Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on a Review Report for

trichloroethylene use:

Use as an extraction solvent in caprolactam production

ECHA/RAC/SEAC: AFA-O-0000006681-72-01/D

Consolidated version

Date: 27 May 2019

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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 the following application for authorisation:

Authorisation holder(s)	**SPOLANA s.r.o.** (position in supply chain: downstream user)
Substance ID EC No CAS No	**Trichloroethylene** 201-167-4 79-01-6
Intrinsic property(ies) referred to in Annex XIV	☒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)
Use title	**Use as an extraction solvent in caprolactam production**
	Other connected uses: Not applicable
	Initial application: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/1645/del/50/col/synonymDynamicField_308/type/desc/pre/1/view
Use performed by	☒Authorisation holder ☐Downstream User(s) of the authorisation holder(s)
Use ID (ECHA website)	0129-01
Reference number	11-2120786264-47-0001
RAC Rapporteur	Sonja Kapelari
SEAC Rapporteur SEAC Co-rapporteur	Ivars Bergs Endre Schuchtár

ECHA Secretariat	Mercedes Marquez-Camacho Sanna Henrichson Elina Liopa Piotr Sosnowski

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the review report	16/08/2018
Date of payment, in accordance with Fee Regulation (EC) No 340/2008 on	26/10/2018
The review report has been submitted 18 months before the expiry of the review period of the granted authorisation and the authorisation holder can benefit from the transitional arrangements.	☒Yes ☐No
Public Consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	14/11/2018 - 09/01/2019
Comments received	☒Yes ☐No Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/21201/del/50/col/synonymDynamicField_308/type/desc/pre/1/view
Request for additional information in accordance with Article 64(3)	10/12/2018 16/01/2019 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/21201/del/50/col/synonymDynamicField_308/type/desc/pre/1/view
Date of the trialogue meeting	28/01/2019
Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the authorisation holder	☐Yes ☒No

The review report included all the necessary information specified in Article 62 that is relevant to the Committee's remit.	☒Yes ☐No
Agreement of draft opinion in accordance with Article 64(4)(a) and (b) on	RAC: 15/03/2019, agreed by consensus.
	SEAC: 15/03/2019, agreed by consensus.
Date of sending of the draft opinion to the authorisation holder	14/05/2019
Date of authorisation holder's decision not to comment on the draft opinion, according to Article 64(5)	27/05/2019
Date of receipt of authorisation holder's comments, according to Article 64(5), received	Not relevant
Adoption of opinion, according to Article 64(5), on	RAC: 27/05/2019, adopted by consensus.
	SEAC: 27/05/2019, adopted by consensus.
Minority positions	RAC: ☒N/A
	SEAC: ☒N/A

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the risk management measures described,
- the assessment of the hazards related to the alternatives as documented **in the submitted review report** taking into account the information submitted by interested third parties, as well as
- other available information.

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

RAC concluded that there appear to be no alternatives that would further reduce the overall risks.

RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk provided that they are adhered to.

The suggested monitoring arrangements and adjustment of RMMs are expected to address RAC's concerns.

THE OPINION OF SEAC

SEAC has formulated its opinion on:

- the socio-economic factors, and
- the suitability and availability of alternatives associated with the use of the substance as documented in the review report, taking into account the information submitted by interested third parties, as well as
- other available information.

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

SEAC concluded that there appear to be no suitable and available alternatives by the end of the review period of the granted Authorisation.

SEAC concluded that the authorisation holder's assessment of: (a) the potential socio-economic benefits of the continued use, (b) the potential adverse effects to human health of the continued use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the authorisation holder's conclusion that overall benefits of the continued use outweigh the risk to human health, whilst taking account of any uncertainties in the assessment.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Monitoring arrangements

a) The authorisation holder shall continue to conduct regular occupationally exposure measurements. Those measurements shall comprise personal inhalation exposure and biomonitoring and take place at least annually.

b) The authorisation holder shall continue to conduct regular environmental monitoring to quantify the release factors and emissions to TCE to all environmental compartments. Sampling shall be done at least annually.

c) The information gathered via the measurements and related contextual information shall be used by the authorisation holder to further optimise the RMMs and OCs in place in order to minimise releases and exposure, particularly with regard to fugitive emissions of TCE. This should include the improvement of the TCE unloading station as described in the review report, and the review of the working practices for the installation of new equipment.

d) The information from the monitoring programmes including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent national authority of the Member State where the authorised use will take place.

e) The authorisation holder may reduce the frequency of measurements, once the authorisation holder can clearly demonstrate to the national Competent Authority of the Member State where the use takes place that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the authorisation holder and the comments received on the broad information on use, the duration of the review period for the use is recommended to be **twelve years**.

SUMMARY OF THE REVIEW REPORT / USE

Type of review report (authorisation holder)	☐Upstream (M/I/OR or group of) ☐Upstream (Formulator or group of) ☐Downstream (group of users) ☒Downstream (single user) ☐Other [specify, e.g. Group of M/I/OR/DU]?
Indicative number and location of sites covered	There is **one** site in Neratovice, Czech Republic.
Annual tonnage of Annex XIV substance used per site (or total for all sites)	ca. 100 tonnes. The maximum amount of TCE at the site is approximately 250 tonnes. A quantity of **180-200 tonnes is used** in a closed loop and 50 tonnes in maintained storage.
Function(s) of the Annex XIV substance. Type of products (e.g. articles) made with Annex XIV substance and their market sectors	TCE is used as an extraction solvent in the industrial manufacture of caprolactam from cyclohexanone (i.e. via Beckmann rearrangement). Caprolactam is used as a precursor in the manufacture of nylon 6 (PA-6). The production of caprolactam is technologically linked with the generation of the by-product ammonium sulphate and the manufacture of sulphuric acid (and subsequent generation of oleum).
Shortlisted alternatives discussed in the review report	Alternative substances considered: Toluene, benzene Alternative technologies considered: Alternative extraction technology (name confidential)
Annex XIV substance present in the products (e.g. articles) made by the downstream users	☐Yes ☒No ☐Unclear ☐Not relevant
Number of workers exposed per site (or total for all sites):	Directly: 100 Indirectly: 3 100
Number of humans exposed via the environment	Local scale: 260 Regional scale: 8 011 432

Environmental compartments affected:	☒Air ☒Water ☐Soil ☐None
Authorisation holder has used the dose response relationship recommended by RAC	☒Yes – https://echa.europa.eu/documents/10162/13641/carcinogenicity_dose_response_tce_en.pdf/ad8db350-0e22-4c45-b721-028579c371cb ☐No
All endpoints listed in Annex XIV were addressed in the assessment	☒Yes ☐No
All relevant routes of exposure were considered	☒Yes ☐No
Adequate control concluded by authorisation holder for the relevant endpoint(s)	☐Yes ☐No ☒Not Applicable – non-threshold substance
Level of (combined, daily) exposure/release used by authorisation holder for risk characterisation	Worker: Inhalation & Dermal*: 0.00167 – 3.18 mg/m^3 Consumer: Not applicable Humans via environment: Inhalation: 0.00000325 –0.00496 mg/m^3 Dermal: not applicable Oral: 0.0000800 – 0.0540 µg/kg bw/day Environment: Air: 1.37 kg/day Water: 3 kg/day Soil: 0 kg/day * based on biomonitoring

Combined risk level	Workers: **3.82×10^{-5}** Consumer: not applicable Humans via environment: 2.43×10^{-10} – 3.41×10^{-7}
Authorisation holder is seeking authorisation for the period of time needed to finalise substitution (‘*bridging application*’)	☐Yes ☐No ☒Unclear The authorisation holder is working on several different potential alternatives together with its research partners and states that it is committed to implementing any alternative that this research identifies as feasible. The authorisation holder has presented a detailed theoretical time plan for the implementation of an alternative technology, although it would be dependent on the research results.
Review period argued for by the authorisation holder (length)	12 years
Most likely Non-Use scenario	Implementation of the alternative extraction solvent toluene, resulting in a temporary shutdown of the caprolactam, ammonium sulphate and sulphuric acid units.
Authorisation holder concludes that benefits of continued use outweigh the risks of continued use	☒Yes ☐No Annualised: - Authorisation holder’s benefits of continued use: €2.15 – 7.22 million - Society’s benefits of continued use: €3.15 million - Monetised health impact on workers: €73 - Monetised health impact on the general population €53 ☐Not Applicable – threshold substance with adequate control

SUMMARY OF RAC AND SEAC CONCLUSIONS[1]

2. Operational Conditions and Risk Management Measures are appropriate and effective in limiting the risk?

2.1. Conclusions of RAC:

Conclusion for workers:

- The application holder addressed the deficiencies identified by RAC in the original application for authorisation and provided detailed information on the OCs and RMMs in place.
- The application holder has made significant efforts to reduce emissions in the work area and consequently to minimise exposure to workers through the improvement of the RMMs in place (e.g. improvements in containment, installation of closed sampling systems, etc.).
- The application holder has improved the RMMs according to the hierarchy of control.
- The application holder should continue the monitoring arrangements and use the results to further optimise the RMMs and OCs in place to minimise exposure to workers, particularly with regard to fugitive emissions of TCE. This should include the improvement of the TCE unloading station as described in the review report, and the review of the working practices for the installation of new equipment.
- RAC did not identify any substantial uncertainties of concern with the OCs/RMMs/ described.

OCs / RMMs implemented are:

Appropriate: ☒Yes ☐No

Effective: ☒Yes ☐No

Conclusion for environment and / or Humans via environment (HvE):

- The application holder addressed the deficiencies identified by RAC in the original application for authorisation and provided detailed information on the OCs and RMMs in place.
- The application holder has made significant efforts to minimise emissions to the environment and consequently exposure to humans via the environment through the improvement of the RMMs in place (e.g. recommission of central exhaustion of the working space into a gas absorption column, stripping of TCE prior discharge to process water, etc.)
- The application holder should continue the monitoring arrangements and use the results to further optimise the RMMs and OCs in place to reduce releases to the environment, particularly with regard to fugitive emissions of TCE.
- RAC did not identify any substantial uncertainties concerning the RMMs/OCs in place.

[1] The numbering of the sections below corresponds to the numbers of the relevant sections in the Justifications.

OCs / RMMs implemented are:

Appropriate: ☒Yes ☐No

Effective: ☒Yes ☐No

Additional monitoring arrangements related to exposure assessment are recommended for the authorisation:

☒Yes ☐No

[Section 8.1]

Recommendations to the authorisation holder related to the content of the potential Review Report are made:

☒Yes ☐No

[Section 9]

3. Exposure Assessment

Combined exposure level used by RAC for risk characterisation:

Workers:

Inhalation & Dermal*: 0.00861 – 3.18 mg/m^3

Humans via environment:

Inhalation: 0.00000325 – 0.00496 mg/m^3

Oral: 0.0000800 – 0.0540 µg/kg bw/day

Environment:

Air: 1.37 kg/day

Water: 3 kg/day

Soil: 0 kg/day

* based on biomonitoring

Conclusions of RAC:

RAC considers that the exposure assessment of workers is reliable and representative in relation to the tasks and number of workers. The measured and estimated exposure levels are reliable and do not raise any significant uncertainties.

The exposure assessment for humans via the environment is reliable and representative. The measured and estimated exposure levels are reliable and do not raise significant uncertainties.

Additional monitoring arrangements related to exposure assessment are recommended for the authorisation

☒Yes ☐No

[Section 8.1]

Recommendations to the authorisation holder related to the content of the potential Review Report are made

☒Yes ☐No

[Section 9]

4. Risk Characterisation

Risk level used for health impact assessment calculated by RAC:

Workers: 2.73×10^{-8} - 3.82×10^{-5}

Humans via environment: 2.43×10^{-10} – 3.41×10^{-7}

Conclusions of RAC:

RAC is of the opinion that the application includes all relevant tasks and routes of exposure as well as endpoints and populations.

5. Suitable alternatives are available before the end of the review period?

Conclusions of SEAC and RAC:

☐Yes ☒No

1. The review report contains extensive descriptions regarding the authorisation holder's process and functional requirements, various alternative substances and technologies, as well as the technical and economic feasibility and availability of the short-listed alternative solvents.
2. The authorisation holder's technical feasibility criteria have been developed for drop-in alternatives, meaning that any alternative that would require changes to the plant could be deemed technically infeasible. Nevertheless, the authorisation holder has provided extensive arguments and cost information to justify why the commercially proven alternatives that would require plant modifications are discarded. The shortlisting of toluene and benzene seems reasonable to SEAC.
3. Based on all the information provided in the review report and in the written answers to questions, SEAC finds it credible that benzene and toluene could only be implemented through extensive modification of the existing plant. While the actions required for making the shortlisted solvents technically feasible seem credible, SEAC is not able to fully scrutinise the required timelines of 12 years claimed by the authorisation holder. Because of this, the downtime costs may also be overestimated. Nevertheless, SEAC finds that the investment costs alone are enough to conclude that the alternatives would not be economically feasible for the authorisation holder.
4. SEAC recognises the recent efforts made by the authorisation holder in R&D activities related to the search for and development of alternatives. SEAC notes that a lot of detail is provided on the R&D goals, activities, financing sources as well as implementation plans.
5. SEAC agrees with the authorisation holder that no technically and economically feasible other alternatives are currently suitable for the authorisation holder.
6. SEAC considers that the implementation of benzene or toluene would require major investments in the order of tens of millions of euros, making the alternatives economically infeasible for the authorisation holder.

Additional conditions or monitoring arrangements related to the assessment of alternatives are recommended for the authorisation

☐Yes ☒No

Recommendations to the authorisation holder/s related to the content of the potential Review Report

☐Yes ☒No

6. Have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

Conclusions of SEAC:

☒Yes ☐No

The authorisation holder's impact assessment contains an extensive list of the main impacts of a refused authorisation, with the impacts being incremental to the continued use scenario. SEAC overall concurs with the methodological approach used.

The authorisation holder has provided extensive uncertainty analysis concluding that in any scenario the benefits of the continued use of TCE would be large enough to by far outweigh the costs to society.

Although SEAC is not entirely convinced that the implementation of toluene and the associated 12-years temporary shut-down of the caprolactam plant would be realistic, the authorisation holder has provided sufficient information to allow SEAC to concur that the benefits would still outweigh the risks by at least several thousand times even if the temporary shutdown was shorter or if the plant was shut down completely.

SEAC considers that the socio-economic analysis carried out by the authorisation holder thoroughly captures the changes in impacts and allows SEAC to conclude that the benefits of continued use of TCE outweigh the associated risks. SEAC considers none of the uncertainties to be of such magnitude that they could affect this overall conclusion.

Recommendations to the authorisation holder related to the content of the potential Review Report

☐Yes ☒No

7. Proposed review period for the use

☐ 4 years

☐ 7 years

☒ 12 years

☐ Other – … years

8. Proposed additional conditions and monitoring arrangements for the authorisation

RAC:

Additional conditions:

For workers	☐Yes	☒No
For the environment / HvE	☐Yes	☒No

Monitoring arrangements :

For workers	☒Yes	☐No
For the environment / HvE	☒Yes	☐No

[Section 8.1]

SEAC:

Additional conditions: ☐Yes ☒No

Monitoring arrangements: ☐Yes ☒No

9. Proposed recommendations for the review report

RAC:

For workers ☒Yes ☐No

For the environment / HvE ☒Yes ☐No

[See section 9]

SEAC:

AoA ☐Yes ☒No

SEA ☐Yes ☒No

10. Authorisation holder(s) commented on the draft opinion

☐Yes ☒No

Action(s) taken resulting from the analysis of the authorisation holder's comments?

☐Yes ☐No ☒Not applicable

JUSTIFICATIONS: FULL VERSION:

1. Short description of use

1.1. Description of the process in which Annex XIV substance is used

Table 1: Exposure contributing scenario presented in the use

Contributing scenario	ERC / PROC	Name of the contributing scenario	Size of the exposed population
ECS1	ERC 4	Use of non-reactive processing aid at industrial site	Local scale: 3 100 workers and 260 residents; Regional scale: 8 011 432 residents;
WCS2	PROC 2	Use in closed system, including storage, transfers, sampling, recycling, waste transfers	25 operators & 6 technologists
WCS3	PROC 8b	Transfer of TCE from railway tank car	6 unloading operators
WCS4	PROC 28	Ad-hoc and annual cleaning and maintenance	25 maintenance workers (different from operators)
WCS5	PROC 15	Laboratory quality control	16 lab staff
WCS6	N/A	Work in sewage treatment plant (STP) (indirect exposure)	21 STP workers
WCS7	PROC 8b	Waste handling by external waste operators	25 operators (same as in WCS 2) 1 external waste operator

The exposure scenario is comprised of one Environmental Contributing Scenario (ECS) and six Worker Contributing Scenarios (WCS). According to the authorisation holder, the exposure scenario includes all relevant processes and tasks associated with the use of TCE that could result in either exposure to workers or to humans via the environment.[2]

Trichloroethylene (TCE) is used in a closed loop system as an extraction solvent in the industrial manufacture of caprolactam from cyclohexanone (i.e. via Beckmann rearrangement) at the site in Neratovice (Czech Republic). TCE is used to recover caprolactam from a two-phase aqueous system comprised of caprolactam in water (containing approx. 72% caprolactam, termed “raw lactam”) and ammonium sulphate (containing 0.8% caprolactam). Caprolactam is subsequently back-extracted into demineralised water and the TCE is recycled and partially regenerated by distillation.

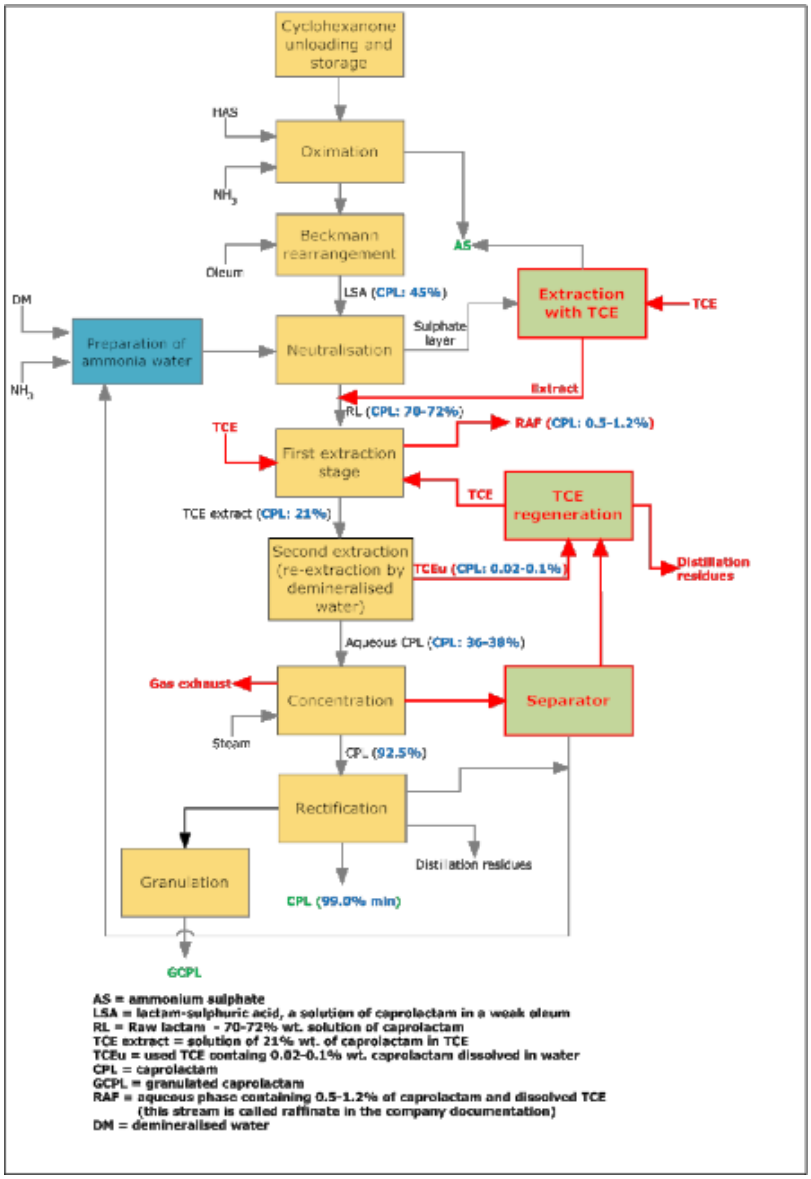
The authorisation holder is applying for the use of up to 100 tonnes per year of TCE to replace solvent losses from the system (the closed loop system contains a total of about 180-200

[2] The CSR and the WCSs have been significantly updated based on the RAC opinion on the original application for authorisation. The authorisation holder has provided a comparison of the contributing exposure scenarios in the original application for authorisation and in the review report to facilitate the understanding of the revisions.

tonnes of TCE). The maximum amount of TCE on site at any one time is ca. 250 tonnes (50 tonnes are at storage). From 2018 onwards, the amount applied for (100 tonnes) is expected to decrease to about 85 tonnes per year (see also section 2).

The manufacture of caprolactam occurs in seven steps as described in the simplified scheme below. The production is technologically linked with the generation of the by-product ammonium sulphate and the manufacture of sulphuric acid (and subsequent generation of oleum); not only is sulphuric acid formed from hydroxylammonium sulphate in the oximation step and consequently neutralised by ammonium, but also sulphuric acid and thereon oleum required for Beckmann rearrangement is produced from sulphur in the independent sulphuric acid plant.

Figure 1: Caprolactam production process in Spolana's Neratovice plant



The elements of the process that involve TCE are indicated in red colour.

All processes involving TCE are automated.

There are no consumer, downstream user or article service-life exposure scenarios relevant to the use applied for.

1.2. Key functions and properties provided by the Annex XIV substance

The key functional requirements for the solvent used for caprolactam extraction are:

1. Solvent extraction efficiency (90-95%)
2. Solvent loading capacity for caprolactam (solvent loading capacity for caprolactam should be about 20% at 20ºC)
3. Solvent viscosity (the value of viscosity should not exceed that of TCE, which stands at 0.55 mPa.s at 30°C in order to avoid pressure loss in pipes)
4. Solvent density (the density difference between the solvent and caprolactam must exceed 0.2 kg/l)
5. Solvent solubility in water (the solvent must be immiscible or only partially miscible with water)
6. Solvent boiling point (a boiling point between 50°C and 100°C is required) and recyclability
7. Flammability (the caprolactam plant is designed to operate with non-flammable extraction solvent)
8. Compatibility with existing process requirements (a solvent that would not require major plant modification, no specific threshold)
9. Feedstock requirements
10. By-product(s) of caprolactam manufacture
11. Process energy consumption

1.3. Type/s of product/s made with Annex XIV substance and market sector(s) likely to be affected by the authorisation

TCE is used as an extraction solvent in the industrial manufacture of caprolactam from cyclohexanone. Ammonium sulphate is a by-product of the process and is commercialised by the authorisation holder as a fertiliser. The production is also technologically linked with the manufacture of sulphuric acid and the subsequent generation of oleum.

Caprolactam is used as a precursor in the manufacture of polyamide 6 (nylon 6). End-use applications for nylon 6 include fibres and engineering resins. Nylon fibres are used in clothing, carpets, tyre cord, and others, while engineering resins can be found in automotive and appliance components, electrical power distribution, and a wide variety of consumer goods and packaging film.

1.4. For upstream applications: Downstream User survey

Not applicable.

2. Operational Conditions and Risk Management Measures are appropriate[3] and effective[4] in limiting the risk?

Workers ☒Yes ☐No

Environment/Humans via Environment ☒Yes ☐No Workers

2.1. Workers

The production process is fully automated. The following RMMs have been identified by the authorisation holder:

Technical Risk Management Measures:

- Closed process
- Equipment separation (blind flanges)
- Closed sampling

Organisational Risk Management Measures:

- Weekly checks of the equipment tightness by portable photoionization detectors (PID)
- Yearly OSH training of all employees (e.g. operators, unloading operators, maintenance workers and lab staff) including trainings on the use of PPE and fit testing of RPE
- Maintenance work procedures (e.g. permit procedure, cleaning procedure and responsibilities for decisions on maintenance work)

Personal protective equipment (PPE):

- Operators and maintenance workers have to use full masks in case of any expected exposure to TCE
- Use of gloves

The authorisation holder stated that Spolana is certificated according to ČSN EN ISO 9001:2009, ČSN EN ISO 14001:2005, ČSN OHSAS 18001:2008 and ČSN EN ISO 50001:2011 and that the company has the right to use the RESPONSIBLE CARE logo.

Since the granting of the authorisation for the use of TCE, Spolana has implemented a series of improvements in technology in order to minimise emissions from the process and reduce worker exposure. These improvements include: recommission of the central exhaustion of the working space into the absorption column C14, installation of siphons on the output of TCE from extractors and vacuum pumps, installation of closed sampling systems, implementation of glandless pumps to further increase the tightness of the installation, stripping of TCE from aqueous raffinate prior to discharge to process wastewaters, etc. In addition, new improvements are planned for 2019. According to information provided in the CSR, the authorisation holder plans to optimise the TCE unloading station with the installation of new seals and fittings (Gore seals and Klinger fittings) to improve the containment and with the addition of a vapour recovery system.

According to information provided by the authorisation holder to RAC, the annual consumption

[3] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls and compliance with the relevant legislation.
[4] 'Effectiveness' – evaluation of the degree to which the RMM is successful in producing the desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

of TCE per tonne of caprolactam manufactured has been reduced by more than 12% in 2018 compared to 2017. There is no specific information on the effectiveness of the technical RMMs in place but, according to the authorisation holder, a reduction of (fugitive) emissions of about 17 tonnes of TCE due to the improvements of the equipment and organisation measures introduced in the last years is expected. In the authorisation holder´s view, the yearly consumption of TCE will decrease further (to about 85 tonnes/year) in spite of an increase in caprolactam production.

Table 2: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs)

Contri-buting scenario	**Concen-tration of the sub-stance**	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV)**+ effectiveness as stated by the authorisation holder**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the authorisation holder**	**Organisational controls** (access control, procedures, training)
WCS2 / PROC 2 Indoor, Operating temperature 40° C	100 %	Duration: 12 h/day; Frequency: continuous process	- Closed continuous process with occasional controlled exposure; - Closed sampling; - Basic general ventilation (1-3 air changes/hour);	Gloves (95% effectiveness)* RPE (90% effectiveness)*	- Advanced occupational Health and Safety Management System;
WCS3 / PROC 8b Outdoor	100 %	Duration: 300 min/day; Frequency: 2 x/year;	- Closed sampling; - Dedicated unloading station;	Gloves (95% effectiveness RPE (90% effectiveness)	- Trained and authorised personnel
WCS4*** /PROC 28 Indoor or outdoor	100 %	Duration: 12 h/day (2-shifts (11 persons), 12 h (daily work, 14 persons); Frequency: every day*;	- Permit procedure; - Flushing with water under pressure prior to any equipment dismantling and line opening; -PID monitoring after cleaning to define whether RPE is required; - good general ventilation;	Gloves (95% effectiveness) RPE (90% effectiveness)**	- Trained and authorised personnel;
WCS5 / PROC 15 Indoor, Operating temperature ;40° C	100 %	Duration: 12 h/day – 2 shifts (10 persons), 12 h (daily work, 2 persons), 8 h daily work 2); Frequency: every day	- Local exhaust ventilation (90% effectiveness) - Basic general ventilation (1-3 air changes/hour);	Gloves (95% effectiveness)	- Advanced occupational Health and Safety Management System;

WCS6 / N / A Indoor, Operating temperature 40° C	0.001% (TCE concentration in STP influent)	Duration: 8 h/day; Frequency: every day;	---	---	- Advanced occupational Health and Safety Management System;
WCS7 / PROC 8b Outdoor	Up to 5.0%	Duration: 1.5 h/day; Frequency: 2 x/year at max.;		Gloves (95% effectiveness)	- Specific training to handle waste – performed by an external waste operator;

* The use of PPE/RPE is defined for specific tasks (e.g. return of samples from the quality control lab).

** RPE has to be used if PID measurements indicate high exposure potential (> OEL).

*** Maintenance and/or cleaning tasks are performed every day but there is not always exposure to TCE, according to the authorisation holder. The maintenance workers are employed by different companies and are assigned to three different departments, reflecting different maintenance work (e.g. machinery maintenance, electrical maintenance, measurements and control).

2.2. Environment / Humans via Environment

Technical measures in place for control of emissions to:

Air:

In addition to the described closed system (see section 2.1. “workers”), continuous measurements of TCE in the ventilation system are performed with registration of measured values in a Distributed Control System (DCS) in order to detect potential TCE leakages in case of equipment failure.

According to the authorisation holder, the outlet of absorption column C14 receiving input from vacuum pumps is the only outlet from the closed TCE cycle of the caprolactam unit. In order to reduce emissions to air via this outlet, relevant equipment is being improved; for example two older vacuum pumps have been replaced in November 2017 and a new absorption column C14 has been installed in 2018. Emissions from this outlet are subject to regular monitoring under the IPPC Directive.

Water:

Almost all TCE is removed from the aqueous raffinates by stream stripping before any discharge to process wastewater. The stripping of TCE from the lyes before evaporation was recently renewed resulting in a reduction in TCE loss from 4 tonnes/year to 0.4 tonnes/year, according to information in the CSR (p. 30).

Wastewaters are treated in a biological STP before being discharged into the river Elbe. Before entering the STP, the process wastewater from the caprolactam unit is diluted with other wastewater streams. Between STP effluent and the discharge of the effluent into the river Elbe, the wastewater resides in a sedimentation pond.

Soil:

The TCE concentrations in sludge are well below 0.1% (at maximum 0.0000586%, according to measurement data provided by the authorisation holder). Therefore, the sludge from the STP is considered to be essentially free of TCE. It is mixed with ashes from the power plant

and used for recultivation of Spolana´s landfill. Spolana is certified for this activity by the Ministry of Environment of the Czech Republic.

Waste:

Liquid waste (distillation residues) is collected by an external company certified to collect hazardous waste and is incinerated by an authorised company according to national legislation.

2.3. Discussion on OCs and RMMs in place and relevant uncertainties

From 2015 on, continuous improvements on technical and organisational RMMs have been implemented (e.g. technical equipment modification (e.g. new absorption column, replacement of old vacuum pumps, closed sampling systems), reduction of number of samples, discontinuation of production lab analyses by operators and transfer to the quality control department). In the implementation of RMMs, the authorisation holder follows the hierarchy of control principles.

The already implemented measures and the one(s) planned for 2019 are listed in the CSR (p. 29-32, Table 5).

Since TCE is used in a closed and fully automated process, control and maintenance of the technical equipment is crucial. According to information in the CSR, monitoring of the system is installed (e.g. continuous measurement of TCE in the ventilation system which enables signalling of increased TCE concentration on the control panel; weekly checking of equipment tightness by portable photoionization detector) and maintenance is performed regularly.

The technical RMMs are supplemented by organisational RMMs (e.g. regular OSH training; permit procedure for maintenance activities). In addition, RAC notes that there is an obligation to use personal protective equipment (PPE/RPE) in case of any exposure potential to TCE for the dermal/inhalation route.

According to the authorisation holder, the implemented RMMs and OCs have resulted in a significant reduction of exposure to workers and a reduction of fugitive emissions, based on combined monitoring data from 2017 and 2018. However, RAC points out that the last monitoring data in 2018 show an increase in worker exposure (see discussion in section 3.1) that introduces an uncertainty regarding the effectiveness of the RMMs recently implemented (i.e. closed sampling). It is understood that the next monitoring campaign in 2019 will provide further data regarding the effectiveness of the RMMs including the implementation of closed sampling.

The installation of the closed sampling system and the exchange of flanges and pump seals took place during full operation of caprolactam production in March 2018 (p. 64, CSR) might have resulted in rather high emissions and the exposure for workers might also have been increased during the installation of new equipment. Therefore the realisation of the installation of new equipment cannot be evaluated by RAC as an example for good practise with regard to minimisation of exposure.

In addition RAC notes that fugitive emissions are estimated to have been reduced by 17 tonnes due to the improvements in the RMMs and OCs introduced by the authorisation holder. RAC considers that further reductions should be expected as a result of the implementation of RMMs already planned for 2019 (improvement of the TCE unloading station) and of further optimisation of RMMs and OCs to minimise TCE emissions from the caprolactam plant.

2.4. Conclusions on OCs and RMMs

The application holder addressed the uncertainties identified by RAC in the original application for authorisation and provided detailed information on the OCs and RMMs in place. RAC acknowledges that the application holder has improved the RMMs according to the hierarchy of control.

Conclusion for workers:

The application holder has made significant efforts to reduce emissions in the work area and consequently to reduce exposure to workers (e.g. installation of closed sampling system, improvements in containment). RAC considers that the application holder should continue the improvement of the RMMs and OCs in place in order to further minimise exposure to workers, particularly with regard to fugitive emissions of TCE. This should include the improvement of the TCE unloading station as described in the review report, and the review of the working practices for the installation of new equipment.

Conclusion for environment / HvE:

The application holder has made significant efforts to minimise emissions to the environment (e.g. recommission of central exhaustion of the working space into a gas absorption column, stripping of TCE prior discharge to process water). RAC considers that the application holder should continue the improvement of the RMMs and OCs in place in order to further minimise emissions and consequently exposure to humans (via the environment) particularly with regard to fugitive emissions of TCE.

Overall conclusion: RAC acknowledges the efforts made regarding the implementation of RMMs to reduce exposure for workers and for humans via the environment. The RMMs described are considered to be appropriate and effective in limiting the risk. However, the authorisation holder should continue this process of improvement of their RMMs and OCs to further reduce TCE emissions based on measurement results of releases to air and wastewater and regular air and biomonitoring campaigns. This should include the improvement of the TCE unloading station as described in the review report, and a review of the working practices for the installation of new equipment.

Any uncertainties with regard to the OCs and RMMs identified by RAC were of relatively low/minor concern.

3. Exposure assessment

3.1. Inhalation exposure

Monitoring (air monitoring and biomonitoring):

Four personal air monitoring campaigns (comprising 281 measurements, LoD: 0.1 mg/m^3) and four biomonitoring campaigns measuring TCA (trichloroacetic acid)/L urine (comprising 256 valid[5] measurements, LoD: 0.1 mg TCA/L urine, corresponding to an TCE air concentration of 0.275 mg/m^3) were conducted between October 2016 and March 2018.

The authorisation holder decided to base the inhalation exposure assessment for WCS 2 on the biomonitoring data for the operators from 2017 and 2018 and to use aggregated data

[5] Samples showing creatinine concentrations below 0.3 g/L urine were excluded from the evaluation, since they may underestimate exposure.

(biomonitoring and air monitoring data) for the technologists because they do not wear (in contrast to the operators) any RPE in general. The exposure assessment for WCS 5 is for the same reason (no use of RPE) based on aggregated data of three air monitoring and biomonitoring campaigns.

The exposure assessment for WCS 3, covering the transfer of TCE from a railway tank car at a dedicated unloading station at the Spolana site by two (not otherwise TCE exposed) unloading operators is based on the maximum biomonitoring value out of three monitoring campaigns due to the low number of measured data available. Modelled data are also provided for this WCS (see section below)

Maintenance workers (WCS 4) were monitored (air measurements and biomonitoring) during ad-hoc cleaning maintenance activities in three campaigns in 2017 and 2018 and during the annual maintenance activities in August 2017. Since the dataset of ad-hoc and annual maintenance tasks do not show relevant differences, the authorisation holder combined the monitoring results for ad-hoc maintenance and annual maintenance in the exposure assessment and aggregated the results (90^{th} percentile) from biomonitoring and air monitoring. According to the authorisation holder, this might be the most appropriate approach since maintenance workers do wear RPE only in case of demonstrated exposure above the national OEL.

For WCS 6, the results of the air monitoring as well as the biomonitoring campaigns in 2017 and 2018 were below the respective LoD (air monitoring: 0.1 mg/m^3; biomonitoring: LoD: 0.1 mg TCA/L urine). Due to the lower LoD for the air monitoring method compared to biomonitoring, the authorisation holder used the air monitoring data for the exposure assessment.

Since only two air concentration measurements (January 2018) were available for WCS 7 (one for the external waste operator and one for the Spolana operator), the authorisation holder used modelled data for the exposure assessment (see Table 4 below). It is to be noted that this task takes place only once or twice per year.

Air monitoring was performed according to ČSN EN 482 by the air analysis laboratory of Spolana, which is certified by the National Institute of Public Health in Prague. Biomonitoring was performed by an external medical service provider and the samples analysed by an external accredited laboratory according to NIOSH Method: 8322, Issue 1.

For the monitoring (air measurements and biomonitoring), the following statistics are presented in the CSR: arithmetic mean, median, 90^{th} percentile and maximum values. Sampling results below the LoD were taken forward for the exposure assessment as half of the LoD.

Workplace air monitoring was based on personal sampling while measurements of releases to air were performed with stationary sampling.

Modelling:

For those WCSs covering infrequent tasks (WCS 3 and WCS 7), the authorisation holder provided modelled data using Advanced REACH Tool (ART v. 1.5; 90^{th} percentile) for inhalation exposure since the number of monitoring data available is small. The input data are provided in the CSR. The aim of the modelling was either to underpin the outcome of the monitoring data (WCS 3) or to use the modelled data as basis for the exposure assessment (WCS 7).

3.2. Dermal exposure

Modelling:

For dermal exposure calculation RISKOFDERM (90th percentile) was used. The authorisation holder acknowledges the conservativeness of the model when estimating exposure for substances of high volatility like TCE since the model was developed for substances and situations with significant dermal exposure.

In addition, the authorisation holder considered the potential of dermal exposure (see CSR, p. 106-111) using two types of modelling (model 1: calculation of the evaporation time and model 2: calculation of the fractions evaporated and absorbed). Based on the modelling results, the authorisation holder concludes that TCE evaporates rapidly from the gloves and absorption through the skin is minimal (0.01%), even if no gloves would be used.

Monitoring:

Monitoring data for dermal exposure as such are not available. However, biomonitoring data cover not only the TCE uptake by inhalation but also by the dermal route.

Table 4: Exposure – dermal and inhalation

Contributing Scenario	Method of assessment	Exposure value, 8 h TWA	Frequency factor*	Exposure value corrected for frequency
WCS 2 (PROC 1)	Biomonitoring data [1] (N=58 for operators) Aggregated data (N=22) on air monitoring (N=12) and biomonitoring (N=10) for technologists	2.84 mg/m^3 (90th percentile) 1.48 mg/m^3* (90th percentile)	---	**2.84 mg/m^3** **1.48 mg/m^3**
WCS 3 (PROC 8b)	Biomonitoring[1] (N=4)	3.1 mg/m^3 (Max.)	0.00278**	**0.00861 mg/m^3**
WCS 4 (PROC 28)	Aggregated data (N=141) on air monitoring (N=73) and biomonitoring[1] (N=68) for maintenance workers (annual (N=29) and ad-hoc (N=112) maintenance)	3.18 mg/m^3 (90th percentile)	---	**3.18 mg/m^3**

WCS 5 (PROC 15)	Aggregated data (N=91) on air monitoring (N=46) and biomonitoring[1] (N=45)	1.06 mg/m^3 (90th percentile)	---	**1.06 mg/m^3**
WCS 6	Air monitoring (N=44)	0.05 mg/m^3 (=1/2 LoD) since all measured data were < LoD	---	**0.05 mg/m^3**
WCS 7 (PROC 8b)	Modelled data (ART v. 1.5) for inhalation route	0.2 mg/m^3 (90th percentile)	0.00208for WCS 2 operator*** 0.00833 for external waste operator***	**0.000417 mg/m^3** **0.00167 mg/m^3**
	Modelled data (Riskofderm)	10.4 µg/kg/day (value already corrected for PPE)	0.00833 for external waste operator since WCS 2 operator do not have any dermal contact (due to supervising tasks only)	**0.0866 µg/kg/day**

[1] Measured TCA concentrations in urine are converted in TCE concentration in air by using the correlation described by Drexler and Harwig , 2011.[6]

* Calculated with Analyse-it software. Using MS Excel® the value obtained would be 1.56 mg/m^3. According to authorisation holder, 90th percentile values calculated in MS Excel® are not adequate due to the small sample sizes.

** There are six unloading operators, but only two perform the unloading. Each of the six worker only takes part in every third event since two events occur/year. The frequency correction factor is therefore: 2/240 x 2/6 = 0.00278.

*** The frequency correction factor for the external waste operator is 2/240 = 0.00833. The frequency correction factor for any of the four WCS 2 operators is 2/240 x 1/4 = 0.00208.

There was no need to correct the provided data for RPE/gloves since the use of PPE was either already considered (e.g. biomonitoring data, modelling) or no PPE has to be by the workers.

RAC notes that dermal modelling is only provided for WCS 7 since for all other WCS biomonitoring data are available which would also include any dermal uptake.

3.3. Environmental emissions

Release factors to the environment were calculated based on measured data for the release of TCE to air and water. The exposure assessment for human via the environment at local scale was based on air monitoring data from eight stationary sampling locations situated approximately 100 m from the main point sources (inhalation exposure) and EUSES modelling (oral exposure) (version 2.1.2). The exposure assessment at regional scale was based on EUSES modelling (version 2.1.2). Relevant physico-chemical data (reported in CSR, p. 33) for modelling were taken from the literature (ECB, European Chemicals Bureau, 2004) while

[6] Biologische Arbeitsstoff-Toleranz-Werte (BAT-Werte), Expositionsäquivalente für krebserzeugende Arbeitsstoffe (EKA), Biologische Leitwerte (BLW) und Biologische Arbeitsstoff-Referenzwerte (BAR). Arbeitsmedizinisch-toxikologische Begründungen.

environmental fate parameters (e.g. partition coefficient and bioaccumulation factors) were taken from EUSES.

Water:

According to the CSR (p. 35), TCE releases from the process were monitored in wastewater at four locations e.g. at the entry point of the process wastewater from the caprolactam unit into the canal K 4-4/3 after steam stripping (24 h composite sample - daily); prior to entry into the STP after dilution with other wastewater streams (24 h composite sample - weekly; in the STP effluent (24 h composite sample – weekly) and in the effluent prior to discharge (24 h composite sample – 2-3 times per week) until discharge into the river Elbe.

However, for the calculation of the TCE releases to wastewater, the arithmetic mean of the TCE concentrations measured at the only release from the caprolactam unit (K 4-4/3) and the arithmetic mean of measured flow rates were used (covering the years 2011 up to 2017; n=2 346) since there was no clear time trend on TCE release reduction in the last years. These samples are mixed samples over 24 hours, therefore the dataset can be considered as representative. Minor discharges from the quality control lab into the STP through a separate sewer pipe are of about 0.013 kg/day. They are considered to be included in the calculated rounded release rate of 3.0 kg/day by the authorisation holder as in the last three years the maximum calculated release rate was 2.953 kg/day.

The release rate of TCE to water can be considered as worst case since neither the effectiveness of the STP was taken into account nor was it considered that TCE concentrations already decrease prior to the STP due to dilution of the wastewater stream with other wastewater streams (flow rates are not known) and due to volatilisation of TCE (which is covered by monitoring data of STP workers and stationary monitoring data) since the wastewater stream containing TCE is led to the STP via an open canal.

The dilution factor of the effluent to the river Elbe is based on the arithmetic mean of the calculated discharge rates from the site from 2011-2017 and on the low flow conditions of the river according to information of the Czech Hydrometerological Institute.

Drinking water from Spolana´s canteen and from to houses using their own wells were analysed by Spolana´s lab (LoD 2 µg/L).

The concentration of TCE to groundwater are available from six measurements (2015-2017) under EU Water Framework Directive by an accredited laboratory. The TCE concentration in these samples were all below at or below 0.1 µg/L.

Air:

The release factor to air is calculated using the arithmetic mean of TCE emissions to air (1.37 kg/day) based on annual measurements of TCE concentrations at the only outlet including the years 2013 up to 2017, since according to the authorisation holder no clear time trend in emission reduction was obvious. Each of these measurements is comprised of three samples. Only in 2016 two measurement campaigns were performed, in June (prior to the annual plant shut-down) and in November, resulting in six samples.

The results of the measurements are not provided. However, according to the authorisation holder, the corresponding release estimates were calculated from the arithmetic mean of the measured concentrations multiplied by the corresponding maximum measured gas volume (flow) and the release duration (24 h/day).

Monitoring of STP workers and stationary monitoring conducted around the STP in May 2017 and March 2018, about 460 m from the caprolactam unit, cover potential exposure resulting from volatilisation from wastewater according the authorisation holder. However, these data

were not used for the exposure assessment.

Fugitive emissions were measured in four stationary sampling campaigns (November 2016, May 2017, November 2017, June 2018) at eight sample locations located 100 m from either the caprolactam unit (four sites) or the STP (four sites), and at four further locations distributed around the Spolana site (at distances of 1.6 km and 2.5 km from the caprolactam unit and 1.7 and 2.4 km from STP) between 2014 and 2018. The sampling was in general performed for 24 hours (LoD 0.71-0.86 µg/m^3, Mean LoD: 0.78 µg/m^3) but in May 2017, sampling duration was six hours resulting in an LoD of 6 µg/m^3.

All of the 23 measurements at a distance of more than 1.6 km from the caprolactom unit were below the LoD, except one value of 2.88 µg/m^3 in Neratovice in 2016. No reason could be identified for that concentration but it may result from sources other than the Spolana site, according to the authorisation holder. While, in general, these measurements support the modelled value for regional scale (0.00325 µg/m^3) around the point source with a radius of 113 km, the measurement results from sample locations at distances of 100 m around the caprolactam unit are at least one order of magnitude higher (AM: 25.6 µg/m^3 (2016), 6.95 µg/m^3 (May 2017), 7.26 µg/m^3 (June 2018)) than the calculated TCE concentration in air predicted by EUSES (0.732 µg/m^3). Therefore, the authorisation holder proposes the arithmetic mean of the 2017-2018 monitoring data from the eight sample locations around the caprolactam unit and the STP (4.96 µg/m^3) for the PEC_{local} for local scale exposure assessment. Measurement results from November 2017 are not considered as there was an unplanned shut-down in this period.

Soil:

Based on three analyses campaigns (October 2016, November 2016 and February 2018), it could be shown that TCE is not absorbed by sludge. In any case, sludge from the STP is not applied to soil.

Table 5: Summary of environmental emissions

Release route	Release factor	Local release rate	Release estimation method and details
Water	1.095% (before on site RMMs)*	3 kg/day	The release factor was calculated based on measured data of TCE concentrations and the mean flow volume at the only point of direct process emissions release from the plant to the wastewater.
Air	0.5% (after on site RMMs)	1.37 kg/day	The release factor was calculated based on measured data of TCE concentrations and the flow volume at the only point of direct process emissions of TCE to the air.
Soil	0	0	The STP sludge is not applied to soil.
Waste	0	0	The waste is incinerated.

*Standard effectiveness of biological STP: 89.6%

Table 6: Summary of indirect exposure to humans via the environment

Parameter	Local	Regional
PEC in air	4.96 µg/m^3 (stationary measurements ~100m from STP or caprolactam plant)	0.00325 µg/m^3 (EUSES 2.1.2)
PEC in surface water	n.a.	n.a.
Daily dose via oral route	0.0540 µg/kg bw/d (EUSES 2.1.2)	0.000080 µg/kg bw/d (EUSES 2.1.2)

3.4. Discussion of the information provided and uncertainties related to exposure assessment

Worker exposure

The exposure assessment for inhalation and dermal exposure provided in the CSR, is mainly based on biomonitoring data, supported by the results of air monitoring campaigns and modelled data for infrequent tasks. Only for WCS 7, modelled data were used for the exposure assessment.

RAC agrees with the authorisation holder that the exposure evaluation can be considered as robust.

RAC notes the general decline in TCE exposure for workers in WCS 2 (except in March 2018, where according to the authorisation holder, the closed sampling equipment was installed during full operation at the same time as the March monitoring campaign was performed). Since the data of March 2018 were included in the exposure assessment, RAC is of the opinion that the uncertainties related to the higher exposure values are considered in the assessment. However, it remains unclear to RAC whether the higher exposure levels obtained in the March 2018 biomonitoring campaign relates to the installation work of new equipment.

RAC also accepts the approach taken by the authorisation holder to assess exposure for WCS 7 based on modelled data.

In addition it is noted that the authorisation holder discussed all monitoring data in detail in the CSR.

Summing up, according to RAC, there are no significant uncertainties in the worker exposure assessment.

Humans via the environment

The assessment of human exposure via the environment at local scale is based on air monitoring data (inhalation route) and EUSES modelling (oral route). Measurements were performed at approximately 100 m of the caprolactam unit and 100 m of the STP. The air monitoring data are combined and used to estimate indirect exposure to TCE for workers on the site (not involved in the caprolactam unit) and for the local population (living within the radius of 1 km).

On the other hand the authorisation holder uses EUSES for the assessment of humans exposure via the environment at regional scale (both for inhalation and oral exposure). The results of ambient monitoring at four locations around the Spolana sites are used to validate the EUSES exposure data.

RAC supports the authorisation holder´s method. Although no measurement reports are available, RAC considers the dataset as reliable and notes that the sampling and analyses were performed by accredited external laboratories.

Samples below the limit LoD were evaluated as ½ of the LoD. In principle, this approach is acceptable. However, RAC points out that the LoD for air emissions in the measurement campaign in May 2017 was relatively high, so the data might result in an underestimation of the air emissions. In addition, it is not completely clear to RAC to what extent the measured TCE concentration in Neratovice is caused by Spolana. Summing up, there are some minor uncertainties related to exposure emissions to air.

The authorisation holder is aware of uncertainties related to the air release emissions and discussed them in detail in the CSR (p. 54 and 56) but stressed that the fugitive emissions show a clear decline and are very likely the result of the improvements implemented. RAC acknowledges the improvements implemented by the authorisation holder and considers that further improvements to minimise exposure, particularly due to fugitive emissions, may be achieved by the authorisation holder.

3.5. Conclusions on exposure assessment

RAC considers that the exposure assessment of workers is reliable and representative in relation to the tasks and number of workers. The measured and estimated exposure levels are reliable and do not raise significant uncertainties.

The exposure assessment for humans via the environment is reliable and representative. The measured and estimated exposure levels are reliable and do not raise significant uncertainties.

4. Risk characterisation

4.1. Workers

Table 7: Combined exposure and risk characterisation

Group of workers	WCSs	No of workers	Exposure route	Exposure	Excess risk	Combined excess risk*
Operators	WCS 2	25	Inhalation & dermal	2.84 mg/m^3	3.41 x 10^{-5}	3.41 x 10^{-5}
	WCS 7			0.000417 mg/m^3	5.00 x 10^{-9}	
Technologists	WCS 2	6	Inhalation & dermal	1.48 mg/m^3	1.78 x 10^{-5}	1.78 x 10^{-5}
Unloading operators	WCS 3	6	Inhalation & dermal	0.00861 mg/m^3	1.03 x 10^{-7}	1.03 x 10^{-7}
Maintenance staff	WCS 4	25	Inhalation & dermal	3.18 mg/m^3	3.82 x 10^{-5}	3.82 x 10^{-5}
Lab staff	WCS 5	16	Inhalation & dermal	1.06 mg/m^3	1.27 x 10^{-5}	1.27 x 10^{-5}

STP workers	WCS 6	21	Inhalation No dermal exposure	0.050 mg/m^3	6.00 x 10^{-7}	6.00 x 10^{-7}
External waste operators	WCS 7	1	Inhalation	0.00167 mg/m^3	2.00 x 10^{-8}	2.73 x 10^{-8}
			Dermal	0.0866 µg/kg/day	7.27 x 10^{-9}	

* The combined excess risk presents the risk from both exposure routes as well as from all tasks related to a WCS.

RAC supports the authorisation holder's view that the risk characterisation is reliable and representative. The authorisation holder used the 90th percentile value for exposure assessment. In general the 90th percentile value represents the reasonable worst case exposure level of a distribution within a generally suitable dataset (according to Guidance on Information Requirements and Chemical Safety Assessment, Part R. 14: Occupational exposure assessment, Version 3.0, August 2016).

Summing up, RAC has not identified any noteable uncertainties resulting from the information provided by the authorisation holder and used for exposure and risk assessment.

4.2. Environment and/or Humans via Environment

The authorisation holder presented the risks for human via the environment for the local and the regional scale. As previously discussed, the authorisation holders has estimated the risk to workers indirectly exposed in a similar way to the local population. Although some overestimation of risks may result as consequence of the approach taken by the authorisation holder (since the assessment of humans via the environment takes into account oral exposure which is not considered a relevant route of exposure for workers) RAC considers that the approach does not significantly impact the assessment.

Table 8: Exposure and risk to humans via the environment – local and regional scale

	Workers indirectly exposed		**Local population**		**Regional population**	
	Exposure	**Excess risk**	**Exposure**	**Excess risk**	**Exposure**	**Excess risk**
Human via Environment – Inhalation	4.96 µg/m^3	5.96 x 10^{-8}	4.96 µg/m^3	3.18 x 10^{-7}	0.00325 µg/m^3	2.08 x 10^{-10}
Human via Environment – Oral	0.0540 µg/kg bw/day	2.34 x 10^{-8}	0.0540 µg/kg bw/day	2.34 x 10^{-8}	0.0000800 µg/kg bw/day	3.46 x 10^{-11}
Human via Environment - Combined		8.29 x 10^{-8}		3.41 x 10^{-7}		2.43 x 10^{-10}

4.3. Uncertainties

The uncertainties affecting the risk characterisation seem to be minor and related mainly to the minor uncertainties identified in the exposure assessment.

4.4. Conclusions on risk characterisation

RAC is of the opinion that the application includes all relevant tasks and routes of exposure as well as endpoints and populations.

There are no significant uncertainties related to the characterisation of risks.

5. Evaluation of the suitability and availability of alternatives

The review period of Spolana's authorisation expires on 21 April 2020 but the authorisation holder wishes to continue using TCE beyond this date while carrying out research towards the identification of a feasible alternative.

The authorisation holder has made significant changes and improvements in its analysis of alternatives (AoA) in the review report, compared to the original AoA. Changes include:

(1) updating and enhancing the description of the Spolana's use of TCE and the technical parameters of the caprolactam manufacturing process which affect Spolana's ability to identify and implement suitable alternatives;

(2) undertaking a more extensive screening and analysis of potential alternatives;

(3) providing a detailed account of R&D undertaken after the original application's AoA in 2015 as part of new R&D collaborations which Spolana has established with R&D partners in order to develop a technically feasible and economically affordable alternative to the use of TCE-based extraction. Four specific projects and additional other collaborations have been included in an R&D substitution strategy, with one of the projects expected to run over the review period argued for (depending on the R&D results) up to the end of the lifetime of the authorisation holder's current caprolactam plant (the plant is expected to be operational until at least 2035).

5.1. Summary of the Analysis of Alternatives by the applicant/s and of the comments received during the public consultation

The authorisation holder has conducted an extensive review of existing literature on potential alternative substances (58 substances), mixtures (25 combinations), extraction technologies (4 possibilities) and synthetic routes to produce caprolactam (12 technologies). Among the potential alternative substances are aromatic hydrocarbons, aromatic nitro-compounds, chlorinated hydrocarbons, alkanes (alicyclic and aliphatic hydrocarbons), alcohols, esters, ethers, ketones, alkyl phenols, aliphatic diols and alkyl hydrogen phosphates. The combinations of substances which are considered for the replacement of TCE in caprolactam extraction are typically mixtures of alcohols and alkanes (e.g. a heptanol-heptane or a 1-octanol-cyclohexane mixture). The different synthetic routes comprise four alternative synthetic routes that do not require cyclohexanone oxime as an intermediate, five routes that still use cyclohexanone oxime as an intermediate but use a different oximation reaction, one manufacturing process which uses a different oximation reaction and introduces changes to the traditional Beckmann rearrangement, and two manufacturing processes starting from non-aromatic feedstocks such as butadiene or adiponitrile. Desk- and laboratory-based investigations with the aim of developing new alternatives have been undertaken by the authorisation holder's R&D partners, some of whose names and results are claimed confidential (see section 5.5 for more information).

It should be noted that the authorisation holder's production of caprolactam is technologically linked with the generation of the by-product ammonium sulphate and the manufacture of sulphuric acid. These two products play an important role in the economics of the operations of the authorisation holder and the technical feasibility criteria also reflect these products. If caprolactam production would cease at the authorisation holder's site, the production of ammonium sulphate and sulphuric acid would also be discontinued.

The authorisation holder also provides information on the processes and extraction solvents used by its EU-based competitors. This overview shows that toluene is a commonly used extraction solvent of the caprolactam process. While the authorisation holder does not have access to information about the processes of all competitors, it states that benzene is likely to be used in the EU as well. According to the authorisation holder, only benzene and toluene would be technically implementable alternatives at the end of the initial review period as they are the only commercially proven alternative extraction solvents. However, both of them would require the construction of a replacement plant able to accommodate the physicochemical properties of these alternative solvents and the quality of the by-products might be inferior.

Public consultation comments

One submission was received during the public consultation from a non-profit organisation. The comments in this submission were generally related to the alternatives for the authorisation holder's use of TCE as well as the possible alternatives to caprolactam, and to the end-product nylon-6. The comments highlighted that alternatives to TCE are used by competitors of the authorisation holder and on that basis questioned the authorisation holder's conclusion that none of the alternatives are feasible.

The authorisation holder provided detailed answers regarding why neither toluene nor benzene are suitable for them and noted that extensive arguments had already been provided in the review report. The authorisation holder also clarified that caprolactam is essentially used by his customers to manufacture polycaprolactam (also known as polyamide-6 or nylon 6). SEAC concurs that there is no alternative other than caprolactam to produce nylon-6. While additional discussion was held during the trialogue, it did not bring up any new significant and/or valuable information.

5.2. Short-listed alternatives and past substitution R&D efforts

In the original application for authorisation alternatives were mainly identified based on a literature search and the AoA was deficient in that neither benzene nor toluene was shortlisted in the detailed analysis of alternatives. The AoA in the review report has been based on a more extensive search for alternatives and on ongoing R&D programmes presented in detail in section 5.5. According to the authorisation holder itself, it finances the "most comprehensive" research on alternatives for TCE undertaken in recent years.

In total, the authorisation holder has established eleven technical feasibility criteria based on the parameters of the use of TCE at the authorisation holder's plant and through analysis of literature related mainly to the extraction. Where relevant, acceptability threshold values and tolerance ranges are given for each of the above. The criteria can be divided into two sub-sets of criteria:

a) Feasibility criteria (numbered from 1 to 8 in the Report) which assess Spolana's ability to continue its efficient production of caprolactam, without any major modifications to the production plant, process or equipment:

1. Solvent extraction efficiency (90-95%)
2. Solvent loading capacity for caprolactam (solvent loading capacity for caprolactam should be about 20% at 20°C)
3. Solvent viscosity (the value of viscosity needs not to exceed that of TCE, which stands at 0.55 mPa.s at 30°C in order to avoid pressure loss in pipes)
4. Solvent density (the density difference between the solvent and caprolactam must exceed 0.2 kg/l)
5. Solvent solubility in water (the solvent must be immiscible or only partially miscible with water)
6. Solvent boiling point (a boiling point between 50°C and 100°C is required) and recyclability
7. Flammability (the caprolactam plant is designed to operate with non-flammable extraction solvent)
8. Compatibility with existing process requirements (a solvent that would not require major plant modification, no specific threshold)

b) Feasibility criteria (numbered from 9 to 11 in the Report) which, whilst relevant to technical or technological aspects of Spolana's manufacturing process and unit, mostly have a profound influence on the economics of production.

9. Feedstock requirements
10. By-product(s) of caprolactam manufacture
11. Process energy consumption

Based on the R&D efforts, literature searches, consideration of market conditions and business requirements, the authorisation holder presents ten theoretical alternatives which are described in detail. These include both technical (solvents, solvent mixtures, processes) and managerial (relocation, change of business model, different shutdown options) alternatives (these managerial alternatives are discussed further in section 6.2).

A total of 58 individual potential alternative extraction solvents (Alternative 1 in the Report) are identified. The alternative extraction solvents that are closest to meeting the criteria include four chlorinated hydrocarbons (carbon tetrachloride, chloroform, 1,1,1-trichloroethane and dichloromethane) whose basic physicochemical properties are most closely compatible with Spolana's caprolactam plant, as well as the aromatic solvents benzene and toluene, which would require a more complex technical implementation in the Neratovice plant but have the advantage of being commercially proven. Internal research and scientific literature on the distribution of caprolactam between organic solvents and water and the selectivity of a range of potential extraction solvents have shown that the four chlorinated hydrocarbons cannot be considered feasible alternatives. Carbon tetrachloride is discarded because of its high viscosity; chloroform because of too high water solubility; 1,1,1-trichloroethane because of too high water solubility and viscosity; while dichloromethane has high water solubility and a too low boiling point. Thus the authorisation holder concludes that the only realistic alternative extraction solvent would be benzene or toluene.

Alternative solvent mixtures, extraction technologies and plant conversion to an alternative caprolactam manufacturing technology (Alternatives 2—4) are also assessed in detail but concluded to be unsuitable. The mixture of 1-octanol/cyclohexane is the most promising alternative solvent mixture and subject to ongoing R&D but it is discarded due to its

physicochemical properties which are incompatible with the current plant, flammability and the fact that it is not proven on a commercial scale. Some non-classic solvents (e.g. based on ionic liquids) analysed as part of theoretical alternative extraction technologies (alternative 3) for the extraction of caprolactam have been presented and discarded due to the lack of commercial applications on the industrial scale and because they would require substantial changes to the manufacturing process. There are six alternative technologies for the manufacture of caprolactam (alternative 4) that are known to be currently active on the market. The authorisation holder analyses them based on their compatibility with existing feedstock, whether they have analogous by-products and their reaction compatibility, concluding that none of the alternative manufacturing technologies meet these criteria. Furthermore, all of them would require the construction of a new plant and a new license, which the authorisation holder estimates would cost €250-350 million, which the authorisation holder considers to be economically infeasible for them. The authorisation holder also presents different kinds of managerial options (alternatives 5-10), which are discussed further in section 6.2.

SEAC evaluation of the shortlisting exercise

SEAC considers that the technical feasibility criteria for solvents have been developed for drop-in substances while the alternative technologies have also been analysed from the perspective of their compatibility with the authorisation holder's current installations, systems and expertise. Because of this, any alternative that would require changes to the plant could be deemed technically infeasible.

Nevertheless, the authorisation holder has provided extensive arguments and cost information to justify why the commercially proven alternatives that would require plant modifications are discarded. These arguments seem credible and the cost estimations are backed up by detailed calculations made by the authorisation holder. SEAC considers the calculation sufficiently substantiated to provide an order of magnitude estimation.

SEAC also considers that the final three solvent feasibility criteria seem to be economic rather than technical feasibility criteria, as claimed by the authorisation holder in both the review report and its written answers to SEAC. Nevertheless, SEAC concurs that the last three criteria are also relevant for assessing the suitability of the alternatives to the authorisation holder. It further concurs that there is no drop-in substance.

Based on all the information provided, the shortlisting of benzene and toluene is accepted by SEAC. The detailed assessment of these two alternatives is outlined further in section 5.4.

5.3. Would the implementation of short-listed alternative/s lead to an overall reduction of overall risks?

☐Yes

☒No

☐Not applicable

The authorisation holder based the comparison of the hazard profile of benzene and toluene to TCE in principle on the harmonised classification of these substances but they did also consider other information (e.g. registration data, OECD Screening Information Dataset, other relevant information relating to SVHC properties like evaluations of carcinogenicity by other

organisations and / or evidence for endocrine disrupting properties).

TCE is classified for hazards with regard to human health (Carc. 1B, Muta 2) and to the aquatic environment (Aquatic Chronic 3) while toluene is classified as Repro 2 but has no classification for the environment. Benzene is known to be a mutagenic and carcinogenic substance (Muta 1B, Carc. 1A). Benzene and toluene may be fatal if swallowed and enter airways.

In contrast to TCE, toluene and benzene are flammable liquids (Flam. Liq 2). Therefore the explosion limits and the low flash points (toluene: 4° C; benzene: -11°C) are of concern. Both substances are Seveso III substances, listed under Seveso Categories P5a, P5b and P5c.

The classification of TCE, toluene and benzene is shown in Table 9 below.

Table 9: Comparison of the classification according to CLP

	TCE		**Toluene**		**Benzene**	
Harmonised classification	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Class and Category Code(s)	Hazard Statement Code(s)
	-	-	Flam. Liq. 2	H225	Flam. Liq. 2	H225
	Skin Irrit. 2	H315	Skin Irrit. 2	H315	Skin Irrit. 2	H315
	Eye Irrit. 2	H319	-	-	Eye Irrit. 2	H319
	-	-	Asp. Tox. 1	H304	Asp. Tox. 1	H304
	STOT SE 3	H336	STOT SE 3 STOT RE 2	H336 H373	STOT RE 1	H372
	Carc. 1B	H350	-	-	Carc. 1A	H350
	Muta. 2	H341	-	-	Muta. 1B	H340
	-		Repr. 2	H361d	-	-
	Aquatic Chronic 3		-	-	-	-

All in all, the hazardous properties of the alternatives described do not point to a significant reduction of risk in case of substitution, definitely not for benzene but also toluene might not be a good option, particularly due to its flammability. It is doubtful that TCE could be suitably replaced by toluene that is flammable and has a Repro 2 classification. A proper risk assessment would be required taking all the intrinsic properties of the substances into account (toxicological, ecotoxicological and physico-chemical) in order to assess the risk reduction capacity of the potential alternative substances.

It is to be noted that the authorisation holder tried to assess the risks of toluene, benzene and TCE using ECETOC TRA software. RAC acknowledges the efforts made by the authorisation holder in this regard. However, the model might not be able to consider all the hazardous properties in an adequate way, especially taking into account the non-threshold mode of action of TCE. Besides, to compare the risks of the use of different substances not only the physico-

chemical and toxicological profile of the substances have to be known but also the exposure (e.g. worker, environment) resulting from the use has to be taken into account.

5.4. Are the short-listed alternatives technically and economically feasible and available before the end of the review period?

☐Yes

☒No

The actions required for making the shortlisted alternatives technically feasible have been the basis of detailed cost and time calculations. Additional clarifications by the authorisation holder related to costs and implementation schedules, in response to the questions of SEAC, helped to reduce uncertainties.

On the basis of the current state of knowledge on alternatives, switching to a proven alternative would according to the authorisation holder require a period of at least 12 years. Even if a new alternative would be identified through Spolana's ongoing extensive R&D programme, its implementation may require a longer time period than the established alternative substances.

Authorisation holder's analysis of the alternative extraction solvents

The already mentioned eleven technically feasibility criteria have been used to analyse the technical feasibility of benzene and toluene. Neither of these two solvents meet the criteria related to extraction efficiency, loading capacity, solvent density, process energy consumption, flammability and compatibility with existing process requirements. Furthermore, benzene does not meet the criterion regarding solvent solubility in water, which the authorisation holder states that would cause fundamental problems to the extraction process within the current configuration, while toluene does not meet the criterion regarding solvent boiling point and recyclability.

Based on the analysis of technical feasibility, the authorisation holder concludes that benzene or toluene could only be implemented by replacing the extraction unit, as the current unit was designed to operate with TCE. This would essentially mean building a replacement plant that would be tailor-made for benzene-/toluene-based extraction. The authorisation holder states that this would for either solvent, at a minimum, include:

- Ensuring compliance with the ATEX regulations for flammable liquids by reviewing, modifying or replacing electrical and mechanical parts of the plant, as the existing plant cannot accommodate the needs of a flammable liquid.
- Replacing the extraction columns, since the current extraction could not be undertaken for a solvent lighter than water.
- Significant modification and/or replacement of units affected by the higher mass flows that would be required as a result of the alternatives' lower extraction efficiency.

For benzene, modification of wastewater treatment would also be required as releases of benzene to water would be higher than TCE due to its higher water solubility. For toluene, modification of one column, its reboiler and the stripping section would also need to be replaced, as they would currently not be able to meet the requirements of a solvent with a higher boiling point and a worse extraction efficiency for caprolactam.

The cost elements that would be of relevance to the authorisation holder for the theoretical implementation of benzene or toluene include:

(1) Investment costs, including:
    (1) Capital investment cost for new equipment and its installation,
    (2) Costs of R&D and delivery of the plant conversion project;
    (3) Downtime cost;
    (4) Cost of the disposal of leftover TCE;
(2) Changes to operating costs, including:
    (1) Changes to the cost of and profits from operating the caprolactam production line;
    (2) Changes to the cost of and profits from operating the ancillary product lines;
    (3) Cost of finance (interest payments);
(3) Other costs:
    (1) Licence payments;
    (2) Opportunity costs.

The authorisation holder has generated detailed estimates for the investment cost by recalculating the cost of building the existing extraction line, adjusted to present values and to a larger size, as necessary for the alternative extraction solvent. The downtime costs assume that the manufacture of caprolactam would need to cease for 12 years, which is the theoretical time plan for the implementation of the alternative according to the authorisation holder. The time plan is based on the estimated duration of 20 required steps, taking into account possible overlaps and concurrent actions.

The associated total costs are presented in the table below.

Table 10: Costs of implementing an alternative extraction solvent

Cost category	**Cost element**	**Benzene**	**Toluene**
Investment and downtime costs	Plant conversion costs	€10-25 million	€15-30 million
	Downtime costs	€100-150 million	€100-150 million
	TCE disposal	Low – not considered	Low – not considered
	Regulatory compliance costs	Cannot be quantified	Cannot be quantified (if any)
Changes to operating costs	Increase in manufacturing costs	Moderate – not quantified	Moderate – not quantified
	Loan interest payments	€1-3 million	€1-3 million
Impacts on quantity and quality of products	Market losses	Possible impact on quality of ammonium sulphate (not quantified)	Possible impact on quality of ammonium sulphate (not quantified)
Other costs	Opportunity costs	Profits potentially arising from projects worth €20-40 million jeopardised (NB. not included in aggregate below)	Profits potentially arising from projects worth €20-40 million jeopardised (NB. not included in aggregate below)
Total costs (excluding Other costs)		**€111-178 million**	**€116-183 million**

While comparing the costs associated with the implementation of both solvents, it should be realised that the relative size of the equipment for the use of benzene is 2.2 times larger than in the case of TCE and for the use of toluene it is 3.5 time larger.

Information on the hazardous properties and risk assessment is presented too. According to the authorisation holder, from a technical and economic view, toluene is a less advantageous alternative to TCE compared to benzene; however, it is more beneficial than benzene in terms of risk reduction to worker's health and long-term compliance. However, the authorisation holder points out that both solvents have undesirable properties, described further in section 5.3.

SEAC evaluation on the authorisation holder's conclusion on feasibility and availability of shortlisted alternatives

While no assessed substance seems to be able to replace TCE in accordance with the eleven strict feasibility criteria of the authorisation holder, SEAC underlines that the criteria have been set to assess whether drop-in substances could be introduced with no technical modifications of the caprolactam plant required. While agreeing that benzene or toluene cannot be considered feasible drop-in alternatives, SEAC notes that they are possible alternatives in theory, since they are used by competitors (as also recognised by the authorisation holder). Whether the alternatives are really technically infeasible, as argued by the authorisation holder, could therefore be questioned.

Nevertheless, the authorisation holder has provided extensive information in the AoA, in response to SEAC's questions and in its answers to comments received during the public consultation outlining that these two shortlisted alternative substances are not compatible with the authorisation holder's caprolactam unit configuration. Based on all the information provided, SEAC finds it credible that these alternative solvents could only be implemented through extensive modification of the existing plant, although it notes that this is more of an economic feasibility issue. Considering the three last feasibility criteria (feedstock and by-product requirements, process energy consumption), SEAC recognises that the by-products of the authorisation holder's caprolactam manufacture (i.e. ammonium sulphate and sulphuric acid) play an important role in the economics of the operations of the authorisation holder, as an extensive market analysis has been given in the review report.

SEAC finds that the actions required for making the shortlisted solvents technically feasible seem credible although SEAC cannot draw a definitive conclusion about the relevance of each one. However, SEAC asked the authorisation holder for additional justifications for the required timetable of at least 12 years argued by the authorisation holder, as some of the steps seemed overly lengthy and it was not clear why specific steps could not be done simultaneously. The authorisation holder provided clarifications and additional justifications for these steps. For example, it noted that as part of the R&D and laboratory work, the differences in conditions would need to be verified from the point of view of the quality of all generated products. It also mentioned that this step takes into account information obtained from its research partners. For the step related to the pilot plant, the authorisation holder explained that it would also be necessary to obtain legislative authorisation, stating that the legislative process and construction of the pilot plant would require at least one and a half year, as this is prescribed by law and can be confirmed by their own experience. While this additional information gives SEAC more confidence in the estimated timetable, it is not possible for SEAC to confirm that at least 12 years would indeed be needed to implement an alternative.

SEAC considers that the methodology used for the selection of relevant cost elements and the calculations are compatible with the guidance so that the estimates are overall credible. While SEAC is not able to evaluate the likelihood of the projected profit losses for caprolactam, ammonium sulphate or sulphuric acid, it finds them overall in line with the publicly available financial information about the authorisation holder. However, since SEAC is not convinced that the plant would really need to be shut down for 12 years, it finds that the total downtime costs may be overestimated. While it is not possible for SEAC to determine for how long the authorisation holder would incur profit losses, SEAC finds that the investment costs alone are enough to conclude that the alternatives would not be economically feasible for the authorisation holder.

5.5. Is the authorisation holder already engaged in a substitution programme and / or R&D and is it seeking a defined transitional period to phase out the use the Annex XIV substance?

The authorisation holder has not identified a suitable alternative yet but since 2014 it has been involved in extensive R&D to develop an alternative technology that would eliminate the use of extraction solvents.

After the submission of the initial application for authorisation for the use of TCE as an extraction solvent in 2014, the authorisation holder came to an agreement with two partners, the Technical University of Ostrava and TECHEM CZ, s.r.o. under a project titled “Trichlorethylene replacement in crude caprolactam refining (RAFKAPR)”. The project was intended to be completed by 31 December 2018. The aims of this project were to:

(1) Develop a new process for the refining of crude caprolactam without the use of TCE; and,

(2) Obtain the technical and technological basis for implementation of the developed refining process either on the existing production facility or on a newly installed pilot plant at the authorisation holder’s site.

Initial results indicate that the RAFKAPR project cannot meet its intended goal of preparing the technical and technological documentation for a pilot plant.

To continue R&D activities using the information and conclusions gathered during the RAFKAPR project the authorisation holder has engaged in the following activities:

(1) June 2017 - due to the need to strengthen research and development capacities both in the search for an alternative technology and in the drafting of modifications of existing equipment in order to reduce TCE emissions to the technologically and economically achievable minimum, the authorisation holder signed a cooperation contract with another R&D partner. The main subject, goals and tasks of the contract are confidential (but disclosed to ECHA), except that this R&D project will last until 2025;

(2) January 2019 – the authorisation holder intends to start additional R&D aimed at identifying an alternative extraction solvent or technique (the ELTRIS Project). ELTRIS is a follow-up of the RAFKAPR Project and aims to address some of the technical challenges identified during the RAFKAPR Project. This R&D project is intended to be completed by 30 June 2022. The project intends to develop optimisation of refining condition and the technical documentation for the pilot plant;

After completion of the ELTRIS project, assuming that its results are positive, the authorisation holder would aim to establish a pilot plant for the further testing of the caprolactam extraction

technologies that might not require the presence of any solvent (all the details of this project are claimed to be confidential). The timeline of this project (the RESUK project) is not yet known.

The authorisation holder has provided a detailed theoretical time plan for the implementation of an alternative technology under the ongoing/planned R&D projects. It has been estimated that, depending on the selected alternative, the R&D may last approximately 15 to 16 years.

In SEAC's view the activities included in the theoretical time plan seem logical, although it notes that the duration of some of these activities seem longer than it would expect (mainly the activities related to R&D, pilot scale testing and managerial activities like decision-making, selection of contractors, securing investment funds). On SEAC's request, the authorisation holder provided further information regarding the expected duration of the steps, based on regulatory requirements and its experience from similar activities in the past. While the justifications provided by the authorisation holder seem reasonable, SEAC is not able to fully verify whether the argued time would really be needed for the implementation of an alternative technology.

SEAC also asked the authorisation holder to elaborate and provide at least indicative costs of implementing one of the alternative technologies in the current R&D projects. This was done with the aim of comparing the potential costs of this alternative with the cost of the chosen non-use scenario. During the trialogue the authorisation holder provided information about the preliminary cost estimates for the different steps, amounting to a total investment cost of €10-50 million.

5.6 Conclusions on the analysis of alternatives

1. The review report contains extensive descriptions regarding the authorisation holder's process and functional requirements, various alternative substances and technologies, as well as the technical and economic feasibility and availability of the short-listed alternative solvents.
2. The authorisation holder's technical feasibility criteria have been developed for drop-in alternatives, meaning that any alternative that would require changes to the plant could be deemed technically infeasible. Nevertheless, the authorisation holder has provided extensive arguments and cost information to justify why the commercially proven alternatives that would require plant modifications are discarded. The shortlisting of toluene and benzene seems reasonable to SEAC.
3. Based on all the information provided in the review report and in the written answers to questions, SEAC finds it credible that benzene and toluene could only be implemented through extensive modification of the existing plant. While the actions required for making the shortlisted solvents technically feasible seem credible, SEAC is not able to fully scrutinise the required timelines of 12 years claimed by the authorisation holder. Because of this, the downtime costs may also be overestimated. Nevertheless, SEAC finds that the investment costs alone are enough to conclude that the alternatives would not be economically feasible for the authorisation holder.
4. SEAC recognises the recent efforts made by the authorisation holder in R&D activities related to the search for and development of alternatives. SEAC notes that a lot of detail is provided on the R&D goals, activities, financing sources as well as implementation plans.
5. SEAC agrees with the authorisation holder that no technically and economically feasible other alternatives are currently suitable for the authorisation holder.

6. SEAC considers that the implementation of benzene or toluene would require major investments in the order of tens of millions of euros, making the alternatives economically infeasible for the authorisation holder.

6. Have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ Yes

☐ No

☐ Not relevant (adequate control demonstrated for threshold substance)

6.1. Additional statistical cancer cases and costs (monetised Human Health risks) of continued use

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 4 and the estimation of the number of exposed people provided by the authorisation holder. Lifetime human health impacts have been considered (40 years for workers and 70 years for the general population), but for the purpose of the comparison of benefits and risks, the monetised excess risk has been adjusted to a 12-year assessment period.

The authorisation holder considered in the health impact assessment also the exposure of workers in other nearby plants located in the Neratovice industrial site. The number of these workers is 3 100 and in the table below they are included in the row “Indirectly exposed workers”.

It has been assumed by the authorisation holder that the general population exposed to TCE from the Neratovice site is located within an area of 40 000 km^2 (according to the EUSES software). It is estimated that the number of locally exposed residents is 260 while the number of regionally exposed inhabitants reaches approximately 8 million. Since the authorisation holder has provided detailed data and used the standard methodology, SEAC finds the assessment of exposed inhabitants to be sound and justified.

The authorisation holder has relied on data from the World Health Organisation’s GLOBOCAN database on kidney cancer incidence and mortality rates in the Czech Republic. According to this database the average mortality ratio for kidney cancer (including renal, pelvis & urethra cancers) was presumed to be 33.05%.

The values for mortality and morbidity cases have been set in accordance with the study led by the Charles University in Prague (Alberini and Ščasný, 2014) and undertaken for ECHA. For the review report, the figures were updated to 2017 prices. This has been achieved by applying the Eurostat EU GDP deflator (1.052) arriving at €3.68 million per fatal kidney cancer and €0.43 million per morbidity case.

RAC notes that these calculations are based on the estimation of exposed populations as provided by the authorisation holder. The summary of the additional statistical fatal cancer cases are presented in Table 11 and the non-fatal ones are presented in Table 12.

Table 11: Summary of additional statistical fatal cancer cases:

	Excess level risk	Number of exposed people	Estimated statistical fatal cancer cases	Value per statistical fatal cancer case	Monetised excess risk per year[1]
Workers[2]					
Directly exposed workers[3]	2.73×10^{-8} - 3.82×10^{-5}	100	6.37×10^{-4}	€3.68 million	€59
Indirectly exposed workers[4]	8.29×10^{-8}	3 100	8.49×10^{-5}	€3.68 million	€8
General population[5]					
Local	3.41×10^{-7}	260	2.93×10^{-5}	€3.68 million	€2
Regional	2.43×10^{-10}	8 011 432	6.43×10^{-4}	€3.68 million	€34
Total		**8 014 892**	**1.39×10^{-3}**	**€3.68 million**	**€103**
Latency (years)	Latency effects have not been taken into account by the Authorisation holder. It is assumed that all cancer cases arise within the 12-year assessment period.				

Table 12: Summary of additional statistical non-fatal cancer cases:

	Excess level risk	Number of exposed people	Estimated statistical non-fatal cases	Value per statistical non-fatal cancer cases	Monetised excess risk per year[1]
Workers[2]					
Directly exposed workers[3]	2.73×10^{-8} - 3.82×10^{-5}	100	1.29×10^{-3}	€0.43 million	€13
Indirectly exposed workers[4]	8.29×10^{-8}	3 100	1.72×10^{-4}	€0.43 million	€2
General population[5]					
Local	3.41×10^{-7}	260	5.94×10^{-5}	€0.43 million	€0.4
Regional	2.43×10^{-10}	8 011 432	1.3×10^{-3}	€0.43 million	€8
Total		**8 014 892**	**2.83×10^{-3}**	**€0.43 million**	**€23**
Latency (years)	Latency effects have not been taken into account by the Authorisation holder. It is assumed that all cancer cases arise within the 12-year assessment period.				

Notes:

1. Annualised to a typical year based on the time horizon used in the SEA;
2. Worker exposure is estimated over a lifetime working exposure (typically 40 years);
3. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8-hour Time Weighted Average (TWA) of a representative worker. The excess risk is different for different workers and the individual risks are outlined in Table 7 of this opinion;
4. Indirectly exposed workers (bystanders) do not use the substance. Also, those workers who work in Neratovice site but are not employees of the authorisation holder are included;
5. General population exposure via the environment is estimated over a typical lifetime exposure (typically 70 years)

Based on the values set in the review report, the authorisation holder monetised the health impacts over a 12-year period (with a 4 % discount rate, ignoring latency periods) and arrived at a net present value of €1 093 for both on-site workers and the general population. SEAC concurs with this value.

6.2. Benefits of continued use (cost of non-use scenario)

Non-use scenario

Since the change in Spolana's ownership in 2016, the authorisation holder has become part of the Unipetrol RPA group, a large producer and distributor of refinery, petrochemical and agrochemical raw materials.

In identifying possible non-use scenarios, the authorisation holder has evaluated 10 potential alternatives, including both technical and managerial alternatives. The practicalities of the alternatives are described and, where possible, the associated costs are presented. The fact that the authorisation holder is now part of the whole Unipetrol RPA group of companies' production cycle has played a role when shortlisting likely non-use scenarios because the authorisation holder consumes several of the group's products, including ethylene, ammonia and sulphur from Unipetrol/PKN refineries. The authorisation holder concludes that the only possible non-use scenarios are implementation of an alternative extraction solvent (alternative 1) or complete shutdown of the caprolactam and other caprolactam-dependent units (alternative 8).

Among these shortlisted alternatives, complete shutdown of the caprolactam and other caprolactam-dependent units seems to be less costly to the authorisation holder than the use of an alternative extraction solvent, which would involve temporary shutdown of the caprolactam, ammonium sulphate and sulphuric acid units with the parallel conversion of the caprolactam unit to toluene or benzene.

However, despite this theoretical cost advantage, from the viewpoint of the authorisation holder, complete shutdown of the units is the least preferable from a business and long-term realism perspective, taking into account the priorities of the wider group. The authorisation holder would therefore instead opt for an alternative extraction solvent. While the implementation of benzene would be less costly than the implementation of toluene, the substitution to a substance with the hazardous profile of benzene would according to the authorisation holder not fit with the environmental and health protection policy of the Unipetrol RPA Group.

Therefore, the authorisation holder has selected the implementation of toluene as the most-likely non-use scenario if authorisation is not granted.

SEAC's view on the credibility of the non-use scenario

SEAC asked the authorisation holder to explain in more detail the suggested implementation schedule of 12 years for the implementation of toluene, as the necessary time for several activities seemed to be exaggerated. Although the answers provided by the authorisation holder contained detailed rationale and justification, SEAC is unable to verify the credibility of the duration of each step.

With consideration to the difficulty of entering the market again after being away for 12 years during the implementation of toluene, SEAC requested further analysis of the authorisation holder's future market position. It did not seem credible to SEAC that the authorisation holder would have a strong market position after being away for 12 years. SEAC also challenged the

authorisation holder on the likelihood that the decision of switching production to toluene at some point could be switched to a complete shutdown of the caprolactam unit (alternative 8) as a next best option. In the response to these questions, the authorisation holder explained that it is imperative that the caprolactam plant continues to operate and that every effort would therefore be made to switch to an alternative that ensures the manufacture of caprolactam and by-products. It referred to confidential information on the authorisation holder's recent strategic business decisions and ongoing activities. The authorisation holder also acknowledged that there indeed might be some risk that Spolana's new owner might consider a change to the overall business plan and order the complete shutdown of the caprolactam plant in Neratovice, although it is clear that the preferable option is to retain the authorisation holder within the established production cycle. SEAC has acknowledged this possibility and has done some benefits/cost (B/C) sensitivity test evaluating the scenario if Alternative 8 (shutdown of caprolactam plant) is to be selected during the first few years after continuous authorisation is not granted. SEAC concludes that the costs still exceed benefits by a magnitude of several thousand times.

SEAC also asked the authorisation holder to explain why alternative technologies currently under development (see chapter 5.5.) were not shortlisted for the more detailed analysis of alternatives or even chosen as the non-use scenario since plant conversion to toluene would always seem economically infeasible from the authorisation holder's viewpoint. The authorisation holder responded that TCE substitution to an alternative extraction solvent was chosen as the most probable non-use scenario because it is essentially the only feasible alternative that is proven on the industrial scale at the moment. During the trialogue the authorisation holder further clarified that this technology was not shortlisted for the more detailed analysis of alternatives because of insufficient knowledge of this process at the time of preparing and submitting the review report.

Although the authorisation holder has provided extensive information on various options considered, SEAC is not entirely convinced that the implementation of toluene and the associated 12-years temporary shut-down of the caprolactam plant would be realistic. SEAC believes that it may also be possible that the authorisation holder would shut down the caprolactam plant completely after the end of the review period or that it would start implementing toluene but then later switch to either complete shutdown (in case of unsuccessful R&D related to toluene or alternative technologies, severe caprolactam market changes or other critical factors) or to the development of new caprolactam extraction technologies if the ongoing R&D brings successful results. Nevertheless, the authorisation holder has provided sufficient information to allow SEAC to concur that the benefits would still outweigh the risks by at least several thousand times.

Furthermore, as will be discussed later, the authorisation holder has not included the avoided profit losses in the total benefits of continued use. Therefore, even if the 12 year shut-down would be exaggerated, the benefits of continued use as reported by the authorisation holder may even be underestimated.

Costs of non-use scenario

Economic costs

The authorisation holder's estimation of the costs of a refused authorisation assumes that the authorisation holder would need to construct a new caprolactam plant for the implementation of toluene and that the operations at the current plant (comprising the caprolactam, the ammonium sulphate and the sulphuric acid units) would cease for approximately 12 years.

The authorisation holder has provided extensive analysis on costs which will be incurred by:

(1) the authorisation holder;
(2) suppliers of authorisation holder;
(3) downstream users of authorisation holder;
(4) actors outside authorisation holder's supply chain; and
(5) consumers;

if the authorisation is not granted.

As far as it has been possible, the authorisation holder has provided quantification of these costs as well as the distributional effects related to these costs. While the costs to different actors are identified and quantified, the authorisation holder has only brought those costs that it considers social costs forward for the benefit/cost ratio. Table 10 summarises the costs that have been brought forward for the benefit/cost ratio.

The cost estimation of installing new equipment for the extraction of caprolactam and the regeneration of the solvent in the substitution of TCE with toluene is very detailed and contains information on more than 100 past construction and technological investments. The cost estimation is based on previous experience and historical data by applying different cost indexes. The total investment cost is estimated to be in the range of €15-30 million.

In addition to the plant conversion cost, the authorisation holder has provided detailed rationale regarding why on-site waste water treatment plant (WWTP) efficiency will have to be improved before the caprolactam unit is closed (due to a significant drop in total wastewater flow to the WWTP, the proportion of organic chlorinated substances in wastewater flow will significantly increase; also, there is a necessity to introduce a nitrification-denitrification process). It is expected that external dosing of bacteria nutrients might be necessary. The costs associated with inefficiencies affecting the on-site WWTP seem to be credible, are justified in detail and should be included in the calculations of the benefits of continued use. The total present value of these costs is according to the authorisation holder in the range of €1-10 million.

The authorisation holder has calculated that lost profit during the downtime of the 12-year period would reach €100-150 million. The authorisation holder assumes that this figure reflects the benefits for other EU-based caprolactam producing and/or trading companies (thus, the profit loss is not included in the B/C calculations) although at the same time it argues that EEA caprolactam producers may not be able to cover the deficit of caprolactam. Taking this into account SEAC asked the authorisation holder to elaborate more on what part of the indicated €100-150 million gains may realise outside EEA countries. In the answer the authorisation holder estimated that most likely 8-16% of the above-mentioned distributional benefits might be gained by companies from Russia and/or China. In that case, the authorisation holder's profit loss would result in a net producer surplus loss for the EEA. Hence, the exclusion of the profit loss from the calculations is likely to lead to some underestimation of the benefits of continued use.

SEAC notes that the authorisation holder would still run the chlor-alkali and PVC plants on their own in the non-use scenario. The main technical linkage between the chlor-alkali plant and the caprolactam plant is that sulphuric acid is supplied to the chlor-alkali plant for chlorine drying and spent sulphuric acid is subsequently treated at the ammonium sulphate unit which belongs to the caprolactam plant. Shutdown of the caprolactam plant would require the authorisation holder to purchase sulphuric acid from the market and implement suitable treatment of the spent acid after chlorine drying. The total present value of these costs is according to the authorisation holder in the range of €1.1-11 million.

The authorisation holder has also identified several potential costs that have not been quantified although the authorisation holder considers that their magnitude and impact is only either minor or moderate:

(1) Cost of TCE stock disposal;
(2) Increase in manufacturing costs of caprolactam;
(3) Costs associated with impacts on the balance of utilities production/consumption;
(4) Loss of reliable regional/local supply for the customers of the authorisation holder;
(5) Increases in the prices of car batteries and fertilisers in parts of Central Europe;
(6) Loss of an estimated 58 jobs at companies providing services to authorisation holder.

SEAC concurs with the approach provided by the authorisation holder although there were some uncertainties (e.g. complete exclusion of lost profits from the B/C calculations, inclusion of opportunity costs associated with projects potentially becoming jeopardised) that were partially cleared by the written answers provided by the authorisation holder and during trialogue procedure.

Social costs

The authorisation holder expects that 155 jobs would be lost if the authorisation is not granted. These represent employees from the caprolactam unit, the sulphuric acid/oleum production unit, the ammonium sulphate production unit and the Quality Control Department. The value of the job loss is estimated according to the report "Valuing the social costs of job losses in applications for authorisation" (*Dubourg, R., 2016*). The benefits of the avoided job losses are estimated to be in the range €1-5 million (exact value is claimed to be confidential). Since the authorisation holder indicated that there are plans to hire more employees in the caprolactam, sulphuric acid/oleum and ammonium sulphate production units, SEAC asked for more detailed information with an intention to understand whether the number of directly exposed employees to TCE and redundant workers (if the authorisation is not granted) may be even higher. The authorisation holder explained that these employees could be exposed only via the environment, not via direct exposure in the workplace, because they are located quite far from the source of TCE emissions. The authorisation holder did not include the additional employees in the B/C calculations but instead only included the expected job loss of 155 current employees. Although this would have a very minor impact on the exposure calculations (costs of continued use, through the man via environment), it leads to an underestimation of the benefits related to the retention of existing jobs.

The authorisation holder has also described in detail why there might be a loss of an estimated 58 jobs at the companies providing services to the authorisation holder. However, this cost is not included in the B/C calculations.

Table 13 below summarises the above benefits for a 12-year period.

Table 13: Socio-economic benefits of continued use

Description of major impacts	Quantification of impacts
1. Benefits to the authorisation holder(s) and/or their supply chain	
1.1 Profit loss due to investment and/or production costs related to the adoption of an alternative	Total: €19 - 63 million, incl.
1.1.1 Cost of converting caprolactam unit;	*€15-30 million*
1.1.2 Additional loan interest payments needed to finance the conversion of the caprolactam unit;	*€1-3 million*
1.1.3 Cost of constructing a new chlorine drying unit	*€1-10 million*
1.1.4 Cost of system for the alkaline hydrolysis of chlorine-containing wastewater at the VCM plant	*€1-10 million*
1.1.5 Cost of nitrification-denitrification process	*€1-10 million*
1.2 Profit loss due to ceasing the use applied for[7]	Not included in net benefits of continued use as profit losses are assumed to be taken over by alternative producers. However, they are quantified at €50-100 million.
1.3 Relocation or closure cost	Not applicable
1.4 Residual value of capital	Not applicable
1.5. Additional cost for transportation, quality testing, etc.	Total: €0.11-1.1 million, incl.
1.5.1. Additional cost of purchasing sulphuric acid from the open market for chlorine drying	*€0.1-1 million*
1.5.2. Cost of external dosing of nutrients	*€0.01-0.1 million*
Sum of benefits to the authorisation holder(s) and / or their supply chain	€19.11-64.1 million
2. Quantified impacts of the continuation of the SVHC use applied for on other actors	
2.1 Net job loss in the affected industry[8]	€1 - 5 million
2.2 Spill-over impact on surplus of alternative producers	Not available
2.3 Consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	Negligible
2.4 Other societal impacts (e.g. avoided CO_2 emissions or securing the production of drugs)	Competitors are assumed to take over all profit losses of the authorisation holder (€50-100 million)
Sum of impacts of continuation of the use applied for	€1 - 5 million
3. Aggregated socio-economic benefits (1+2)	€28 million

[7] SEAC notes that the exclusion of profit losses from the calculations is likely to underestimate the total benefits.

[8] Job losses to be accounted for only for the arithmetic mean period of unemployment in the concerned region/country as outlined in the SEAC paper on the valuation of job losses (See The social cost of unemployment and Valuing the social costs of job losses in applications for authorisation).

SEAC's view on the costs of the non-use scenario

In SEAC's evaluation of the costs, it noted that the authorisation holder had by mistake included the opportunity cost associated with projects potentially becoming jeopardised in the total costs of the non-use scenario, even if the review report stated that this cost was not taken forward. The authorisation holder acknowledged this miscalculation and confirmed that if the opportunity cost was omitted, the overall benefits of continued use would be €28 million, rather than the €53 million stated in the review report. This would give a B/C ratio of over 25 000 according to the authorisation holder.

SEAC notes that some of the benefits of continued use might be underestimated (e.g. number of employees potentially becoming redundant) or even not included in the B/C calculation. For example, the authorisation holder did not include any social costs related to the profit losses in the B/C calculations, even though it argues that some of its profit losses are likely to be taken over by competitors outside the EEA, thereby resulting in a loss to the EEA.

During the trialogue the authorisation holder was asked whether the planned investments will have to be made anyway at the end of the lifetime of the existing plant, i.e. if the investment cost is just brought forward in the non-use scenario. The authorisation holder acknowledged that this was the case but noted that the precise plant replacement timelines are not known and that the plant could be operational for much longer than the minimum time mentioned in the review report. SEAC notes that this means that the investment costs may be overestimated but that, even with the minimum expected lifetime of the current plant, the benefits of continued use would still be thousands of times higher than the human health costs.

In this respect, SEAC considers that the uncertainties associated with the approach adopted by the authorisation holder's analysis are small in relation to the ratio between the assessed socio-economic benefits and health costs of continued use.

6.3. Combined assessment of impacts

The authorisation holder is applying for an authorisation for a long review period of 12 years, stretching from 2020 to 2032. All benefits and costs have been estimated for the price level of 2017. SEAC considers the information provided in the review report, along with the responses to SEAC's questions in writing and during the trialogue, to be sufficient to assess both the benefits and health impacts and to conclude on a positive benefit-cost ratio.

While combining the present values of the different benefits of continued use, the authorisation holder has applied variable discount rates (10 % for the cost of capital for Spolana; 4 % as a social discount rate) which leads to a lower net present value for the capital costs.

According to the authorisation holder, the costs of a refused authorisation would be at least €28 million, which is more than 25 000 times the benefits over the 12-year period (when the opportunity cost associated with projects potentially becoming jeopardised is not taken into account). Considering that this benefit-cost ratio is based on a higher discount rate for the cost of capital to the authorisation holder and that profit losses are not included, the authorisation holder stresses that the above ratio should be considered conservative.

SEAC finds that the benefits estimated by the authorisation holder are overall plausible and agrees that the exclusion of any profit losses could mean that the real societal costs would be higher. SEAC concludes that the monetised risks of continued use are €1 093 over the 12-year review period, while the socio-economic impacts of a non-granted authorisation (investments, increased operational costs and job losses together) are at least €28 million over the requested 12-year review period.

Such orders of magnitude between costs and benefits of continued use shall be enough to erase any residual uncertainty related to this assessment, providing a good margin to support SEAC's conclusions that the benefits of the authorisation holder's continued use of TCE outweigh the risks.

The authorisation holder calculated the annualised values for the remaining risks. SEAC has annualised the socio-economic benefits of continued use for the purpose of the tables below.

Table 14: Comparison of socio-economic benefits and risks of continued use

Socio-economic benefits of continued use (annualised to € per year)		**Monetised excess risks associated with continued use (annualised to € per year)**	
Benefits to the authorisation holder(s) and/or their supply chain	€2.15 – 7.22 million	Monetised excess risks to workers directly exposed in the use applied for	€73
Quantified impacts of the continuation of the SVHC use applied for on other actors	€0.11 – 0.56 million	Monetised excess risks to the general population and indirectly exposed workers	€53
Additional qualitatively assessed impacts	Costs associated with impacts on the balance of utilities production/consumption; Loss of reliable regional/local supply for customers of authorisation holder; Increases in the prices of car batteries and fertilisers in parts of Central Europe; Loss of an estimated 58 jobs at companies providing services to authorisation holder	Additional qualitatively assessed risks	Not available
Aggregated socio-economic benefits	€3.15 million	Aggregated monetised excess risk	€126

Table 15: Benefit / cost summary

Annualised net benefits (€)	€3.15 million
Benefit/monetised risk ratio	**25 000**

6.4. Conclusion on the socio-economic analysis

The authorisation holder's impact assessment contains an extensive list of the main impacts of a refused authorisation, with the impacts being incremental to the continued use scenario. SEAC overall concurs with the methodological approach used.

The authorisation holder has provided extensive uncertainty analysis concluding that in any scenario the benefits of the continued use of TCE would be large enough to by far outweigh the costs to society.

Although SEAC is not entirely convinced that the implementation of toluene and the associated 12-years temporary shut-down of the caprolactam plant would be realistic, the authorisation holder has provided sufficient information to allow SEAC to concur that the benefits would still outweigh the risks by at least several thousand times even if the temporary shutdown was shorter or if the plant was shut down completely.

SEAC considers that the socio-economic analysis carried out by the authorisation holder thoroughly captures the changes in impacts and allows SEAC to conclude that the benefits of continued use of TCE outweigh the associated risks. SEAC considers none of the uncertainties to be of such magnitude that they could affect this overall conclusion.

7. Proposed review period

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. years)

☐ Other:

When recommending the review period SEAC took note of the following considerations:

7.1. RAC's advice:

RAC did not offer any advice to SEAC regarding the length of the review period.

7.2. Substitution and socio-economic considerations

In identifying the proposed review period, SEAC took note of the following considerations:

(1) With regular maintenance, the caprolactam unit is expected to continue operating at a profit at least until 2035. To achieve this, the authorisation holder is making significant financial commitments (new installations, revamping existing units and investing in new, cleaner technologies leading also to reduced TCE consumption and emissions). The authorisation holder has demonstrated that the investment cycle for the caprolactam unit is longer that the review period applied for;

(2) The authorisation holder has been unable to identify a technically and economically feasible alternative. Although alternative extraction solvents are used by competitors, neither toluene nor benzene can be considered as an economically feasible alternative for the authorisation holder. These alternative solvents could only be implemented through extensive modification of the existing plant which would essentially mean the erection of a replacement plant tailor-made for benzene/toluene-based extraction. It shall be noted that these two alternative solvents also have undesirable properties (benzene is Carc. 1A and Muta. 1B, toluene is suspected of damaging the unborn child (Repr. 2) and has narcotic effects, both have adverse effects on the environment and are Seveso III substances) which means that there might not be significant human health benefits in comparison with the continued use scenario;

(3) The analysis of the information presented in the review report, in written answers to questions and during the trialogue allows SEAC to conclude that there are no significant technical or scientific uncertainties of such magnitude that they could change the conclusion that there are no suitable alternatives available for the authorisation holder and that the benefits of continued use outweigh the risks;

(4) The benefits of continued use (even though there are some minor uncertainties) outweigh the human health impact by a magnitude of at least at least several thousand times;

(5) SEAC takes note of the fact that the R&D efforts of the authorisation holder appear extensive and that there is a clear plan of R&D activities until at least 2025. Planned activities, including R&D partners and their respective budgets, have been clearly identified in the review report. While SEAC is not able to verify how long would be needed to implement an alternative technology, according to the authorisation holder it may take approximately 16 years and this term corresponds to the end of the life-cycle of the existing caprolactam production unit;

(6) Overall, regardless of whether the authorisation holder aims to implement a known alternative (toluene being the preferred alternative among the commercially proven solvents) or a newly developed alternative technology that eliminates the use of extraction solvents (depending on the R&D results), a review period longer than the normal review period of 7 years would be required.

Taking into account these points SEAC considers that the criteria for a long review period are fulfilled, and recommends a 12-year review period.

8. Additional conditions and/or monitoring arrangements for the authorisation proposed

☒ Yes

☐ No

8.1. Description:

RAC

Additional conditions

None

Monitoring arrangements

1) The authorisation holder shall continue to conduct regular occupationally exposure measurements. Those measurements shall comprise personal inhalation exposure and biomonitoring and take place at least annually.

2) The authorisation holder shall continue to conduct regular environmental monitoring to quantify the release factors and emissions to TCE to all environmental compartments. Sampling shall be done at least annually.

3) The information gathered via the measurements and related contextual information shall be used by the authorisation holder to further optimise the RMMs and OCs in place in order to minimise releases and exposure, particularly with regard to fugitive emissions of TCE. This should include the improvement of the TCE unloading station as described in the review report, and the review of the working practices for the installation of new equipment.

4) The information from the monitoring programmes including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent national authority of the Member State where the authorised use will take place.

5) The authorisation holder may reduce the frequency of measurements, once the authorisation holder can clearly demonstrate to the national Competent Authority of the Member State where the use takes place that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible.

SEAC

Additional conditions

None

Monitoring arrangements

None

8.2. Justification:

RAC acknowledges the efforts made regarding the implementation of RMMs to reduce exposure for workers and for humans via the environment. Although there are some minor uncertainties regarding the effectiveness of the RMMs recently implemented (see discussion in section 3.1), RAC considers that the RMMs described are appropriate and effective in limiting the risk. Further optimisation of the RMMs and OCs in place should be expected as a result of the monitoring programmes to be conducted by the applicant holder to minimise releases and exposure, particularly with regard to fugitive emissions of TCE. This should include the improvement of the TCE unloading station (already planned by the application holder for 2019) and the review of the working practices for the installation of new equipment.

9. Recommendations for the review report proposed

☒ Yes

☐ No

9.1. Description:

The review report shall document the results of the monitoring programs and the optimisation of RMMs and OCs carried out by the applicant in order to minimise fugitive emission.

9.2. Justification:

The application holder should provide evidence of the efforts made to further decrease fugitive emissions based on the results of the monitoring programs.

10. Did the authorisation holder provide comments on the draft final opinion?

☐ Yes

☒ No

10.1. Action/s taken resulting from the analysis of the authorisation holder's comments:

☐ Yes

☐ No

☒ Not applicable – the authorisation holder did not comment