Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Trichloroethylene

Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist

ECHA/RAC/SEAC: AFA-O-0000006101-90-02/D

Consolidated version

Date: 11 September 2015

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Consolidated version of the

Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to an application for authorisation for:

Chemical name(s):	**Trichloroethylene**
EC No.:	**201-167-4**
CAS No.:	**79-01-6**

for the following use:

Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist

Intrinsic property referred to in Annex XIV:

Article 57 (a) of the REACH Regulation.

Applicant:

DOW DEUTSCHLAND ANLAGENGESELLSCHAFT mbH

Reference number:

11-2120060042-74-0000

Rapporteur, appointed by the RAC: Urs SCHLÜTER
Co-rapporteur, appointed by the RAC: Elodie PASQUIER

Rapporteur, appointed by the SEAC: Stavros GEORGIOU
Co-rapporteur, appointed by the SEAC: Elina Velinova STOYANOVA-LAZAROVA

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 18 August 2014 DOW DEUTSCHLAND ANLAGENGESELLSCHAFT mbH submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **28 October 2014** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **12 November 2014**. Interested parties were invited to submit comments and contributions by **7 January 2015**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

The draft opinions of RAC and SEAC take into account the responses of the applicant to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **23 June 2015**.

The applicant informed on **30 July 2015** that it wished to comment the draft opinions of RAC and SEAC according to Article 64(5) and sent his written argumentation to the Agency on **6 August 2015**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **5 June 2015**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of RAC was adopted by consensus on **11 September 2015**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **13 March 2015**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of SEAC was adopted by consensus on **11 September 2015**.

THE OPINION OF RAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC has formulated its opinion on the risks arising from the use applied for and the appropriateness and effectiveness of the described risk management measures, and on the assessment of the risks related to the alternatives as documented in the application and on information submitted by interested third parties as well as other available information.

RAC confirmed that it is not possible to determine a DNEL for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that the operational conditions and risk management measures in the application appear not to limit the risk.

THE OPINION OF SEAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC has formulated its opinion on the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application and on information submitted by interested third parties as well as other available information.

SEAC took note of RAC's confirmation that it is not possible to determine a DNEL for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC took note of RAC's confirmation that the risk management measures and operational conditions as described in the application are not appropriate and effective in limiting the risk to workers from the use of the substance.

SEAC confirmed that there appear to be no suitable alternatives in terms of their technical and economic feasibility for the applicant.

SEAC considered that the applicant's assessment of (a) the potential socioeconomic benefits of the use, (b) the potential adverse effects to human health or the environment of use and (c) the assessment used to compare the two is based on acceptable socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health or the environment, whilst taking account of any uncertainties in the assessment, provided that the suggested conditions and monitoring arrangements are adhered to.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Conditions

The following conditions are recommended in case the authorisation is granted:

- Use of TCE for cleaning only where specific requirements (system of use-parameters) exist;
- Prior to the first supply under the authorisation after the sunset date, all downstream users shall provide their supplier with a written declaration that they carried out an analysis of alternatives and that no suitable alternatives exist for them with regard to their authorised use. The analysis of alternatives and the written declaration shall be renewed 3 years and 6 years after the sunset date. The analysis of alternatives shall be documented;
- Within 30 months and 66 months after the sunset date, the Applicant shall ensure that all downstream users it supplies under the authorisation for this use are provided with an obligatory training on alternative cleaning solutions and on the methodology for analysis of alternatives;
- After the sunset date, TCE is used exclusively in an ECSA Type IV or V machines;
- The process must be performed under vacuum, if possible; and
- Training for downstream users as specified by the applicant in the CSR is recommended by RAC.

Monitoring arrangements

The following monitoring arrangements are recommended in case the authorisation is granted:

The applicant and/or their downstream users must implement regular campaigns of occupational exposure measurements (sampling at least annually) relating to the use of TCE described in this application for the workplaces covered by this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and comprise personal inhalation exposure sampling, be representative of the range of tasks undertaken where TCE exposure is possible and of the total number of workers that are potentially exposed (i.e., the campaign shall include process, maintenance, and other types of workers involved, geographical distribution). Biomonitoring, i.e., measurement of the TCE metabolite TCA in urine, might also be of relevance. The results of the monitoring must be included in case an authorisation review report is submitted. Information needs to be provided about the relevant exposure determinants in the workplaces, such as the ECSA Type of degreaser used, size of the machine, number of machines per room, relevant process parameters, and cleaned part types.

In addition, the information gathered in the monitoring campaigns must be used for the workplaces covered by this authorisation to review and improve the risk management measures and operational conditions, to further reduce workers' exposure to TCE. The hierarchy of control principles must be followed in the selection of RMMs. The outcomes and conclusions of this review, including those related to the implementation of the additional RMMs, must be documented.

The resulting report – including the documentation of reduced exposure at the concerned workplaces over time – must be included in the event an authorisation review report is submitted.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant, the comments received on the broad information on use and comments received from the applicant on the draft opinion, the duration of the review period for the use is recommended to be **seven (7) years**.

JUSTIFICATIONS

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property/properties:

- ☒ Carcinogenic (Article 57(a))
- ☐ Mutagenic (Article 57(b))
- ☐ Toxic to reproduction (Article 57(c))
- ☐ Persistent, bioaccumulative and toxic (Article 57(d))
- ☐ Very persistent and very bioaccumulative (Article 57(e))
- ☐ Other properties in accordance with Article 57(f) [please specify]:

2. Is the substance a threshold substance?

- ☐ YES
- ☒ NO

Justification:

Trichloroethylene (TCE) has a harmonised classification with Carc. 1B; H350 and Muta. 2; H341 according to CLP. Based on studies which show its genotoxic potential, the Risk Assessment Committee (RAC) has concluded that TCE should be considered as a non-threshold carcinogen with respect to risk characterisation (reference to the studies examined are included in the RAC document RAC/28/2014/07 Rev. 2 Final).

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC has established a reference dose response relationship for kidney cancer following exposure to TCE (RAC 28/2014/07 Rev. 2 Final). Based on epidemiological data (cited in the RAC document) an increased risk of kidney cancer occurring with cytotoxicity was found following relatively high occupational exposure including very high peak exposure. Thus a linear dose-response relationship would overestimate the risk at low exposure levels where no cytotoxicity would occur. Therefore a sub-linear approach with a break point at 6 ppm (33 mg/m^3) was considered by RAC to be the most scientifically justified approach. RAC has not derived a DMEL value for TCE.

In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose-response relationship adopted by RAC.

4. Exposure assessment. To what extent is the exposure from the use described?

The applicant provided detailed descriptions of the activities and processes involved in the use of TCE for parts cleaning by vapour degreasing in closed Systems. Also the description of the individual worker contributing scenarios (WCS) is detailed.

Worker exposure

The applicant developed two reasonable worst case scenarios. The first scenario describes the typical daily 'production'. The second is a typical three-monthly 'equipment cleaning and maintenance' scenario.

In the typical daily 'production' scenario, a worker is executing the following degreaser activities during an 8 hour shift:

- loading (1 hour);
- degreasing (4 hours);
- unloading (1 hour);
- short-term equipment cleaning activities (1 hour); and
- quality control activities (sampling, analysis, disposal, re-stabilisation; 1 hour combined).

Table 1 gives an overview about the most important tasks and the expected exposure values for these tasks in this typical daily 'production' scenario.

Table 1 Exposure estimates for a typical daily 'production' scenario (8 hour TWA shift)

WCS[1]	Descriptive title of process	PROC	Duration (hours)	Inhalation exposure (mg/m³) Measured data	Inhalation Exposure (mg/m³) TRA modelling	Inhalation Exposure (mg/m³) ART modelling	Dermal exposure (mg/kg/day) TRA modelling
3	loading	3	1	9.730	2.737	3.800	0.069
	unloading (conservative estimate[3])	8b	1	12.530	41.059	58.000	0.069
	unloading (typical estimate)					19.000	
4	degreasing	1	4	6.370	0.055	0.720	0.034
5	equipment cleaning and maintenance (conservative estimate)	8a	1	13.690[2]	13.686	28.500	1.371
	equipment cleaning and maintenance (typical estimate)					9.500	
6	sampling	8b	0.25	4.180	13.686	19.000	1.371
	analysis	15	0.25		5.475	5.700	0.034
	disposal	8b	0.25		13.686	19.000	1.371
	stabilisation	8b	0.25		13.686	19.000	1.371
	8 hr TWA shift exposure (conservative estimate)		**8**	**8.201[4]**	**8.667**	**13.607**	**0.335**
	8 hr TWA shift exposure (realistic estimate)					**6.635**	

[1] WCS 1 Storage in SAFE-TAINERs (closed systems) and WCS 2 SAFE-TAINER transfers (closed systems) do not feature in the typical daily 'production' scenario the 8 hour TWA shift

[2] This value is a modelled value. The 90th percentile of measured personal sampling data was 43.39 mg/m^3. When this value is corrected for a respirator with 95% effectiveness, the inhalation exposure is 2.17 mg/m^3. Since this is significantly lower than the modelled value, the applicant used the value from ECETOC TRA modelling.

[3] The applicant chose to use the expressions "conservative estimate" ,"typical estimate" and "realistic estimate". RAC would use for these situations the expressions "reasonable worst case" and "realistic case"

[4] This level of exposure is consistent with a 90th percentile of 10.95 mg/m^3 derived from the personal measurements for operators of closed system degreasers.

In the typical three-monthly 'equipment cleaning and maintenance' scenario, a worker is executing more extensive equipment cleaning and maintenance activities in an 8 hour shift as follows:

- storage activities (1 hour);
- transfer activities (1 hour);
- quality control activities (sampling, analysis, disposal, re-stabilisation; 1 hour combined); and
- cleaning and maintenance activities (5 hours).

These activities amount to an 8 hour shift, but are only carried out once per quarter. The 8 hour TWA shift exposure estimates are presented in Table 2.

Table 2 Estimated 8 hour TWA shift exposures for a typical three monthly 'equipment cleaning and maintenance' scenario

Inhalation Exposure (mg/m³)				Dermal exposure (mg/kg/day)
Measured data	TRA modelling	ART modelling, conservative estimate	ART modelling, realistic estimate	TRA modelling
10.231	**13.437**	**20.250**	**8.375**	**1.162**

The applicant stated to supply the European market through DOW's subsidiary SAFECHEM and through approximately 16 distributors.

Good quality measurement data have been obtained from 9 companies in the UK. These measurements were obtained from a monitoring program conducted in the period December 2013 till June 2014. The companies involved covered a range of industry sectors using closed system degreasers meeting at least the Type III classification according to ECSA (ECSA 2011). In addition, personal exposure data have been obtained from 2 companies in France, producing small metal articles/parts. Both companies are using degreasing machines meeting the ECSA type IV classification.

RAC notes the uncertainties related to the available measured data. Considering

- the likely number of companies that would benefit from authorisation applied for;
- the possible variations of the operational conditions (e.g. the number and types of machines and their simultaneous operation

in the same workshop, the size of the workshop, its ventilation, process parameters like duration, frequency, volume or temperature); and

- their geographical distribution,

the measurements presented, while relatively robust in their own right, may not be representative of exposure levels experienced by workers across the wide spectrum of workplaces. For a deeper assessment more (from more than 11 companies and from more than 2 European countries) data would need to be available.

Following a request by RAC, the applicant indicated the type of machine that was used when monitoring data were collected. Only the following could be concluded from the evaluation of the limited data:

- ECSA Type III machines do not seem to be the most widely used machine anymore in the UK. However, it is not clear if the available data is a representative sample.
- No correlation between the machine type and worker exposure could be identified. This however does not mean that the machine type has no effect on worker exposure and exposure of man via environment. In order to characterise a relationship between the machine type and worker exposure, more data points would be needed and information on other relevant parameters would need to be available, such as
    - process parameters (e.g., temperature);
    - size of the machine, number of machines per room;
    - cleaned part types; and
    - size and setting of the room (e.g., ventilation).
- The data gives a confirmation of the applicant's view that the machine type is only one out of many of the parameters driving occupational exposure.

In Annex I to the Analysis of Alternatives a relationship is suggested between worker exposure and the type of machine: Type III would be associated with near field air concentrations of 24.0-35.5 mg/m^3, 7.6 mg/m^3 with Type IV and 3.3 mg/m^3 with Type V.[1]

In order to show that the available measured data are also relevant for more than the monitored workplaces, the applicant also provided modelling results on a Tier 1 level (ECETOC TRA) and a Tier 2 level (ART) for inhalation exposure.

For dermal exposure assessment only modelling results on a Tier 1 level (ECETOC TRA) were presented.

Input parameters are documented thoroughly and results are presented transparently for these exposure estimates.

The effect of operational conditions (OC) and risk management measures (RMMs) was taken into account in the derivation of some of the exposure estimations. The most relevant OCs and RMMs are:

- The use of closed and automated systems for some of the WCS (storage, transfers, degreasing) and semi-open or open for other WCSs (loading/unloading, cleaning, maintenance, analysis).

[1] The values are based on exposure modelling and average sized machines. Using a factor of 5.46 to convert values from ppm into mg/m³ at 20°C (Grote 2003), an air concentration of 4.4-6.5 ppm corresponds to 24.0-35.5 mg/m^3, 1.4 ppm to 7.6 mg/m^3 and 0.6 ppm to 3.3 mg/m^3.

- The use of ECSA Type III degreaser machines or higher. In this context, it has to be noted that different types of degreasers (Type III, IV and V) are covered by this application and will impact worker exposure as well as exposure of man via environment (due to, e.g., different level of containments, integrated LEV).
- The threshold concentration for opening the door lock of the chamber is <1 g/m^3 in the cleaning chamber.
- The SAFE-TAINER^{TM} system is used for storage and transfer operations.
- Different Personal Protective Equipment is used for the different WCSs:
    - all WCSs require the use of gloves with 90% efficiency,
    - a full face mask is required to have a efficiency of 95% during WCS 5 (equipment cleaning),
    - a half face mask is required to have a 90% efficiency during WCS 6 (sampling, analysis, disposal and stabilisation).
- In some cases chemical resistant clothes (WCS 5) and safety goggles are used (all WCSs, when handling the substance or product or where direct contact with the substance is likely).

In addition to the OCs and RMMs described above, and whose effect has been included in the exposure estimations where relevant, the applicant describes additional RMMs to limit the exposure. The implemented occupational health and safety management system includes supervision and training, also in relation to personal protective equipment and emergency procedures. Implementation of such requirements can be expected to differ according to the individual workplace because of different settings but also because of different occupational hygiene practises.

DOW's subsidiary SAFECHEM offers training courses for downstream users about the correct use of TCE for degreasing activities. The exact influence of such trainings on the level of exposure is difficult to evaluate and only a limited number of the relevant downstream users have received the offered training so far.

Environmental exposure

The application for authorisation only needs to cover risks arising from the intrinsic hazardous properties specified in Annex XIV. In case of trichloroethylene, the risk assessment is only related to human health (renal cancer). The environmental contributing scenario (ECS) describes therefore only exposure of humans via the environment.

Indirect exposure of Man via environment

Release rates into water and soil are based on default ERC releases (ERC 7) for and tonnages of TCE. For air, the release factor was based on the findings of a PhD thesis that have been validated using actual measured data. It is noted that the corresponding release factor (5.97 %) is higher than the default release factor of the ERC (5%) and the use of this data is considered appropriate. Distribution in the environment and concentrations relevant for secondary exposure of humans (oral and inhalation) were calculated using conventional algorithms (EUSES). The local oral exposure was estimated to be 5.45×10^{-4} mg/kg bw/day and the local inhalation exposure 1.51×10^{-4} mg/m^3. The regional oral exposure was estimated to be 2.70×10^{-4} mg/kg bw/day and regional

inhalation exposure 5.92 $x10^{-5}$ mg/m^3.

By design ECSA Type IV and V degreasers are expected to emit less TCE than Type III machines since the former have no exhaust but fully closed air loops. The air emissions according to Annex I to the Analysis of Alternatives are typically 155 g/h with Type III degreasers and 38 g/h with Type IV. Type V uses vacuum technology further reducing emissions and increasing solvent life because of lower operating temperature (no emission estimates available).

Conclusion

RAC concludes that the information provided by the applicant to describe the exposures in general appears to be sufficient for the assessment of the use applied for.

With respect to inhalation exposure of workers, the measured data seems to corroborate the results of modelling (or vice versa). Nevertheless, there are significant uncertainties related to the representativity of the available measured data considering the likely number of companies that would benefit from the authorisation applied for.

For dermal exposure, only Tier 1 exposure models were used for the assessment. It is assumed that the resulting dermal exposure values are conservative.

Regarding the assessment of exposure of man via the environment it is concluded that calculations using conventional algorithms are appropriate.

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

RAC has concluded that TCE should be considered as a non-threshold carcinogen with respect to risk characterisation.

6. If adequate control is not demonstrated, are the operational conditions and risk management measures described in the application appropriate and effective in limiting the risk?

☐ YES

☒ NO

Justification and conclusion on the remaining risk:

The calculation of the remaining human health risk is based on the dose - response relationship published by RAC (RAC 28/2014/07 Rev. 2 Final) and the estimated combined exposure levels. The overall risk is determined for three population groups:

- Risk to workers directly exposed to TCE
- Risk to workers indirectly exposed to TCE

- Risk to the general population due to the exposure via the environment through inhalation and oral intake.

Risk to workers

Kidney cancer in workers due to inhalation and dermal exposure to TCE is considered to be the critical effect for risk assessment of workers.

For inhalation, based on the sub-linear dose response relationship established by RAC, the excess lifetime kidney cancer mortality risk for workers has a breakpoint at 33 mg/m^3 (6 ppm) with an excess kidney cancer risk in EU workers at 4.0 x 10^{-4}. The excess risk at 33 mg/m^3 and above is 1.3 x 10^{-4} per mg TCE/m^3 – 0.0039, and below 33 mg/m^3 the excess risk is 1.2 x 10^{-5} per mg TCE/m^3 (based on 8h exposure 5 days/week during 40 years).

For dermal exposure the breakpoint for the sub-linear dose-response curve is 4.72 mg/kg bw/day with an excess kidney cancer risk in workers at 4.0 x 10^{-4}.

At 4.72 mg/kg bw/day and above the excess risk is 9.09 x 10^{-4} per mg/kg bw/day – 0.0039 and below 4.72 mg/kg bw/day 8.4 x 10^{-5} per mg TCE/kg bw/day (again based on 8h exposure 5 days/week during 40 years).

Directly exposed workers

For inhalation, based on the best use of measured and modelled data, the 8-hour TWA shift exposure for a typical daily 'production' scenario is 8.201 mg/m^3.

A higher shift exposure of 10.231 mg/m^3 is estimated for the 'equipment cleaning and maintenance' scenario although occurring with a significantly reduced frequency of only 4 times a year.

Since the 'equipment cleaning and maintenance' scenario occurs only 4 times per year, the relative contribution of this scenario to workers exposure on a yearly basis is a fraction of daily exposure: 1/60 or 0.017. Considering the very minor influence of the 'equipment cleaning and maintenance' scenario on the total excess risk for workers, for simplicity the excess risk will be calculated on the basis of the 'production' scenario only.

For dermal contact, based on modelled data, the 8-hour TWA shift exposure for a typical daily 'production' scenario is 0.335 mg/kg. A higher shift exposure of 1.162 mg/kg is expected for the three monthly 'equipment cleaning and maintenance' scenario although it occurs with a frequency of 4 times a year.

None of the activities described for this use result in an exposure exceeding the breakpoint of the sublinear dose-response relationship and thus the dose-response curve below the breakpoint has been used.

Table 3 Estimated excess of kidney cancer risk for an 8 hour TWA shift, directly exposed workers, 40y exposure

	8-hour TWA shift exposure	Excess of kidney cancer risk
Inhalation	8.201 mg/m^3	9.84 x 10^{-5}
Dermal	0.335 mg/kg/day	2.81 x 10^{-5}
Combined		**1.26 x 10^{-4}**

Indirectly exposed workers

Indirectly exposed workers are considered to be exposed to the local PEC by inhalation. No dermal exposure is expected as there is no handling of TCE.

The corresponding exposure level does not exceed the breakpoint of the sublinear dose-response relationship and the dose-response curve below the breakpoint has been used for calculation of excess of kidney cancer risk.

Table 4 Estimated excess of kidney cancer risk for an 8 hour TWA shift, indirectly exposed workers, 40y exposure

	8-hour TWA shift exposure	Excess of kidney cancer risk
Inhalation	1.51×10^{-4} mg/m^3	1.81×10^{-9}

Risk to general population exposed via the environment

Kidney cancer following indirect exposure of man via the environment due to inhalation and oral exposure to TCE is considered to be the critical effect for this part of the risk assessment. For inhalation, based on the sub-linear dose response relationship established by RAC, the excess lifetime kidney cancer mortality risk for the general population has a breakpoint at 6.2 mg/m³ with an excess kidney cancer risk in the general population of 4.0×10^{-4}. For inhalation exposure the excess risk at 6.2 mg/m³ and above is 6.9×10^{-4} per mg/m³ – 0.0039, and below 6.2 mg/m³ the excess risk is 6.4×10^{-5} per mg/m³ (based on 70 years of exposure).

For oral exposure the breakpoint for the sub-linear dose-response curve is 0.92 mg/kg bw/day with an excess kidney cancer risk in the general population at $4x10^{-4}$. At 0.92 mg/kg bw/day and above the excess risk is 4.66×10^{-3} per mg/kg bw/day – 0.0039 and below 0.92 mg/kg bw/day 4.32×10^{-4} per mg/kg bw/day (based on 70 years of exposure).

The exposed general population includes people in the direct neighbourhood of the facilities that are exposed by inhalation and oral intake as estimated by the local PEC.

The applicant also includes people living in an area of 200 x 200 km around the facilities that are considered exposed to the regional PEC. This virtually covers the whole EU-28 population of 507 162 571 people.

The regional and local PECs do not exceed the breakpoint of the sublinear dose-response relationship and the dose-response curve below the breakpoint has been used for calculation of excess of kidney cancer risk.

Table 5 Estimated excess of kidney cancer risk for man via environment exposure, 70y exposure

Population	Exposure route	Exposure level	Excess of kidney cancer risk
Direct neighbourhood	oral	5.45×10^{-4} mg/kg/day	2.35×10^{-7}
	inhalation	1.51×10^{-4} mg/m^3	9.66×10^{-9}
	Combined		**2.45×10^{-7}**
Broader vicinity	oral	2.70×10^{-4} mg/kg/day	1.17×10^{-7}
	inhalation	5.92×10^{-5} mg/m^3	3.79×10^{-9}
	Combined		**1.21×10^{-7}**

Conclusion

RAC notes that an excess of cancer risk of 1.26×10^{-4} is observed for workers involved in degreasing activities. Additionally, a relatively high risk is observed for the three-monthly 'equipment cleaning and maintenance' scenario. However this scenario is performed with a significantly reduced frequency of only 4 times a year.

RAC notes that the applicant has included an extensive analysis of the excess risks for the general population both at a local and regional level. This analysis has shown relatively low excess risks for the general population.

Due to the uncertainties related to the representativeness of the worker exposure estimates and the relatively high risk levels for directly exposed workers, RAC considers that the risk management measures and operational conditions as described in the application in general appear not to be appropriate and effective in limiting the risk to workers.

Use of ECSA Type III degreasers, utilizing a lesser degree of containment, is expected to lead to higher exposure of workers and of man via environment compared to ECSA Type IV or V equipment. Therefore, at the latest by the end of their service life, ECSA Type III machines should be replaced with Type IV or preferably Type V machines.

At all use locations, information and training needs be provided (as already required by the ES) to all exposed workers on the safe use of the equipment, in particular its loading and unloading.

7. Justification of the suitability and availability of alternatives

7.1 To what extent is the technical and economic feasibility of alternatives described and compared with the Annex XIV substance?

Description:

The main function of the Annex XIV substance in the context of this application is as a cleaning substance in closed cleaning equipment, generating dry parts of high organic cleanliness without undesired surface modifications such as corrosion, oxidation or staining.

The applicant describes the technical and economic feasibility of nine types of

alternatives to the use of the Annex XIV substance. The alternatives considered by the applicant represent all those alternatives which have been considered in the existing extensive research studies and knowledge databases on potential alternatives for use in industrial parts cleaning. These databases reflect the existing search for alternatives as a result of existing public and legislative pressures. As such they can be considered to reflect the state of the art in proven substitution possibilities.

Although the applicant acknowledges that in principle all liquid organic substances could be seen as potential alternatives, the analysis of alternatives focuses on a limited number of possible alternatives, previously considered in the various research studies and knowledge databases, which have already proven some feasibility as cleaning agents in industrial parts cleaning and have already been subject to previous R&D work on substitution in the area of industrial surface cleaning. The alternatives which are considered are based on either making the function performed by trichloroethylene redundant (i.e., by using a different principle of soil removal than dissolution), or finding an alternative substance that can perform the same function as trichloroethylene (i.e., dissolving organic contaminants at the molecular level).

The alternatives considered by the applicant and taken forward for the assessment of technical and economic feasibility include: aqueous cleaning; hydrocarbon based cleaners with flashpoints above 55°C; oxygenated hydrocarbon based cleaners with flashpoints above 55°C; natural oil esters; cleaning with other halogenated solvents including perchloroethylene, dichloromethane, n-propyl bromide (1-bromopropane); cleaning with fluorinated solvents; and physical and electrical methods of cleaning, including plasma and corona cleaning. The description of technical feasibility of the alternatives identifies the main general advantages, disadvantages and limitations of each compared to trichloroethylene. The descriptions and discussion are quite detailed and appropriately technical to a relevant audience.

In considering the choice of alternatives, the applicant determines that substitution possibilities are case-specific. The range of parts to be cleaned and related process characteristics defines the possible combinations of characteristics that describe any particular surface cleaning use case. Given the wide variety of industrial processes where surface cleaning is used, there are very many separate use cases, for which it is possible to evaluate alternatives. As such, it is not possible to generate a single set of characteristics covering every use case, and for which all alternatives could be assessed against. Hence, in the context of performing a manageable analysis of alternatives, the applicant identifies a number of key requirements/conditions associated with downstream users that can be consolidated and described in terms of combined sets of 19 Use-Parameters. These parameters are defined in Table D 3.1-1 of the Analysis of Alternatives.

According to the combination of Use-Parameters, individual use cases can be described in such a way that it is possible to evaluate the feasibility of possible substitutes and describe the processes that would be covered under the authorisation if granted. For each Use-Parameter there are a number of critical functions defined, and upon which the suitability of alternatives is assessed as compared with trichloroethylene. On this basis, the applicant has established a “Selection Grid” evaluation tool, which lists the Use-Parameters and their critical functions, alongside their identified possible alternatives.

By combining Use-Parameters to reflect specific use cases, it is possible to identify whether common alternatives exist amongst the individual Use-Parameters that define the specific use case. A “Suitability Matrix” can then be constructed, which depicts the sets of 2 Use Parameters that can be combined

from the 19 possible Use Parameters, and for which there exist common alternatives (or not). The “Suitability Matrix” could be seen as a simplified version of the “Selection Grid”. In those use cases in which at least 2 Use-Parameters do not have a common alternative (or for which a Use-Parameter has no alternative at all), the applicant considers the use of trichloroethylene to be essential (that alternatives are currently not suitable). This approach, based on Use-Parameters and associated critical functions, thus allows a practical assessment of alternatives compared to trichloroethylene, as well as allowing the consequential regulatory scope of authorisation to be defined in terms of its validity for any individual downstream user in accordance with the Use-Parameters applicable in their case. The technical and economic feasibility of the various alternatives are considered by the applicant in the light of the Use-Parameters used to define use cases.

For each alternative, except n-propyl bromide (1-bromopropane) and physical and electrical methods of cleaning, the technical feasibility assessment evaluates the alternative in terms of the critical functions of the Use-Parameters discussed earlier. Given the relevant expertise of SEAC, it is not always easily to understand the reasons why the alternatives are not technically feasible for any particular use parameter. For example, the critical functions for the “complex approval process” Use-Parameter are:

- Complex value chains requiring approval along the value chain for any essential changes;
- Industry wide standards, military standards requesting TCE and or excluding alternatives which would be feasible;
- Big number of customers/Big number of products, each with specific customer specs requiring a big number of specs to be changed.”

This particular Use-Parameter is essentially a customer requirement which determines that a particular technical or functional requirement/criterion is necessary. In this respect, it is unclear to SEAC which technical performance criteria related to the customers’ requirements have been assessed and judged not to have been met in the applicant’s assessment of this Use-Parameter. Moreover, some of the parameters are more appropriately considered economic feasibility criteria, e.g., “high throughput is critical”.

For the assessment of economic feasibility, the applicant undertakes a largely qualitative assessment, due to the fact that only general considerations are possible given the large variation between use-cases. In general, the economic feasibility (cost) assessment gives an adequate indication of the likely direction of economic impacts of substitution, though the description and/or derivation of its magnitude are often lacking and all too brief. However, SEAC notes the difficulty in this respect, given the large variation in use-cases.

The applicant only considers those alternatives previously considered in the various research studies and knowledge databases, which have already proven some feasibility as cleaners in industrial parts cleaning. SEAC note that the public consultation did not generate any substantive suggestions for alternatives and no information was obtained from the public consultation that disputed the applicant’s conclusions. Moreover, the applicant gives no indication of any ongoing or planned development and testing of substances and technologies.

Whilst SEAC is content with the descriptions and comparison of alternatives considered by the applicant at a general level, questions nevertheless remain about the scope of alternatives considered, as well as the extent to which alternatives have had their technical infeasibility assessed and justified in the case of all the Use-Parameters.

7.2 Are the alternatives technically and economically feasible?

☐ YES

☒ NO

Justification:

The analysis of alternatives undertaken by the applicant sets out the various known alternatives that have been considered in the existing extensive research studies and knowledge databases on potential alternatives for use in industrial parts cleaning. In accordance with the applicant's assessment approach based on Use-Parameters and critical functions, the applicant reaches the conclusion that although for a majority of use-cases (defined by a set of Use-Parameters) potential alternatives can be used, there are combinations of Use-Parameters for which no alternatives currently exist.

The applicant limited the scope of the applied for use through the condition that specific Use-Parameters need to exist. In other words, if alternatives exist for a specific use case, then the use case is not covered by the applied for use and the downstream user cannot benefit from the authorisation (if granted).

According to the applicant's conclusions on technical feasibility, while some alternatives are not suitable for parameters such as complex surface treatment due to their physico-chemical properties like viscosity, others have a limit in stainless cleaning as boiling points are low, such that condensation of humidity leads to stains. Moreover, the majority of alternatives are not currently suitable for corrosive soils in particular, as stabilisation systems to avoid corrosion have not yet been developed. High boiling alternatives are considered to lead to constraints for temperature sensitive parts as well as for cleaning corrosive soils. The applicant claims that for parts that need specially defined surface properties, e.g., post coating processes, only trichloroethylene universally provides the required properties. Some alternatives are said to need to go through a long lasting approval process, whilst in others the cleaning process needs adaptation to ensure a uniform process. In some industry sectors, there is a complex approval process that goes beyond the cleanliness of the part. Finally, the applicant suggests that a number of other Use-Parameters can limit the substitution possibilities, such that currently there are no alternatives available.

Regarding economic feasibility, the applicant suggests that there is wide variability amongst use-cases, making only general observations possible. In this respect, it is claimed that most alternatives require new equipment, at costs of between €50,000 and €500,000. Moreover, the variability in companies' size, financial situation, etc., means that it is difficult to conclude on economic feasibility. Nevertheless, it is argued that some alternatives have a significantly higher price than trichloroethylene, whilst it can also be very expensive to undertake the necessary R&D to define and approve an alternative.

Given the detailed and highly specialised technical nature of the discussion in relation to the development of the Use-Parameters and their critical functions, as well as the associated assessment of technical feasibility of alternatives, SEAC has no reason to disagree with the general conclusions reached by the applicant. Nevertheless, SEAC does have reservations in offering unequivocal support of the applicant's conclusions in a number of respects. As outlined in the previous section, there are a number of gaps in the analytical approach and transparency with which the applicant has reached their conclusions. In particular, SEAC has some concerns regarding the technical transparency of some aspects of the system of Use-Parameters. Some of the applicant's assessment considerations appear to conflate arguments that are more concerned with the appropriate

length of review period than with the achievement of technical functionality *per se*. Moreover, and importantly, the applicant does not adequately describe across the various use parameters and alternatives the possibilities for substitution looking ahead, particularly in terms of ongoing or planned development and testing of substances and technologies. Instead, a historic case study is showcased as an exemplar of the R&D needs required to identify alternatives. Whilst SEAC has no reason to question the veracity of this individual case study, its general applicability and representativeness across the range of use cases has not been demonstrated and cannot be confirmed. Taken together with the limited scope of alternatives examined by the applicant, which as acknowledged only stretches to those with proven feasibility as cleaners in industrial parts cleaning, SEAC has some reservations regarding the applicant's claims regarding the lack of possibilities for substitution across all of the use cases in scope.

SEAC also takes note of comments submitted in the public consultation on the application, suggesting the use of sodium hydroxide solution as a degreasing agent. In response to this comment, the applicant states that the suitability of this alternative has already been considered within the general category of aqueous cleaners considered in the assessment of alternatives, and shown to be unsuitable for all use-cases. SEAC is thus unable to confirm the general suitability of this alternative as a substitute for trichloroethylene.

The assessment of economic feasibility, whilst not particularly well established in terms of quantitative justification, does provide a broad qualitative justification that there are likely to be economic feasibility issues in general, though this has not been demonstrated universally.

In sum, although SEAC is content with the descriptions and comparison of alternatives considered by the applicant at a general level, questions remain about the applicability of the general conclusions regarding the technical and economic feasibility of alternatives to all use cases potentially in scope of this application. Nevertheless, in the comments to the draft opinion, the applicant proposed changes in its conditions of supply to downstream users (see section 10) that would largely overcome SEAC's reservations regarding the possibilities for substitution across all of the use cases in scope.

7.3 To what extent are the risks of alternatives described and compared with the Annex XIV substance?

Please describe:

The applicant has submitted an analysis of the reduction of risks for 9 possible alternatives including 8 substances or groups of substances and 1 alternative technique.

For each possible alternative an attempt has been made to discuss the hazard and the exposure potential of the alternative in comparison to TCE. For most possible alternative substances, it is based on a comparison of classification and exposure potential for workers and a comparative assessment of bioaccumulation, persistence, global warming potential and ozone depletion potential. RAC notes as a limit to this approach that classification does not reflect the potential uncertainties on hazard that may result from a limited database for some substances. It is noted that the potential for environmental release and for exposure of man via environment has generally not been assessed.

7.4 Would the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk?

☐ YES

☐ NO

☒ NOT APPLICABLE

Justification:

The main conclusions are summarised below for each possible alternative. Some alternatives are considered to represent an overall risk reduction compared to TCE but the risk reduction is considered inexistent, negligible or uncertain for others (e.g. tetrachloroethylene, dichloromethane, n-propyl bromide, fluorinated solvents).

- Aqueous cleaning

Aqueous cleaning involves a wide range of alternative substances that are usually used in combination. The applicant concluded that substitution with aqueous cleaners would lead to a reduction of risks. Some risks specific to these alternatives would need to be managed such as corrosiveness to skin and eyes, potential for alkali induced eczema, potential for exothermic reactions and environmental releases into water. RAC however notes that some of the substances listed as examples (i.e. borax) have a similar level of hazard (CMR 1) as TCE. Although a reduction of risk is likely for most aqueous cleaners, the overall reduction of risk is therefore not possible to assess for such a wide range of possible components.

- Tetrachloroethylene (PER)

With similar exposure potential and environmental profile, some reduction of risks was identified by the applicant for PER is mainly based on the less stringent carcinogenic classification of PER (Carc 2) and similar process parameters. However, although this implies that there are more uncertainties regarding the carcinogenic potential of PER, it does not necessarily mean that the corresponding risk is lower. RAC notes that the scientific committee on occupational exposure limits (SCOEL) identified similarities between the metabolic pathway of TCE and PER and therefore the hazard properties of the two substances are considered to raise a similar concern. The CMR and PBT properties of PER are currently under assessment in the Substance Evaluation process by Latvia. In sum, it is not expected that the risk would be significantly reduced by replacing TCE with PER.

- Hydrocarbon solvents

Hydrocarbons solvents have a lower hazard profile. However, their use introduces risks related to their flammability. Additionally, depending on the particular hydrocarbon solvent, the potential for exposure can vary of a wide range.

- Oxygenated hydrocarbon based cleaners

This category relates mainly to n-butoxypropanol. The risk reduction anticipated by the applicant is related to a lower hazard profile but a higher exposure is possible. Without a detailed assessment it is not possible to decide if these alternatives for TCE will lead to an overall reduction of risk.

- Natural Oil Esters (NOE) solvents

Anticipated risk reduction is related to a lower hazard profile (no harmonised classification). A higher exposure is anticipated. Without a detailed assessment it

is not possible to decide if NOEs as alternatives for TCE will lead to an overall reduction of risk.

- Dichloromethane

Some reduction of risk was identified by the applicant, mainly based on the less stringent carcinogenic classification of dichloromethane (Carc 2). However, although this implies that there are more uncertainties on the carcinogenic potential, it does not necessarily mean that the corresponding risk is lower. Therefore, it is considered that there is no evidence that the risk would be (significantly) reduced by replacing TCE with dichloromethane.

- n-propyl bromide

No reduction of risk is anticipated by the applicant based on a similar hazard level (Repr 1B) and on an additional risk due to flammability.

- Fluorinated solvents

A potential reduction of risk for health is compromised by a global warming potential with the main fluorinated substance investigated listed in the Kyoto protocol and to a lesser extent by additional flammability.

- Plasma and corona cleaning

The chemical risk is considered to be reduced by the use of this alternative technology.

Considering that the applicant claims that no alternative is technically and economically suitable for industrial cleaning where specific requirements exist as defined in the suitability matrix (certain combination of use parameters), the question of reduction of risks is not applicable. Overall, RAC can agree with the applicant's conclusions regarding the risks of alternatives but stressed that the conclusions need to be interpreted with caution, considering the uncertainties resulting from the different level of information available on the (eco)toxicological properties of the alternatives compared with TCE as well as the absence of a full risk assessment for each of the alternatives.

7.5 If alternatives are suitable (i.e. technically, economically feasible and lead to overall reduction of risk), are they available?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

Given the conclusion that in general, the range of alternatives considered are not technically and economically feasible, SEAC agrees that the alternatives cannot at this time be considered generally suitable for the applicant. However, given that there do not appear to be any constraints on the availability of alternatives, SEAC recognises the need for the applicant to continue to examine opportunities for substitution where possible. In the comments to the draft opinion, the applicant proposed changes in its conditions of supply to downstream users that would facilitate substitution of TCE with alternatives (see section 9 and 10).

8. For non-threshold substances, or if adequate control was not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Additional statistical cancer cases estimated by RAC

RAC has reviewed the information provided by the applicant related to the exposure of workers and humans via the environment and the calculation of the cancer risk resulting from exposure to TCE for both groups.

The number of additional statistical cancer cases resulting from presented exposures has been calculated for consideration in the analysis of the human health cost of continued use of TCE. The results of the calculations, including the populations exposed are presented in the Table 6 below.

RAC considers the excess risk estimates for the general population exposed via the environment are overly conservative. In addition, the assumption for the number of exposed people is very conservative. As a consequence, the resulting estimated number of statistical cancer cases is overestimated.

Table 6: Estimated statistical numbers of cancer cases for workers and general population

	Excess kidney cancer risk	Number of exposed people*	Estimated statistical cancer cases
Directly exposed workers, 40y exposure			
Degreasing activity – "typical" daily 'production'	1.26×10^{-4}	10,000 – 100,000	1.26 – 12.6
Indirectly exposed workers, 40y exposure			
Manufacturer site	1.81×10^{-9}	100,000 – 10,000,000	<1
General population exposed via environment, 70y exposure			
Direct neighbourhood – combined	2.45×10^{-7}	1,000,000 – 10,000,000	0.245 – 2.45
Broader vicinity – combined	1.21×10^{-7}	507,162,571 (EU population)	61.37

* The exact number of exposed people is claimed confidential by the applicant. Therefore the numbers are presented as a range.

Assessment of impacts

The assessment of impacts associated with this authorisation application and which has been undertaken by the applicant includes a quantitative monetary assessment of the societal impacts associated with the "non-use" (i.e. assuming

authorisation is not granted) of trichloroethylene.

The perspective of the analysis is such that it can be used to show that there are net losses to society as the necessary corollary that the benefits of continued use exceed the risks of continued use over the analytical timeframe considered in the applicant's analysis. Although the assessment does not provide an overall "net loss" estimate for the *non-use* scenario, the comparison of benefits and costs undertaken makes this, in principle, straightforward. It should also be noted that the analytical timeframe considered in the applicant's analysis is based on a period of 12 years, which is the period of authorisation being sought by the applicant. Although this raises some analytical issues concerning the appropriate inclusion of latent cancer burden estimates (see *benefits* section below), this does not invalidate the overall conclusions derived since any bias introduced will tend to induce conservatism (overestimation) in the economic burden of health impact estimates derived. This will have the effect of reducing the economic impact estimates of "non-use" required as the necessary corollary that the benefits of continued use exceed risks.

The applicant undertakes an analysis of the socioeconomic impact and health impacts of the "non-use" scenario, which is based on estimating the impacts in 10 case studies of firms using trichloroethylene for surface cleaning, and then making use of extrapolation to extend the results to the total number of firms who use trichloroethylene supplied by the applicant for surface cleaning. This approach is used since the analysis of the impacts on each individual firm would be impractical and time consuming.

More specifically, the approach assesses the impacts of 10 case studies from different industry sectors with a view to capturing the variation in impacts across all companies supplied. The case study with the lowest level of socioeconomic impacts and another case study with the highest population exposures amongst the 10 case studies are then used as the respective lower bound and upper bound exemplar of socioeconomic and health impacts in order to extrapolate across all companies supplied by the applicant with trichloroethylene for the purpose of surface cleaning. The use of the respective lower and upper bound exemplar case studies for the extrapolation of socioeconomic and human health impacts is done in order to provide a conservative measure of the socioeconomic impacts (i.e. underestimate) and human health impacts (i.e. overestimate) of "non-use" for comparison.

Whilst SEAC considers that the approach based on extrapolation from a limited number of case studies makes the assessment tractable, it nevertheless raises concerns regarding the extent to which the analytical scope (boundary of analysis) covered by the extrapolation approach reflects and is representative of the impacts of "non-use" in reality. More specifically, it is unclear to what extent the 10 case studies are representative of the impacts in all companies that would fall within scope of the Use-Parameter requirement for authorisation. Given that the sampling approach used to pick the 10 case studies is based on a "random" (sic) selection from most industry sectors covered, it is not clear if this is consistent with the extrapolation approach based on the minimum socioeconomic and maximum health impacts. The approach based on random selection with such a small sample may be inappropriate, particularly in the context of distributions of impacts that may have large variability.

It is thus unclear to what extent the extrapolated impacts derived are thus indeed conservative estimates. Moreover, as will be discussed later, the aggregated socioeconomic impacts are questionable in a number of respects as far as generating a methodologically robust measure of the total net economic cost to society of the non-use scenario for the analytical scope being considered by the applicant (see costs section for details. As a result the exact magnitude of the net

economic costs is considered by SEAC to be somewhat uncertain.

Turning to the analysis of the (economic burden of) human health impacts, this is based on established procedures for the calculation of economic welfare changes as a result of human health risk reductions, albeit with the proviso noted above about the time period regarding latent effects associated with cancer exposures.

Overall, whilst an acceptable economic valuation methodology underpins the assessment of health impacts, the overall methodological approach underpinning the assessment of economic impact cannot be relied upon to provide robust (accurate) estimates of the net economic welfare costs to society from non-use for the scope of use-cases within this application. In this respect, although SEAC considers that the information provided is sufficient to indicate that benefits are likely to exceed risks, there are significant uncertainties relating to the scope of the analytical boundary used in the analysis, as well as the magnitude by which benefits exceed risks.

Benefits of continued use

As described above, the applicant's analysis of the cost of "non-use" (benefits of continued use) is based on extrapolation of the socioeconomic impacts of non-use, which is estimated using the 10 case studies. The approach undertaken by the applicant in the 10 case studies in order to arrive at a quantitative assessment of the socioeconomic impacts suffers a number of general methodological issues in terms of it being used to measure the net economic costs to society of "non-use", as follows:

- The approach is based on aggregating the different types of impacts (economic, social, and wider economic). As such, it is not based on a net economic welfare analysis and hence the total cannot be considered to represent the net economic costs to society[2]. Whilst the social and wider economic impacts might be important in the context of regional economic analyses, their inclusion in a net economic welfare (cost-benefit) analysis is not justified.
- In a number of the case studies, the applicant estimates the economic impacts in terms of the loss of sales revenues. Although such losses provide a measure of the change in gross financial flows, the relevant measure for use in estimating net economic costs to society in this context is producer surplus losses (i.e. profit). As such, although the estimates may be useful from an accounting analysis standpoint, they cannot be used directly within a net economic welfare analysis.
- In those cases where impacts have been monetised, the applicant in estimating the present value of impacts over the analytical timeframe of 12 years has included a factor to account for inflation (through a GDP deflator). However, this means that the associated present values are not given in terms of a constant price level, contrary to acceptable norms in cost-benefit practice.
- In some of the case studies (including the key case study used in the extrapolation), the applicant does not take into account costs which should otherwise be included. Such costs include those associated with the need for one-time investment in new machinery. According to the applicant,

[2] So for example, the social impacts include the loss of jobs, but since employment of labor represents opportunity costs to society, then the loss of jobs represents a negative cost (i.e. a benefit). Moreover, tax revenues, depending on whether they are direct or indirect, can be considered societal transfers and hence should not be included in a net economic welfare analysis.

such expenditures also represent extra revenues to the companies that sell those machines and hence should not be included when assessing net impacts to society. However, whilst this may be true in terms of a net analysis of financial flows, this is not true in the context of a net economic welfare (cost-benefit) analysis, where such costs represent real opportunity costs to society and hence should be included. In some cases the applicant also does not include the extra operational costs associated with the use of such machinery. Likewise, the applicant also does not include other legitimate costs associated with non-use such as the costs of relocation of plant, in some case study circumstances.

- In some of the case studies, the expenditures on production inputs that would no longer be undertaken under the non-use scenario are counted as economic costs of non-use. However in terms of a net economic welfare analysis, such inputs have an opportunity cost in use and hence (given that they are not destroyed under the non-use scenario) are incorrectly included as costs of non-use (instead of cost savings).

In addition to these general methodological issues, SEAC notes that the applicant provides no direct link between the non-use scenarios used in each of the case studies in the socioeconomic analysis and the assessment of alternatives undertaken in the analysis of alternatives. As a result it is difficult to establish and confirm the appropriateness of the non-use scenarios used in the SEA case studies, beyond a face-value acceptance of the consequences of non-use as described in each case study. This lack of a direct link between the SEA case study approach and the Analysis of Alternatives also makes it difficult to establish how well the case study non-use scenarios characterise the range of possible non-use scenarios and impacts across all use-cases, such that it makes it difficult to ascertain whether the length of review period requested is appropriate across all use-cases.

Although the case study that is taken forward for extrapolation of costs suffers relatively few of the above methodological problems, given the problems of sampling strategy it is unclear how representative this cases study is of the minimum level of socioeconomic impacts across all use cases and companies in scope. Moreover, whilst the applicant provides itemised estimates of the additional production costs necessary under the non-use scenario, SEAC was unable to scrutinise and confirm the basis on which those estimates were derived. This is also a problem in many of the other case studies, especially since some of the case study companies were unwilling (or unable) to disclose the necessary information.

Given the nature of the methodological and empirical issues noted above, SEAC's concerns are such that the estimates of socioeconomic impact provided by the applicant cannot be relied upon to provide an accurate assessment of the economic welfare losses (costs) to society from non-use.

Nevertheless, SEAC is also mindful that on the basis of the information presented, net economic costs to society will indeed be incurred under the non-use scenario, albeit at a total magnitude which SEAC cannot confirm based on the data and analysis presented. Accepting at face value some of the estimates of impact provided by the applicant, these net economic costs may be upwards of €1.5 million at an individual company level, though it is unclear given the analytical approach taken by the applicant how representative this might be across all use-cases and companies.

Risks of continued use

The quantitative analysis of the risks associated with the "continued use" of trichloroethylene is based on a health impact assessment using an 'impact-pathway' type methodology. This estimates the change in physical health impacts (disease burden) due to changes in exposures as a result of the "non-use" scenario. The approach is based on linking quantitative relationships between exposure and the health impact of interest. This general procedure is widely used for the assessment of benefits related to pollutants and is considered to be an appropriate methodological approach. The sole endpoint considered in the quantitative health impact is the number of excess cases of kidney cancer. SEAC is unaware of any other relevant human health endpoints or environmental concerns that could be used for quantitative estimation of impacts.

Concerning the estimation of economic welfare losses associated with this number of excess kidney cancer cases, the applicant makes use of WTP based values for the avoidance of cancer recommended by the ECHA guidance on SEA. Although it is unclear if the study from which these WTP values were derived included medical costs and productivity losses, in addition to the welfare loss from mortality/morbidity, the unit WTP values can be considered as being in the range of values that would be expected in the literature for all (total) of the economic value components of an avoided case of cancer mortality/morbidity. SEAC confirms that despite some relatively minor issues with the approach taken (for example, whether the implicit assumption of a linear relationship between risk and years of exposure is correct; whether other components of economic welfare loss are included in the WTP estimates; and the failure to apply any discounting to take into account the latency of cancer[3]; double counting of some of the exposed populations), the methodology, assumptions and studies used are in general appropriate and proportionate. Although the issues mentioned above give rise to some uncertainties concerning the robustness of the ("non-use" scenario) health benefits derived, this is likely to lead to an overestimation of benefits at the individual case study level. Nevertheless, the representativeness of the case-studies is unclear, such that SEAC is unable to confirm the aggregated benefit estimates provided by the applicant, although SEAC accepts that these are likely to provide reasonable order of magnitude estimates. The risks of continued use were estimated by the applicant at between €12.1 million and €21 million (depending on the upper and lower bound WTP value used for cancer cases; 2016 price level) over the 12 year analytical timeframe. In conclusion, SEAC finds that the approach and assumptions used to derive the health benefits of "non-use" are on the whole clear and transparent. Moreover, although there are some issues and uncertainties with the analysis as discussed above, the methodology, assumptions and studies used to derive the benefit estimates can be considered on the whole acceptable in providing order of magnitude estimates of health impacts, particularly since the estimates of statistical cancer cases were considered to be overestimated (see RAC sections).

Comparison of benefits and risks of continued use

Overall the level of risks associated with the applicant's use of trichloroethylene is considered to result in less than 20 statistical cases of cancer, albeit with some uncertainty regarding the exact magnitude. As such, order of magnitude

[3] Although the applicant considers the WTP values to implicitly include discounting for the latency associated with cancer cases, SEAC upon further consideration of the data from the NewExt study from which the WTP values are taken, find that this is not the case. Irrespective, this would only serve to underline that the monetized health risks have been overestimated by the applicant.

estimates of risks of continued use are around €12.1 million to €21 million. Due to the deficiencies noted earlier, the applicant's estimates of total socioeconomic impacts are not commensurable with these estimates of health benefits under the non-use scenario. SEAC has nevertheless been able to establish that the benefits of continued use could be of the order of at least €1.5 million at an individual company level, though it is unclear how representative this is across the range of use-cases and companies that may be in scope. Moreover, it has been difficult for SEAC to assess how well the analytical scope used in the analysis corresponds with the scope of use-cases and companies that would be affected in reality. Nevertheless, accepting at face value the figure of €1.5 million would mean that if even only 15 companies had benefits of continued use of this magnitude, then those benefits would outweigh the risks (costs) of continued use. Even if risks were an order of magnitude higher, then benefits of continued use of €1.5 million in around 20% of the all companies would be sufficient for benefits to outweigh risks. Nevertheless, as described throughout this opinion there are uncertainties and issues with the analytical approach taken and estimates found, such that **whilst SEAC accepts that the benefits of granting the authorisation certainly outweigh the risks, the scope of the analysis and its applicability to the use-cases and companies in reality raises some concerns, which would need to be taken into account in any future review report.**

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements:

RAC

The OC and RMMs described in the ES need to be followed strictly due to a relatively high risk that was identified in this assessment. Training for downstream users as specified by the applicant in the CSR is recommended by RAC.

Additionally to the implementation of OC and RMM as described in the ES, the following conditions have to be complied with:

- Use of TCE for cleaning only where specific requirements (system of Use-Parameters) exist;
- At the minimum by the end of their service life, ECSA Type III machines should be replaced with Type IV or preferably Type V machines; and
- The process must be performed under vacuum if possible.

The applicant and/or their downstream users must implement regular campaigns of occupational exposure measurements (sampling at least annually) relating to the use of TCE described in this application for the workplaces covered by this application. These monitoring campaigns must be based on relevant standard methodologies or protocols, comprise personal inhalation exposure sampling and be representative of the range of tasks undertaken where TCE exposure is possible and of the total number of workers that are potentially exposed (i.e., the campaign shall include process, maintenance, and other types of workers involved, geographical distribution). Biomonitoring, i.e., measurement of the TCE metabolite TCA in urine, might also be of relevance. The results of the monitoring must be included in case an authorisation review report is submitted. Information needs to be provided about the relevant exposure determinants in the

workplaces, such as the ECSA Type of degreaser used, size of the machine, number of machines per room, relevant process parameters, and cleaned part types.

In addition, the information gathered in the monitoring campaigns must be used for the workplaces covered by this authorisation to review and improve the risk management measures and operational conditions, to further reduce workers' exposure to TCE. The hierarchy of control principles must be followed in the selection of RMMs. The outcomes and conclusions of this review, including those related to the implementation of the additional RMMs, must be documented.

The resulting report – including the documentation of reduced exposure at the concerned workplaces over time – must be included in the event an authorisation review report is submitted.

SEAC

SEAC recommends the following additional conditions:

- Prior to the first supply under the authorisation after the sunset date, all downstream users shall provide their supplier with a written declaration that they carried out an analysis of alternatives and that no suitable alternatives exist for them with regard to their authorised use. The analysis of alternatives and the written declaration shall be renewed 3 years and 6 years after the sunset date. The analysis of alternatives shall be documented;
- Within 30 months and 66 months after the sunset date, the Applicant shall ensure that all downstream users it supplies under the authorisation for this use are provided with an obligatory training on alternative cleaning solutions and on the methodology for analysis of alternatives; and
- After the sunset date, TCE is used exclusively in an ECSA Type IV or V machines.

Description of conditions and monitoring arrangements for review reports:

None in addition to the above.

Justification for additional conditions and monitoring arrangements:

RAC notes that there are uncertainties related to the appropriateness and effectiveness of risk management measures in limiting the exposure and risks related to use of TCE described in this application. These uncertainties are caused especially by the limited representativeness of the provided measurement data.

RAC also notes that use of ECSA Type III degreasers is expected to lead to higher exposure of workers and of man via environment compared to ECSA Type IV or V equipment.

SEAC recommends to include the conditions specified above based on the main elements proposed in the applicant's specific supply conditions to downstream users. This would facilitate substitution of TCE with alternatives.

SEAC noted the condition of RAC regarding the type of degreaser machines as well as the proposal in the Applicant's comments to the draft opinion to introduce a requirement to downstream users to use TCE exclusively in ECSA Type IV and V machines.

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (4 years)

☐ Other:

Justification for the suggested review period:

In identifying the review period SEAC took note of the following considerations

- RAC has brought to SEAC's attention that the uncertainties related to the exposure assessment coupled with the estimated cancer risk level for workers indicate that a more than normal review period seems inappropriate in this case.
- The risks associated with continued use are considered to be less than 20 statistical cases of kidney cancer, although this is likely to be overestimated since RAC considered the risk estimates for man via environment overestimated.
- The applicant's own justification for a review period of 12 years is rather general, given that the application covers a wide range of industry sectors and use-cases. In this respect the applicant discusses transition periods of 6-14 years and considers that the time needed depends on the specific circumstances of each user. The applicant does provide an example case study of the possibilities and timelines for a transition to alternatives, though the general applicability of this case is unclear. SEAC considers that the justification for the review period suggested by the applicant is not clearly specified and motivated in accordance with the variety of use-cases in scope of authorisation. In other words, SEAC has concerns regarding the justification for requesting the same 12 year review period for all of the use-cases.
- Although there has been significant movement and active work by industry (and others) towards substitution and finding alternatives to the use of trichloroethylene in surface cleaning applications, it is difficult to discern the state of play across the different sectors and use-cases, in particular with a view to considering what substitution may take place over a shorter time horizon. Moreover, the applicant has not provided any information on future plans to develop and test possible substitutes, despite the wide variety of use-cases that may allow for substitution possibilities to be examined.
- The broad scope of the application has meant that it has been difficult to assess how well the analytical approach taken has been able to incorporate within its boundaries of analysis the full distribution of impacts and possibilities for substitution.
- Although there appear to be no technically and economically feasible alternatives in accordance with the system of Use-Parameters, SEAC considered that some of the Use-Parameters were not strictly technical function impediments to substitution, but rather regulatory or procedural issues, which may be easier to overcome in the near term. Given the nature of the system of Use-Parameters, it was difficult for SEAC to properly evaluate within the analytical scope boundaries how binding a constraint these Use-Parameters would be in terms of the ability of companies to substitute over different periods of time.

- The broad scope of the application and its reliance on the 'Suitability Matrix/Selection Grid' is such that it appears to potentially place much responsibility on the downstream user and authorities from an enforcement point of view. This may necessitate additional resources and costs (though see below bullet concerning this), which have not been taken into account in the SEA.
- The applicant has described changes it intends to implement in its supply model, including the implementation of specific conditions before supplying TCE for the authorised use to its downstream users. These changes to the supply model allay SEAC's concerns regarding the broad scope of the application and the associated lack of justification regarding the extent to which the opportunities for potential substitution across all of the use cases in scope align with the proposed review period of 12 years. Specifically, the applicant will roll out across the entire affected supply chain a 'chemical leasing' business model for supply of downstream user with trichloroethylene under authorisation. In addition to process (operating conditions) optimisation and training including information on alternative cleaning solutions, trichloroethylene would only be supplied if a downstream user makes a written declaration that an analysis of alternatives has been undertaken and no suitable alternatives exist. Substitution possibilities would be checked by downstream users using the Use-Parameter and Suitability Matrix concepts as specified in the application for authorisation. This analysis of alternatives and substitution check and written declaration would be contractually required to be undertaken every 3 years. Moreover, the downstream user would be required to conduct an annual exposure monitoring program. Whilst the full implementation of the above arrangements would take 2-3 years, downstream users' support to enlist in such a contractual arrangement is more likely to be forthcoming the longer is the review period granted (given the associated increase in supply predictability and security for a downstream user operating within such an arrangement). The above arrangements would place an increased burden of ensuring compliance with the conditions of the authorisation on the applicant, whilst at the same time generating documentation that would facilitate the enforcement activities of authorities. Given that any increases in costs associated with the arrangements as such will mainly fall on industry actors, these will act as a further incentive to substitution.
- SEAC is mindful of the need for companies to be able to ensure continued supply of services in order to remain competitive vis-à-vis non-EU suppliers. Uncertainty over continued supply may lead to transferral of business outside the EU, particularly in those sectors (e.g. aviation) for whom longer term supply issues are paramount.
- Although SEAC accepts that at the general level the benefits of granting the authorisation certainly outweigh the risks, the exact magnitudes are somewhat uncertain. This reflects some deficiencies in the analytical approach taken.

Taking into account these points, SEAC recommends a default "normal" review period of **7 years**. This would give some certainty of supply in the medium term, whilst providing a continuing, longer term incentive towards substitution and at the same time promoting more short term substitution across the different use cases (in accordance with the authorisation monitoring arrangements and conditions).

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Addendum to the

Consolidated version of the opinion
on an application for authorisation for
trichloroethylene
Used as in industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use parameters) exist

ECHA/RAC/SEAC: AFA-O-0000006101-90-02/D

Applicant: DOW Deutschland Anlagengesellschaft mbH (currently Blue Cube)

30 November 2016

This addendum, prepared by the ECHA-Secretariat in collaboration with the RAC Rapporteurs responsible for this case, provides further clarification on RAC's opinion, as requested by the Commission.

Summary

In this relatively early opinion in the Authorisation process, the explanation of the identified risk control concerns was limited and inadvertently gives the impression that RAC was responding to the level of individual risk associated with certain aspects of the use; this was not the case, although some of the language used may be ambiguous.

This addendum clarifies the opinion without reopening the case. It attempts to provide a better explanation of RAC's concerns to the Commission; it may also be of assistance to the applicant.

Brief description of the process and tasks resulting in exposure

Delivery and storage is performed in double walled safety systems using vapour return lines during solvent transfer and retake of spent solvent in SAFE-TAINERs for external recycling or disposal.

The parts cleaning process starts with entering the parts, manually or automated, into the cleaning chamber of the equipment. Parts can be of all sizes and geometries, with or without cavities. The size of the machine can vary significantly with a filling volume from 100L to 8000L. After parts loading the door of the cleaning chamber is hermetically sealed. The process may be run under vacuum, but not in all cases.

The parts cleaning process can operate over a wide temperature range and is adjusted to the conditions needed for the specific use case. Physical action to support the cleaning can also be added (e.g., movements of the parts, ultrasonic waves).

Prior to opening the cleaning chamber, a closed loop solvent vapour abatement process is started. This process runs until a solvent concentration of less than 1g/m³ is reached. In modern machines the door is locked until this concentration is reached.

Sampling of TCE for quality checks, re-stabilisation of the solvent and cleaning / maintenance activities (like filter changes) cannot be fully performed in a closed system. Appropriate PPE needs to be used to limit exposure to the substance whilst these tasks are undertaken.

Risk control concerns

The consolidated RAC and SEAC opinion[1] includes RAC's evaluation of the operating conditions (OCs) and risk management measures (RMMs) put in place by the applicant to limit worker exposure to TCE. This evaluation is made in part against the context of the available worker exposure data. The details and conclusions of RAC's evaluation of the representativeness of exposure data (to the OCs and RMMs described in the use) are provided in the justification to the opinion.

The RAC evaluation identified concerns in relation to the level of detail, specificity and representativeness of the OCs and RMMs in the ES, considering the number of downstream users that would benefit from authorisation applied for and the many possible variations of the OCs and RMMs[2]. This concern was further underpinned by a lack of clear information on the relationship between the OCs and RMMs applied and resulting worker exposure levels. These concerns were sufficient for RAC to conclude that the OCs and RMMs defined by the ES were not demonstrated to be appropriate and effective in limiting the risk. The intention was therefore to express 'risk control' concerns in relation to the appropriateness and effectiveness of the OCs and RMMs described by the applicant.

Given the many downstream users and the scale of possible variations of the OCs and RMMs, with the exception of the condition regarding the use of ECSA Type III degreasers[3], it was not possible for RAC to identify specific additional OCs and RMMs that could achieve appropriate and effective limitation of risk.

RAC's concerns could be addressed by the development of more specific ESs validated with representative exposure data. There are some indirect references to these concerns and how they are expected to be dealt with in the justification, e.g. from the wording used in the condition: *"In addition, the information gathered in the monitoring campaigns must be used for the workplaces covered by this authorisation to review and improve the risk management measures and operational conditions, to further reduce workers' exposure to TCE. The hierarchy of control principles must be followed in the selection of RMMs. The outcomes and conclusions of this review, including those related to the implementation of the additional RMMs, must be documented"*.

Although RAC recommended conditions, it was not possible for RAC to identify specific additional conditions to address all of their risk control concerns. Therefore, RAC

[1] https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1655/term.

[2] E.g., due to: the number and types of machines and their simultaneous operation in the same workshop, the size of the workshop, the ventilation, process parameters like duration, frequency, volume or temperature, duration and frequency of tasks.

[3] ECSA 2011 "Guidance on Storage and Handling of Chlorinated Solvents"

communicated the uncertainties related to the exposure assessment and the exposure control concerns to SEAC and recommended that a more than normal review period seems inappropriate in this case (in RAC 'opinion tree' terms this would be a combination of R4 and R5). A normal review period will allow RAC to evaluate the progress made in reducing these uncertainties and whether the operational controls and risk management measures are appropriate.

Specific clarifications

The conclusion of Section 6 of the justification to the opinion states:

> *"RAC notes that an excess of cancer risk of 1.26 x 10^{-4} is observed for workers involved in degreasing activities. Additionally, a relatively high risk is observed for the three-monthly 'equipment cleaning and maintenance' scenario. However this scenario is performed with a significantly reduced frequency of only 4 times a year."*

It is important to differentiate between the long-term excess risks for workers in the typical daily 'production' scenario and the excess risk for infrequent tasks such as typical three-monthly 'equipment cleaning and maintenance' scenario. The words "*relatively* high risk" (emphasis added) indicate that compared to the long-term excess risk for workers in the 'production' scenario, the risks in the 'equipment cleaning and maintenance' scenario are greater, although the opinion proceeds to note that this scenario is undertaken only 4 times per year and therefore this scenario only has a very minor influence on the total excess risk for workers involved in this use.

Section 10 of the justification to the opinion furthermore states:

> *"In addition, the information gathered in the monitoring campaigns must be used for the workplaces covered by this authorisation to review and improve the risk management measures and operational conditions, to further reduce workers' exposure to TCE. The hierarchy of control principles must be followed in the selection of RMMs. The outcomes and conclusions of this review, including those related to the implementation of the additional RMMs, must be documented."*

Regarding the words "review and improve", the following clarification of the intention can be provided: The information gathered in the monitoring programmes shall be used by the applicant and the downstream users covered by the application to review the risk management measures and operational conditions. When doing so, the overarching objective should be the progressive reduction of exposures and releases to as low a level as technically and practically possible (as required under Article 60(10) of REACH).