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

For Trixylyl Phosphate, CAS No 25155-23-1 (EC No 246-677-8)

Addressees: Registrant(s)[1] of Trixylyl Phosphate (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 National Institute of Health on behalf of Ministry of Health as the Competent Authority of Italy (evaluating MSCA, eMSCA), 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 4 September 2014, i.e. the day until which the evaluating Member State granted an extension for submitting dossier updates which it would take into consideration.

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.

Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Italy has initiated substance evaluation for Trixylyl Phosphate (TXP), CAS No 25155-23-1 (EC No 246-677-8) 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.

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

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to Environment/Suspected PBT/vPvB, Exposure/Wide dispersive use, exposure of the environment, exposure of workers, high RCR, high (aggregated) tonnage, Trixylyl Phosphate was 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 Italy was appointed to carry out the evaluation.

In the course of the evaluation the evaluating MSCA identified additional concerns regarding: potential risk for soil compartment and for secondary poisoning.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 26 March 2015.

On 4 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 10 June 2015 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA took into account the comments received from the Registrant(s) and where considered appropriate the draft decision has been amended accordingly.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH regulation, on 4 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, some Competent Authorities of the Member States submitted comments and proposals for amendment to the draft decision. The evaluating MSCA has reviewed the proposals for amendment received and where considered appropriate the draft decision has been amended accordingly.

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.

Referral to Member State Committee

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

By 10 May 2016, the Registrant(s) provided comments on the proposals for amendment, in accordance to Article 51(5) and on the draft decision.

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 May 2016 in a written procedure launched on 13 May 2016.

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

I. Information required

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

1. Enhanced ready biodegradation test (test method: enhancement of any of the four respirometric tests, OECD Test Guidelines for Ready Biodegradability No. 301 B, C, D or F), as specified in Section III below*;

2. Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309). Simulation test shall provide also the identification of transformation products/pathways. The test temperature shall be 12°C as specified in Section III below; and**

3. Sediment simulation testing (test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308) or Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307). Simulation tests shall provide also the identification of transformation products/pathways. The test temperature shall be 12°C as specified in Section III below;

** The Registrant(s) are given the option to choose if performing an enhanced biodegradability test first, or perform directly the simulation tests. Simulation tests shall be performed if the enhanced test is not conclusive or it is not performed as further explained in Section III below.*

*** If the substance is found to meet the Persistent/very Persistent (P/vP) criteria in water, there is no need to perform further simulation tests in soil or sediment.*

4. Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous or dietary exposure) as specified in Section III below;

5. Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232 as specified in Section III below;***

6. Effects on terrestrial organisms – Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, EU C.21./OECD 216), as specified in Section III below;***

**** If the PBT concern is confirmed, soil toxicity testing (requests n.5 and 6) is not needed.*

7. Missing information on risk management measures as specified in Section III below.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit a full

study report of the performed enhanced ready test, in order to allow ECHA to fully assess the results, as specified in the section III below.

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by the following deadlines, 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: **08 July 2019** in case the enhanced test is not performed, **09 March 2020** in case the performed enhanced test fails. The timeline has been set to allow for sequential testing as appropriate.

II. Statement of reasons

1-2-3. Enhanced ready biodegradation test and Simulation testing (water and sediment or soil)

Further information is required to clarify in a conclusive way whether the substance is persistent or not (initial grounds for concern: suspected PBT/vPvB), according to the PBT assessment strategy (ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment, version 2.0, November 2014), taking into account that the substance fulfils the criteria for Toxicity based on the Harmonised classification (CLP Annex VI) as Reproductive toxicant category 1B.

As shown by the ready biodegradation test (OECD Guideline 301 D), TXP is not readily biodegradable. The result is based on a screening approach and therefore the substance shall be considered as potential P/vP. Through the definitive criteria on P (Annex XIII to the REACH) it is possible to decide if a substance shall be regarded as P/vP.

In order to select the appropriate test type, a careful consideration of the physico-chemical properties and the environmental fate of TXP is necessary. In this case the Registrant(s) are given the option to choose if performing an enhanced biodegradability test first (Option 1), or perform directly the simulation test(s) (Option 2). Simulation test(s) shall be performed if the enhanced test fails or it is not performed, as explained below.

Option 1: Enhanced biodegradation screening test. Before conducting any of the simulation test(s) cited in Section II, the Registrant(s) are given the option to choose, as an initial step, to perform an enhancement to the ready biodegradation test.
Such enhancements of some of the standard conditions of the ready biodegradability screening tests address test duration, accessibility of test item for the microbial inoculum, test vessel size. Generation of data allows P assessment to be considered at the screening phase, without the immediate simulation level testing. Page 38 of ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11 states: *"Given the time, costs and in some cases practical difficulties associated with a simulation test, an enhanced ready biodegradation test design offers a cost effective intermediate screening test. If sufficient degradation is shown in such a test, i.e. the pass level is reached, the substance can be considered as "not P"".*

[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).

Due to the little experience currently available on the use of these approaches for the P assessment, an enhanced biodegradation test could be considered on a case-by-case basis and it is justifiable when some biodegradation has been observed in a standard ready biodegradability test or it is supported by additional data (from QSARs or other structural analogues). If sufficient degradation is shown in such a test, i.e. the pass level is reached, the results is used to indicate that the substance will not persist in the environment and a further simulation test is considered not needed. In this regards, see also page 45 of Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: *"For example, a result of more than 60% ultimate biodegradability (ThOD, CO2 evolution) or 70% ultimate biodegradability (DOC removal) obtained during 28 days in an enhanced ready biodegradability test may be used to indicate that the criteria for P are not fulfilled"*. However, test substances that degrade in these enhanced biodegradation screening tests will not be considered as readily biodegradable.

According to the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b: Endpoint specific guidance (Version 2.0 November 2014), sections R.7.9.4 and R.7.9.5, the approaches in enhanced biodegradation screening tests could include: test duration extension (up to 60 days), testing in larger vessels, increasing the accessible fraction of low water soluble substances by use of test systems with the test substance on silica particles.
Furthermore, due to the low water solubility and the high adsorption potential of the test substance, the Registrant(s) shall decide on the appropriate test method among any of the four respirometric tests: OECD Test Guidelines No. 301 B, or C, or D, or F, as specified in the Appendix R. 7.9-3 of ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b.

In case the Registrant(s) decide to perform an enhanced ready test, ECHA requires adequate and exhaustive details on the test design and arguments justifying the choice of the enhancements type. Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall provide a full study report of the performed enhanced ready test.

In case the outcome of the enhanced test, as reported in the full study report, did not allow the Registrant(s) to exclude unequivocally the Persistence property (i.e. the enhanced ready test is not conclusive), simulation testing shall be performed to clarify conclusively the concern, as required in the following option.

Option 2: Biodegradation Simulation testing. An alternative option for the Registrant(s) is to perform directly reliable simulation test(s) in order to determine a half-life under relevant conditions, to clarify definitively the P property according to Annex XIII criteria, without further screening tests.
The order in which the simulation biodegradation tests shall be performed needs to take into account the intrinsic properties of the registered substance, the identified uses and release patterns, which could significantly influence the environmental fate of the registered substance.

According to the approach recommended by ECHA[3], in general, the aquatic pelagic study simulation test is the most meaningful to clarify the P-assessment and the Registrant(s) are required to consider first the OECD 309 test, if it is demonstrated to be technically feasible.

[3] Assessment of Persistent, Bioaccumulative and Toxic (PBT) substances in different EU legislations, publicly available on: http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm

TXP has a low water solubility and hydrophobic properties and the data from modelling studies (e.g. the Mackay fugacity level III multimedia "Unit world" relative mass distribution with release pattern air/water/soil: 1:1:1 (default) or 0:1:0 (typical for many industrial used substances) and the relative mass distribution in Sewage Treatment Plants (biodegraded Fraction/, sludge adsorption/, volatilization/ emission to surface water) included in the EPIWIN v. 4.1 program) indicate that the majority of the substance will partition to soil and sediment rather than surface water, even though also the surface water may be significantly exposed.

ECHA highlights that if the substance is found to meet the P/vP criteria in water simulation test, there is no need to perform further simulation studies. Otherwise, in addition to the aquatic pelagic simulation study, the Registrant(s) shall perform another simulation test either on sediment or on soil compartment (EU C.23/OECD 307 or EU C.24/308).

The registered substance is used and released in EU within the context of the REACH Regulation. Therefore, the Registrant(s) are requested to perform the studies at 12 °C (285K), as this temperature is indicated in the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.16: Environmental Exposure Assessment, Version 3.0 (February 2016), Table R.16-8: characterisation of environmental compartments as the average environmental temperature for the EU to be used in the Chemical Safety Assessment (CSA).

When analytically possible, identification, stability, behavior, molar quantity of degradation products relative to the parent compound shall be evaluated. In addition, degradation half-life, logKow and potential toxicity of the metabolites shall be investigated.

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

1. Enhanced biodegradation screening test (test method: enhancement of any of the four respirometric tests, OECD Test Guidelines for Ready Biodegradability No. 301 B, C, D or F)*

2. Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309) at a temperature of 12 °C and**

3. Sediment simulation testing (test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308) at a temperature of 12 °C or Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) at a temperature of 12 °C.

** The Registrant(s) are given the option to choose if performing an enhanced biodegradability test first or perform directly the simulation tests. Simulation tests shall be performed if the enhanced test is not conclusive or it is not performed as explained above.*

*** If the substance is found to meet the P/vP criteria in water, there is no need to perform further simulation tests in soil/sediment. Simulation tests shall provide also the identification of transformation products/pathways.*

The Registrant(s) reported in their comments that the provided OECD 301D study is deemed not reliable when considering the propensity of this material to biodegrade because it is considered that the lack of agitation has affected the outcome of the study.

ECHA highlights that in the IUCLID dossier for the test OECD 301D (Klimisch 1) the Registrant(s) stated that: *"during the performance of the cited test the test solutions were ultrasonicated for 5 minutes to ensure a good dispersion"*. In conclusion, in ECHA's opinion the information on the lack of ready biodegradability, provided in the current registration dossier, is reliable and not sufficient to conclude on the P property of the substance. Moreover ECHA cannot approve the approach claimed by Registrant(s) to accept the P property without the need to conduct further testing, because the substance evaluation process requires to clarify uniquevocally the initial concerns.

Therefore according to ECHA assessment, the best approach is to consider the enhanced ready test (option 1), or perform simultation test(s) (option 2), as above indicated, in order to conclusively clarify the P property of the substance. In particular, the Registrant(s) shall demonstrate the enhanced bioavailability of the substance during the test (e.g. with the substance coated on silica or similar).

In the second commenting phase, the Registrant(s) agree to conduct further enhanced ready test, in particular the OECD 301D study, to determine the likely persistency or definitively assess the propensity of the substance to biodegrade.
Moreover they state: *"if the substance does not biodegrade in this test, the "P" criteria will be accepted without the need to conduct further testing. If the substance is not proposed to be a "B" substance on the basis of data for the group of aryl phosphates, then a further investigation of "P" would not be required to assess risk, which can be addressed on the basis of suitable risk management measures"*.
ECHA agrees partially with the above strategy: in this specific case, it is acceptable to provide first an enhanced ready test (OECD 301D study) and in case the test is not conclusive, then it is allowed to clarify the B property, including the possibility to provide adequate read across on the basis of data for the group of aryl phosphates (see also point 4). However ECHA underlines that the "P" criteria could not be accepted without further conclusive test, and in case B is confirmed, then the P property should be unequivocally clarified, according to Option 2, as explained above.

Moreover, the Registrant(s) express concerns relating to the technical feasibility of conducting the requested Simulation testing on ultimate degradation in surface water (test method: EU C.25/OECD 309), due to low solubility of TXP (less than $2x10^{-5}$ g/l at 20 °C ± 1°C, EU method A6/OECD 105). About this issue, ECHA already specified to consider first the OECD 309 test, if it is demonstrated to be technically feasible, because the aquatic pelagic study simulation test is the most meaningful to clarify the P-assessment. However, in general the Registrant(s) need to take into account the intrinsic properties of the registered substance (other than identified uses and release patterns), before deciding the order in which the simulation biodegradation tests shall be performed.

As a general comment the Registrant(s) consider that further evaluation for PBT criteria is considered to be unnecessary since this substance would eventually become subject to authorisation on the basis of the CMR characteristics.
ECHA specifies that TXP would eventually become subject to authorisation on the basis of the Reprotox 1B property, in accordance with Article 57(c).
In general, a PBT/vPvB identification would affect the inclusion on Annex XIV in term of conditions of authorisation procedure, according to Article 57(d) and/or 57(e). In fact if the substance properties fulfil the PBT/vPvB criteria, being a so-called "NON-treshold" substance, an authorisation may only be granted if it is shown that the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies (socio-economic analysis (SEA) route, Pursuant to Articles 60(4)).

Moreover, the inclusion of the PBT/vPvB concern, implies the evaluation of environmental Exposure Scenario, demonstrating that the releases are minimized in the uses applied for. Therefore, ECHA considers appropriate the requests for further testing to clarify the PBT/vPvB concern with the registered substance.

4. Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous or dietary exposure)

Information resulting from Bioaccumulation (B) in aquatic species test is required in order to clarify whether the substance is bioaccumultive (initial grounds for concern: Suspected PBT/vPvB) and to clarify the identified additional concern for a secondary poisoning. This information is thus needed to establish whether the suspected concerns are verified. According to the PBT assessment strategy (ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment, version 2.0, November 2014), concern on P should generally be addressed before the B and Toxicity (T) criteria (in this case TXP already fulfils the criteria for Toxicity based on the Harmonised classification (CLP Annex VI) as Reproductive toxicant 1B). However, because ECHA considers the bioaccumulation study necessary to clarify also the identified additional concern for a secondary poisoning, irrespectively of the PBT/vPvB concern, the test shall be performed in parallel to the tests required for the persistence assessment.

The log Kow value of TXP is > 6.2 (OECD 117), therefore TXP fulfills the screening criteria for B.
On the basis of a weight of evidence approach, the Registrant(s) conclude that the substance is not bioaccumulative because the Bioconcentration Factor (BCF) is considered <2000 (geometric mean: 669,24 L/kg ww).

The Registrant(s) admit that it is not possible to provide a definitive BCF value, due to the variation in the results collected with QSAR derivation, literature data on trixylyl phosphate and read across to structural analogues. In order to derive a BCF value, the Registrant(s) consider appropriate to utilize a geometric mean across the data set, on the ground of what is stated in the ECHA Guidance on Information Requirements and Chemical Assessment" Chapter 10, section R.10.2.2 "Evaluation and interpretation of data".
ECHA notes that the reference cited above by the Registrant(s): "Guidance in information requirements and chemical assessment" chapter 10- section R10.2.2 "Evaluation and interpretation of data" is not on the B assessment, but on characterization of the Predicted No Effect Concentration (PNEC), where in some cases the experimental results can be harmonized by a geometric mean. Instead, the Registrant(s) shall take into account the "Guidance in information requirements and chemical assessment" chapter R.7c-section R.7.10.4.5. "Remaining uncertainty for aquatic bioaccumulation". In this section it is reported that "*when more reliable BCF values are available for the same species and life stage etc., the geometric mean (of the lipid normalized values, where appropriate) may be used as the representative BCF value for that species for B- and risk assessment.*" Therefore, a geometric mean for the BCF evaluation can be used only when more reliable BCF values, by experimental studies, are available for the same species and life stage etc. ECHA notes that it is not the case provided by the Registrant(s).

ECHA highlights that the information provided suggest that the substance is close to fulfilling the B criterion. The Registrant(s) report two experimental studies (no guideline followed) where the product tested contained triphenyl phosphate, cresyl diphenyl phosphate (two main components), tricresyl phosphate (three main components) and trixylenyl phosphate (synonymus of trixylyl phosphate) (three main components).

In reference to the experimental data on bioaccumulation reported by the Registrant(s) and for the first experimental study ([redacted]), ECHA notes that: the study is based on uptake durations shorter than what is recommended for the OECD 305 method; no guideline was followed; the test was carried out at 10°C; steady state was reached within the 14-day exposure period for triphenyl phosphate, the cresyl diphenyl phosphate components and two of the tricresyl phosphate components of the mixture. Steady-state bioconcentration factors (BCFs) were determined as 400 l/kg, 100-220 l/kg and 800 l/kg for these components respectively. For the other components, steady state was approached, but had not been reached by the end of the 14-day uptake period; the non-steady state BCFs estimated at 14 days were 400 l/kg for the remaining tricresyl phosphate component and 1,300-1,900 l/kg for the three trixylenyl phosphate components; and the values obtained of BCF have not been lipid normalized content.
Moreover, in reference to the second experimental study (World Health Organisation) the results are not comparable with any thresholds in Annex XIII and they could be considered only for supporting analysis.

In reference to the experimental study on tricresyl phosphate (TCP) (read-across, RA), ECHA noted that this experimental test is proposed to be acceptable in the context of a weight of evidence approach just for TCP (from public registration dossier for TCP on ECHA website: "*The data is proposed to be acceptable in the context of a weight of evidence approach*"); therefore, due to general level of uncertainty, the data cannot be considered as supporting information in a weight of evidence approach for the registered substance subject to the present decision on TXP.

Regarding the QSAR estimations provided by the Registrant(s), ECHA notes that these estimations cannot be considered as screening or definitive criteria for B/vB, but they could be used in a weight of evidence approach, only to support reliable experimental studies, that it is not the case of TXP.

In summary, data are not lipid normalized, the steady state is not reached in one of the study ([redacted] and the available dietary study is difficult to interpret.
As a result, ECHA considers that the provided information does not allow to exclude the B criterion. As a consequence, the substance should be considered as potentially B/vB.

According to ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11 "PBT and vPvB assessment" and, as explained above, since the weight-of-evidence approach described under "Conclusions on the Endpoint" is not considered by ECHA sufficient to draw a conclusion, an experimental bioaccumulation test is required, according to the test guideline OECD 305.

Moreover, ECHA identified a potential concern for secondary poisoning for the following reasons: as stated in the ECHA Guidance on information requirements and chemical safety assessment Part B: Hazard assessment, "*Substances that are bioaccumulative and have a low degradability may accumulate in food chains and, eventually, cause toxic effects in predatory fish, birds and mammals (so called (top) predators) at higher levels of the food chains, including man. This effect is called secondary poisoning*".
The Registrant(s) do not provide a risk characterisation for this endpoint, but just a generic assessment concluding that secondary poisoning does not pose a hazard because they consider the potential bioaccumulation partially negated by the calculated values and that release to the environment is prohibited.

ECHA highlights that, in accordance to the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R. 16.6.7:*"if a substance has a bioaccumulation potential and a low degradability (e.g. not readily biodegradable or not hydrolysable) and has also a potential to cause toxic effects if accumulated in higher organisms, a detailed assessment of secondary poisoning should be conducted (see also B.7.2.7)"*. As already stated, TXP is potentially Bioaccumulative and is not ready biodegradable; moreover, TXP is classified based on the Harmonised classification (CLP Annex VI) as Reprotox 1B, (H360F "May damage fertility") on the basis of mammalian toxicity data; therefore, fish BCF (and Biomagnification Factor, BMF) values shall be used by Registrant(s) to calculate concentrations in fish as part of a detailed secondary poisoning assessment (PEC/PNEC ratio), performed according to ECHA Guidances on Information Requirements and Chemical Safety AssessmentChapter R.10; Section R.7.10.5; and Section R.16.6.7.

The conditions under which the bioaccumulation study has to be conducted are specified in the test guideline OECD 305 *"The aqueous exposure test is most appropriately applied to stable organic chemicals with log Kow values between 1.5 and 6.0 but may still be applied to strongly hydrophobic substances (having log Kow > 6.0), if a stable and fully dissolved concentration of the test substance in water can be demonstrated. If a stable concentration of the test substance in water cannot be demonstrated, an aqueous study would not be appropriate thus the dietary approach for testing the substance in fish would be required[...]. For strongly hydrophobic substances (log Kow > 5 and a solubility below ~ 0.01-0.1 mg/L), testing via aqueous exposure may become increasingly difficult. Reasons for constraints may be that the aqueous concentration cannot be maintained at a level that is considered to be sufficiently constant (e.g. due to sorption to the glass of exposure containers or rapid uptake by the fish) or that the aqueous concentrations to be applied are so low that they are in the same range as or below the analytical limit of quantification. For these highly hydrophobic substances the dietary test is recommended, provided that the test is consistent with the relevant regulatory framework and risk assessment needs."*
Therefore ECHA specifies that a dietary study shall be used by the Registrant(s), if it is technically not possible to conduct the aqueous exposure test as consequence of the properties of TXP.

Therefore, the Registrant(s) are required to carry out the following test using the registered Substance:
Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous or dietary exposure).

In their comments, the Registrant(s) proposed a new read-across approach based on an analogous substance Phenol, isopropylated, phosphate (3:1), CAS number: 68937-41-7 (OECD 305 GLP study, 2015).
ECHA highlights that the substance is part of aryl phosphate esters evaluated as a group by UK. In the document *"An overview of the environmental risk evaluation reports for aryl phosphate esters"* published of UK Environment Agency (August 2009), the overall conclusions of the PBT assessment was that trixylenyl phosphate and tris(isopropylphenyl) phosphate cannot currently be excluded as meeting the PBT/vPvB criteria.

The new OECD 305 GLP study (2015), cited by the Registrants for the substance tris(isopropylphenyl) phosphate (CAS number: 68937-41-7) and reported in ECHA's website, seems to clarify that tris(isopropylphenyl) phosphate is not considered to be bioaccumulative, against the provisions of the screening data.

ECHA notes that all the aryl phosphate esters of the category meet the screening criteria for potential bioaccumulation (logKow>4.5) as reported in the above mentioned document: "*An overview of the environmental risk evaluation reports for aryl phosphate esters*" published of UK Environment Agency (August 2009)[4]. However, it is also considered that using the methods recommended in the test guideline OECD 305, the BCF values for fish can be estimated using the provided Kow. The estimated values can result higher than those determined in the experimental studies (therefore more adequate) based on interested substance. This indicates an overestimation of the actual BCF for some triaryl phosphates, probably because no metabolism is assumed.

In the second commenting phase, the Registrant(s) confirmed that they do not see the value in conducting an animal study to confirm this result, given that sufficient data is available on analogues, and to address this endpoint, updated read-across and existing data on the substances will be utilized.
In conclusion, despite ECHA agrees with the Registrant(s) that a subsequent review of the data set available for aryl phosphate esters (group) could indicate that these are not likely to be bioaccumulative, the request of experimental test is confirmed because in the current registration dossier the new information and adequate justification document for read-across approach are missing. The requested information will be properly evaluated when available in the updated dossier.

5-6. Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates and Effects on soil micro-organisms

The information request is relevant to clarify the identified additional concern: potential risk for soil compartment.
The high adsorption to soil (log Koc value of 5.08 at 25 °C) indicates that the majority of the substance will partition to soil and sediment rather than water. As such, adsorption to soil is deemed to be high, based on this study assessment.

The Registrant(s) provide only one acute test on plants (based on read-across) to evaluate soil toxicity, claiming that direct and indirect exposure of the terrestrial compartment is unlikely. This statement is incongruent with the exposure assessment provided in the Chemical Safety Report (CSR). Indeed, according to the exposure scenarios provided in the CSR, the direct release to soil is not expected, but an indirect exposure to soil is not unlikely to occur. In fact, at least 3 exposure scenarios (ESs 5, 7 and 9) show an indirect soil exposure, through release of the substance to the municipal Sewage Treatment Plant (STP), and the following application of STP sludge to agricultural soils. Moreover, as already highlighted, the substance is not readily biodegradable, the Registrant(s) state that the majority of the substance will partition to soil and sediment rather than water and also on the basis of consolidated information the substance is expected to largely distribute in soil and sediment. Therefore, ECHA considers that, in this scenario, a risk for the soil compartment cannot be excluded, because an indirect exposure is expected and in view of the initial ground of concerns of the substance as wide dispersive use, exposure of the environment, and high (aggregated) tonnage.

Under these circumstances, the information requirements have to be fulfilled in order to clarify the identified additional concern: potential risk for soil compartment.

[4] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/290484/scho0809bqtz-e-e.pdf

ECHA specifies that, following the Integrated Testing Strategy of the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7C (version 2.0, November 2014), in this case the screening assessment is not adequate: the substance is highly adsorptive, and is considered very toxic to aquatic organisms, therefore TXP falls into the soil hazard category 4, for which the screening assessment based on the equilibrium partitioning method (EPM) is not recommended. For such soil hazard category, long-term toxicity tests on three trophic levels are suggested. Despite this, ECHA considers that the acute test on plants provided under read-across approach, which do not reveal any phytotoxic effects, *"cover a sensitive stage in the life-cycle of a plant and therefore data obtained from this study have been used as estimates of chronic toxicity"* (as highlighted in ECHA Guidance R.7C). Furthermore, the aquatic tests show that invertebrates (*Daphnia*) are the most sensitive organisms and the algae have shown no significant toxic effects.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to submit the following information derived with the registered substance subject to the present decision:

Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232) and

Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, EU C.21./OECD 216).

In view of the test results, the Registrant(s) shall recalculate $PNEC_{soil}$ using the lowest value among the newly generated data and applying the adequate assessment factor. Moreover, the Registrant(s) shall use the new value of $PNEC_{soil}$ to calculate the ratio Predicted Environmental Concentration in soil (PEC_{soil})/$PNEC_{soil}$ (Risk Characterisation Ratio, RCR).

In their comments, the Registrant(s) proposed to refine the environmental assessment with a new read-across approach based on the analogous substance Phenol, isopropylated, phosphate (3:1), CAS number: 68937-41-7 (OECD 207 and OECD 216 GLP studies). These results, in addition to the plant toxicity test already presented and with the Risk Management Measures (RMMs) in place, will be utilised to demonstrate that there is no concern to terrestrial organisms for this category of substances.

ECHA notes that, since the substance has a potential to adsorb to soil, the long-term tests on terrestrial invertebrates are considered appropriate to clarify the identified additional concern: potential risk for soil compartment. The choice of the appropriate test protocol is left to the Registrant(s), since that depends on species sensitivity and substance properties. Therefore, the proposal to provide a short term test (OECD 207) is not in compliance with the ECHA request.

Regarding the Read Across justification and the OECD 216 test on terrestrial microorganisms, ECHA will evaluate the announced information when available in the updated dossier.

Therefore, despite ECHA agrees with the Registrant(s) approach to utilise read-across and existing data on the substances to address the soil toxicity endpoints, ECHA expects a read-across justification in accordance with Annex XI, 1.5. of REACH and the revised chemical safety assessment of the registered substance, including the recalculations of PNECsoil and PECsoil/PNECsoil (RCR). The announced information will be properly evaluated when available in the updated dossier. Meanwhile, the requested information is mantained.
Finally, as indicated in Section II, these requests no. 5 and 6 shall be conditional on the persistence and bioaccumulation results, because there is no need to investigate soil toxicity

if the PBT/vPvB concern is confirmed.

In the second commenting phase, the Registrant(s) confirmed that they will utilize read-across and existing data on the substances to address toxicity to soil microorganisms, and they agree to conduct a further long-term toxicity to terrestrial invertebrates (test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232) to address the additional risk factors requested.

7. Missing information on risk management measures

This information is required for concluding on the initial concerns posed by the substance: wide dispersive use, exposure of the environment, high (aggregated) tonnage; and on the identified additional concerns: potential risk for soil compartment and for a secondary poisoning.

As stated in "ECHA Guidance on Information Requirements and Chemical Safety Assessment, Part D: Exposure Scenario Building" (Version 1.2, October 2012), the risk management measures related to the environment should describe type and effectiveness of single options or combination of options and they should be quantified for waste water, waste gas, protection of soil.

If risk management measures are used to limit the releases into the environment, they always need to be described in details in each exposure scenario. The deviation from the default release factor of the respective environmental release category shall be clearly justified, especially when null release to a particular environmental compartment (air, water, soil) is assumed.

Moreover, if additional onsite waste water treatment or waste air treatment is needed to limit the release, the corresponding suitable treatment techniques are to be identified in the Exposure Scenario (ES) and appropriate references shall be reported. Information about the allocation of effluent and sludge shall be also provided.

In the CSR, the Registrant(s) report, under the chapters "Condition of use" of each ES, information about adopted technical/organization measures that are similar for all exposure scenarios and, in case of industrial and professional use, the same measures are utilized. The refinement of exposure assessment seems based on conditions applied reducing to zero the default release factors for air and water compartments for all exposure scenarios.

Concerning the use of Sewage Treatment Plant/Waste Water Treatment Plant (STP/WWTP), for all ESs, the Registrant(s) report that the release to municipal STP is avoided. This assumption does not match, for ESs concerning professional use (ESs 5, 7 and 9), with the declaration of presence of STP and of application of the STP sludge on agricultural soil, as reported on the tables.
For all ESs the Registrant(s) consider an on-site acclimated biological treatment in WWTP with efficiency >90%. For ESs from 3 to 9 (industrial and professional uses) the Registrant(s) consider a physical/chemical waste water treatment with efficiency of 70%, without any reference.

ECHA highlights that the "Environmental Risk evaluation report: TXP CAS N 25155-23-1" (August, 2009) of the UK Environment Agency reports the distribution of the substance between effluent (49,4%) and sludge (50,6%), estimated using EUSES model and a degradation rate constant of 0.3 h^{-1}, a Koc of 8,486 l/kg and a vapour pressure of $8,7x10^{-6}$. Considering the expected behaviour of TXP during waste water treatment and the high adsorption to soil, the final disposal of the sludge of STP/WWTP and the possible reduction in spreading of sludge are not clearly specified.

Moreover, in every case (except ES1), the Registrant(s) consider the biological treatment "where possible". It is not clear what happens in cases where the treatment is "not possible".

For the air compartment, the Registrant(s) reduce to zero the default release factors for air. However, for ES1, they do not report any specific measure for removal of contaminants prior to release to air and, for ESs from 2 to 9, they report the assumption of vapour recovery at 90% efficiency, without any reference.

In the CSR, the Registrant(s) do not provide specific and scientific justification on measures driving the release factors considered for the environmental exposure assessment.

Therefore, more detailed/additional information is requested to fill the gap on environmental exposure and to better address the risk evaluation. Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are requested to submit the following information derived with the registered substance subject to the present decision:

Update the CSR, providing for each ES specific and detailed information on risk management measures which are realistic and ensuring a safe use.

In particular they are requested to:

- Clarify the presence/absence of STP
- Justify the efficiency of the WWTP, where adopted
- Clarify the final disposal and the possible restriction in spreading of the sludge of STP/WWTP
- Clarify what happen when the WWTP is not possible
- Clarify the adopted measures for removal of contaminants prior to release to air.

In their comments, the Registrant(s) acknowledged ECHA's request and claimed to have substantially revised the CSR in 2015 on the basis of a new vapour pressure test and the use of ATIEL SPERC's in the derivation of emissions to the environment.

ECHA will evaluate the announced information when available in the updated dossier. Meanwhile ECHA mantains the above information requirement.

III. Adequate identification of the composition of the tested material

In relation to the required experimental stud(y/ies), 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 test(s) must be shared by the Registrant(s).

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

In relation to the experimental stud(y/ies) 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 Registrants to perform the stud(y/ies) on behalf of all of them.

V. 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[5] by Ofelia Bercaru, Head of Unit of Evaluation, 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.

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