~~Confidential~~

Helsinki, 06 September 2021

**Addressees**
Registrant(s) of JS_111-70-6_Heptanol as listed in the last Appendix of this decision

**Date of submission of the dossier subject to this decision**
02/04/2015

**Registered substance subject to this decision ("the Substance")**
Substance name: Heptan-1-ol
EC number: 203-897-9
CAS number: 111-70-6

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

## DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed in A.1 below by ***13 March 2023*** and all other information listed below by ***13 March 2024***.

Requested information must be generated using the Substance unless otherwise specified.

### A. Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

### B. Information required from all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) by oral route, in rats, specified as follows:
   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

   You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

Reasons for the request(s) are explained in the following appendices:

- Appendices entitled "Reasons to request information required under Annexes IX to X of REACH", respectively.

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH, the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

**How to comply with your information requirements**

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

**Appeal**

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

**Failure to comply**

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] 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 to request information required under Annex IX of REACH

### 1. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "*It is laid down in the REACH Regulation EC 1907/2006 Annexes IX, section 9.1.6, column 2, that long-term fish toxicity testing shall be proposed by the registrant if the chemical safety assessment (CSA) indicates such a need. Since the CSA indicates that both freshwater and marine water RCRs are all inferior to 1, no further aquatic toxicity testing is needed.*"

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

In your comments to the initial draft decision you agree to perform the study with the Substance according to the OECD TG 210.

## Appendix B: Reasons to request information required under Annex X of REACH

### 1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

You have provided pre-natal developmental toxicity studies in rats with the analogue substances pentanol and hexanol.

We have assessed this information and identified the following issue:

In order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.

You have not provided information on a second species.

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

In your comments to the initial draft decision, you indicated a tonnage band decrease to Annex IX and that based on available information this requested study is not warranted for Annex IX registration. On 3 March 2021, ECHA provided you a communication outlining that a change in your tonnage band will not have an impact on the decision-making process of this draft decision. ECHA's evaluation of your registration dossier is based on the specific tonnage band at which your substance was registered at the time, the draft decision was submitted to you i.e. Annex X. This information was also stated in the notification letter to your draft decision. This endpoint is a standard information requirement in Annex X to the REACH Regulation. As stated above the information you provided do not fulfil the information requirement.

In your additional comment submitted 17 March 2021 you indicate that this study is not warranted for an Annex IX registration, and you do not find that it could be triggered at Annex IX as there is a screening reprotoxicity test according to OECD TG 422 guideline performed up to limit dose where no effects were seen. However, as explained above the standard information requirements of Annex X still apply to your registration.

On this basis, the information in your comments is not sufficient for ECHA to make an assessment. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation).

*Information on study design*

A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as the preferred species. The test in the first species was carried out on analogues substances pentanol and hexanol by using a rodent species (rat). Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

*Administration route*

The study must be performed with oral[2] administration of the Substance.

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

## 2. Extended one-generation reproductive toxicity study

An Extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is a standard information requirement in Annex X to the REACH Regulation.

You provided the following adaptation: "*The waiving the of two generation study is based on the following arguments: There is a screening reprotoxicity test according to OECD 422 guideline perfomed with heptanol where no effects on fertility, mating, pregnancy and early post-natal development were observed at 1000 mg/kg/day. There is a subchronic 90 day toxicity study performed with pentanol, a close structurally analogue of heptanol, where no effects were seen on reproductive organs at 1000 mg/kg/day. There is no effect in a rat development study performed with the analogue Hexanol at the highest achievable concentration. In addition, the waiving of the two generation is proposed because aliphatic alcohols are recognised to be of low order of toxicity upon inhalation, oral or dermal exposure upon repeated exposure (See HPV of long chain alcohols, SIAM 22 (2006)). The proposed rat developmental study will help in identifying whether any alert are reported and will therefore determined if the waiving of the two generation study is justified. Furthermore, n-heptanol-1 is currently recognized by the US Food and Drug Administration (FDA) as GRAS ("generally regarded as safe") for its intended use as flavoring substances (See US- EPA, Food additives database http://viness.narod.ru/food_additive_database.htm).*"

In support of your adaptation, ECHA understands that you refer to the following sources of information:

(i) Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test according to OECD TG 422 (2012), performed with the Substance;
(ii) Subchronic toxicity study similar to OECD TG 408 (1978), performed with the analogue substance pentanol;
(iii) Non-guideline developmental toxicity study in rats (1989), performed with the analogue substance hexanol;
(iv) Assessment conclusions from the OECD HPV Chemicals Programme on the long chain alcohols category (2006);
(v) Assessment conclusions from the US FDA on the Substance used as flavouring substance.

You also refer to a proposal for a developmental study in the rat. However, no such testing proposal is provided in the dossier for ECHA to consider.

While an adaptation was not specifically indicated by you, ECHA has evaluated the provided information according to Annex XI, Section 1.2 (weight of evidence).

Annex XI, Section 1.2 states that there may be sufficient weight of evidence (WoE) from several independent sources of information leading to 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.

According to ECHA Guidance R.4.4, a WoE adaptation involves an assessment of the relative values/weights of different pieces of the available information which is defined by e.g. the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory endpoint. Subsequently, the lines of evidence should be integrated considering their relative values or weights in order to draw a conclusion.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

You have not included a justification for your WoE adaptation, which would include an assessment of relative weights of the individual pieces of information and the subsequent conclusions drawn.

You present assessment conclusions (iv) and (v) to justify the conclusion/assumption that the Substance has not a particular dangerous property investigated by the required study.

However, these assessments have been prepared for different purposes than REACH and you have provided no explanation how this would be relevant under REACH. The assessment (iv) relates to the OECD HPV "Long Chain Alcohols (C6-22 primary aliphatic alcohols)" category, which differs from the read across hypothesis provided in your dossier and seems based on a different dataset. As part of the OECD HPV Chemicals Programme, the assessment (iv) is meant for toxicity screening and only provides screening level hazard conclusions for human health and/or the environment. The assessment (v) could not be retrieved through the link you provided and the corresponding dataset was not accessible. Neither the assessment (iv) nor the assessment (v) does weigh the pieces of evidence individually or together and lead to the conclusion that the Substance has or has not a particular dangerous property.

Irrespective of the above mentioned deficiencies on the documentation, which in themselves could lead to the rejection of the adaptation, ECHA has assessed to what extent the information submitted enables a conclusion of hazardous properties for information requirement of Section 8.7.3 at Annex X and identified the following deficiencies:

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.7.3 at Annex X includes similar information that is produced by the OECD TG 443 design as specified in this decisions. At general level, it includes information on 1) sexual function and fertility, 2) toxicity to offspring and 3) systemic toxicity.

*1.Sexual function and fertility*

Sexual function and fertility on both sexes must include information on mating, fertility, gestation (length), maintenance of pregnancy (abortions, total resorptions), parturition, lactation, organ weights and histopathology of reproductive organs and tissues, oestrous cyclicity, sperm count, sperm analysis, hormone levels, litter sizes, nursing performance and other potential aspects of sexual function and fertility.

The sources of information (i) and (iii) provide relevant information on sexual function and fertility, although the source (iii) informs on sexual function and fertility only in females and only for one aspect, maintenance of pregnancy. Repeated dose toxicity study (ii) provides relevant information on integrity of reproductive organs in both sexes.

However, the sources of information (i), (ii) and (iii) have the following deficiencies (1-2) affecting their reliability.

1. Information on sexual function and fertility (functional fertility and histopathology of reproductive organs and tissues) must be investigated in parental P0 animals during a continuous exposure from premating until termination, and after at least ten weeks premating exposure duration to ensure steady state of the Substance in parental animals

and the coverage of full spermatogenesis and folliculogenesis before mating as indicated in ECHA guidance[3].

The source of information (i) investigates sexual function and fertility with a premating exposure duration of two weeks for the parental P0 animals. The other sources (ii) and (iii) do not have any premating exposure.

Neither of the sources of information (i), (ii) or (iii) investigates the sexual function and fertility in the P0 generation with sufficient premating exposure duration to ensure the coverage of full spermatogenesis and folliculogenesis before mating.

In the absence of reliable information on the sexual function and fertility after exposure to the Substance over a pre-mating period of 10 weeks, no conclusion can be drawn on sexual function and fertility as required by the information requirement.

2. Statistical power of the information (number of animals) from the relevant sources of information must be on the similar range than that foreseen to be investigated in an OECD TG 443 with the study design specified in this request.

   The number of females tested in information sources (i), (ii) and (iii) is 10, 15 and 15, respectively, instead of 20 as indicated in OECD TG 443. The number of breeding males is 10 for (i) and 15 for (ii), while breeding males were not treated in (iii) and their number is not specified.

   The studies (i), (ii) and (iii) have not investigated the dangerous properties at the similar range of the statistical power as required in the OECD TG 443 as explained above. Therefore, the results are not reliable.

*2.Toxicity to the offspring*

Toxicity to offspring must cover information on deaths before, during or after birth, growth, external malformations, clinical signs, sexual maturity, oestrous cyclicity, organ weights and histopathology of reproductive organs and tissues in adulthood and other potential aspects of toxicity to offspring.

The sources of information (i) and (iii) provide relevant information on toxicity to the offpsring. The source of infomration (ii) does not investigate the offspring. The source of information (i) provides some information on toxicity to the offpsring up to post-natal day 4. The other source (iii) informs on *in utero* development of offspring.

However, the information provided on toxicity to offspring is limited and does not cover all relevant and essential aspects as defined above. None of the sources of information (i) or (iii) informs on toxicity to the offspring up to adulthood, as investigated in the OECD TG 443. Therefore, no conclusion can be drawn on toxicity to the offspring as required by the information requirement.

*3.Systemic toxicity*

Systemic toxicity must include information on clinical signs, survival, body weights, food consumption, haematology (full-scale), clinical chemistry (full-scale), organ weights and histopathology of non-reproductive organs and tissues (full-scale) and other potential aspects of systemic toxicity in the parental P and F1 generation up to adulthood.

[3] ECHA Guidance R.7a, Section R.7.6

The sources of information (i), (ii) and (iii) provide relevant information on systemic toxicity. The source of information (i) informs on systemic toxicity, especially haematology, clinical chemistry and organ weight and histopathology of non-reproductive organs from 10 parental animals/sex/group. The source of information (ii) informs on systemic toxicity in P0 adults to a level similar to OECD TG 408. The source of information (iii) includes only very limited investigations in dams.

However, the information provided on systemic toxicity is limited and does not cover all relevant and essential aspects as defined above. In particular, there is no information on systemic toxicity from F1 generation, such as clinical signs, body weights, haematology, clinical chemistry, organs weights and histopathology of non-reproductive organs in adulthood. Therefore, the information does not cover the required aspects on systemic toxicity and no conclusions on the systemic toxicity and its relationship with reproductive toxicity can be made.

Taken together, the relevant sources of information as indicated above provide information on:

- sexual function and fertility on parental P0 generation, but its reliability is significantly affected by an insufficient premating exposure;
- toxicity to offspring, but not covering relevant life stages of the F1 generation (post-natal period up to adulthood);
- systemic toxicity, but not covering relevant life stages of the F1 generation (post-natal period up to adulthood).

Therefore, a significant amount of essential information is limited or totally lacking in order to conclude on sexual function and fertility, toxicity to offspring and systemic toxicity.

Based on the assessment above, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous property foreseen to be investigated in an OECD TG 443 study as specified in REACH. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In your comments to the initial draft decision, you indicated a tonnage band decrease to Annex IX and that based on available information this requested study is not warranted for Annex IX registration. On 3 March 2021, ECHA provided you a communication outlining that a change in your tonnage band will not have an impact on the decision-making process of this draft decision. ECHA's evaluation of your registration dossier is based on the specific tonnage band at which your substance was registered at the time, the draft decision was submitted to you i.e. Annex X. This information was also stated in the notification letter to your draft decision. This endpoint is a standard information requirement in Annex X to the REACH Regulation. As stated above your adaptation is rejected and the information requirement is not fulfilled.

In your additional comment submitted 17 March 2021 you indicate that this study is not warranted for an Annex IX registration, and you do not find that it could be triggered at Annex IX as there is a screening reprotoxicity test according to OECD TG 422 guideline performed up to limit dose where no effects were seen. However, as explained above the standard information requirements of Annex X still apply to your registration.

On this basis, the information in your comments is not sufficient for ECHA to make an assessment. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according

to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation).

Specifications for the study design

*Premating exposure duration and dose-level setting*

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required to obtain results adequate for classification and labelling and /or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration.

Therefore, the requested premating exposure duration is at least ten weeks.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

You have to provide a justification with your study results that demonstrates that the dose level selection meets the conditions described above.

*Species and route selection*

The study must be performed in rats with oral[4] administration.

*Cohorts 1A and 1B*

Cohorts 1A and 1B belong to the basic study design and must be included.

*Further expansion of the study design*

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and/or Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during the conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance[5].

[4] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[5] ECHA Guidance R.7a, Section R.7.6.

## Appendix C: Requirements to fulfil when conducting and reporting new tests for REACH purposes

### A. Test methods, GLP requirements and reporting

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

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

3. 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 on How to report robust study summaries[6].

### B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - 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.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[7].

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

**Appendix D: Procedure**

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 08 April 2020.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests but amended the deadline.

> In your comments on the draft decision, you requested an extension to one of your deadlines, to provide information from 12 to 18 months from the date of adoption of the decision.
>
> You justify the extension by stating "…the availability of slots is currently low. This is one example that suggests that, at the moment of reception of the final decision on this Compliance Check, it may be challenging to find a laboratory capable of committing to a 12-month timeframe. For this reason, we would kindly request a period of 18 months to conduct the OECD 210 study."
>
> On this basis, ECHA has modified the deadline to provide the information. Therefore, the deadline is amended to 18 months for this specific study request.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

**Appendix E: List of references - ECHA Guidance[8] and other supporting documents**

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 where relevant.

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 where relevant.

Read-across assessment framework (RAAF, March 2017)[9]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)

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.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[10]

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

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

**Appendix F: Addressees of this decision and the corresponding information requirements applicable to them**

You must provide the information requested in this decision for all REACH Annexes applicable to you.

| Registrant Name | Registration number | Highest REACH Annex applicable to you |
|---|---|---|
| [redacted] | [redacted] | [redacted] |

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.