EUROPEAN CHEMICALS AGENCY

Helsinki, 10 February 2020

Addressees
Registrant listed in the last Appendix of this decision

Date of submission for the dossier subject of this decision
28/11/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Dioctadecyl disulphide
EC number: 219-702-5
CAS number: 2500-88-1

Decision number: [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***17 February 2021***.

A. Requirements applicable to all the Registrants subject to Annex IX of REACH[1]

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

2. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the Substance (as specified under Appendix A, Section 2);

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa.

The Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH

The test material used to perform the required studies must be selected and reported in accordance with the specifications prescribed in the Appendix entitled Observations and technical guidance.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

[1] Testing required under this Annex can only be started or performed after the decision has been adopted according to Article 51.

Appeal

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

Authorised[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix A: Reasons for the requests to comply with Annex IX of REACH

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII-IX to the REACH Regulation.

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

Assessment of the Weight of evidence adaptation under Annex XI, Section 1.2.

You have adapted the information requirement for a PNDT study in a second species by using weight of evidence (WoE) according to Annex XI, Section 1.2.

As a justification for your weight of evidence adaptation you have provided the following information:

- Claims of low toxicity (acute/sub-chronic/chronic effects, skin/eye irritation, skin sensitisation, mutagenicity).
- Lack of teratogenic effects in a Combined chronic/carcinogenicity/one-generation toxicity study.
- Information on use and exposure: *"the registered substance is exclusively used in polymeric matrixes as stabilizer. Therefore, the exposure to consumers can be excluded. It can be assumed that workers who are involved in industrial manufacture and formulation processes are trained in handling chemicals and according to general occupational health regulations an exposure of pregnant workers to* [redacted] *at the production site is excluded."*

We have assessed your WoE adaptation against the Annex IX, Section 8.7.2. information requirement (PNDT study in a first species), because a PNDT study in a second species is not a standard information requirement under Annex IX to REACH (unless there is further concern for information based on the outcome of a PNDT study in a first species or other relevant data).

ECHA has assessed to what extent the information submitted enables a conclusion of hazardous properties for prenatal developmental toxicity and identified the following deficiencies:

Annex XI, Section 1.2 states that there may be sufficient weight of evidence *"from several independent sources of information"* leading to an assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion

You have only provided one source of information (Combined chronic/carcinogenicity/one-generation toxicity study) that contributes to the evaluation of intrinsic hazardous properties for (prenatal) developmental toxicity.

In order to allow concluding on no (prenatal) developmental toxicity for the substance in a weight of evidence adaptation, the information in the justification must cover the key elements (parameters) foreseen to be investigated in an OECD TG 414 study.

The studies provided, alone or together, do not inform on the property for (prenatal) development toxicity because they do not cover the main developmental toxicity investigations, such as examination of the foetuses for structural malformations and variations.

In your comments on the initial draft decision you claim that the WoE adaptation is justified with a conclusion that further testing on developmental toxicity is not required because *"all fundamental parameters of the maternal and fetal development are scientifically sound covered"*. You presented the data included in your dossier and you included a table comparing the parameters to be examined according to the OECD TG 414 and corresponding observations reported in the combined reproductive and chronic toxicity study included in your dossier. As presented in your table, the adult animals did not indicate any symptoms or histopathological findings reflecting structural soft tissue / skeletal malformations in your study.

First of all, ECHA points out that you still rely on information from one study only. However, as already expressed above, an adaptation under Annex XI, Section 1.2 must be based on several independent sources of information.

Secondly, you present that clinical symptoms, i.e distress, abnormal behavior, reduced food consumption etc, indicating suffering due to malformation or severe affected skeletal development, were not observed. You also state that the soft tissue examination to be performed on all pups as required by OECD TG 414 is sufficiently conducted because at termination in adults *"all animals were necropsied, and a complete histopathology was performed on all essential organs it is concluded"*.

However, you have not substantiated your claim with data: You have not provided evidence on the predictability and reliability of the type of information provided to predict prenatal developmental toxicity for the Substance. The investigations you claim to inform on malformations (clinical symptoms, necropsy and organ histopathology) are not producing reliable information on prenatal developmental toxicity. You seem to admit that skeletal malformations and variations were not investigated in the combined study. For visceral malformations you provide information from autopsy of the adult animals and histopathology of organs and tissue. However, based on the information in your current robust study summary, potential morphological changes due to developmental origin in organs were not specifically investigated.

In addition, contradictory to your claim, examinations for structural external, skeletal and soft tissue malformation and variations were not conducted as required by the OECD TG 414 guideline from all live unborn pups (foetuses). In your study only selected pups as adult animals were examined for toxic effects in organs and tissues. In OECD TG 414 *foetuses* are examined for structural malformations and variations because rodent dams tend to eat malformed pups, live or dead, (after birth) reducing the possibility to detect malformations in the offspring. This is also indicated in OECD GD 43, paragraph 59: *"The prenatal developmental toxicity study design includes sacrifice of the rodent or rabbit dam one day prior to expected delivery, in order to ensure that malformed foetuses are not lost to maternal cannibalism (Schardein et al., 1978), as could happen in a reproduction study."* A few cannibalised malformed pups is not visible in mean values of the litter sizes but are important evidence of prenatal developmental toxicity that cannot be detected anymore in adults.

Therefore, evaluation of the adults (or pups) for malformations (and variations) can not inform on malformation and variation rates.

Furthermore, it is important to investigate also other developmental effects than malformations, such as minor anomalies, variations, foetal death and growth as indicated in OECD GD 43, paragrah 60: "*The sensitivity of the test for detection of rare events such as malformations is limited, due to the use of a relatively small number of animals. With the normal group sizes of 20 pregnant rats, it is not possible to identify any increase in major malformations unless high dose levels are administered or the substance studied is highly embryo/foetotoxic (Palmer 1981). To assess the developmental toxicity of a chemical, it is therefore important to include information on other developmental effects such as minor anomalies, variations, foetal death and growth.*"

In conclusion, none of the pieces of information alone or together, and taking into account your justification for the weight of evidence adaptation, allows to conclude whether the Substance has or has not hazardous properties related to (prenatal) developmental toxicity, because information on key investigations on prenatal developmental toxicity like special examination of the foetuses for structural malformations and variations is not available. Therefore, your adaptation according to Annex XI, Section 1.2. is rejected.

In addition, you intend to demonstrate that your Substance is of low toxicological activity and that human exposure is low. However, for such adaptation claims, the specific adaptation rule under Annex IX Section 8.7, Column 2, first paragraph, third indent applies. Hence, ECHA assesses below your adaptation according to this specific rule of adaptation.

Assessment of the column 2 adaptation under Annex IX, Section 8.7.

According to Annex IX, Section 8.7., Column 2, first paragraph, third indent, the corresponding study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, two of them being:

i. that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
ii. that there is no or no significant human exposure.

In your dossier you provided:

i. Two toxicokinetic studies (dated 2012 and 1981) performed with the Substance. The study results showed that 87.7-93% of the administered dose was recovered in feces, "*supporting the low bioaccessibility*".
ii. The only use included in the dossier is manufacture (PROCs 3, 8b, 9, 14). In your WoE adaptation justification you mention that "*the registered substance is exclusively used* [redacted]. *Therefore, the exposure to consumers can be excluded. It can be assumed that workers who are involved in industrial manufacture and formulation processes are trained in handling chemicals and according to general occupational health regulations an exposure of pregnant workers to* [redacted] *at the production site is excluded*". No details on exposure are included in the dossier or CSR.

The study results show detectable concentrations of the Substance in blood and tissues "*[...] detectable concentrations of* [redacted] *in blood were observed after 3 h and peaked in the high dose at the 6 h sampling point. After 6 h, the blood levels of* [redacted] *decreased to reach the limit of detection 24 h after administration of 100 mg/kg bw. In animals administered 1000 mg/kg bw,* [redacted] *was still detectable in blood 96 h after administration. [...] Administration of* [redacted] *also caused a dose- and time-dependent*

increase of the test item mesentheric lymphnodes, liver and kidneys. However, organ levels were below 1.2 nmol/g organ and therefore very low, even after administration of the high dose". Therefore, the information provided cannot be considered as proof of no systemic absorption.

As no details on exposure scenarios, conditions of use and exposure estimates are included in the dossier or CSR, the information provided cannot be considered as proof of no or no significant human exposure. Your statement "*It can be assumed that workers who are involved in industrial manufacture and formulation processes are trained in handling chemicals and according to general occupational health regulations an exposure of pregnant workers to* [redacted] *at the production site is excluded"* is unsubstantiated and does not provide, for example, assessment of exposure and is thus considered irrelevant as it does not bring evidence to prove lack of exposure.

In your comments on the initial draft decision you presented new information on the uses by professionals and consumers. You stated that the substance is used as [redacted] with a concentration of [redacted] The mostly used applications are [redacted] You concluded that the parts that have the highest concentration are in contact with skin only on operations by professionals and exposure to consumers is very limited.

ECHA notes that in your comments on the initial draft decision, you have identified new consumer and professional uses of the plastic articles in addition to manufacture of the registered substance. You have provided one exposure scenario for professional use [redacted] supported with dermal exposure estimations calculated with CHESAR and with a justification of low dermal absorption. However, you have still not provided any information on the conditions of use and/or exposure estimates during manufacture (PROCs 3, 8b, 9, 14). ECHA further notes that the production of [redacted] is not addressed.

In order to justify the omission of a standard information requirement, you must demonstrate that there is no or no significant human exposure.[3] You have not provided quantitative justification of negligible risk for workers nor you have demonstrated that strictly controlled conditions are applied during manufacture of the registered substance and production of articles. In the absence of information ECHA cannot verify whether there is no or no significant human exposure to your substance.

Based on the above, your adaptation is rejected.

No study provided that meets the standard information requirement

To be considered compliant and enable assessing if the Substance is a developmental toxicant, the information provided has to meet the requirements of OECD TG 414 in one species.

You have not provided information following OECD TG 414. Instead, you have provided a "Combined chronic/carcinogenicity/one-generation toxicity study".

This study does not show adequate and reliable coverage of the key parameters required to be investigated in OECD TG 414. Specifically there are no investigations and information on skeletal malformations and variations, visceral variations, external malformations and variations (except for those three investigated: club feet, cleft palate and hydrocephalus).

[3] ECHA Guidance R.5. Section 5.1.5.2.

The induction of malformations/variations can be addressed only when foetuses are specifically investigated just before birth according to OECD TG 414.

In your comments on the initial draft decision you wrote that "*It is unclear what is meant by the ECHA comment "the induction of malformation/variations can be addressed only when fetuses are specifically investigated just before birth according to OECD TG 414". It is a scientifically acknowledged fact and part of their definition, that malformations and variations (skeletal or visceral) when become manifest are not reversible. Thus, leading to the conclusion that they can be identified at any time after their appearance. [...] It is concluded that malformations and variations as examined by the OECD guideline 414 cannot only be addressed by the investigation of fetuses but also be identified in the adult organism. As these parameters are examined in the available reproductive toxicity and chronic toxicity study and no effects are observed, the test substance is considered to be not developmental toxic.*".

ECHA does not agree with your claim that malformations can be identified at any time after their appearance. As indicated above, prenatal developmental toxicity can be investigated reliably only in studies where the foetal examinations are done just before birth. Only then it is possible to gather reliable information on all different kinds of developmental defects and their incidences. Thus, there is no reliable information on the property of prenatal developmental toxicity.

Based on the above, the information you provided does not fulfil the information requirement.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[4] administration of the Substance.

2. Identification of degradation products (Annex IX, 9.2.3.)

Identification of the degradation products is a standard information requirement at Annex IX of REACH. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided if the substance is readily biodegradable.

You have sought to adapt this information requirement based on Annex IX, Section 9.2.3. Column 2.

ECHA has assessed this justification and identified the following issue:

Chemical Safety Assessment needs to assess and document that risks arising from the Substance are controlled to demonstrate that there is no need to conduct further testing (Annex IX, Section 9.2, Column 2).

In particular the following element(s) need to be included:
- justification for why there is no need to provide any further information for the degradation products to be considered in hazard assessment/ and exposure assessment
- PBT/vPvB assessment including information on relevant degradation products

Identification of degradation products does not need to be conducted if the substance is readily biodegradable (Annex IX, Section 9.2.3, column 2).

You justified the adaptation by stating that CSA does not indicate that further information on

[4] ECHA Guidance R.7a, Section R.7.6.2.3.2.

degradation is not needed. You concluded the Substance as not readily biodegradable based on following studies:

- Key study: OECD TG 301F (2011) with the Substance showing 32 % degradation after 28 days.
- Key study: OECD TG 301F study (2013) with the Substance showing 20% degradation after 60 days.

You have not provided any information on the potential degradation products and their fate properties.

Your adaptation is rejected because the Substance is not readily biodegradable, you have not provided any justification in your chemical safety assessment (CSA) or in the dossier for why there is no need to provide information on the degradation products. You have claimed that there is no need to further assess the PBT/vPvB properties of the Substance. However, you have not assessed nor documented that the risks arising from potential degradation products are controlled. This information is needed for the PBT/vPvB assessment /and risk assessment.

In your comments on the initial draft decision, you submitted two figures showing the biodegradation of the Substance obtained from the studies mentioned above. First figure shows <30 % biodegradation of the Substance after 60 days and the second figure shows approximately 30 % biodegradation of the Substance after 28 days. However, in both cases, pass-levels are not achieved.

The ECHA guidance document R7b and R11 states that;

- where substances have not achieved the pass level for ready biodegradability in the 28-day ready biodegradability test duration the substances are considered to be not readily biodegradable (R7b Section R7.9.4.1);
- Positive results from enhanced screening tests may be used together with other supporting information to conclude that the substance is not P/vP, if the pass level (without 10-day window) is achieved (R11 Section R11.4.1.1.1, Table R11-4);
- If the results of enhanced screening test are negative (i.e. above criterium and other criteria are not met), then it is generally not possible to definitively conclude on the persistence or absence of persistence of the substance and further testing will be needed (R11 Section R11.4.1.1.1, Table R11-4).

Based on the figures you provided, the Substance can neither be considered ready biodegradable nor not P/vP. Thus, it is not possible to definitely conclude on the persistence or absence of the persistence of the Substance and its potential degradation products.

Therefore, your adaptation does not fulfil the information requirement.

Regarding the appropriate and suitable test method you are recommended to perform a simulation test (OECD TG 307, 308 or 309). The OECD TG 309 is the preferred test if technically feasible. The information currently available in the technical dossier on water solubility (WS <0.5 mg/L) does not allow to conclude that the Substance is highly insoluble in water. If you choose to conduct the OECD TG 309 you must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11). To overcome the potential analytical limitations in the identification and quantification of major transformation products you may use higher concentrations of the Substance (e.g. >100 µg/L) as specified in the OECD TG 309 and a temperature of 20 °C.

Non-extractable residues (NER) must be quantified in all simulation studies, also when conducting them for the purpose of the identification of degradation products because these residues may consist of parent substance and/or degradation products. NER are bound to suspended particulate matter, soil or sediment particles and the analytical detection of transformation products within these residues is challenging. The reporting of your results must include a scientific justification of the extraction procedures and solvents used. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when considering the relevance of the degradation products (ECHA Guidance Chapter R.11 and Options to address NER in regulatory P assessment, 2019[5]).

In your comments on the initial draft decision you provide explanation that the currently reported WS (<0.5 mg/L) is based on the limit of detection of the analytical method used. Furthermore, you provide two predictions of WS using QSAR (3.433e-014 mg/L (based on WSKOW v.1.42) and (5.7111e-007 mg/L)), without QMRF/QPRF. Based on the predicted WS, it may be plausible that the Substance is highly insoluble in water, thus OECD TG 309 may not be suitable. However, we cannot establish the scientific validity of the predictions based on the information you provide in your comments on the initial draft decision. Furthermore, ECHA notes that even if the Substance is highly insoluble in water and thus OECD TG 309 may not be feasible to conduct, OECD TG 308 or TG 307 are still possible simulation tests which you may choose to perform.

You may also use other appropriate and suitable test methods to provide information on the identity of the transformation/degradation products for example by enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the Substance, when analytically possible. In addition, degradation half-life, log Kow and potential toxicity of the transformation/degradation products may be investigated.

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

Appendix B: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of the REACH Regulation.

The compliance check was initiated on 21 March 2019.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA took into account your comments and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-68 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix C: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[6].

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance. The test material must be representative of the composition of the Substance.

   While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

[6] https://echa.europa.eu/practical-guides

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

5. List of references of the ECHA Guidance and other guidance/ reference documents[7]

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[8]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents[9]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document supporting the OECD TG 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD151.

[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[8] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.