treated with rat liver S-9 to generate metabolites. The authors of the study concluded that monostyrenated phenol was predominantly responsible for the activity seen.
b. Additional work, for which ECHA has only received a brief summary, concluded that specific (estrogenic) effects were seen for monostyrenated phenol. Effects for 2,6-distyrenated phenol were seen in the estrogen receptor assay, but indicated to be at concentrations known to induce non-specific effects. No significant activity was seen for 2,4-distyrenated phenol or tristyrenated phenol.

As there is currently insufficient information to allow firm conclusions to be drawn on the ED concern, ECHA considers that further testing with aquatic organisms is necessary to better define the actual hazard shown.

Based on the current weight of evidence, ECHA concludes that the monostyrenated constituent is of most concern for ED. In the interests of animal welfare, *in vivo* testing is proposed only on the monostyrenated phenol constituent at this stage, and the Registrant(s) is required to perform a Fish Sexual Development test (OECD 234) for the monostyrenated phenol constituent of the registered substance.

A decision on the need for further *in vivo* testing on the distyrenated phenol constituents will await ECHA's evaluation of the OECD 234 study using monostyrenated phenol.

Any consideration of ED testing for the tristyrenated constituent will await ECHA's evaluation of the results of the PBT testing of that constituent.

ECHA considers that in this case there is sufficient evidence from two independent level 2 screening assays to justify requiring a level 4 test with respect to the OECD framework (OECD Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption, monograph no. 150). ECHA has considered the animal welfare benefit of a level 3 study (for instance OECD 229 or 230) which uses fewer fish. However in this instance the weight of evidence suggests that the outcome of a lower tier test will be positive for monostyrenated phenol. Therefore, there is a good likelihood of the OECD 234 test being required following a level 3 test. In that scenario a much greater number of fish would be used than if the OECD 234 test was performed alone. The OECD 234 test also has the advantage of generating apical data that can be used for risk assessment purposes.

[4] Ogawa Y, Kawamura Y, Wakui C, Mutsuga M, Nishimura T and Tanamoto K. Estrogenic activities of chemicals related to food contact plastics and rubbers tested by the yeast two-hybrid assay. 2006. Food Additives and Contaminants, 23(4), 422-430.

One Registrant sought clarification about which distyrenated phenol component is of concern, and the requirements for this and tristyrenated phenol. ECHA confirms that no vertebrate ED tests are sought on either (2,4- or 2,6-)distyrenated phenol or tristyrenated phenol in this decision. However, future ED testing on these components cannot be excluded at this stage. There are differences in the available screening studies for these constituents. In some cases this may be explained by the particular constituents present in the test material (for example this is unclear for one of the positive tests using distyrenated phenol). However, there is still some remaining unexplainable differences of results between studies, and therefore uncertainty. ECHA agrees that as a starting point the principle constituent of concern is monostyrenated phenol. If monostyrenated phenol does not exhibit significant endocrine activity, the need for the investigation of ED properties of other constituents of the registered substances will be considered by ECHA before making a final decision about further testing (also taking account of the need for appropriate risk management measures identified for other concerns).

The Registrant also suggested that the FELS test using tristyrenated phenol requested as part of the PBT assessment would not provide information for the endocrine assessment of that constituent. ECHA notes that the FELS test does not measure any specific endocrine-related endpoints. However, if adverse effects are observed in the FELS test, comparisons could be made to any adverse effects seen in the OECD 234 study using monostyrenated phenol. It is recognised that the adverse effects may be different, and have different underlying mechanisms. However, as part of a weight of evidence analysis, the observations from the FELS test should not be excluded at the outset.

The Registrant had several queries relating to the test protocol. ECHA confirms that five test concentrations in addition to the control (and if needed solvent control) are required as a robust NOEC needs to derived from the test results.

The Registrant also queried which of the two monostyrenated phenol isomers needs to be tested, and the strategy required. The Registrant suggested that the choice of isomer should be made based on an *in vitro* screening test. If one isomer is positive, and the other negative, the positive one should be tested. Where there is only a weak (or no) difference, both isomers should be tested. The alternative is not to perform a screening study and simply conduct tests on both isomers. The Registrant expresses a preference for the first strategy for ethical reasons of minimising vertebrate testing.
ECHA considers that the outcome of the testing needs to be sufficiently robust to be able to conclude on ED for both monostyrenated phenol isomers, but ECHA shares the Registrant's animal welfare concerns. In the view of ECHA, it would be preferable to perform one test based on the outcome of an *in vitro* screening assay regardless of whether there are differences or not. Where one isomer is more potent than the other in the *in vitro* screening study, the FSDT should be performed on the more potent isomer. Where there is no obvious difference in effects from the screening study to decide for one isomer or the other, a mixture of the two isomers should be tested in the FSDT. The Registrant should decide and justify the level of potency required for the test strategy chosen. This can also include suitable QSAR predictions if validity can be shown. If the Registrant is able to make a case for read-across of the results of the FSDT to the other (non-tested) isomer (rather than conducting a second FSDT test) this would be acceptable provided this is adequately justified. ECHA will review the data and decide the need, if any, for any additional information. The Registrant will need to justify any screening *in vitro* assay chosen.

A different Registrant considers that the aquatic PNECs they have derived in their CSR are sufficiently low to be protective of endocrine effects. They also commented that as the role of ED in risk assessment has not been resolved, and the environmental occurrence of the registered substance constituents have not been determined or monitored, there was no urgent need for the test. In response ECHA notes that the concentration at which endocrine

effects might occur for this substance is unknown. For monostyrenated phenol there are no valid chronic aquatic toxicity data, or even measured acute aquatic toxicity data, so the level of protection afforded by the current aquatic PNEC is unknown. ECHA agrees that a decision about how ED substances should be risk managed has not yet been agreed. However, tests for other chemicals with an ED concern have been requested under the substance evaluation process, and five chemicals have already been agreed by the Member State Committee as Substances of Very High Concern based on environmental ED. While environmental monitoring may provide useful information for the risk assessment, it is not a prerequisite for endocrine testing.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the monostyrenated phenol constituent of the registered substances subject to this decision:

- Fish Sexual Development Test (test method: OECD 234) using five test concentrations and appropriate controls

## 7. Information on the endocrine disruption potential of their respective substance with respect to human health

During the evaluation it was noted that a number of *in vivo* and *in vitro* studies had been provided to assess the endocrine modulatory effects of styrenated phenol. In particular, styrenated phenol showed weak oestrogen agonist activity in two non-standard uterotrophic assays employing ovariectomised rats. It should be noted that these studies had a number of deficiencies compared to the modern protocol.

In the repeated dose toxicity study on styrenated phenol, an increased incidence of minimal focal thyroid hyperplasia was observed at a dose causing significant systemic toxicity (body weight reduction -20%). Since hormone levels were not measured, it was not possible to determine whether this effect should be considered related to altered endocrine action.

As mentioned above *in vitro* tests using various compositions of styrenated phenol indicated that the substance did have estrogenic activity, with the mono- and di-styrenated components possessing the highest binding affinity for the oestrogen receptor. Additionally during the evaluation year, further *in vitro* investigations were being performed on the endocrine activity of the individual styrenated phenol constituents.

One Registrant indicated in their dossier that a combined repeat dose/extended-one generation study being conducted with methylstyrenated phenol could be used to fulfil the reproductive toxicity endpoint for styrenated phenol. Given that *in vitro* and QSAR studies have been performed with constituents of methylstyrenated phenol and similar findings to styrenated phenol were reported, the results of this study might provide more information of the *in vivo* significance of the estrogen receptor binding of styrenated phenol. However it was noted that the read-across justification would need to be strengthened. On this basis, whilst there may be concern of ED relevant to human health and mammalian wildlife the evaluating MSCA decided to wait for results of the ongoing studies before considering whether further information was needed, thus the draft decision sent to the Registrant(s) for commenting did not include this request.

One MSCA proposed to amend the draft decision to include developmental/reproductive toxicity and ED relevant for human health as a concern in the decision due to the available *in vitro* and *in vivo* data (see above). It was agreed that it is useful to consider both non-mammalian vertebrate and mammalian (in this case rodent) studies when considering ED. However, a concern for developmental/reproductive toxicity relevant for human health (and mammalian wildlife) would be a consequence of the concern for ED, if that concern is confirmed for the registered substance. A concern for developmental and reproductive

toxicity is therefore not included at this stage, but may be further investigated once the new information has been evaluated.

To investigate these concerns the same MSCA proposed to request a read-across justification between "Oligomerisation and alkylation products of 2-phenylpropene and phenol, previously registered as methylstyrenated phenol (CAS No 68512-30-1)" and this substance (styrenated phenol (CAS No. 61788-44-1)) on reproductive/developmental toxicity and ED. Alternatively, in the case that the read-across is not plausible an EOGRTS (OECD TG 443) (without the F2, but including the DNT (2A and 2B) and DIT (3) cohorts) should be requested on the Registered substance.
However, given the complexity of the situation with respect to the different constituents covered by these registrations, this read-across may not be relevant for all Registrant(s). Therefore each Registrant is requested to make an assessment of the ED potential of their registered substance on the basis of the information available. Any read across used must be fully justified and in line with the REACH Regulation Annex XI and the ECHA Read-Across Assessment Framework (RAAF)[5]. As the ED concern for human health (and mammalian wildlife) is based on limited data, it may be useful to expand this *in vitro* database to include other relevant styrenated phenols to further elucidate the read-across justification. Such information may help substantiate any proposed read-across.

Any further information needed to clarify the ED potential, including the potential for developmental/ reproductive toxicity of styrenated phenol will be considered once the information requested in this decision has been evaluated.

One Registrant provided detailed comments on these PfAs which were supported by two other Registrants. They argued that introducing a new complex concern at such a late stage was outside the scope of the evaluation as agreed with the evaluating MSCA. They preferred to take the original approach of focussing first on the "environmental" ED properties with the information gained being relevant for the assessment of human health ED properties as well. They also did not support the proposal to read across from methylstyrenated phenol due to the differences in compositions of the substances registered under the CAS number 61788-44-1. Their approach has been to look at the ED properties of the individual constituents. Finally, they did not agree to the proposal to perform an EOGRTS on "the registered substance" due to the different substances covered which could result in testing for many substances without gaining an understanding of the properties of individual constituents. They preferred to continue with the ongoing work and, if further testing were necessary, there are other options as provided in the OECD conceptual framework. One Registrant also indicated they preferred to use existing studies rather than perform a new animal test. Another Registrant agreed that there are scientific grounds to generate oestrogenic effects data for monostyrenated phenol, but see no reason for using isolated constituents.

ECHA considers the current request allows each Registrant to make an assessment of the available data and how it is relevant for their substance. This will help decide whether any further information is needed in a further decision. Whether they consider their registered substance, a structural analogue(s) or individual constituents, their approach should be fully explained and justified.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following:

- Information on the endocrine disruption potential of their respective substance with respect to human health

[5] http://echa.europa.eu/documents/10162/13628/raaf_en.pdf

## Environmental risk assessment

### 8. Update of environmental risk assessment

ECHA has performed an environmental risk assessment of the constituents of styrenated phenol and is concerned that this suggests risks to different environmental compartments in a number of scenarios. In their full registrations, the Registrants have performed environmental modelling based on one constituent to represent the whole substance. ECHA does not consider that this is appropriate. This is because the physico-chemical differences between mono-, di- and tristyrenated phenol mean that their environmental fate and behaviour will also be different. Due to this ECHA considers that the Registrant(s) should evaluate these constituent groups (i.e. mono-, di- and tristyrenated phenol) individually for the purposes of environmental risk assessment. In particular, the Predicted Environmental Concentrations (PECs) and Risk Characterisation Ratios (RCRs) should be determined separately for each of the main constituent groups, and then summed to give the overall RCR, to provide a more realistic indication of the actual risk from the substance.

It is appreciated that simple summing may not take account of all possible modes of action, but despite this uncertainty ECHA considers this approach to be a pragmatic starting point. It builds on the assumption that the constituents have at least some similar Mode of Actions (MoAs), which means that when addressing their toxicity, concentration addition should be employed. This approach is deemed to be more scientifically justified and reliable and relevant than assuming that the MoAs of the constituents within each of the three constituent groups are so different that their toxicity operates by independent action (i.e. leading to use of an "effects addition" approach).

ECHA has used this approach for the current exposure scenarios provided in the registration dossiers. This indicates RCRs greater than 1 for at least one compartment for all exposure scenarios in the registration dossiers. ECHA is therefore concerned this implies that the current Risk Management Measures (RMM) recommended by the Registrant(s) may not be sufficient to limit the risks to the environment from these scenarios. In addition, some lifecycle stages have not been well covered in the exposure scenarios in the CSR, particularly waste and the possibility of recycling of articles containing styrenated phenol. Therefore, the Registrant(s) are required to update their environmental exposure assessment to include an evaluation of emissions from waste for each exposure scenario, or alternatively providing clear justification where this is judged by the Registrant(s) to be insignificant. The Registrant(s) are also required to update their environmental exposure assessment to include an evaluation of the emissions of styrenated phenol from the recycling of articles containing styrenated phenol.

Finally, risks are suggested for marine aquatic and sediment compartments for some scenarios. The Registrant(s) shall provide information about whether direct emission to the marine environment, without wastewater passing through a sewage treatment plant, is likely to occur for these scenarios (and reflect any conclusions in the relevant exposure scenarios).

Risk based considerations (including the best possible emission and exposure information) are important for two reasons. Firstly to inform risk management decisions if one or more constituent is determined to be an SVHC as a result of the PBT and ED assessment. Secondly, if there are no SVHC concerns, to inform the need for any further testing for the quantitative PEC/PNEC assessment.

In comments on a proposal for amendment, one Registrant sought clarification that a

substance containing multiple constituents is only an SVHC itself if one of the constituents is SVHC and is present at a concentration exceeding 0.1% w/w. ECHA confirms that a relevant constituent (including as an impurity) for SVHC is a concentration equal to or greater than 0.1% w/w.

One Registrant queried how the environmental risk assessment should be performed. As described above, ECHA considers that performing an assessment for the whole substance using combined properties or a representative constituent is not scientifically robust due to the markedly different physico-chemical properties of the constituents. This means that their environmental fate and behaviour will also be markedly different, and why ECHA has requested the Registrants to account for all major constituents. ECHA suggest that the most appropriate way to address this is by performing three separate risk assessments for the mono-, di- and tristyrenated phenol constituent groups. The supply tonnage input to each assessment should reflect the total supply tonnage and constituent ratio of the Registrant. For example, if a ratio of 20:50:30 mono-:di-:tristyrenated phenol is supplied at 1,000 tonnes/year, the risk assessment should be conducted using 200 tonnes/year mono-, 500 tonnes/year di- and 300 tonnes/year tristyrenated phenol. The resulting RCRs should be summed per exposure scenario. If there are risks at either a constituent group level (see above) or whole substance level, these should be addressed by the Registrant(s). ECHA clarifies that "constituent group" for environmental risk assessment purposes means that all monostyrenated phenol constituents are modelled together, all distyrenated phenol constituents are modelled together, and finally all tristyrenated phenol constituents are modelled together. Depending on the approach chosen for test 1, if different log Kow values are determined for the different monostyrenated phenol constituents, the Registrants shall choose, with justification, the most representative value for the risk assessment.

Another Registrant queried which exposure scenario requests related to their registration. ECHA confirms that the decision is being sent to all Registrants, but it is appreciated that not all exposure scenarios (or uses) apply to all Registrants. Therefore Registrants should review each request in relation to their registration. If an exposure scenario is not relevant to a particular Registrant, there is no requirement for them to fulfil that request (and so they should provide this explanation in their submission). To clarify, ECHA is seeking updates to the existing CSRs (i.e. full registrations). No exposure assessment is formally required for registrations of transported isolated intermediates.

A different Registrant has questioned the approach of ECHA to conduct the environmental risk assessment on a constituent basis, and sum the resulting RCRs. In their view, while exposure should be assessed separately, the effects assessment should be based on worst-case PNECs, which they consider should be derived from monostyrenated phenol. They consider that the risk assessment should be refined by exposure information in the first instance by generating environmental monitoring data. They also indicate that it is unclear which calculations ECHA are referring to in deriving the risks. Finally, they remark that the approach proposed by ECHA will have a higher probability of RCRs exceeding one.

ECHA's original concern was that the approach of the Registrant(s) could potentially underestimate the risks from some of the other constituents present in the registered substance (particularly distyrenated phenol and, if present, tristyrenated phenol). Accounting for all major constituents by performing the exposure assessment on a constituent group basis will be necessary for a realistic risk assessment. ECHA remains concerned that the sediment and soil PNECs derived for monostyrenated phenol via equilibrium partitioning may not be protective for di- and tristyrenated phenol. As the ecotoxicity and bioaccumulation tests relating to environmental risk assessment have been deleted, ECHA will review the updated risk assessment performed by the Registrant(s) using their suggested approach and determine what if any further requirements exist after the other information requested in this decision has been submitted. As described above, the

summing of the RCRs separately for the monostyrenated, distyrenated and tristyrenated fractions of the registered substance is still reflective of the supply tonnage provided the individual assessments are performed at tonnages proportional to the composition. While environmental monitoring data may be useful, it is difficult to obtain a sufficiently representative sample for "local" emission modelling. This is aside from whether the properties of the registered substance prevent monitoring from being feasible, as described earlier in the decision. As stated above, ECHA has used the emissions modelling from the Registrants' CSRs, but applied the constituent physicochemical properties. Given the diversity of these properties, these should be modelled separately as their fate will be quite different. The text above is clear that the aggregated tonnage volume of the constituents does not exceed the substance registration tonnage. The approach of ECHA may mean that sediment and soil exposure is higher than currently modelled by the Registrant. This is because distyrenated and tristyrenated are likely to preferentially partition to these compartments (i.e. as raised by the same Registrant in one of their earlier comments about the choice of compartment for simulation testing). While the Registrant claims that this is a completely new risk assessment, they refere to Brookes et al (2009) in their comments (referenced in footnote 3 of this decision), which is the original assessment setting out the constituent risk assessment approach.

In response to further comments from the same Registrant on a proposal for amendment, they have performed their environmental risk assessment in the CSR using the physicochemical and environmental fate properties of monostyrenated phenol to represent the whole substance. In the view of ECHA this is not scientifically justified. The lower log Kow and Koc of monostyrenated phenol compared to distyrenated phenol and tristyrenated phenol, mean that this constituent group will generally partition to water in more significant amounts. This is in contrast to the higher log Kow and Koc values for distyrenated phenol and tristyrenated phenol constituent groups which will generally partition to sediment and soil[6] (as per this registrant's comment regarding the simulation testing). As a result risks to the sediment and soil compartment will be underestimated as a much larger fraction of the substance will partition to water using the approach of the registrant. For example if the registered substance is only 10% monostyrenated phenol, ECHA do not consider that it scientifically reasonable to assess sediment and soil risks based on the monostyrenated phenol log Koc. The approach requested by ECHA would consider the fate of each constituent group in turn according to their fate and their proportional tonnage within the registration. As the tonnage is proportional per constituent group, this needs to be summed to provide the risks from the total tonnage of the registration.

The Registrant comments that PNEC they derive being lower than Brooke et al 2009 (referenced in footnote 3). ECHA highlights that no testing of these compartments is requested in this decision. However, even using a PNEC with a larger value than the Registrant proposes indicates risks for some scenarios. If these cannot be refined using additional exposure information, sediment and soil testing will be needed to address the risk. ECHA also note that the current risks also include some for secondary poisoning. In the Registrant(s)' CSRs there is no PNEC derived for secondary poisoning as each claims that there is no potential for bioaccumulation. In contrast ECHA considers that there is a concern for secondary poisoning, for example one of the constituents is confirmed as meeting the vB criteria of REACH. Therefore it is important to include an assessment of risks from secondary poisoning.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to update their environmental risk assessment to:

[6] For example, the SIMPLETREAT model which estimates partitioning in a typical wastewater treatment plant predicts the following partitioning: monostyrenated phenol 83.3% water & 16.7% to sludge; distyrenated phenol 16.9% to water & 83.1% to sludge; tristyrenated phenol 9.1% to water & 90.9% to sludge. For all three constituent groups air and degraded fractions are minimal/zero.

- Account for all major constituents of the registered substance (mono-, di- and tristyrenated phenol).
- Justify the exclusion of environmental emissions arising from waste generation.
- Assess environmental emissions from the recycling of articles containing styrenated phenol.
- Provide information on direct marine emissions for each exposure scenario.

## IV. ADEQUATE IDENTIFICATION OF THE COMPOSITION OF THE TESTED MATERIAL

In relation to the required experimental studies, unless indicated otherwise, 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 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 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/regulations/reach/registration/data-sharing

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the studies on behalf of all of them.

## VI. DEADLINE

In the original draft decision the time indicated to provide the requested information was 51 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision requested also other toxicity tests on aquatic invertebrates, sediment and terrestrial organisms and a bioaccumulation test in terrestrial organisms. As these requests are not addressed in the present decision, ECHA considers that a reasonable time period for providing the currently required information in the form of an updated registration is 39 months from the date of the adoption of the decision (27 months if the FELS study is not needed). The decision was therefore modified accordingly.

## VII. 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.

Authorised[7] by Claudio Carlon, Head of Unit, Evaluation 2, on behalf of Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

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