Case study: Impacts of REACH authorisation of trichloroethylene

State of play in January 2022

Disclaimer

Version	Changes	
1.01	Added information about the substitute of TCE as vulcanisation accelerating agents in Section	20 March 2022

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Abbreviations

BPA	Bisphenol A
BPS	Bisphenol S
Cap	caprylic acid methylester
ECHA	European Chemicals Agency
EU	European Union
FRAM	Centre for Future Chemical Risk Assessment and Management Strategies, University of Gothenburg
HFC	hydrofluorocarbon
PER	perchloroethylene
RAC	Committee for Risk Assessment
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals
R&D	research and development
TCE	trichloroethylene
SEAC	Committee for Socio-Economic Analysis
SVHC	substance of very high concern

Summary

The European Commission added trichloroethylene (TCE) to the REACH Authorisation List (Annex XIV to REACH) in 2013 for all its uses because of its carcinogenic effects. It causes serious eye and skin irritation, and is suspected of causing genetic defects.

REACH registration data shows that the quantities of TCE available on the EU market were about 50 000 tonnes[1] in 2010. Since 2016, users were required to have an authorisation for its continued use. This report takes a closer look at the applications for authorisation to estimate the impacts that the REACH authorisation requirement has had on uses of TCE in the European Union (EU).

As of January 2022, authorisations for 18 uses had been granted by the European Commission to 11 companies. 15 of these authorisations are still valid at the time of writing. ECHA has not received any review reports (that is, applications for renewed authorisation) after 2020 for the use of TCE in industrial metal parts cleaning. The same was also the case for uses in rubber coated conveyor belts in underground hard coal mining, the synthesis of vulcanisation accelerating agents for fluoroelastomers and the extraction solvent for bitumen in asphalt analysis. These uses and the corresponding tonnages have either already ceased or will cease soon, once the authorisation expires in 2023.

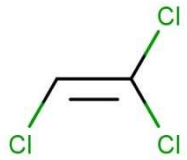
Following the initial authorisations, ECHA has received five review reports applying to continue the use of TCE. The aggregated volume in these uses is around 300 tonnes per year. In addition, the authorisation holders have the Commission's authorisation to use about 800 tonnes of TCE per year for uses that are currently authorised. As there are no other authorised uses (apart from packaging and formulation) in the EU in 2022, it can be concluded that over 95 % of uses of TCE within the scope of authorisation have been phased out in the EU since the substance was added to the Candidate List in 2010. While there may be other reasons for this significant decline, it seems that the authorisation requirement has been its main driver.

As the use of TCE has declined in the EU, alternatives have been used. While ECHA does not have a full picture of all alternatives, it is clear from a study made by the University of Gothenburg (FRAM 2021) that the most common substitute for TCE used in industrial metals part cleaning has been perchloroethylene (PER). PER is toxic to aquatic life with long-lasting effects and is also suspected of causing cancer. For vulcanisation accelerating agents the authorisation holder has found acetonitrile as technically and economically feasible substitute to TCE.

In conclusion, the authorisation requirement of TCE has reduced the volumes used and, as such, the risks related to its use. However, if the risks of the alternatives are not addressed, the overall risk reduction may diminish as risks related to the use of alternatives may increase through substitution. Therefore, it is recommended to address the risks of structurally related substances simultaneously in groups.

[1] These uses are subject to authorisation. Intermediate use is not reported in this volume.

1. Introduction



TCE (EC 201-167-4, CAS 79-01-6) is registered under the REACH Regulation and is manufactured in or imported to the European Economic Area in the tonnage band of 10 000-100 000 tonnes per year.[2]

Under the CLP Regulation, TCE has a harmonised classification and labelling as a substance that may cause cancer (Carc. 1B), causes serious eye irritation (Eye irrit. 2), is suspected of causing genetic defects (Muta. 2), is harmful to aquatic life with long-lasting effects (Aquatic Chronic 3), causes skin irritation (Skin Irrit. 2) and may cause drowsiness or dizziness[3].

France identified TCE as a substance of very high concern (SVHC) and ECHA included it in the Candidate List for authorisation as a carcinogenic substance on 18 June 2010.[4]

Based on ECHA's recommendation of 20 December 2011[5], the European Commission added TCE to the REACH Authorisation List (Annex XIV to REACH) on 17 April 2013 (entry 15)[6]. Based on this, anyone intending to use TCE in the EU needed to apply for an authorisation by 21 October 2014. Without an authorisation application submitted, companies had to cease their use of TCE by the sunset date of 21 April 2016[7].

As a result of this the status of TCE in January 2022 was as follows:

- ECHA has received 11 applications for authorisation for 18 uses;
- ECHA has received five review reports for five uses;
- Three granted authorisations have expired; and
- For two granted authorisations, ECHA received no review report.

The aim of this study is to give a preliminary analysis on the impact of the Commission decision to require authorisation of TCE. Specifically, this study aims to identify to what extent substitution of TCE has taken place and the risks been reduced.

In order to achieve this aim, the following will assess all of the available data including:

- REACH registration data on TCE uses and tonnages,
- Data submitted via REACH applications for authorisations and review reports and
- the study "Substitution of trichloroethylene in metal parts cleaning in the European Union" performed by the University of Gothenburg.

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[2] https://echa.europa.eu/substance-information/-/substanceinfo/100.001.062 The tonnage band includes intermediate uses.

[3] https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/124309

[4] https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e180e4a415

[5] https://echa.europa.eu/documents/10162/13640/3rd_a_xiv_recommendation_20dec2011_en.pdf/22d19030-4756-4c95-b120-7c582e1335c6

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0348&qid=1616436867672

[7] https://echa.europa.eu/authorisation-list/-/dislist/details/0b0236e1807e1a4f Intermediate uses do not require an authorisation

The outcome of the study also feed into ECHA's efforts under REACH Article 69(2) regarding whether risks associated with uses of TCE in articles (including those imported) are adequately controlled or whether a REACH restriction is required.

2. Registered uses of trichloroethylene

TCE is a non-flammable, colourless liquid with a sweet odour and a sweet burning taste. It is used mainly as a solvent to remove grease from metal parts, but it has also been used as an ingredient in adhesives, paint removers, typewriter correction fluids and spot removers etc[8] in the past.

TCE has also been used in the manufacture of a range of fluorocarbon refrigerants such as 1,1,1,2-tetrafluoroethane, more commonly known as HFC-134a. TCE was also used in industrial refrigeration applications due to its high heat transfer capabilities and its low temperature specification. Many industrial refrigeration applications used TCE up to the 1990s in applications such as car testing facilities. According to the European Environment Agency's report, HFC-134a is still being manufactured in the EU[9].

The overall volume of TCE used in the EU has been declining significantly during the last decades. Since the introduction of REACH in 2007, TCE was registered in the 10 000-100 000 tonnes per year tonnage band. According to REACH Registration data, in 2010 some 53 000 tonnes of TCE was placed on the market in the EU. The demand for TCE for example as a degreaser began to decline already in the 1950s in favour of less toxic alternatives.

According to ECHA's REACH registration data[10], the largest manufacturers of TCE in 2010 were Safechem[11] (formerly Dow and Blue Cube), Banner Chemicals Benelux and Chimcomplex.

Figure 1 provides estimates of how much TCE has been available in the EU over the past decade from all registrants. Some decline in volume seems to have taken place after the addition of TCE into the REACH Authorisation List (Annex XIV) in 2013 as industry anticipated this regulatory move. There is a substantial drop in volume right after the sunset date (the date from which non-authorised uses were no longer permitted) in 2016.

It is noteworthy that the amounts registered under REACH after 2016 have been well below the amounts applied for in applications for authorisation. Approximately 40 000 tonnes of TCE were applied to be used per year by the latest application date in 2014. The European Commission authorised these uses under REACH.

Registered amounts have continued to decline further since 2016 to around 12 000 tonnes in 2019. As ECHA has received five review reports for future use, it is estimated that registered volumes have dropped further since 2019 and have continued their decline since.

[8] https://pubchem.ncbi.nlm.nih.gov/compound/Trichloroethylene

[9] https://www.eea.europa.eu//publicat`ions/fluorinated-greenhouse-gases-2020 (table A5.17)

[10] https://echa.europa.eu/brief-profile/-/briefprofile/100.001.062

[11] According to the legal entity change in early 2022 Safechem Europe GmbH is now the holder of the authorisation of Blue Cube Assets GmbH & Co KG.

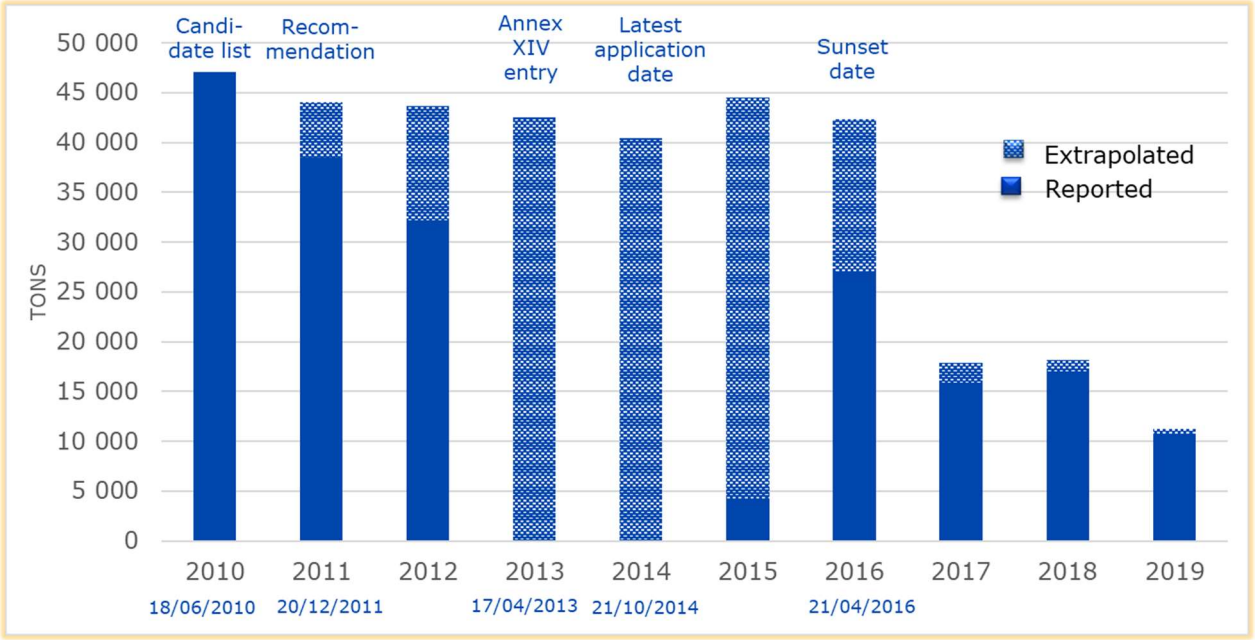

Figure 1 Estimated TCE volumes imported and manufactured in the EU, 2010-2019

Source: REACH registration data of full dossiers (i.e. intermediate registrations are excluded), with linear interpolation between those years where registrants did not report the tons placed on the EU market.

3. Uses of trichloroethylene subject to REACH authorisations

By the latest application date of TCE ECHA received 11 applications for authorisation for 18 uses. At the time of writing, the authorisation had already expired in three authorisations. In addition, ECHA had received review reports applying for the continuation of five uses. ECHA's scientific Committees of Risk Assessment (RAC) and Socio-economic Analysis (SEAC) have adopted an opinion on three of them while the opinion concerning the others are currently under development.

In ECHA's recent report on the socio-economic impacts of REACH authorisations (ECHA 2021a), TCE is shown to have been applied for 11 uses performed by downstream users who have applied for their own uses and seven uses performed by the downstream users of the applicants. Uses are described as

Formulation: 2 uses

Packaging: 1 use

Solvent: 15 uses

Aggregated use volume of these authorisations were about 40 000 tonnes per year at the time when applications were made in 2014. These uses covered largely the total amounts of TCE produced or imported to the EU.

Table 1 shows the names of the applicants, the uses and tonnes applied for and the regulatory status.

Table 1: Regulatory status of applications of trichroloroethylene as of January 2022

Name of the applicant	Use applied for	Tonnes or tonnage ranges/year*)	Status	Review report due	End of review period
Microporous	Solvent	10-100	Review report received	21/09/2021	21/03/2023
Roquette	Solvent	3 (8 in review report)	Pending Commission decision on review	21/10/2026	21/04/2028
Domo	Solvent	245	Review report received	21/10/2021	21/04/2023
Spolana	Solvent	150 (200 in review report)	Commission decided to extend authorisation	21/10/2018	(21/04/2020) 21/04/2032
Safechem (Blue Cube)	Solvent	10-100 (100-200 in review report)	Pending Commission decision on review	21/10/2021	21/04/2023
Vlisco	Solvent	4 (uses combined)	On-going	21/10/2026	21/04/2028
Parker Hannifin	Solvent	20	On-going	21/10/2026	21/04/2028
Grupa Azoty	Solvent	100-500	On-going	21/10/2026	21/04/2028
Safechem (Blue Cube)	Packaging and Formulation	10 000-100 000	On-going	21/10/2026	21/04/2028
Geiss	Packaging and Formulation	100-1000	On-going	21/10/2026	21/04/2028
Safechem (Blue Cube)	Solvent	100-1000	No review report received	21/10/2021	21/04/2023
A.L.P.A. & Caffaro industrie	Solvent	40	No review report received	21/10/2021	21/04/2023
Safechem (Blue Cube)	Solvent	1000-2000	Expired	21/04/2019	21/10/2020
Chimcomplex	Solvent	808	Expired	21/08/2017	21/02/2019
RAG	Solvent	1.4	Expired	21/10/2018	21/04/2020
TOTAL		**40 926***)			

*) Includes tonnages or tonnage ranges as indicated in the original applications.
Source: Applications for authorisation and review reports received by ECHA.

The average review period recommended by ECHA's committees for authorised uses of TCE was 8.8 years. In 42% of the authorised uses of TCE, ECHA's scientific committees required conditions such as monitoring arrangements or additional risk management measures. In 89% recommendations for the review report were made.

The benefits of continued use of TCE were estimated to be at least €79 million per year while the associated monetised risks were estimated to cost €2 million per year. Therefore, the total net benefit of authorising the uses of TCE was estimated to add up to €77 million per year (or the benefit/risk ratio was 40). In one application, (Blue Cube/metals parts cleaning) the benefits of €2.4m were just above the monetised risks of €2.2m.

Status of received review reports

By January 2022, ECHA had received five review reports from authorisation holders wishing to continue using TCE after the expiry of their initial authorisation. These were:

1. Microporous GmbH submitted a review report to use TCE as extraction solvent in the manufacture of polyethylene separators for lead-acid batteries.

   Annual tonnage in the review report is 10-30 tonnes per year. The requested review period is for 12 years from the end of the initially granted review period, i.e. until April 2035.

   At the time of writing this application is under opinion development in ECHA.

2. Roquette Frères submitted a review report to use TCE as a processing aid in the biotransformation of starch to obtain betacyclodextrin. Review period requested for 12 years.

   The authorisation holder decided to submit a review report well before the end of the granted authorisation because they intend to increase the use of TCE from 3 tonnes per year to 8 tonnes per year.

   The monetised net benefit to society from the continued use of TCE is estimated by the applicant to be higher than in their original application whereas according to the applicant the value of negative human health impacts associated with the continued use of TCE would be lower than in their original application.

   At the time of writing this review report is pending the decision of the European Commission.

3. Domo Caproleuna GmbH submitted a review report for TCE in industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil. Estimated annual tonnage used in the review report is 30 - 100 tonnes per year. Review period is requested for 12 years.

   At the time of writing this review report is under opinion development in ECHA.

4. Spolana a.s. submitted a review report to use TCE as an extraction solvent in the industrial manufacture of caprolactam from cyclohexanone. Caprolactam is used as a precursor in the manufacture of polymers. Review period requested for 12 years.

   The monetised net benefit to society from the continued use of TCE were now estimated by the authorisation holder at €53 million over 12 years (present value, 2017 prices). The present value of negative human health impacts associated with the continued use of trichloroethylene were now estimated at €1 093 over 12 years. The applicant

concluded that the benefit risk ratio of the continued use of TCE would be 48 500.

According to the applicant approximately 100 tonnes of TCE per year is used to replace solvent loss from the system and consumption is gradually declining. The annual tonnage in the initial application was 150 tonnes, and thus a reduction of 50 tonnes per year i.e. a third is expected.

On 4 March 2021, the European Commission decided to extend the authorisation until 21 April 2032.

5. Safechem (which took over the authorisation from Blue Cube Germany Assets GmbH & Co. KG due to legal entity change) submitted a review report on the industrial use of TCE as process chemical (enclosed systems) in Alcantara material production. This use had been authorised by the European Commission on 10 August 2018 for seven years. The expiry date was set to 21 April 2023 and the authorisation would have ceased to be valid if a review report wouldn't have been submitted by 21 October 2021. The authorisation decision was based on the assessment concluding that the socio-economic benefits of this use outweigh the costs of the risk to human health arising from it and there were no suitable alternative substances or technologies available in terms of their technical and economic feasibility.

   A review report has been received with estimated annual tonnage used in range of 100 – 200 tonnes. New review period is requested until end 2030. According to the authorisation holder the socio-economic benefits would continue to be significantly higher than the costs of health impacts of continued use and according to the substitution plan no alternative substances or technologies will be available before 2030.

   At the time of writing this review report is pending the decision of the European Commission.

Current uses of trichloroethylene

To understand better what the actual use of TCE is in the EU, an extract of Table 1 is presented in Table 2. All expired uses have been removed, including two granted authorisations where ECHA has not received review report. Furthermore, the authorisations that concern only "packaging" and "formulation" have been removed, too. An authorisation for "packaging" means that the authorisation holder can, for instance, fill TCE or a mixture containing TCE, from a big container to smaller ones. In "formulation", the authorisation holder produces mixtures (with no chemical reaction taking place during the process) and sells them further down the supply chain. Thus, if the authorisation concerns only packaging or formulation, the authorisation holder sells TCE to other companies, who actually use the substance for making products (e.g. articles). This means that it is not enough for an authorisation holder to have the right to "package" or "formulate" TCE, there also needs to be an authorisation to use TCE for something, e.g. as an extraction solvent for "for the purification of caprolactam from caprolactam oil" or "in the manufacture of polyethylene separators for lead-acid batteries". In other words, the authorisation holders in Table 2 are using the substance a solvent and purchase TCE as such or in mixtures from those authorisation holders that have been authorised to "package" or "formulate" TCE.

Due to confidentiality, applicants have not always wanted to disclose the actual tonnage that they would be using but provide ranges. Thus, while it is not possible to disclose the actual volumes per authorisation holder it is possible to report the total amount of TCE that is being used according to the authorised uses and review reports in 2021. Table 2 avoids just double counting of the tonnages actually used in 2021 in the EU. Based on current authorised uses and review reports, the total amount of TCE used in the EU is 1 207 tonnes per year.

Table 2: Regulatory status of trichroloroethylene, excluding expired and expiring authorisations as well as packaging and formulation, as of January 2022

Authorisation holder	Tonnes applied	Status in December 2021	Review report due
Microporous	10-30	Review report received	21/09/2021
Roquette	8	Pending Commission decision on review	21/10/2026
Domo	245	Review report received	21/10/2021
Spolana	200	Commission decided to extend authorisation	21/10/2018
Safechem (Blue Cube)	100-200	Pending Commission decision on review	21/10/2021
Vlisco	4	On-going	21/10/2026
Grupa Azoty	100-500	On-going	21/10/2026
Parker Hannifin	20	On-going	21/10/2026
Total	**1 207**		

Source: Applications for authorisation and review reports received by ECHA.

4. Alternatives to trichloroethylene after the expiry of authorisation

The three authorised uses of TCE that expired are:

1. Chimcomplex's authorisation on industrial use of TCE as "a solvent as a degreasing agent in closed systems" expired on 21 February 2019 (Chimcomplex 2014)

2. Rag Aktienges' authorisation use of TCE-containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber coated conveyor belts in underground hard coal mining expired on 21 April 2020 (RAG 2014a).

3. Safechem's authorisation use of TCE in "industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist" expired on 21 October 2020 (DOW 2014a)

Furthermore, ECHA had not received review reports by the deadline of 21 October 2021 from

4. A.L.P.A S.P.A and Caffaro Industries S.P.A. for the use of TCE "as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers" (A.L.P.A. 2014a)
5. Safechem (Blue Cube) as an "extraction solvent for bitumen in asphalt analysis" (DOW 2014a).

It is therefore likely that these uses will cease by the end of review, 21 April 2023.

Below an attempt is made to describe what alternatives the authorisation holders had planned to use or are using.

Metals parts cleaning

ECHA has not received review reports (applications for renewed authorisation) after 2020 for using TCE in industrial metal parts cleaning. As this was one of the main uses of TCE it is important to see what substances or techniques replaced the TCE in these applications. In other words, the question is to what extent the aim that "substances [of very high concern] are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable" (Article 55 of the REACH Regulation) has been achieved.

It is of interest to learn to what alternatives industry started to use given that in its opinion SEAC (ECHA 2015b) stated that it was "not expected that the risk would be significantly reduced by replacing TCE with PER". It was anticipated in 2015 that industry would substitute TCE mainly with PER, as there was no restriction or authorisation requirement on its use.

PER was the main substitute for TCE in metals parts cleaning (FRAM 2021). PER has several unwanted properties:

- it fulfilled criteria for persistence (P), but not for bioaccumulation (B) and toxicity (T).
- Skin irritant [Skin Irrit. Category 2, H315 (Xi, R38)]
- Eye irritant [Eye Irrit. Category 2, H319 (Xi, R36)]
- Skin sensitizer [Skin. Sens. 1B, H317 (R43)]
- Possible carcinogen [Carc. Category 2, H351 (Carc. Cat. 3, R40).

In the substance evaluation of PER (Latvia, 2014), it was concluded that "ECETOC TRA v2 modelling for 7, highest long term RCR for combined routs (inhalation + dermal) is estimated to be 0.89 not causing concerns with respect to workers' health."

Other alternatives for TCE in metal parts cleaning were

- Hydrocarbon solvents (concern: flammability)
- Dichloromethane (Concern Carc 2).
- n-propyl bromide (Concerns: Repr 1B and flammability)
- Fluorinated solvents (Concern: Greenhouse gas)
- Aqueous cleaning
- Plasma and corona cleaning
- Natural Oil Esters
- Oxygenated hydrocarbon based cleaners

FRAM (2021) investigated what the consequences were of TCE no longer being used in metal parts cleaning. The findings were, amongst others, the following:

i) Inclusion of TCE in the REACH authorisation list incentivised substitution,
ii) the main reason for substituting TCE has been to avoid the cost of having to renew the application for authorisation, and
iii) a large share of the companies substituted TCE to PER due to relatively low substitution cost.

Rubber coated conveyor belts in underground hard coal mining

The applicant concluded that its two main alternatives to using TCE were in the process of being tested in 2014 (RAG 2014b). It made the application to be able to fulfil its legally binding obligations to German authorities and customers up until 2020 by which time its two coal mines were closed (ECHA 2015a).

Extraction solvent for bitumen in asphalt analysis

In its analysis of alternatives, the applicant concluded that toluene was the only technically

feasible alternative to TCE as an extraction solvent for bitumen in asphalt analysis (DOW 2014b). While the applicant stated that all other solvents would R&D activities and adaptation it concluded that PER would most likely be implemented if TCE could not be used. This was because existing machinery at asphalt laboratories could run with PER, a drop-in alternative to TCE. The applicant identified a non-hazardous alternative -- caprylic acid methylester (Cap) -- was the preferred alternative solvent among asphalt manufacturers, subject to additional R&D. TCE is still used for Asphalt Analysis as testing at certain standardized labs require to apply a DIN Standard, which requests TCE. This DIN standard has not yet been revised. If testing according to this standard is not an absolute requirement perchloroethylene is considered as the most likely substitute.

Synthesis of vulcanization accelerating agents for fluoroelastomers

The applicants had identified over 30 alternatives to TCE[12] in the analysis of alternatives of the synthesis of vulcanization accelerating agents for fluoroelastomers (A.L.P.A 2014b). These alternatives were non-flammable or flammable substances with different boiling and flash points. The applicant had not verified the technical and economic feasibility of the alternatives but had pointed out that some alternatives would not reduce risks (e.g. PER, 1,2 dichloroethate and methylchloroform - the last one due to ozone depleting properties).

On 16 March 2022, A.L.P.A. (2022) informed ECHA that it intends to use acetonitrile (EC 200-835-2, CAS 75-05-8) instead of trichloroethylene (TCE) as a solvent for the synthesis of accelerating vulcanisation agents.

Acetonitrile is considered to be a better solution than TCE in terms of health and environmental aspects. It does not require new plant configuration or different safety systems compared to plants using TCE.

According to A.L.P.A. (2014b), acetonitrile has many advantages compared to other solvents:

i) Good solvent properties for both the PN1 synthesis (intermediate 1) and benzylation (intermediate 2) phases. With similar chemical properties to TCE, acetonitrile shows an optimal compromise for the process as it is sufficiently both aprotic and not very polar solvent.

ii) Reactions using acetonitrile as a solvent have the same overall production yield as reactions using TCE as a solvent. During the research, other solvents showed that they could only be optimal for one of the two syntheses (intermediates 1 or 2). Therefore, removal of the first would have been required for a passage to the second reaction.

iii) As with the reaction using TCE as a solvent, it is possible to use the same solvent during the production of both intermediates.

iv) Chemical compatibility with the materials present in the plant.

v) TCE (87.2 °C) and acetonitrile (82 °C) have similar boiling points, so in terms of temperature and pressure, the same operating conditions are maintained.

[12] These were 1,1 and 1,2 dichloroethane; 1,2-1,4 dichlorobenzene; 1,1,1 and 1,1,2 trichloroethane; 1,4 dioxane; 2,2,4 trimethylpentane; cyclohexane; cyclopentane; cyclo-octane; dichloromethane; dichloropropane; dichlorobutane; methylcyclohexane; methylcyclopentane; monochlorobenzene; N-octane; N-bromopropane; N-heptate; N-hexane; percholoroethylene; toluene; trichloromethane; vertrel sdg; xylene and zeorora.

vi) The solvent is recoverable and reusable for other syntheses, minimising its consumption and waste production.

vii) The expected date for changing the solvent is confirmed to be no later than March 2023.

5. Conclusions

In 2010, when TCE was added to the Candidate List, its registered use was about 50 000 tonnes in the EU. After TCE was included in the REACH Authorisation List in 2013, the uses applied for were about 40 000 tonnes. Based on REACH registration data, it can be concluded that after the sunset date in 2016, the use more than halved to under 20 000 tonnes in 2017. The updated registered use was around 12 000 tonnes in 2019. Based on the currently valid authorisations and submitted review reports, the estimated current use of TCE is about 1 200 tonnes – a reduction of more than 95 % from 2010.

In industrial metal parts cleaning, the aim under REACH authorisation to progressively substitute substances of very high concern has been achieved as ECHA has not received any review reports after 2020 on such uses of TCE. REACH authorisation has been identified as one of the main drivers for companies to substitute TCE in their production. Depending on the uses, there have been several alternatives to TCE. In some cases, safer alternatives have been introduced (FRAM 2021) while, for example, switching to other degreasers – such as perchloroethylene – may have introduced other risks to human health and the environment.

To ECHA's knowledge, EU companies have not moved their business to third countries or ceased their business due to REACH authorisation requirements for TCE. In one case, the authorised use moved out of the EU due to the UK's withdrawal from the EU.

Article 69(2) of REACH requires ECHA to consider if the use of TCE in articles is adequately controlled. If not, ECHA has to prepare a restriction dossier. Currently, ECHA is not planning to propose a restriction on TCE in articles. It will monitor the presence of TCE in articles through the SCIP database[13] and substance in article notifications.

The authorisation requirement of TCE, has reduced the risks related to it. A similar conclusion was also made in ECHA (2021b) more generally. If the risks of the alternatives are not addressed, the overall risk reduction of substances subject to authorisation may be diminished. This is because the risks related to the use of alternatives may increase due to substitution.

In this sense, an authorisation requirement shares a similar feature with restrictions, which also addresses only those risks that are in its scope. Therefore, it is helpful to approach the risks of structurally-related substances simultaneously in groups.

[13] Substances of concern in articles as such or in complex objects.

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