

**Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)**

Background document

to the Opinion on the Annex XV dossier proposing restrictions on medium chain chlorinated paraffins ('MCCP') and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17

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BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON
MCCPs

CHANGE VERSION HISTORY

Version	Change history	Date
1.0	Pre-publication of the Annex XV restriction report and its appendix. Version 1.0 was submitted on 15 July 2022, and published on ECHA website on 20 July 2022 (this version is not meant for consultation).	07 July 2022
1.1	Revised version of the Annex XV restriction report and its appendix to take into account the minor recommendations of the RAC and SEAC rapporteurs made during the conformity check. This version is published on ECHA website on 21 September 2022, and is used for the 6-month Annex XV consultation.	21 September 2022
2.0	Revised version of the Annex XV restriction report and its appendix to improve the readability of some sections. The Annex XV restriction report and its appendices become the 'Background Document and its appendices' which is used by RAC and SEAC during the opinion making. The main changes are listed below: <ul style="list-style-type: none">- Minor editorial changes and typo corrections.- Section 2.5 of the Background Document: clarification of the proposed restriction entry, in particular the wording used in paragraph 1 of the entry.- Section 3.1 of the Background Document: footnote added in Table 19 to clarify the uncertainty U6.- Appendix B.1.3: table on the theoretical chlorine content of CA:C14-C17 congener groups updated to reflect the outcome of the POP risk profile agreement.- Appendix B.1.5.2: reference to available (certified) standards added	14 December 2022
2.1	Revised version of the Background Document and its appendix to reflect the comments received during the Annex XV consultation. The main changes are listed below: <ul style="list-style-type: none">- Section 1.3.4 of the Background Document: clarification added- Section 2.5 of the Background Document: clarification of the proposed restriction entry option B, in particular the wording used in paragraph 8 of the proposed entry.- Appendix A.2: updated with information received via the Annex XV consultation- Appendix E.4: additional calculations of 'avoided emissions' added (considering different concentration levels, and lengths of transition period)- Appendix G: updated	9 June 2023

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LIST OF ACRONYMS AND ABBREVIATIONS

Acronym	Meaning
BfR	Bundesinstitut für Risikobewertung in German. German Federal Institute for Risk Assessment
CA:C14-17	Chloroalkanes with carbon chain lengths within the range from C14 to C17
C/E	Cost Effectiveness ratio
CfE	Call for Evidence
Cl	Chlorine
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
CP	Chloroalkane (or chloroparaffin)
CSR	Chemical Safety Report
DU	Downstream User
EEA	European Economic Area, i.e. EU countries + Norway, Liechtenstein and Iceland
EEE	Electrical and Electronic Equipment
EiF	Entry into Force
EP	Extreme Pressure Additive
EPA	Environmental Protection Agency
ERC	Environment Release Category
EU	European Union. In this report, the terms 'European Union', 'EU' and 'EU-wide' cover the EEA unless stated otherwise
FR	Flame Retardant
IG	Insulating Glass
LCCP	Long Chain Chlorinated Paraffins
MCCP	Medium Chain Chlorinated Paraffins as defined in the Candidate List, i.e. 'UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17'
MWF	Metalworking Fluid
MSC	Member State Committee
NPV/PV	Net Present Value / Present Value
OCF	One Component Foam
PBT	Persistent Bioaccumulative and Toxic
POP	Persistent Organic Pollutants
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
RMM	Risk Management Measure
RO	Restriction Option
SDS	Safety Data Sheet

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Acronym	Meaning
SPERC	Specific Environmental Release Categories
SVHC	Substance of Very High Concern
TP	Transition Period
UVCB	Substances of <u>U</u> nknown or <u>V</u> ariable composition, <u>C</u> omplex reaction products or of <u>B</u> iological materials
vPvB	very Persistent very Bioaccumulative
WWTP	Waste water treatment Plant

BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON MCCPs

ABOUT THIS REPORT

The proposed restriction was initiated based on Article 69(1) of the REACH Regulation at the request of the European Commission (EU Commission, 2021c, EU Commission, 2022a). This report consists of a summary of the proposal, a main report setting out the key evidence justifying the proposed restriction and Appendices with more detailed information and supporting analysis.

ECHA (hereafter referred to as the Dossier Submitter) would like to thank the stakeholders that made contributions to the calls for evidence, the ECHA Market Survey, the laboratory survey, and the Registrants' survey.

This version of the report has been reviewed for confidential information and any such information has been redacted.

SUMMARY

The proposed restriction aims at "assessing and addressing the potential risks to human health or the environment arising from the manufacture, use or placing on the market of 'MCCP' (defined in the Candidate List as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) and other substances containing the same congener groups with PBT and/or vPvB properties as 'MCCP'" as per the request of the Commission (EU Commission, 2021c, EU Commission, 2022a).

The substances in the scope of the proposed restriction are substances which are also proposed for listing in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (UNEP, 2021). The REACH restriction process will therefore also support the discussions in the POP Review Committee of the Stockholm Convention and facilitate the development of the EU position for the Conference of Parties in which the listing of the substances as POP substances will be decided.

During the SVHC identification of 'MCCP', the ECHA Member State Committee (MSC) concluded in its assessment that some "congener groups of 'MCCP' have PBT and/or vPvB properties in accordance with the provisions of Annex XIII to the REACH Regulation" as well as long range transport (LRT) potential, and that "substances other than 'MCCP' may contain these congener groups with PBT/PvB, and LRT properties". Throughout the report, the Dossier Submitter refers to 'CA:C14-17' to describe 'the congeners/congener groups¹ of chloroalkanes with carbon chain lengths within the range from C14 to C17'. The acronym 'MCCP' is only used to refer to the Candidate List definition.

According to REACH Annex I, the risks of PBT and/or vPvB substances cannot be adequately controlled. Therefore, any congener identified as PBT/vPvB may cause severe and irreversible adverse effects if released. In addition, regulating UVCB substances that contain hazardous constituents on an individual basis (i.e. on a substance-by-substance basis) will have limited effectiveness where the same hazardous constituents are also present in other substances. Regulating UVCB substances on one-by-one basis could lead to regrettable substitution to other UVCBs that contain the same hazardous constituents. Therefore, rather than a restriction on substances, the Dossier Submitter is proposing to restrict the presence of CA:C14-17 with PBT and/or vPvB properties. The proposed approach to grouping congeners is in line with the ECHA approach to 'Regulating substances based on constituents' presented to CARACAL and RIME+ in 2020 and 2021 (ECHA, 2020, ECHA, 2022).

The Dossier Submitter is proposing to restrict the presence in substances, mixtures and articles of:

'Linear chloroalkanes with the following molecular formulae:

- $C_{14}H_{30-y}Cl_y$ where $y = 3$ to 11
- $C_{15}H_{32-y}Cl_y$ where $y = 3$ to 8
- $C_{16}H_{34-y}Cl_y$ where $y = 3$ to 8
- $C_{17}H_{36-y}Cl_y$ where $y = 6$ to 9 '

which corresponds to the CA:C14-17 identified by the MSC as having PBT and/or vPvB properties.

The Dossier Submitter identified 69 substances that may contain CA:C14-17 having PBT and/or vPvB properties. However, it is not possible to establish an exhaustive list of substance identifiers as the basis for a restriction. It is estimated that ~55 000 tonnes of CA:C14-17² are used annually in EU with EC 287-477-0 as the main contributor to this tonnage.

CA:C14-17 have been detected in various environmental media (e.g., surface water and sludge, air, sediments and soils, other biota) in Europe but also in remote locations such

¹ 'congeners', 'congener group' or 'group of congeners' is defined as 'a group of constituents sharing the same molecular formula irrespective of the position of the chlorine substituents on the carbon chain (e.g. the $C_{15}Cl_7$ congener group).

² Equivalent to ~79 000 tonnes of substances containing CA:C14-17

as the Arctic, the Antarctic and the Tibetan Plateau at high altitude. Substances containing CA:C14-17 are mainly used as plasticisers, flame-retardants, or lubricants in the formulation of various mixtures and articles that are subsequently used by industry, consumers and professionals. Substances containing CA:C14-17 are used in various sectors, and in a broad range of applications such as in PVC, adhesives and sealants, rubber, metalworking fluids, paints and coatings and leather fatliquor. Releases may happen at all stages of the life-cycle including during the waste phase. The Dossier Submitter estimated the current releases of CA:C14-17 to the environment to be between 5 200 and 6 300 tonnes per year in Europe. This corresponds to a total of approximately 104 000 to 126 000 tonnes of CA:C14-17 released to the environment during the 20-year assessment period used in this Annex XV report. Uses in PVC and in adhesives and sealants are the largest contributors in term of release. Due to the PBT and/or vPvB properties, a quantitative risk assessment is not appropriate, and releases of CA:C14-17 are therefore used as proxy for risk (and risk reduction).

While some (limited number of) substances containing CA:C14-17 are already on the Candidate List, this is not sufficient to address the risk posed by the congeners with PBT and/or vPvB properties. In addition, the operating conditions and risk management measures in place are not effective to address the risk associated with the broad, and wide-dispersive uses of the substances containing CA:C14-17. Thus, an action on a Union-wide basis is warranted to effectively reduce the environmental exposure to PBT and/or vPvB substances in the EU. An EU-wide action would also limit the potential for trans-boundary exposure from EU sources, and would avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

The Dossier Submitter assessed several Union-wide risk management measures ranging from voluntary measures (e.g., Ecolabelling, voluntary industry commitment or action) to legislative ones (e.g., Industrial Emission Directive, RoHS, Biocidal Products Regulation, Product Safety Directive, Waste Directive, REACH authorisation, REACH restriction). It was concluded that a REACH restriction would be the most appropriate EU-wide measure to address the risk posed by CA:C14-17 with PBT and/or vPvB properties. Among the issues to be addressed, the Dossier Submitter noted a lack of transparency and communication in the supply chain re. the presence (or absence) of CA:C14-17 with PBT/vPvB properties in other substances, mixtures and articles. The Dossier Submitter performed the impact assessment of several restriction options (ROs) to restrict the presence of CA:C14-17 with PBT and/or vPvB properties in substances, mixtures and articles. The ROs assessed were:

- RO1 – Ban on placing on the market
- RO2 – Ban on placing on the market and use
- RO3 – Ban on manufacturing and placing on the market
- RO4a, RO4b and RO4c – Ban on placing on the market with derogations for specific uses or sectors
- R05 – Complementary measures to accompany the communication down the supply chain.

The assessment of the different ROs is underpinned by information on uses, releases, availability of alternatives and socio-economic impacts, and was supported by three calls for evidence and multiple interviews and meetings with stakeholder associations and companies to explore the impacts of the various ROs on different sectors.

The Dossier Submitter concluded that (i) RO1, RO3, RO4a, and RO4b would address the identified risk and would fulfil the REACH Annex XV criteria for a restriction in terms of effectiveness, practicability (including enforceability) and monitorability, and that (ii) RO5 would support and enhance their enforceability, and effectiveness.

Indeed RO1, RO3, RO4a, and RO4b are (i) targeted to the risk posed by the presence of congeners with PBT and vPvB properties, (ii) capable of reducing the risk (release reduction by ~90 %, and limiting the potential for 'regrettable' substitution) within a reasonable period of time (transition period of 2 years) as suitable alternatives are

available for most of the uses, and (iii) proportionate to the risk, considering that the costs and cost effectiveness ratio of the ROs appear to be in line with the previous restrictions for substances of similar concern and because of the unknown (but potentially significant) damage that the emissions of CA:C14-17 are expected to cause as they continue to accumulate in the environment.

RO1, RO3, RO4a, and RO4b are also concluded to be practical and monitorable both for industry and enforcement authorities, acknowledging that a lot of progress have been made in recent years regarding the detection and quantification of CA:C14-17 in laboratory analysis.

The Dossier Submitter also identified key uncertainties in the assessment and concluded that the individual and collective uncertainties do not impact the conclusions on the effectiveness of RO1, RO3, RO4a and RO4b.

As a result of the impact assessment, and considering that the proposed restriction could also be useful for the on-going discussions in relation to the POP listing of substances containing CA:C14-17 under the Stockholm Convention (which always bans manufacture of POPs (except for the exempted uses)), the Dossier Submitter proposes two restriction entries³ for evaluation by RAC, SEAC and Forum:

- Option A: A combination of RO3 + RO5, i.e. Ban on manufacturing and placing on the market (TP: 2 years, concentration limit 0.1% in substance, mixture and article)
- Option B: A combination of RO4b + RO5, i.e. Ban on placing on the market (TP: 2 years, concentration limit 0.1% in substance, mixture and article) with a longer TP (7 years) and conditional derogation for metalworking fluids

Table 1 provides a summary of the effectiveness of each option. As reported in the table, the cost-effectiveness ratios are 66 €/kg and 55 €/kg of avoided release for option A and B, respectively. The incremental cost-effectiveness ratio is also informative as it measures the marginal abatement costs for the releases. For example, when moving from option B to option A, an incremental effect of avoiding 600 tonnes⁴ of CA:C14-17 release has an incremental cost of 1 333 €/kg.

Table 1. Summary of the proposed restriction, their associated release reduction potential, cost and cost effectiveness over the 20-year period

Annex XVII proposal	Release reduction (over 20 years)	Cost to society (20-year NPV, 3%)	Effectiveness of the option
Option A	~ 103 000 tonnes ^[1] (74 500 tonnes - NPV, 3 %)	€4.9 billion	~90 % release reduction compared to the baseline C/E: 66 €/kg avoided release
Option B	~ 102 700 tonnes ^[2] (73 900 tonnes - NPV, 3 %)	€4.1 billion	~89-90 % release reduction compared to the baseline C/E: 55 €/kg avoided release

Note: [1] value rounded to the nearest thousand
[2] value rounded to the nearest hundredth

³ For the proposed wording of the Annex XVII entry, please refer to Table 17 and Table 18.

⁴ NPV, 3 % - over 20 years

REPORT

1. Problem identification

1.1. Background

Chloroalkanes, also known as chlorinated paraffins or chloroparaffins, are a family of UVCB⁵ substances which are composed of a broad range of constituents. These constituents may vary in terms of their carbon chain length and the degree of chlorination. Chloroalkane constituents sharing the same empirical formula are commonly described as 'congener groups'⁶.

In Europe, chloroalkanes may be qualified as 'short', 'medium' or 'long' depending on the length of their carbon chain. Typically, 'medium' chain chloroalkanes have a carbon chain length in the range of C14 to C17 which corresponds to an approximate molecular formula of: $C_xH_{(2x-y+2)}Cl_y$, where $x = [14, 17]$ and $y = [1, 17]$. 'Short' and 'long' chains have respectively carbon chain shorter than C14, and longer than C17.

In June 2021, some linear chloroalkanes were identified by the ECHA Member State Committee as substances of very high concern (SVHC) on the basis of their persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties in accordance with Annex XIII to the REACH Regulation (ECHA, 2021a). These chloroalkanes were subsequently added to the Candidate List with the following description 'MCCP (defined as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17)'.⁷

As agreed by the Member State Committee and summarised in the hazard assessment section (Section 1.4.2) of this report, the identification of 'MCCP' as SVHC with PBT and vPvB properties is based on the presence of "*congener groups with PBT and/or vPvB properties at a concentration ≥ 0.1 %*". Table 7 gives an overview of the 'linear chloroalkanes with carbon chain lengths within the range from C14 to C17', and in particular the ones "*concluded to have PBT and/or vPvB properties in accordance with Annex XIII of the REACH Regulation*".

In addition, the Member State Committee noted that "*other substances may contain 'MCCP' congener groups with PBT and/or vPvB properties*", and that "*such substances could also be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if these congener groups are present in a concentration ≥ 0.1 % (w/w)*" (ECHA, 2021a).

In parallel to the SVHC identification process, the United Kingdom submitted a proposal (UK, 2021) for listing 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥ 45 %' in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (UNEP, 2021).

According to the EU Commission document on the interlinkage between REACH, the Stockholm Convention and the UNECE POP Protocol (EU Commission, 2014b), it is good practice for the EU Member States or the Commission to initiate a restriction procedure under REACH if a substance is nominated to be listed under the POP Convention. On one hand, the REACH restriction process will help to contribute to the scientific documents discussed in the POP Review Committee of the Stockholm Convention and will facilitate the development of the EU position for the Conference of Parties in which the listing of the substances will be decided; on the other hand, as the REACH restriction procedure could be considerably quicker than the POP Convention, it may be desirable to introduce risk management measures in the EU in the form of a REACH restriction which would apply until superseded by the POP Convention and the POPs Regulation.

⁵ UVCB are substances with unknown or variable composition, complex reaction products or of biological materials.

⁶ 'congeners', 'congener group' or 'group of congeners' is defined as 'a group of constituents sharing the same molecular formula irrespective of the position of the chlorine substituents on the carbon chain (e.g. the $C_{15}Cl_7$ congener group).

⁷ A non-exhaustive list of substances falling within the scope of the Candidate List entry is available on ECHA website.

For both these reasons, in July 2021 the European Commission requested ECHA (EU Commission, 2021c) to start investigating the risks arising from the manufacture, use (industrial, professional, consumer) and placing on the market of medium chain chloroalkanes in substances, mixtures and articles and, where appropriate, propose restrictions in an Annex XV report. The request indicated that uses in PVC should be out of scope of the restriction proposal as dedicated risk management work on substances used in PVC was being planned by the Commission. However, ECHA was requested to collect relevant information on the uses in PVC.

In March 2022, the Commission clarified that considering the concerns related to the PBT and/or vPvB properties of some congeners of 'MCCP' (defined in the Candidate List as 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17'), ECHA's investigation should cover all substances containing 'MCCP' congeners with PBT and/or vPvB properties. This clarification aligned ECHA's investigation with the UK POP listing proposal, which is not targeting individual substances but the presence of constituents of concern.

In addition, the Commission also extended the scope of the restriction request by explicitly adding the uses in PVC (EU Commission, 2022a).

In line with this mandate (EU Commission, 2021c, EU Commission, 2022a), ECHA, hereafter referred to as the Dossier Submitter, investigated the manufacture, use (industrial, professional, consumer) and placing on the market of substances, mixtures and articles containing chloroalkanes with medium carbon chain length; and assessed (i) if risks are adequately controlled and (ii) the impacts of risk management measures on society.

Three calls for evidence (CfE) were organised, and the Dossier Submitter also contacted ~120 stakeholder organisations, all registrants and C&L notifiers potentially impacted, as well as laboratories working for Member State enforcement authorities, to gather information for the restriction preparation (cf. Appendix G).

Throughout the report, the Dossier Submitter will refer to 'CA:C14-17' to describe 'the congeners/congener groups of chloroalkanes (chlorinated paraffins) with carbon chain lengths within the range from C14 to C17'. The acronym 'MCCP' will only be used to refer to the Candidate List definition, i.e. 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17'. Unless referring to titles of previous regulatory works or scientific study, this report will use the IUPAC terminology 'chloroalkane' rather than 'chlorinated paraffin'.

1.2. Identification, physical and chemical properties

1.2.1. Identification

The Dossier Submitter is proposing to restrict the presence in substances, mixtures and articles of:

'Linear chloroalkanes with the following molecular formulae:

- $C_{14}H_{30-y}Cl_y$ with $y = 3$ to 11
- $C_{15}H_{32-y}Cl_y$ with $y = 3$ to 8
- $C_{16}H_{34-y}Cl_y$ with $y = 3$ to 8
- $C_{17}H_{36-y}Cl_y$ with $y = 6$ to 9 '

The four main justifications for the proposed approach are:

1. A 'targeted identification'

The scope of the proposed entry corresponds to CA:C14-17 (i.e. constituents/congeners of 'MCCP') that have PBT and/or vPvB properties.

During the SVHC identification process of 'MCCP', the ECHA Member State Committee (MSC) concluded that the congener groups listed above have PBT and/or vPvB properties (ECHA, 2021a). The conclusions of the ECHA Member State Committee assessment underlying the SVHC identification of 'MCCP' are reproduced in Table 7. The original text from the MSC agreement is available in Appendix B4.

2. An 'effective identification'

CA:C14-17 with PBT and/or vPvB properties may be present in many substances. The Member State Committee noted indeed that *"substances other than 'MCCP' may contain congener groups with PBT and/or vPvB properties"*, and that *"such substances could also be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if these constituents/congener groups are present in a concentration ≥ 0.1 % (w/w)"* (ECHA, 2021a).

According to REACH Annex I, the risks of PBT and/or vPvB substances cannot be adequately controlled. Therefore, any congener identified as PBT/vPvB may cause severe and irreversible adverse effects if released.

In addition, it is recognised that regulating UVCB substances that contain hazardous constituents on an individual basis (i.e. on a substance-by-substance basis) will have limited effectiveness where the same hazardous constituents are also present in other substances (ECHA, 2020, ECHA, 2022).

Regulating UVCB substances on one-by-one basis could lead to regrettable substitution to other UVCBs that contain the same hazardous constituents. Therefore, rather than a restriction on substances, the Dossier Submitter is proposing to restrict the presence of CA:C14-17 constituents (congeners) with PBT and/or vPvB properties.

The Dossier Submitter identifies in Appendix B.1 to this report 69 substances that could potentially contain CA:C14-17 with PBT and/or vPvB properties, and could therefore qualify as PBT or vPvB themselves. The list provided in Appendix B.1 is not exhaustive. Constituents of concern may be present in many substances at concentrations <20 % (w/w). However, the large number of substances used in high tonnages in a wide range of uses and potentially containing CA:C14-17 with PBT and/or vPvB properties can lead to significant overall exposure and releases of those constituents to the environment (cf. Appendix A.2 and B.5 and section 1.4.3).

3. A 'practical identification': the marker/indicator concept

During the SVHC identification process of 'MCCP', the ECHA Member State Committee noted that *"other substances than 'MCCP' could be also considered to meet the REACH Annex XIII criteria for a PBT and/or vPvB substance if the congener groups (i.e. CA:C14-17) identified with PBT and/or vPvB properties are present in a concentration ≥ 0.1 % (w/w)"*.

The Member State Committee indicates therefore that CA:C14-17 with PBT and/or vPvB properties may be used as markers or indicators of PBT and/or vPvB concerns in other substances when their concentration is > 0.1 %.

This 'markers or indicators' approach is not new; it has already been used in the past in other restrictions to address risks from substances for which the concern is related to hazardous constituents present in several substances, for example in REACH Annex XVII entry 50 on polycyclic aromatic hydrocarbons (PAH).

The Dossier Submitter also notes that additional indicators could be used to identify the PBT and/or vPvB concerns in other substances. Given the manufacturing process of chloroalkanes, and the chlorination process in particular, CA:C14-17 with higher degree of chlorination (such as the ones identified in Table 7 for which the Member State Committee could not conclude on the PBT and/or vPvB properties) could also be indicators for the presence of CA:C14-17 with PBT and/or vPvB properties as per Table 7. However, it should be kept in mind that the mere absence of such congener group with higher degree of chlorination does not imply that the CA:C14-17 with PBT and/or vPvB properties are absent from the substances.

4. An 'enforceable identification'

When it comes to the identification of a substance, multiple alternatives may be used for describing certain substances under REACH, in particular UVCB substances, as long as the information given is sufficient to enable the substances to be clearly identified (ECHA, 2017).

Therefore, different names or numerical identifiers may have been used for describing certain substances under REACH, and it may not always be possible to list all the relevant associated identifiers. Chloroalkanes fall under this category.

In addition, in the specific case of chloroalkanes, the identifiers used do not necessarily provide a precise representation of the composition. They may for instance not quote the exact carbon chain lengths expected to be present in the composition of the substance described (cf. Appendix B.1). The Dossier Submitter considers that this aspect needs to be taken into account when establishing enforceable elements for defining the substances covered by the proposed restriction.

Further, it should be noted that the concern addressed in this restriction proposal stems from the properties of certain congeners that may be present in the composition of a substance. However, information on the composition is not available for all substances, mixtures or articles manufactured/imported in the EU. Therefore, it may not be possible to establish a list of all the substances relevant to the current restriction proposal.

In light of these considerations, the Dossier Submitter proposes to define the scope of this restriction using molecular formula descriptors that provide a clear characterisation of the congeners of concern, rather than establishing a list of numerical identifiers such as EC or CAS numbers.

As summarised in Appendix B.1 there is a wide range of analytical methods and techniques available to identify and quantify CA:C14-17 with PBT and/or vPvB properties on the basis of their molecular formula. These techniques range from 'binary' screening (yes/no response) to more advanced techniques which provide a more precise quantification of the result.

Other ways to define the substance identity:

Appendix E describes other options to define the scope of the restriction proposal, as well as the reasons why these options were dismissed by the Dossier Submitter during the preparation of the restriction proposal. Each of these options was assessed against the following subset of REACH restriction criteria: Effectiveness (i.e. targeted to the risk, risk reduction), Practicality (i.e. implementable for industry and the supply chain), Enforceability.

1.2.2. Overview of the substances potentially falling within the scope of the proposed entry

The Dossier Submitter identified, in Appendix B.1, 69 substances that may contain CA:C14-17 with PBT and/or vPvB properties and that may fall in the scope of the

proposed restriction. However, some of these substances may have negligible or no current use.

The list in Appendix B.1 was used to estimate the baseline releases and exposure, the availability of alternatives and the impact of the proposed restriction options.

While directly using the list of EC and CAS numbers provided in Appendix B.1 may seem straightforward for defining the substances to be restricted, this approach is not appropriate when the concern to be addressed is related to the presence of constituents of concern. As explained in section 1.2.1, it is not possible to establish an exhaustive list of the relevant substances identified with an EC or CAS number (ECHA, 2020, ECHA, 2022).

As described in Appendix B.1, the presence and concentration of CA:C14-17 of concern in a substance depends on the composition of the feedstock and on the manufacturing circumstances used to manufacture that substance (i.e. specific to each supplier/manufacturer of the substances).

It is therefore not always possible to conclude with certainty if a substance would contain CA:C14-17 with PBT and/or vPvB properties solely on the basis of its identifiers (e.g. EC or CAS number).

The use of EC 264-150-0 (associated to a substance described by the acronym 'LCCP' in Europe) illustrates very well this issue: the EC name 'Paraffin waxes and Hydrocarbon waxes, chloro' that is associated with EC 264-150-0 does not specify the carbon chain lengths expected to be present in the composition of the substance. Based on this identifier it is therefore not possible to conclude on the specific composition of a substance associated to this EC entry and the substance may include CA:C14-17 in its composition.

Similarly, the ECHA dissemination site⁸ (accessed on 13 April 2022) lists 14 compositions registered under REACH, and among them, three compositions clearly indicate the presence of CA:C14-17. The presence of CA:C14-17 with PBT and/or vPvB properties is reported in the composition of the substance identified with EC 264-150-0 in concentrations varying between below 0.1 % up to 20 % depending on the manufacturer (see ECHA market survey).

Information gathered from the BfR products database also indicates that a variety of substances having different carbon chain lengths have been identified as EC 264-150-0 (BfR, 2022). Also, in the POP listing proposal (UK, 2021), the UK indicates that the presence of C14-17 carbon chain lengths is reported in the composition of the substance identified as EC 264-150-0 (based on a C18-20 carbon chain length) in concentrations up to 20 %.

Finally, since the identity of the substances to be restricted under REACH and under POP has not been assessed and agreed, it is not possible to conclude definitely if there may be differences in the scope potentially covered by the UK POP proposal and this restriction proposal. Appendix B.1 provides a snapshot of the main differences between the two proposals. This may evolve in the future.

1.2.3. Physical chemical properties

An overview of the physical chemical properties of CA:C14-17 with PBT and/or vPvB properties is provided in Appendix B.1.

Unless stated otherwise, the main source of the physical chemical properties is the Member State Committee Support document for the SVHC identification of 'MCCP' (defined as UVCB substances consisting of ≥ 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) (ECHA, 2021d, ECHA, 2021b).

1.2.4. Justification for grouping

As explained in section 1.2.1, the grouping based on congeners for the purposes of this restriction is primarily justified as the relevant congeners have a similar chemical structure and hazard profile (vPvB and/or PBT properties).

⁸ REACH registered substance factsheets: <https://echa.europa.eu/registration-dossier/-/registered-dossier/14895>

According to REACH Annex I, the risk to the environment and to human health cannot be adequately controlled for PBT and/or vPvB substances and therefore any congener identified as PBT/vPvB may cause severe and irreversible adverse effects on the environment if releases are not minimised.

The Dossier Submitter is proposing to restrict the presence of CA:C14-17 constituents (congeners) having PBT and/or vPvB properties. This approach differs from the one taken for the Candidate Listing of 'MCCP' where only a limited set of substances is regulated despite the confirmation by the Member State Competent Authorities that the constituents with PBT and/or vPvB properties may be present in other substances (ECHA, 2021a).

Listing a limited number of identifiers for describing the substances relevant for the proposed restriction will not address the concern related to the presence of one or several constituents of concern. This is because, as explained in section 1.2.1 and 1.2.2, it is not possible to draw a list of all the identifiers describing the substances containing CA:C14-17 with PBT and/or vPvB properties.

Congeners having PBT and/or vPvB properties may be present in other substances. It can be reasonably expected that congeners of concern are present in limited amounts <20 % in these substances. However, these substances may be used in high tonnages in a wide range of uses and can possibly lead to significant overall exposure and releases to the environment of congeners with PBT and/or vPvB properties.

Similarity in composition may also make it technically and economically feasible to substitute one chloroalkane with another that contains similar or even additional congener groups of concern. The Dossier Submitter confirmed this assumption by cross-checking the information on uses reported for chloroalkanes and other substances that may contain chloroalkanes in various databases (ECHA dissemination website, SCIP dissemination website, BfR (2022) and other online databases). Detailed information on the uses reported in different sources is available in Appendix A.2 and section 1.3. Substances containing CA:C14-17 are mainly used as plasticisers, flame-retardants, or lubricants in the formulation of various mixtures and articles that are subsequently used by industries, consumers and professionals. The technical properties of the substances are broadly similar.

Considering the above, a substance-by-substance rather than a congener approach to restriction could result in 'regrettable substitution' and reduce the effectiveness of risk management. Indeed, regrettable substitution from short chain chloroalkanes to medium chain chloroalkanes has been observed in the past (Fernandes et al., 2020, Guida et al., 2020).

In addition, it should be noted that it is not always possible to determine the presence of constituents of concern in the composition of a substance on the basis of its identifiers as the EC or CAS identifiers used for describing a substance may not be specific on the carbon chain lengths (cf. Appendix B).

This shows that the approach taken so far to regulate the chloroalkanes individually (or in small groups like in the Candidate List) is not efficient and does not fully address the PBT and vPvB concerns posed by these substances.

The proposed grouping of congener approach is in line with the ECHA document on 'Regulating substances based on constituents' presented to CARACAL and RIME+ in 2020 and 2021 (ECHA, 2020, ECHA, 2022) and follows the key principles from the Chemical Strategy for Sustainability which recommends both (i) "*a gradual move away from assessing and regulating chemicals substance-by-substance to regulating them by groups*", and (ii) "*to prioritise (...all PBT and vPvB substances with professional and consumer uses...) for restrictions (...) through grouping, instead of regulating them one by one (...until the Generic Approach to Risk Management has been extended)*" (EU Commission, 2020a).

A similar grouping approach by congeners, although a bit different, is also proposed by the UK when proposing to list 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥ 45 %' in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (UNEP, 2021). Based on this definition, the UK appears to also consider that many substances may contain the chlorinated paraffins

to be restricted under POP and that an exhaustive list of substances cannot be established (cf Appendix B).

The same concern regarding the designation of the substances to be restricted is also recognised in the conclusion from the RoHS study (EU Commission, 2020b): *"Regarding the global differences to the nomenclature and CAS numbers used in various regions, a restriction of chlorinated paraffins should rather use a definition of chlorine content in relation to a chain length within a certain range instead of referencing to CAS/EC numbers. It is therefore recommended to restrict medium chain chlorinated paraffins and add an explanation that this entry covers chlorinated paraffins containing paraffins with a chain length of C14-17 – linear or branched."*

To summarise, the proposed grouping on congeners is based on structural similarity and PBT and/or vPvB properties. The grouping is also justified by the desire to avoid regrettable substitution and prevent future release of congeners of concern.

1.3. Manufacture, import and uses overview

The information on manufacture, import and uses provided in this chapter is related to the substances that may contain CA:C14-17 and that are identified in Appendix B.1.

1.3.1. Manufacture and Import

Among the substances that may contain CA:C14-17, six of them are registered by 46 active registrants; 33 of the registrants are manufacturers or manufacturers/importers, three are only importers, and 10 are only representatives.

The total registered tonnages are given as public tonnage bands, but one should keep in mind that not all this registered tonnage consists of CA:C14-17.

Table 2. REACH Registration status of substances containing CA:C14-17

EC Number	CAS Number	Substance Name	Tonnage band	Active registrants
287-477-0	85535-85-9	Alkanes, C14-17, chloro	≥ 10 000 to < 100 000 tonnes	11
-	-	Di-, tri- and tetrachlorotetradecane	< 10 tonnes	1
269-145-7	68188-19-2	Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated	Intermediate use only	5
-	1469983-39-8	Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified	≥ 1 000 to < 10 000 tonnes	13
264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro	≥ 10 000 to < 100 000 tonnes	7
-	-	Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified	≥ 100 to < 1 000 tonnes	9

63 other substances are not registered.

Source: ECHA dissemination website consulted on 12 April 2022

Note: intermediate uses are within the scope of REACH restriction except on-site isolated intermediates (REACH Article 68(1) paragraph 2). This substance is not registered as an on-site isolated intermediates and thus is in the scope of the restriction.

There is no information available specifically on the import and placing on the market of the substances containing CA:C14-17 in articles. The registration dossiers do not provide information on the tonnages in articles (REACH Article 7(1) and (5)). Six 'substance in article' notifications (REACH Article 7(2)) were received for four substances listed on the Candidate List, all describing uses in cables and indicating the tonnage produced in the EU but no imported tonnage.

In addition, the analysis of PRODCOM data (Appendix A) on various types of uses and applications relevant for this restriction did not allow to conclude on the quantity of substances containing CA:C14-17 imported in articles. The uncertainty related to the tonnage imported in article is further elaborated in section 3.

Based on information from registrants (collected in registrations and via direct request to Registrants in February 2022), the current tonnages of substances containing CA:C14-17 are reported in Table 3.

Table 3. Estimated aggregated tonnages of substances containing CA:C14-17 and aggregated tonnages of CA:14-17 congeners, manufactured and used in the EU

	Tonnage of substances containing CA:C14-17 (tonnes per year)	Tonnage of CA:C14-17 (tonnes per year)
Tonnage manufactured	51 000	33 000
Tonnage imported	32 000	25 000
Tonnage exported	2 600	2 400
Tonnage used (i.e. manufactured and imported, minus tonnage exported)	~ 79 000	~ 55 000

The details of the assumptions leading to this estimate are reported in Appendix B. In particular, the percentage of CA:C14-17 in chloroalkanes varies between 10 % and 100 % depending on the substance considered.

1.3.2. Uses overview

Substances containing CA:C14-17 are used in a broad range of applications to confer several properties to the final products. The uses as well as the main final products are described in the Table 4 together with the main technical functions provided by the substances covered by this restriction.

The information on uses is based on findings consolidated from various sources:

- Registration data published on ECHA Dissemination website
- Annex XV dossier for SVHC identification (ECHA, 2021b)
- UK RMOA (UK Environment Agency, 2019)
- German RMOA
- RoHS Annex II Dossier for EC 287-477-0 (EU Commission, 2020b) based on the KEMI proposal (KEMI, 2018)
- BfR (2022) product database, SCIP data.

Moreover, stakeholder inputs provided in the context of the CfE1 (only on EC 287-477-0), CfE2 and CfE3 and the findings from ECHA's market survey were used to refine the understanding of current uses, identify obsolete ones and gain a more in depth understanding of the functions of the substances in different applications. For example, based on the information provided by industry (ECHA market survey and CfEs), substances containing CA:C14-17 such as EC 287-477-0 appear to have been phased out or to play a minor role in PVC flooring, PVC coating for textiles, fatliquors, PVC tubes, pipes and paper.

Information on the average concentration of substances containing CA:C14-17 in mixtures or articles is also available in Table 4. The information displayed in the table is essentially based on information gathered from previous reports and the CfEs (CfE1 on EC 287-477-0, while CfE2 and CfE3 were on all chloroalkanes under investigation). In addition, other sources of information such as BfR (2022) (which referred to substances containing CA:C14-17), SCIP data disseminated on the ECHA website (which referred to Candidate List Substances) and the ECHA market survey provided additional information on typical concentration ranges in mixtures or articles. Overall, the data on

concentration are consistent, and in the same order of magnitude between the different sources of information for the various chloroalkanes containing CA:C14-17. In addition, data from the BfR (2022) product database show also similar level of concentration of substances containing CA:C14-17, whatever the chloroalkane used in the formulation (cf. Appendix A.2).

An overview of main uses of substances containing CA:C14-17 is presented in Table 4.

Table 4. Main uses overview

Use number and use name	End products and examples of applications	Main technical functions	Proportion of the use ^[3]	Average concentration of substance containing CA:C14-17 in end products
#00 PVC	Substances containing CA:C14-17 are predominantly used in PVC compounds used for producing PVC cables and sheathing. The presence of these substances may also be identified to a lesser extent in PVC conveyor belts.	Flame retardant Secondary plasticiser	~ 26 %	5 %-18 % ^[5]
#01 Use in adhesive and sealants	Substances containing CA:C14-17 are predominantly used in polyurethane and polysulfide-based sealants to seal cracks or joints. The use of substances containing CA:C14-17 has been identified in the following types of products ^[1] : - One-component foams (OCF) ^[2] – also known as PU foams or PUR foams, used in the construction sector to seal gaps in constructions, for installing door and window frames, for sound insulation, as thermal insulation (Brandsma et al 2021), etc. - Insulating glass polysulfide sealants for the use on windows with multiple panes of glasses (e.g. double glazing, triple glazing, etc). The presence of substances containing CA:C14-17 may also be identified in: - Adhesives used in automotive industry (e.g. self-adhesive foam strips adhesive of interior materials and epoxy-filled adhesives for electronic components) - Tapes used in construction sector and aerospace applications. Rigid polyurethane foams (RPUFs), which have many different applications (e.g. as thermal insulation and structural materials for refrigeration equipment and construction, etc)	Plasticiser Flame-retardant Viscosity modifier Insulant Non-volatile filler Adhesion promoter	~ 60 %	10 %-30 % ^[5]
#02 Use in rubber	Substances containing CA:C14-17 are used in specific types of General rubber goods that require flame retardancy properties, notably in rubber conveyor belts and rubber tubes used in mining and underground activities. Other products which may contain substances containing CA:C14-17 are for example: - O-rings in automotive applications (e.g. oil tanks) - Sleeves for cooling systems	Plasticiser Flame retardant Waterproofing agent	~ 5 %	10-15 % (rubber conveyor belts) 3-10 % (O-rings, sleeve for cooling systems and rubber grommet)

Use number and use name	End products and examples of applications	Main technical functions	Proportion of the use ^[3]	Average concentration of substance containing CA:C14-17 in end products
	- Rubber grommet in electrical components.			
#03 Use in metalworking fluids	Substances containing CA:C14-17 are added to certain types of metalworking fluids (e.g. neat oils) which are used in the processing of certain metals under extreme conditions.	Extreme pressure additive (EP)	~ 5 %	5 % (light machining) up to 70 % (heavy drawing process)
#04 Use in paints and coatings	Substances containing CA:C14-17 are used in specialised solvent-based coatings, e.g.: - Protective coatings and marine coatings, that provide water and chemical resistance to the treated surfaces - Anti-fouling paints and coating (as co-formulant in Biocidal product) - Intumescent coatings, used to protect steel substrates of constructions exposed to fire and which work by increasing in volume when exposed to heat ^[4] . - Flame retardant paints ^[4] .	Flame retardant. Plasticiser Viscosity modifier Adhesion promoter	~ 1 %	4-15 % ^[5]
#05 Use in leather	Substances containing CA:C14-17 are used in fatliquors in the processing of leather (re-greasing of leather)	Softening agent Leather resistance Waterproofness	< 1 %	10 % ^[5]
#06 Use in paper ^[4]			0 %	n/a
#07 Other uses in mixtures (lubricants)	Other products where the presence of substances containing CA:C14-17 can be identified are in particular lubricants.	Lubricants	~ 2 %	n/a

Source: Calls for Evidence (CfEs), BfR (2022), SCIP and ECHA dissemination website, ECHA market survey.

Note: [1] non-exhaustive list.

[2] "PU one-component foam (OCF) system consists of an aerosol can filled with PU prepolymers functionalized with NCO groups together with additives and blowing agents that will pressurize the can" (Marques et al., 2017)

[3] expressed in % of total CA:C14-17 tonnage, Cf. Appendix B.5.

[4] use mostly obsolete. Based on the information provided by the relevant stakeholders, the Dossier Submitter understands that the companies from these sectors are using EC 264-150-0 (with a carbon chain length within the range from C22 to C30), which – based on information provided by registrants – is expected to contain CA:C14-17 with PBT and/or vPvB properties in a concentration <0.1 % (w/w).

[5] lower and higher concentrations were reported in SCIP or BfR (2022) product database. Cf. Appendix A.2.

The products containing CA:C14-17 are used in a wide range of sectors. A non-exhaustive list of these sectors is provided below:

- PVC cables are for example used in the construction sector (for the supply of electricity in buildings and other civil engineering works) and in electrical and electronic applications
- One-component foams and insulating glass sealants are used in the construction sector to seal cracks or joints and so improve the energy efficiency of the buildings.
- Rubber conveyor belts used by the mining sector
- Marine coatings are used in the marine sector "as an intermediate or finishing coating on steel structures in moderately to severely corrosive environment, including permanently submerged surfaces (ECHA, market survey)"

- Metal parts resulting from metalworking operations which rely on the use of metalworking fluids containing CA:C14-17 are used in the manufacture of components for automotive, aerospace and electronic applications. They are also used to produce high spec components for nuclear and military applications, deep sea oil and gas extraction and heat exchangers in conventional and renewable power generation.

The Dossier Submitter notes that some of the studies reviewed during the dossier preparation found CA:C14-17 in very low quantity in various types of food/feed packaging (Chen et al., 2021, Dong et al., 2020, Wang et al., 2019, Wang et al., 2018). According to the authors of some studies, the low concentration may reflect impurities rather than an intentional use of substances containing CA:C14-17 in food/feed packaging (made of various polymers including soft PVC). The sector association Plastics Recyclers Europe also confirmed that the presence of CA:C14-17 in soft PVC packaging would be unintended as there is no need for flame retardancy for this type of use, and that it is *“highly unlikely that substances containing CA:C14-17 would be [intentionally] used in the sector of soft PVC packaging”* (CfE3 #1522).

1.3.3. Waste management

CA:C14-17 do not react or transform during their lifecycle and deliver their technical function during their use as mixtures (e.g. metalworking fluids) and in the articles or materials (other uses). Ultimately, the tonnage used and not lost (i.e. released or destroyed) during the use will be disposed of as waste (EU Commission, 2005). Therefore, it is relevant to consider the waste stage. Detailed information on waste and the fractions sent to the different waste streams is available in Appendix B. This section aims at describing the main waste management streams which are considered relevant for waste containing CA:C14-17.

1.3.3.1. Legislative context and main waste management streams

Directive 2008/98/EC (Waste Framework Directive, WFD)⁹ defines waste as ‘any substance or object which the holder discards or intends or is required to discard’. According to this definition, residues (e.g. losses from application process), empty cans, waste from equipment and surfaces cleaning, waste from risk management measures (RMMs) (e.g. PPE, filters, sludges, particles), used metalworking fluids that are disposed of, are waste.

On the contrary, by-products (‘substance or object resulting from a production process the primary aim of which is not the production of that substance or object’), if meeting certain conditions¹⁰, are not waste. Some industrial uses produce by-products which can be reused in the same industrial settings, such as metalworking fluids (which can be reused after filtering/recycling), or off-specification products which can also be reused (e.g. scrap PVC in industrial production facilities, scrap metal from metal cutting). Hazardous waste is defined as ‘waste which displays one or more of the hazardous properties listed in Annex III’¹¹. Article 7 of the WFD defines a list of waste (LoW)¹² which

⁹ Amended by Directive (EU) 2018/851.

¹⁰ These conditions are: further use is ‘certain’, it ‘can be used directly without any further processing other than normal industrial practice’, it ‘is produced as an integral part of a production process’ and further use is lawful (‘fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts’) (Article 5 of Waste Framework Directive)

¹¹ The main relevant category for CA:C14-17 is “HP 14 – ecotoxic”. Other categories may apply.

¹² COMMISSION DECISION of 3 May 2000 (2000/532/EC) replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste. Entries of the LoW can be divided into absolute hazardous (AH), absolute non-hazardous (ANH), mirror hazardous (MH) and mirror non-hazardous

is binding as regards determination of hazardous waste. Dilution or mixing of hazardous waste to lower the concentration below the limit for defining waste as hazardous is prohibited (Article 7(4)).

A simplified description of waste fate would consider that waste will be either recovered in the EU (including recycling), disposed of in a non-destructive way in the EU (e.g. landfilled), disposed of in a destructive way in the EU (e.g. incinerated), or exported outside the EU for treatment, recycling or storage. Due to lack of data, no export of waste is considered in this assessment. Hence, the assessment provides conservative estimates of e.g. releases from waste in the EU.

The two main waste management streams (landfill and incineration) are described as follows.

Landfill

A landfill is defined as 'a waste disposal site for the deposit of the waste onto or into land (i.e. underground)'. Under the WFD and in accordance with the waste hierarchy, landfilling is the least preferable option for waste management and should be limited to the necessary minimum. The Landfill Directive (Council Directive 1999/31/EC, amended by Directive (EU) 2018/850) introduces targets to reduce landfilling. Some Member States (Germany, Austria, the Netherlands, Sweden, Denmark, Luxembourg, Belgium and Finland) have adopted landfill restrictions for plastic waste (EU Commission, 2022b). Landfills receiving more than 10 tonnes of waste per day or with a total capacity exceeding 25 000 tonnes, excluding landfills of inert waste, are included in Annex I of Directive 2010/75/EU on industrial emissions (IED)¹³ and are subject to provisions set out in Articles 10 to 27, including implementing Best Available Techniques.

Landfills are operated upon delivery of a permit by authorities which includes requirements for the operating phase, closure and after-care phase. 'After-care' includes maintenance, monitoring and control, in particular of leachate, 'for as long as the competent authority considers that a landfill is likely to cause a hazard to the environment' (Article 13 of the Landfill Directive). The aftercare lasts several decades but could in reality be necessary even for centuries. However, in general, the criteria to end after-care do not appear to take into account substance-specific releases, e.g. of CA:C14-17 (Laner et al., 2012).

The real after-care duration is therefore unknown in general and depends on the conditions of each permit. After the 'after-care' period, a landfill should be capped (Turner et al., 2017), but no further control measures are expected and, therefore, landfills remain an important reservoir of CA:C14-17. Challenges related to the presence of persistent organic pollutants in closed landfills are known; in particular, it cannot be expected that the basal and capping liners of a former landfill will remain efficient over decades or centuries and any remediation would entail enormous costs (Weber et al., 2011).

Due to the targets under the Landfill Directive to reduce landfilling, it is expected that the relative tonnage landfilled instead of incinerated or recycled will decrease over time; however, this cannot be quantified.

Incineration

It is assumed that incineration in state-of-the-art facilities with waste gas treatment fully destroys the substances (EU Commission, 2005, EU Commission, 2020b). However, due to the chlorine content, there is also the possibility that hazardous substances (e.g. polychlorinated dibenzodioxins (dioxins) and polychlorinated dibenzofurans (furans)) are formed if incineration is conducted at too low temperature (< 900°C) (McKay, 2002), CfE#1333).

Incomplete combustion of organic waste in the presence of chlorine and metals (that act as catalysts) lead to the formation of dioxins and furans (McKay, 2002). Studies in lab-

(MNH) entries. It is not the purpose of this restriction dossier to attempt to classify waste containing CA:C14-17.

¹³ DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast) (Text with EEA relevance) (OJ L 334, 17.12.2010, p. 17).

scale furnaces suggest that other hazardous compounds can also be formed, such as aromatic and chlorinated aromatic hydrocarbons (low-chlorinated chlorobenzenes, polychlorinated biphenyls, and polychlorinated naphthalenes) (Xin et al., 2017, Xin et al., 2018).

As the formation of hazardous transformation products depends on the conditions of incineration, it is not possible to quantify to which extent these products are formed in standard waste incinerators in the EU in practice. From a regulatory point of view, the Industrial Emission Directive imposes strict limits on the emission of all harmful pollutants from waste incineration plants (Commission Implementing Decision (EU) 2019/2010)¹⁴.

1.3.3.2. Waste management per waste type

Further consideration can be given to the main waste categories relevant for materials and articles containing CA:C14-17, and in particular:

WEEE (waste from electrical and electronic equipment)

Substances containing CA:C14-17 would end up in WEEE from discarded PVC cables mainly. WEEE are regulated under Directive 2012/19/EU on waste electrical and electronic equipment. In principle, WEEE should be collected separately from household waste and recycled (collection target of 65 % in 2019). However the current collection rate is closer to 40-50 % (KEMI, 2018, EU Commission, 2020b). WEEE not collected separately is disposed of as regular municipal waste but can also be exported outside the EU in significant amounts. Collected WEEE is dismantled manually or shredded mechanically in view to separate the materials for further treatment. After separation, the fraction containing CA:C14-17 (e.g. plastic fraction from cables) is either landfilled, incinerated or recycled, as detailed in Appendix B.

Construction and demolition waste

Construction and demolition waste are regulated under the WFD. This category includes all waste produced by the construction and demolition of buildings and infrastructure, as well as road planning and maintenance. Recycling and material recovery is highly variable depending on the Member State¹⁵. The Directive sets objectives to increase recycling and promote safe handling of hazardous substances through selective demolition measures and the establishment of sorting systems for different construction and demolition waste fractions.

Backfilling ('any recovery operation where suitable non-hazardous waste is used for purposes of reclamation in excavated areas or for engineering purposes in landscaping' as per the WFD) is a low-quality recovery, as it replaces a natural resource (soil) with non-hazardous construction waste. Substances containing CA:C14-17 are used in buildings and infrastructures as sealant/insulant (insulating glass sealant in double/triple glazed windows, OCF, rigid PU foam). Upon dismantling and demolition of buildings these materials would be separated and discarded (mainly to landfill and to a lesser extent to incineration) but could also remain attached to the mineral, wood and plastic fractions of the construction waste that is landfilled or used as backfilling, as detailed in Appendix B.

End-of life vehicles:

It is uncertain whether substances containing CA:C14-17 are used in vehicles in significant tonnage. Based on information from stakeholders, registrations, and the SCIP data base, they can be used in lubricant, electronic components (PVC cable), seats (polyurethane foam). Lubricants and other fluids contained in the end-of-life vehicle are removed in specialised and equipped places (car services, etc.) and collected for disposal (CfE2 #1470). Electrical components are eliminated as WEEE. Directive 2000/53/EC on end-of life vehicles establishes that waste from vehicles has to be collected and

¹⁴ COMMISSION IMPLEMENTING DECISION (EU) 2019/2010 of 12 November 2019 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for waste incineration.

¹⁵ https://ec.europa.eu/environment/topics/waste-and-recycling/construction-and-demolition-waste_en, accessed on 18/03/2022.

transferred to authorised treatment facilities.

Releases to the environment from waste management are estimated and presented in section 1.4.3 and Appendix B. Analytical methods already exist to detect the presence of chlorine and therefore the presence of chloroalkanes in different types of waste streams, to enable separation for specific treatment (see section 2.3.4).

1.3.4. Recycling

Any residual CA:C14-17 in a recovered substance/mixture/material/article would be considered an impurity if present below 20 % concentration (ECHA, 2010). Based on the use description, CA:C14-17 could end up in recycled PVC. The major use of PVC-containing CA:C14-17 is in cables. Although the aim of the recycling of cables is the recovery of the metal fraction, some of the plastic fraction can be recycled too. If not landfilled or incinerated, the plastic fraction can be recycled mechanically via conventional technologies that do not break down the polymer chains (resulting in granulated recycled PVC) (EU Commission, 2022b); non-conventional technologies using solvent-based processes or pre-processing (e.g. Vinyloop®) also exist but are less common (KEMI, 2018).

Mechanical recycling of the plastic fraction of cable waste (flexible PVC) entails cleaning and compression or injection moulding directly into thick-walled plastic articles; no extrusion into pellets is possible (EU Commission, 2022b). Additives such as substances containing CA:C14-17 are not removed in these processes. Chemical recycling (feedstock recycling) is not common in the EU for PVC cables (EU Commission, 2022b, KEMI, 2018).

According to Plastics Recyclers Europe (CfE3 #1522), articles produced with recycled flexible PVC from cables include mostly road equipment (road traffic safety), but other articles such as industrial flooring, roofing and insulating membranes, footwear, mats, garden hoses, ropes may also be produced from recycled PVC. Direct reuse in cable insulation is on the contrary unlikely (although it may still occur) due to the impurities recycled PVC contains (KEMI, 2018).

Both the EU Commission (2022b) and Plastics Recyclers Europe note that, although PVC recyclate has usually a good market value and is able to compete with virgin PVC, the recycling of the PVC from cables is not economically attractive for operators. Indeed, following the 2019 Chinese government ban on the import of certain types of plastic, there is currently an abundance of cable waste on the market. Mainly cable sheathing, which is a side product from cable recycling and made from PVC, occurs in large quantities. Due to the abundance, in 2019, the prices for cable sheathing became negative. As detailed in Appendix B, the Dossier Submitter assumes that 20 % of flexible PVC waste containing CA:C14-17 (e.g. cables) would be recycled (KEMI, 2018). This may be an overestimate considering that soft PVC articles containing CA:C14-17 would probably already be treated as waste, and not recycled due to the concomitant presence¹⁶ of phthalates that are identified as SVHC, included in Annex XIV and restricted¹⁷ under REACH (e.g. DEHP, DBP, BBP, DIBP).

Other uses of CA:C14-17 containing substances are not expected to feed the production of recycled articles. Adhesives, sealants, paints, coatings are expected to be discarded when no longer in use; waste from metalworking fluids is expected to be destroyed; leather articles are expected to be discarded as municipal waste (although a fraction may be recycled nevertheless, it is not considered significant).

¹⁶ Substances containing CA:C14-17 are used as secondary plasticiser in soft PVC.

¹⁷ Annex XVII entry 51

1.4. Risk assessment

1.4.1. Classification and labelling

Among the substances that may contain CA:C14-17, only EC 287-477-0 has a harmonised classification according to Annex VI to the CLP Regulation (cf. Table 5).

Table 5. Harmonised classification according to the CLP Regulation 1272/2008

EC number	CAS number	Substance name	Index number	Harmonised classification
287-477-0	85535-85-9	Alkanes, C14-17, chloro	602-095-00-X	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Effect on or via lactation (H362)

For ten substances, classifications were also notified to the ECHA C&L inventory. Table 6 provides an overview of the notified classifications. The classifications reported are essentially related to aquatic toxicity, though human health classifications are notified as well.

Table 6. Notified classifications under article 40 of the CLP Regulation 1272/2008

EC number	CAS number	Substance name	Number of notifiers ^[1]	Notified classification ^[2] (aggregated data)
287-477-0	85535-85-9	Alkanes, C14-17, chloro	549	Aquatic Acute 1 (H400), M-factor: 10 - 100 Aquatic Chronic 1 (H410), M-factor: 10 Effect on or via lactation (H362) STOT Single Exp. 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)
-	-	di-, tri- and tetrachlorotetradecane	1	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
281-985-6	84082-38-2	Alkanes, C10-21, chloro (also known as 'CP52')	33	-
263-004-3	61788-76-9	Alkanes, chloro	965	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Aquatic Chronic 4 (H413) Effect on or via lactation (H362)
-	-	Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified	44	Skin Sens. 1B (H317) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)
264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro	698	Not classified ^[3] Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Carc. 2 (H351) Effect on or via lactation (H362) STOT Rep. Exp. 1 (H372), affected organs: central nervous system STOT Rep. Exp. 2 (H373), affected organs: liver

EC number	CAS number	Substance name	Number of notifiers ^[1]	Notified classification ^[2] (aggregated data)
				STOT Single Exp. 3 (H336), affected organs: central nervous system Acute Tox. 4 H332 Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Flam. Liquid 2 (H225)
269-145-7	68188-19-2	Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated	75	STOT Single Exp. 3 (H335), affected organs: Respiratory system Skin Sens. 1 (H317) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)
-	68410-99-1	Alkenes, polymd., chlorinated	18	Not classified ^[4] Aquatic Chronic 4 (H413) Eye Irrit. 2 (H319) Effect on or via lactation (H362)
287-478-6	85535-86-0	Alkanes, C18-28, chloro	56	Not classified ^[5] Aquatic Chronic 4 (H413)
-	-	Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified	9	Aquatic Acute 1 (H400) Skin Sens. 1B (H317) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)

Source: ECHA dissemination website consulted on 13 April 2022 (Brief profile information and C&L inventory)

Note: [1] the number of notifiers indicates how many companies notified this substance. All members of a REACH registration joint submission and all participants in a group of manufacturers/importers who notified are counted. The grouping is done automatically with no manual verification.

[2] all hazard classes and categories notified via REACH registration or C&L notification processes

[3] 'not classified' is reported by 619 notifiers

[4] 'not classified' is reported by 12 notifiers

[5] 'not classified' is reported by 45 notifiers

1.4.2. Hazard assessment

For hazard properties not currently covered by CLP hazard classes, such as PBT or vPvB, the SVHC identification process may be used as an official mean to confirm these hazard properties.

During the SVHC identification process of 'MCCP' (defined in the Candidate List as 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17'), in its underlying argumentation, the ECHA Member State Committee already concluded that substances containing CA:C14-17 could be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if CA:C14-17 with PBT and/or vPvB properties are present in a concentration ≥ 0.1 % (w/w) (ECHA, 2021a). The ECHA Member State Committee confirmed also the long range transport potential of CA:C14-17.

The Dossier Submitter therefore summarises below the Member State Committee conclusions regarding the confirmation of PBT and/or vPvB properties, and long-range transport potential of CA:C14-17, but will not undertake any additional hazard assessment.

Information in Appendix B gives an overview of monitoring data that underpin the Member State Committee conclusions.

PBT and/or vPvB properties:

In its final agreement, the Member State Committee concludes that the following

CA:C14-17 have PBT and/or vPvB properties (ECHA, 2021a):

- C₁₄Cl₃₋₁₁ constituents/congener groups of 'MCCP' have PBT and/or vPvB properties
- C₁₅Cl₃₋₈ constituents/congener groups of 'MCCP' have PBT and/or vPvB properties
- C₁₆Cl₃₋₈ constituents/congener groups of 'MCCP' have PBT and/or vPvB properties
- C₁₇Cl₆₋₉ constituents/congener groups of 'MCCP' have PBT properties

Table 7 gives an overview of CA:C14-17 (congener groups) and the MSC conclusion regarding their PBT and/or vPvB properties.

Table 7. Congener groups concluded as PBT and/or vPvB

Number of chlorine atoms and Carbon chain length	Cl ₁	Cl ₂	Cl ₃	Cl ₄	Cl ₅	Cl ₆	Cl ₇	Cl ₈	Cl ₉	Cl ₁₀	Cl ₁₁	Cl ₁₂	Cl ₁₃	Cl ₁₄	Cl ₁₅	Cl ₁₆	Cl ₁₇
C ₁₄	-	-	vPvB	vPvB PBT	vPvB PBT	vPvB PBT	vPvB PBT	vPvB PBT	vPvB	vPvB	vPvB	-	-	-			
C ₁₅	-	-	vPvB	vPvB	vPvB PBT	PBT	PBT	PBT	-	-	-	-	-	-	-		
C ₁₆	-	-	vPvB	vPvB	vPvB PBT	PBT	PBT	PBT	-	-	-	-	-	-	-	-	
C ₁₇	-	-	-	-	-	PBT	PBT	PBT	PBT	-	-	-	-	-	-	-	-

Source: Conclusions on the P, B and T properties in (ECHA, 2021a)

Note: grey cells mean congeners were not considered in the PBT/vPvB assessment because they do not exist.

symbol '-' means that not enough information was available to the Member State Committee to conclude whether the congener has PBT and/or vPvB properties.

Long range transport:

In its final agreement, the MSC concludes that “based on their physical-chemical properties, some congeners are predicted to have long-range environmental transport” (ECHA, 2021a).

For the sake of simplicity, the MSC conclusions on long range transport are reproduced here in their entirety.

‘Monitoring data tend to confirm this prediction as it has been found that CA:C14-17 with PBT and/or vPvB properties were found in biota from the Arctic and in air from the Antarctic.

CA:C14-17 have been detected in various media in the Arctic, including in air from Svalbard, in marine sediments from the Barents Sea and the Norwegian Sea, in terrestrial, avian and marine biota samples from the Norwegian Arctic, including in top predators such as Polar Bears. CA:C14-17 were also found in air samples from the Antarctic and from the Tibetan Plateau at high altitude.

The presence of CA:C14-17 at sites remote from known point sources such as the Arctic and Antarctic therefore indicates long-range environmental transport.

Furthermore, monitoring data indicate that concentrations of CA:C14-17 have increased in biota, in sediment and in air (from the Arctic, the Tibetan Plateau and the Antarctic) during the last decades. In addition, in the Antarctic air, an increasing trend was observed in the ratio of CA:C14-17 to ‘SCCP’ (short-chain chlorinated paraffins with carbon chain length below C14) suggesting that the use of CA:C14-17 as substitute to SCCP had increased. Due to the PBT/vPvB properties of CA:C14-17, the increasing trend of the concentrations of CA:C14-17 to the environment gives reason for concern.’

The monitoring data from the SVHC support document (ECHA, 2021d) are reported in Appendix B. The Dossier Submitter complemented this literature review by adding recent publications. Appendix B gives therefore the most recent overview of available studies and monitoring data in EU and worldwide on:

- CA:C14-17 in surface water and sludge
- CA:C14-17 in air
- CA:C14-17 in sediments and soils
- CA:C14-17 in biota (and some foodstuffs)

1.4.3. Release and exposure assessment

CA:C14-17 can be released at all stages of their life cycle. They are incorporated in a variety of mixtures and articles and are not expected to react or be converted during their service life (EU Commission, 2005).

In order to estimate the total tonnage released to the environment, the Dossier Submitter estimated the tonnage manufactured and used in the EU as well as the tonnage per use and life cycle stage (exposure scenarios), and combined it with release factors (i.e. the percentage of the tonnage released to the environment under each exposure scenario, taking into account RMMs) for each use, life cycle stage and environmental compartment.

Details of the approach to estimate the releases and assumptions, as well as detailed estimates, are available in Appendix B. A summary of estimated releases, expressed as tonnes of CA:C14-17 per year, under the baseline, is given in this section. The lower bound corresponds to the releases estimated with the lowest release factors and lowest fraction of substances going to waste. On the contrary, the highest bound is calculated using the highest release factors and highest fraction of substances going to waste. Releases calculated by the Dossier Submitter are not identical to those calculated previously (UK Environment Agency, 2019, ECHA, 2021d), mainly due to differences in input tonnage, uses considered, tonnage split per use, and because sludges have been included in the release calculations (not included in the previous estimates). However, it is noteworthy that reproducing the release estimations with the same overall release factor per use than in UK estimation but using the estimated (updated) tonnages of the restriction, would lead to release estimates of similar magnitude. Therefore, despite the uncertainties noted in section 3 and Appendix F, the release estimates are consistent

with previous assessments.

Table 8 presents the total estimated releases, i.e. from all uses, all life cycle stages incl. the waste stage, per environmental compartment.

Based on the support document for SVHC identification (ECHA, 2021d), CA:C14-17 are hydrophobic, poorly soluble in water (up to 27 µg/L) and have a high log Kow value (log Kow ≥ 6.5). When released to the environment, they are expected to be associated with soil and sediments although initial releases may be to other compartments. In water they are expected to partition to suspended matter and sediment. Due to their low mobility, CA:C14-17 are not expected to reach ground water. Due to the low vapour pressure of the substances, any releases to air are expected to be mostly bound to particles/dusts (e.g. from shredding waste, especially construction material under Use#01) and settle/deposit and transfer to water and soil. No degradation is expected in WWTP; a large fraction of CA:C14-17 is expected to be transferred from waste water to sludges, which are assumed to be either applied on land, incinerated or landfilled in the release estimation. Fate after initial release to the first receiving environmental compartment has not been assessed and therefore the estimations per compartment presented below should be considered indicative. Values are rounded up to two significant digits.

Table 8. Total releases per environmental compartment (from use and waste) (tonnes of CA:C14-17 per year)

	Lower bound	Upper bound
Total releases to surface water	260	430
Total releases to air	3 900	4 000
Total releases to soil	1 100	1 900
Total releases (all environmental compartments)	5 200	6 300

Table 9 presents a breakdown of total releases to the environment per use scenario for the whole life cycle (including the fraction of manufactured tonnage allocated to a use, the use phase itself, and the waste stage).

Those uses that contribute most to the total releases are adhesives/sealants and PVC. This is because these uses represent the highest tonnage placed on the market, even though the release factors, in particular during their actual use phase (formulation, industrial end-use, professional/consumer end use and service life) are not the greatest. Values are rounded up to two significant digits. Release from Use#01 (adhesives and sealants) account for 69-82 % of the total releases considering all life-cycle stages.

Table 9. Tonnage of CA:C14:17 released per use scenario (all life cycle stages included)

Use	Lower bound (tonnes of CA:C14-17 per year)				Higher bound (tonnes of CA:C14-17 per year)			
	release from manufacture for that use	release from use	release from waste from that use	Total (% of total)	release from manufacture for that use	release from use	release from waste from that use	Total (% of total)
#00 - PVC	14	16	410	440 (8.5 %)	14	720	410	1 100 (18 %)
#01 - Adhesives/sealants	32	390	3 900	4 300 (82 %)	32	390	3 900	4 300 (69 %)
#02 - Rubber	3	180	47	230 (4.3 %)	3	190	47	230 (3.7 %)
#03 - Metalworking fluids	3	31	0.5	34 (0.7 %)	3	250	0.5	250 (4 %)
#04 - Paints/coatings	0.6	14	71	85 (1.6 %)	0.6	88	71	160 (2.5 %)
#05 - Leather	0.2	0.6	2	2.6 (0.05 %)	0.2	22	2	24 (0.4 %)
#07 - Other	1	130	4	140 (2.6 %)	1	130	8	140 (2.3 %)
Manufacture for export – not allocated to a use	4.1	-	0.04	4.2 (0.08 %)	4.1	-	0.04	4.2 (0.07 %)
Total				~5 200				~6 300

Table 10 presents total releases to the environment per life cycle stage. Values are rounded up to two significant digits. Overall, it is estimated that releases from industrial settings (manufacture, formulation and industrial uses) account for 5-8 % of the total releases; releases from wide dispersive uses (professional uses, consumer uses and service life) account for 10-21 % of the total releases; the contribution of the waste stage is the highest corresponding to 71-84 % of the total releases due to ultimate disposal of articles and materials containing CA:C14-17 as waste, and the high release factor during shredding of waste, especially waste from Use#01 (waste containing sealants, e.g. construction waste).

Table 10. Releases per life cycle stage (tonnes of CA:C14-17 per year)

	Total releases (tonnes of CA:C14-17 per year)		Relative contribution to total releases	
	Lower bound	Higher bound	Lower bound	Higher bound
Manufacture ^[1]	57	57	1.1 %	0.9 %
Formulation	73	180	1.4 %	2.9 %
Industrial uses	150	280	3.0 %	4.5 %
Professional and consumer uses	320	320	6.2 %	5.2 %
Service life	210	1 000	4.1 %	16 %
Waste	4 400	4 400	84 %	71 %
Waste – Shredding	3 700	3 700		
Waste – Landfill	710	770		
Waste – incineration	1.5	2.0		
Total	5 200	6 300	100 %	100 %

Note: [1] including ~ 4.2 tonnes per year associated to the manufacture for export (which represents max. 0.08 % relative contribution to the total releases of the whole life cycle).

It is important to note that landfills constitute a long-term reservoir of CA:C14-17 that is not accounted for in the values presented above (see Appendix B).

In addition to the release estimates modelled and summarised in Table 10, the presence of CA:C14-17 in the EU environment is confirmed by several studies presented in Appendix B.5.5.

Even though CA:C14-17 are not routinely included in European environmental monitoring programmes, nor listed in the European Industrial Emissions Portal¹⁸ or in IPCHEM¹⁹, the EU data available in literature generally show widespread occurrence of CA:C14-17 in water (at concentrations typically up to a few µg/L), sediment (at concentrations typically up to around 2 mg/kg dw, but up to 65 mg/kg dw (near industrial area) and soils (more limited information, but at concentrations up to around 2 mg/kg dw, and slightly higher near an industrial area). CA:C14-17 is also found in sewage sludge up to 17 mg/kg dw (Norsk Vann, 2018), and in air at a few pg/m³.

With regard to the release associated to industrial activities, releases of CA:C14-17 have been detected in sediments in Czech Republic in concentration up to 5 575 µg/kg dw near the factories where CA:C14-17 are used as additives in PVC, rubber, paints or sealants and adhesives (Guida et al. (2020), citing Pribylova et al. (2006)). Additionally, in the United Kingdom, Nicholls et al. (2001) selected sampling sites around the main industrial factories related to CA:C14-17 application – metalworking fluids, PVC, paintings, leather, sealants, rubber and textiles – and reported that concentrations of CA:C14-17 in sediments varied between 0.2 mg/kg dw and 65.1 mg/kg dw.

Releases of CA:C14-17 from article service life were also detected in indoor dust in Sweden (Friden et al., 2011, Brits et al., 2020).

Monitoring studies demonstrate also widespread contamination of EU wildlife by CA:C14-17 at all trophic levels (including predatory species and sensitive life stages such as birds' eggs). Recent studies detected CA:C14-17 in concentration up to 540 µg/kg lipid in grey seals, up to 720 µg/kg lipid in eagle owl, up to 1 600 µg/kg lipid in moose and up

¹⁸ <https://industry.eea.europa.eu/>

¹⁹ Information Platform for Chemical Monitoring available here: <https://ipchem.jrc.ec.europa.eu/>

to 830 µg/kg lipid in grey wolf from Scandinavia (Yuan et al., 2019), and up to 5 390 µg/kg ww in Atlantic cod liver from Norway (Green et al., 2019). Appendix B.5.5 gives an overview of the studies carried out in Europe, and also worldwide.

1.4.4. Risk characterisation

The ECHA Member State Committee concluded that "*substances containing CA:C14-17 could be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if CA:C14-17 with PBT and/or vPvB properties are present in a concentration ≥ 0.1 % (w/w)*" (ECHA, 2021a).

Due to these intrinsic substance properties, substances containing CA:C14-17 may cause severe and irreversible adverse effects on the environment and on human health if the releases are not minimised.

According to REACH Annex I section 6.5, the risk to the environment and to human health from PBT or vPvB substances cannot be adequately controlled. Consequently, exposure to humans and emissions to the environment should be minimised throughout the lifecycle of these substances.

It is therefore proposed to follow the same approach that has been used in previous Annex XV restriction proposals on other PBT or vPvB substances (e.g. decaBDE, PFOA and related substances, D4, D5 and D6), and to use the release of CA:C14-17 as a proxy for risk.

Accordingly, the reduction of CA:C14-17 releases achieved by the proposed restriction will be used as an estimate of the risk reduction capacity of the proposed restriction.

1.5. Justification for an EU wide measure

The main justification for an EU-wide measure is two-fold:

- Address the risk posed by releases of CA:C14-17 with PBT or vPvB properties which are present in many substances
- Thereby maintain the good functioning of the internal market.

Products (substances, mixture, and articles) containing CA:C14-17 with PBT and/or vPvB properties are manufactured, formulated and used in a broad range of applications in the EU, resulting in releases throughout the EU. Releases and exposure can occur throughout the life cycles of substances, mixtures and articles containing CA:C14-17, including during manufacturing, formulation, use, waste disposal, and recycling (cf. sections 1.3 and 1.4.3).

Releases to the environment occur mainly from wide dispersive uses (professional, consumer and service life) and even more from waste handling. However, since the identification of 'MCCP' as SVHC by the MSC due to their PBT and vPvB properties, no emission minimisation efforts have been documented by the REACH registrants of the four substances explicitly indicated on the ECHA Candidate List (e.g. no changes in recommended operational conditions (OCs) and risk management measures (RMMs) to downstream users and waste operators and no uses advised against targeting these life cycle stages).

The nature of the uses themselves, which are essentially 'open' and 'wide dispersive' such as metalworking fluids applications, lubricants, paints and coatings, adhesives and sealants (OCF cans), additives in consumers mixtures and/or articles, makes it difficult to implement effective risk management measures to limit the releases and exposures. In their RMOA on substance EC 287-477-0, the UK CA concluded that "*risk management measures currently applied by the lead Registrant are sensible and demonstrate that they have taken some responsibility for safe use. However, they may still not be sufficient to minimise releases to the greatest extent technically and practically feasible. In particular, the lead Registrant has not concluded that EC 287-477-0 meets the Annex XIII criteria*" (UK Environment Agency, 2019).

The Dossier Submitter notes that this conclusion is still valid as the lead registrant

concludes that the substance does not meet the Annex XIII criteria for PBT and vPvB. Although the registrants of EC 287-477-0 now advise against all uses (industrial and professional) for which releases are not minimised, they do not provide detailed information on RMMs that would be suitable to achieve this goal.

In addition, it is not known to which extent companies using CA:C14-17 implement suitable RMMs (especially in downstream uses), and what their effectiveness is in reducing the emissions. Additionally, there is no information in registration dossiers and no use advised against targeting the service life and waste handling, which account for the largest part of the emissions.

No exposure scenarios were developed, and hence no RMMs described, in the registration dossiers of substances identified with the name 'di-, tri- and tetrachlorotetradecane' and identified with the EC 264-150-0 (because the tonnage band is below 10 tonnes/year or because the registrants concluded on absence of hazards of the substance). For substances identified with the names 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified', RMMs are described generically for industrial uses, e.g. pre-treatment of waste water, and no RMMs are recommended to minimise releases during service life and waste handling. Substance EC 269-145-7 is claimed to be used under strictly controlled conditions although no information on implemented RMMs has been provided.

Despite the described RMMs, for all registered substances, releases still occur to the environment.

The Dossier Submitter concludes that the measures in place are not effective to address the risk posed by the releases estimated, especially for professional uses, consumer uses, service life and waste handling.

As noted in section 1.3.3, waste management itself can be a significant source of releases and may pose additional risks. In particular, the incineration of waste containing CA:C14-17 can generate dioxins and furans or other hazardous substances if not conducted adequately.

CA:C14-17 have been detected globally, and in the EU environment, in all compartments; indeed, they are widely dispersed in the environment and are found in remote regions such as Tibet, Arctic and Antarctic (cf. Appendix B.5).

In addition, as presented in Appendix B.5, bioavailability of CA:C14-17 is confirmed by a large number of monitoring studies indicating the presence of these congeners in European biota e.g. by Yuan et al. (2022), Knudtzon et al. (2021), Tien et al. (2021), Yuan et al. (2021), or de Wit et al. (2020), for the most recent published studies. CA:C14-17 are also detected in Human samples in Europe even though in low quantity (Agency, 2021).

The Member State Committee concluded that some CA:C14-17 with PBT and/or vPvB properties undergo long range transport (ECHA, 2021a). Emissions from one Member State could therefore result in exposure in another regardless of the efforts undertaken by that Member State, via national legislation for example, to reduce the emissions within its own borders.

Currently, only Norway and Germany have national measures in place to reduce the releases of CA:C14-17. Norway has taken national action by adding EC 287-477-0 to the Norwegian authorities' priority list in 2002 with the objective that use and subsequent emission these substances must be eliminated. In Germany, chloroalkane-containing wastes, e.g. metalworking fluids with a content of over 2 grams of halogen per kg of formulation and halogen-containing plasticisers are classified as potentially hazardous waste and are incinerated.

The Dossier Submitter concludes that these two national measures are not sufficient to address the risks at EU level.

Considering all these elements, the existing operating conditions and risk management in place, as well as the national regulations are not sufficient to address the risks of CA:C14-17 with PBT or vPvB, and LRT properties.

Thus, an action on a Union-wide basis is warranted to effectively reduce the environmental exposure to PBT and/or vPvB substances in the EU. Union-wide action

would also limit the potential for trans-boundary exposure to PBT and/or vPvB substances from EU sources.

Finally, Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

1.6. Baseline

1.6.1. General considerations

The baseline describes how the uses and emissions of CA:C14-17 within the scope of the proposed restriction would evolve over time in the absence of any REACH restriction, or any new regulatory risk management.

Considering that relevant substances have been included in the Candidate list in June 2021, it can be expected that tonnages associated to these substances will be impacted (i.e. they could decrease due to substitution to non-SVHC substances). Based on the information gathered in the Dossier Submitter's market survey and the Registrants' survey, the transition to alternatives seems indeed to occur for the substances on the Candidate List.

However, considering that (i) there is currently no other binding EU obligations or Regulation that would affect the uses and emissions of all other substances containing CA:C14-17, and (ii) only four out of the 69 substances in the scope of the investigation are explicitly indicated on ECHA's website as falling within the Candidate List entry, some uses could be substituted by other substances identified with other EC/CAS numbers not listed explicitly on ECHA website under the Candidate list, but relevant for this restriction as they would contain CA:C14-17 with PBT and/or vPvB properties.

For example, after the listing of SCCP (short chain chlorinated paraffins) under the POP Stockholm Convention, substances like EC 287-477-0 replaced SCCP (Fernandes et al., 2020, Guida et al., 2020). The SVHC identification of EC 287-477-0 and other substances may have a similar effect and trigger substitution of these substances by longer chain chloroalkanes such as EC 264-150-0 and other substances. The SVHC identification of a limited number of substances only could therefore inadvertently promote a shift in production and use of chloroalkanes towards other substances potentially containing a high amount of CA:C14-17 with PBT and/or vPvB properties. Finally, it should be noted that even though other EU-wide regulations are currently under discussion (such as the POP listing under the Stockholm convention, or a potential restriction of medium chain chloroalkanes under the RoHS Directive), it is assumed that no new EU-wide regulation will enter into force before the entry into force of the proposed REACH restriction.

POP listing under the Stockholm convention

As indicated in section 1.1, the UK submitted a proposal (UK, 2021) for listing 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels $\geq 45\%$ ' in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (UNEP, 2021). This proposal might lead to an elimination or a restriction of the production and use of multiple chloroalkanes under the Convention. The inclusion in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (POPs) of chlorinated paraffins (i.e. chloralkanes) containing some CA:C14-17 is excluded from the baseline scenario. Even though the REACH restriction and the POP listing under the Stockholm Convention are interlinked, according to the current planning (cf. Appendix D), it is assumed that the inclusion of chlorinated paraffins (i.e. chloralkanes) containing some CA:C14-17 (of concern) and the scope of a global restriction under the Stockholm Convention would not be concluded prior to the conclusion on the need for a REACH restriction.

If one assumed that a global restriction under the Stockholm Convention would move forward before the entry into force of the proposed restriction under REACH, then obviously the baseline presented in this document would no longer be applicable.

Restriction under RoHS

According to the Commission paper (EU Commission, 2014a) on the interlinkage between REACH and the RoHS Directive (Directive 2011/65/EU), in cases where neither instrument yet regulates the substance in question but action under one or both is contemplated, it has to be clarified how RoHS should be taken into account. This is in particular the case in situations where the placing on the market of articles containing a particular substance is not yet restricted at Union level under either instrument, but a proposal for a restriction under REACH is imminent.

The Commission paper indicates that the RoHS Directive and its national implementing measures themselves are not specific enough to constitute a 'measure already in place', justifying the exemption of EEE, where the substance in question does not yet appear in Annex II to RoHS. Therefore, a restriction could be imposed under REACH and later amended to carve out EEE if/when the substance is added to Annex II to RoHS.

Alternatively, the Commission paper indicates that the REACH restriction procedure could be used to prepare an amendment of RoHS outside the periodic review (expected to be every 4 years). If the opinions of RAC and SEAC confirm that a restriction for a substance in EEE is justified and proportionate, the Commission could decide to implement it via an amendment of the RoHS Directive, rather than an amendment of Annex XVII to REACH.

Finally the Commission paper indicates that when a need to restrict a substance in EEE has already been identified at an earlier stage (e.g. during the regulatory measure options analysis), rather than initiating the restriction procedure under REACH, the Commission or a Member State could also decide to initiate a restriction directly under RoHS. The REACH and RoHS restrictions would then be synchronised so that the REACH restriction could exempt EEE from its scope.

Although the inclusion of 287-477-0 in Annex II to the RoHS Directive was already initiated by the Commission in 2020 and is still on-going, the original and updated request from the Commission (EU Commission, 2021c, EU Commission, 2022a) to investigate the need for a REACH restriction did not exclude the uses covered under the RoHS Directive. Therefore, the potential inclusion of the substances in the Annex II to the RoHS Directive is also ignored in the baseline scenario.

1.6.2. Baseline estimates

Overall there is no compelling justification to assume a decreasing or increasing trend in the uses and releases of CA:C14-17 in the absence of a REACH restriction. The baseline scenario adopted for the analysis is therefore that, in the absence of an EU-wide restriction or other regulatory action, substances containing CA:C14-17 will continue to be used and placed on the EU market as substances, in mixtures or in articles, in the same order of magnitude as today. It is also assumed that the tonnage breakdown per uses would remain constant over the study period (i.e. business as usual scenario). The Dossier Submitter assumes therefore that the releases to the environment will remain stable during the 20-year analytical period used for the impact assessment. In section 1.4.3, the current releases of CA:C14-17 to the environment are estimated to be between 5 200 and 6 300 tonnes per year. This corresponds to a total of **approximately 104 000 to 126 000 tonnes of CA:C14-17 released to the environment during a 20-year period** in case of absence of any EU-wide regulatory measure.

2. Impact assessment

2.1. Analysis of regulatory risk management options

As indicated in sections 1.5 and 2.1.1.5, the following risks and issues related to them need to be addressed at the EU level:

- Risk posed by CA:C14-17 with PBT or vPvB properties which are present in many different substances
- Widespread uses and releases from all stage of the life-cycle including waste
- Lack of communication in the supply chain re. the presence (or absence) of the CA:C14-17 constituents with PBT/vPvB properties in other substances, mixtures and articles.

In addition, any action proposed needs to take into account that alternatives are available and substitution is under way in general (cf. section 2.2.2).

A problem analysis was therefore carried out to identify potential risk management options that would address the risks and issues identified with the manufacturing, placing of the market, and uses of substances, mixtures and articles containing CA:C14-17 with PBT and/or vPvB properties.

The Dossier Submitter identified diverse risk management options which are further detailed in the chapters below:

- REACH restriction options (ROs) with different scopes and permutations (cf. section 2.1.1)
- Other EU-wide measures (cf. section 2.1.2 and Appendix E) ranging from other EU-wide regulatory measures to EU-wide industry initiatives.

Whilst the Dossier Submitter recognises that EU-wide measures other than REACH restriction could have an impact on the identified risk for certain sectors or types of uses, such measures were deemed insufficient to address the risks and issues identified for all the uses and sectors.

Therefore, the Dossier Submitter concludes that a REACH restriction would be the most appropriate EU-wide measure to address the identified risks and issue. For this reason, the impact assessment is focussing on the possible REACH restriction options.

2.1.1. Identification of possible REACH restriction options

In order to address the issues and their main drivers, the following REACH restriction options (ROs) are considered and further analysed in the impact assessment section:

- RO1 – Ban on placing on the market
- RO2 – Ban on placing on the market and use
- RO3 – Ban on manufacturing and placing on the market
- RO4a, RO4b and RO4c – Ban on placing on the market with derogations for specific uses or sectors
- RO5 – Complementary measures to accompany the communication down the supply chain

The ROs analysed are listed by the Dossier Submitter according to the hierarchy of control principle, i.e. elimination and substitution (RO1 to RO3), engineering controls (RO4), and administrative controls (RO5).

The purpose of this section is to describe in general terms the different restriction options analysed. The transition periods and concentration limit selected for the impact assessment are described and justified in section 2.2.3.

2.1.1.1. RO1 description – Ban on placing on the market

Under RO1, the placing on the market of substances, mixtures, or articles containing CA:C14-17 with PBT and/or vPvB properties above a limit of 0.1 % (cf. section 2.2.4) would be banned after a transition period.

A ban on 'placing on the market' would obviously result in EU manufacturers stopping manufacturing of substances containing CA:C14-17 with PBT and/or vPvB properties for the EU market. However, EU manufacture of substances containing CA:C14-17 with PBT and/or vPvB properties for export to outside EU would continue to be allowed.

A ban on placing on the market means also that industrial and professional users, as well as consumers, will not be able to purchase on the EU market (including via Internet) substances, mixtures, or articles containing CA:C14-17 with PBT and/or vPvB properties after the end of the transition period.

Under RO1, the use of substances, mixtures or articles containing CA:C14-17 with PBT and/or vPvB properties is not banned. This means in practice that, as long as they have them in stock, industrial, and professional users, as well as consumers would still be allowed to use the substances, mixtures, and articles purchased before the entry into force of the ban on the placing on the market. RO1 implies therefore the possibility to keep on using and disposing articles containing CA:C14-17 with long service life (e.g. electrical and electronic equipment in automobile, or electronic equipment) even after the end of the transition period.

2.1.1.2. RO2 description - Ban on placing on the market and use

RO2 is similar to RO1 but with an additional ban on use.

This means that all industrial, professional or consumer uses of substances, mixtures or articles containing CA:C14-17 with PBT and/or vPvB properties would also be banned after the transition period has expired.

Given the broad definition of 'use' under REACH, which includes also storage, keeping, filling of containers and transfer from one container to another according to REACH Article 3(24), RO2 would in practice de facto include a ban on manufacturing.

In addition, as uses at industrial and professional downstream users sites, but also uses by consumers would not be allowed anymore, RO2 would also imply in theory either (i) a recall from the market of all substances, mixtures and articles that have not been consumed or reached their end of life (for articles), and/or (ii) an early disposal of material and articles containing CA:C14-17 with PBT and/or vPvB properties.

2.1.1.3. RO3 description - Ban on manufacturing and placing on the market

RO3 is similar to RO1 but includes an explicit ban on manufacturing as releases may occur at the manufacturing stage and risks may arise from the releases of CA:C14-17 with PBT and/or vPvB properties from manufacturing activities in Europe.

This restriction option covers within the scope of its assessment all the releases from manufacturing activities in Europe irrespective of the subsequent fate of the substances (inside/outside EU). As a consequence, and contrary to RO1, manufacturing for export would no longer be possible under RO3 after a transition period. The possibility to export refers only to the manufactured substances or to the mixtures/articles produced by the same actor manufacturing the substance (meaning that they are not placed on the EU market but are exported outside the EU).

2.1.1.4. RO4 description - Ban on placing on the market with derogations for specific uses or sectors

RO4 is similar to RO1 (a ban on placing on the market) but foresees specific transition periods or derogation for the metalworking sector.

RO4 takes into account that alternatives may not be readily available for specific Extreme Pressure metalworking fluids applications (cf. section 2.2.2.4).

Different scopes of RO4 are further analysed:

- RO4a: RO1 with a permanent derogation for the metalworking fluid uses
- RO4b: RO1 with a longer transition period for the metalworking fluid uses.

Even if not explicitly mentioned, RO4a and RO4b imply that EU manufacturers and importers of substances containing CA:C14-17 with PBT and/or vPvB properties would still be allowed to produce and place the restricted substances on the market but make them available to formulators/manufacturers of metalworking fluids only.

In the course of the dossier preparation, the Dossier Submitter also investigated an additional option: 'RO4c: RO4a conditional to the implementation of specific risk management measures'. However, due to the large diversity of metalworking activities covered by the restriction proposal, it was not possible to identify specific risk management measures that would be applicable to all uses of metalworking fluids containing CA:C14-17 with PBT and/or vPvB properties (cf. Appendix E for additional information). This option RO4c was therefore abandoned during restriction preparation.

2.1.1.5. RO5 description – Complementary measures to accompany the communication down the supply chain

RO5 is not a 'stand-alone' restriction option but should be seen as regulatory measures complementary to any of the previously described ROs (RO1 to RO4). RO5 is intended to facilitate the minimisation of releases of CA:C14-17 with PBT and/or vPvB properties to the environment that could occur during industrial, professional or consumer uses by enhancing information availability, and informing about the presence of constituents with PBT and/or vPvB properties in substances, mixtures, and articles at the different level of the supply chains.

RO5 contains two key elements: (i) substances supplier duties and, (ii) supply chain communication duties.

It is also important to note that the requirements set in these complementary measures, both in term of substances supplier duties and supply chain communication, are similar, to some extent, to other existing restriction entries such as entry 71 on 1-methyl-2-pyrrolidone (NMP), and entry 76 on N,N-dimethylformamide, which impose some information to be made available in the Chemical Safety Report and to be communicated down the supply chain.

By making the complementary measures explicit and mandatory in the restriction entry, the Dossier Submitter aims also at (i) improving the compliance with the proposed restriction throughout the supply chain, and (ii) facilitating its enforcement.

Finally these measures aim at avoiding regrettable substitution by making available information on the presence of CA:C14-17 with PBT and/or vPvB properties in substances, mixtures and articles placed on the market.

Background to RO5

During the restriction dossier preparation, the Dossier Submitter faced challenges to obtain substantiated information on the composition of the different chloroalkanes registered and/or placed on the EU market. For example, some registrants of the substances listed in Appendix B.1 informed the Dossier Submitter that they would already fulfil the potential restriction conditions as their substances already contain < 0.1 % of CA:C14-17 (and therefore < 0.1 % of the CA:C14-17 with PBT and/or vPvB properties). However, relevant data supporting these statements are currently not included in their registration dossiers (CfEs and Registrants' survey).

On the contrary, downstream users reported that they did not know the composition of the substances, mixtures or articles they purchased, and that these products may or may not be in the scope of the proposed restriction as they may contain CA:C14-17 with PBT and/or vPvB properties in concentration levels above or below 0.1 %.

During the third call for evidence and when contacting companies during the ECHA market survey (cf. Appendix F), the Dossier Submitter enquired specifically the users of

the substances listed in Appendix B.1 and asked them if “*they receive from their suppliers any information on the presence and concentration of C14-17 chloroalkanes? And if not, how could the transfer of information in the supply chain be improved?*”. In general, the answers to this question were that such information is not provided, neither in the safety data sheet nor in the technical document accompanying the substance, mixture or article (e.g. CfE3 #1528).

With regard to the substance identified as EC 264-150-0 (aka LCCP), where the presence of CA:C14-17 may vary between < 0.1 % and 20 % depending on the quality of the feedstock and the manufacturing conditions, no information on the presence or absence of CA:C14-17 with PBT and/or vPvB properties is currently made available to the downstream users. Some downstream users indicated as well that direct contact with their suppliers did not result in additional information on the presence or not of CA:C14-17 with PBT and/or vPvB properties.

What does RO5 include?

To address the concerns mentioned above, the Dossier Submitter is proposing complementary measures that include two main elements (for the exact wording of RO5 in the restriction entry please refer to section 2.5.) These elements are:

1. Substance supplier duties: the obligation for suppliers of chloroalkanes to indicate/conclude that the substance is a PBT and/or vPvB, unless they can demonstrate and provide detailed information including analytical results that the substance contains CA:C14-17 with PBT and/or vPvB properties in concentration below 0.1 %.
2. Supply chain communication duties: the obligation for suppliers of substances, mixtures, or articles containing CA:C14-17 to inform their downstream users and customers about (i) the presence and concentration of CA:C14-17 with PBT and/or vPvB properties in the substances, mixtures, or articles placed on the market; and (ii) risk management measures recommended to minimise the releases and exposure.

These measures respond to the ‘difficulties’ for suppliers (including registrants) placing substances containing CA:C14-17 on the market (irrespective if the tonnage is below or above one tonne per year). It is assuming that chloroalkanes may contain CA:C14-17 with PBT and/or vPvB properties unless demonstrated otherwise by the suppliers. The first element of the measure will apply to all suppliers of chloroalkanes whatever the tonnage they place on the market. This measure is proposed to avoid regrettable substitution, and to allow a level playing field among all registrants and suppliers of substances containing CA:C14-17, whatever the tonnage they are placing annually on the market.

Suppliers (below 1 tonne per year) will have to gather information to prove that the substances placed on the market do not contain CA:C14-17 with PBT and/or vPvB properties in concentration \geq 0.1 %. It will oblige the suppliers to justify (in case of inspection, or to your customers) with sufficient analytical information, and substantiated data when they conclude that the concentration of CA:C14-17 with PBT and/or vPvB properties is below 0.1 %, and on which basis the supplier conclude that the composition does not meet PBT and vPvB criteria.

The first element of the measure does not impose any format to the suppliers, as long as the requested information is made available to the competent authorities when requested during enforcement. Nevertheless, as REACH registrants (a type of supplier) have the obligation under REACH Article 22 to update their registration dossier once new hazards have been officially concluded²⁰, the registration update appears to be the most relevant way to communicate the requested information. As far as the registrants of

²⁰ For example, updated registration dossiers (accessible on ECHA website in April 2022) still conclude and report that EC 287-477-0 is not a PBT/vPvB despite the hazard confirmation from the Member State Committee. The same applies to the EC 264-150-0 compositions containing more than 0.1 % of CA:C14-17 with PBT and/or vPvB properties.

Other examples of non-updated PBT/vPvB status following a hazard confirmation by the Member State Committee include for example D4, D5, D6.

chloroalkanes are concerned, the first element of the complementary measures is in line with, and complements the REACH data requirements set out in Annex VI, which were updated in March 2022 via the Commission Regulation (EU) 2022/477²¹.

The second element of the proposed complementary measure (i.e. supply chain communication duties) is in line with, and aims to complement REACH Article 31(1)(b), 31(3)(b), 32(1)(d), 34 and 36²², which already foresee obligations for the suppliers, and other actors in the supply chain placing on the EU market substances, and mixtures containing PBT or vPvB constituents to inform their customers but also to keep and make available relevant information for enforcement. Under REACH, formulators, suppliers or importers of a mixture have the responsibility to know about any hazard properties of substances or mixtures. They also have the responsibility (i) to know whether the components are classified or meet the PBT and/or vPvB criteria of REACH Annex XIII, and (ii) pass on this information in their supply chain.

Given the uncertainties regarding the import of articles containing CA:C14-17 highlighted in section 1.3.1, and the fact that the Candidate List currently only lists a limited number of substances of concern out of 69 substances that could potentially fall within the scope of this restriction proposal, the Dossier Submitter proposes that the second element of the complementary measure would apply also to articles. Such a measure is consistent with, and aims at complementing, the obligations under REACH Article 33²³ which should already be applied to the substances on the Candidate List.

It is also important for these additional measures to apply to all chloroalkanes (cf. list of substances in Appendix B.1), as downstream users and customers may then select a supplier proposing substances with or without PBT/vPvB properties, including those with PBT and/or vPvB congeners in concentrations lower than the proposed limit of 0.1 %. Similarly, it is important to maintain these requirements even beyond the proposed transition periods even if the concentration of CA:C14-17 with PBT and/or vPvB fulfils the proposed maximum concentration limit of 0.1 %. Indeed, releases from substances, mixtures and articles containing CA:C14-17 with PBT and/or vPvB in concentrations below the limit of 0.1 % w/w will continue after the transition period has elapsed.

The requirement does not impose any format. If a Safety Data Sheet (SDS) is required under REACH, then the information should be made available in the SDS. In case that no SDS is required under REACH, the information could be recorded and made available to the customers via other means such as a product technical sheet, or labelling (including electronic labelling) for example.

2.1.1.6. Overview of all ROs

Table 11 summarises the main differences and commonalities between the different restriction options.

²¹ Commission Regulation (EU) 2022/477 of 24 March 2022 amending Annexes VI to X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

²² Article 31(1)(b) and 31(3)(b): suppliers of PBT or vPvB substances (either on their own or in mixtures) have to provide their customers with a safety data sheet (upon request or by default). Section 2.3 of the safety data sheet shall specify that the substance or mixture meets the criteria for identification for PBT or vPvB with REACH Annex XIII.

Article 32(1)(d): in cases for which a safety data sheet would not be required, suppliers of substances (either on their own or in mixtures) should make 'available any relevant information about the substance that is necessary to enable appropriate risk management measures'.

Article 34: duty to inform new information on hazard and appropriate RMM down the supply chain. Article 36: obligation to keep information (manufacturer, importer, downstream user, distributor).

²³ Article 33: - Duty to inform on the presence in an article of substances having PBT or vPvB properties AND listed on the Candidate List (concentration \geq 0.1 %)

Table 11. Commonalities and differences in the scope of the different restriction options after the transition period

	Registrants		Industrial or professional DU		Consumer	
	Import	Manufacture	Purchase	Use remaining stock or article	Purchase	Use remaining stock or article
RO1	Banned	Possible ^[1]	Banned	Possible	Banned	Possible
RO2	Banned	Banned	Banned	Banned	Banned	Banned
RO3	Banned	Banned	Banned	Possible	Banned	Possible
RO4a	Banned except for MWF ^[2]	Possible for MWF ^[2] Possible ^[1]	Banned except for MWF	Possible	Banned	Possible
RO4b	Banned except for MWF (longer TP) ^[2]	Possible for MWF ^[2] Possible ^[1]	Banned except for MWF (longer TP)	Possible	Banned	Possible
RO4c	Banned except for MWF (conditional derogation) ^[2]	Possible for MWF ^[2] Possible ^[1]	Banned except for MWF (conditional derogation)	Possible	Banned	Possible
RO5	Substances supplier duties and supply chain communication duties					

Note: ^[1] a ban on 'placing on the market' would obviously result in EU manufacturers stopping the manufacturing for the EU market of substances containing CA:C14-17 with PBT and/or vPvB properties; however, EU manufacture for export to outside EU would continue to be allowed even after the end of the transition period.

^[2] EU manufacturers and importers of substances containing CA:C14-17 with PBT and/or vPvB properties would still be allowed to produce and place the restricted substances on the market but make them available for metalworking applications only.

2.1.2. Identification of other union-wide measures

REACH restriction is better suited to address multiple substances where the concern is related to the presence of the same hazardous constituent (here CA:C14-17 with PBT and/or vPvB properties) (ECHA, 2022). Nevertheless, the Dossier Submitter conducted also a brief review of other Union-wide measures than REACH restriction.

Possible Union-wide risk management measures other than a REACH restriction are outlined in Appendix E. They range from voluntary measures (e.g. Ecolabelling, voluntary industry commitment or action) to legislative ones (e.g. Industrial Emission Directive, RoHS, Biocidal Products Regulation, Product Safety Directive, Waste Directive, REACH authorisation).

Despite the presence of only a limited number of chloroalkanes in the Candidate List, it is not recommended to prioritise these substances for Annex XIV inclusion, neither on its own nor after the proposed restriction would enter into force. Addition on the Candidate List and REACH authorisation as risk management option may lead to potential regulatory uncertainty for Industry in case of future nomination of 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels $\geq 45\%$ to the Stockholm Convention. In particularly considering that at this stage of the process, the scope and substances that will be covered by the POP listing are indeed unknown and may change compared to the initial UK proposal. The EU Commission document on the interlinkage between REACH, the Stockholm Convention and the UNECE POP Protocol (EU Commission, 2014b) states clearly that if a substance is included in Annex XIV and subsequently banned under the Stockholm Convention, not only should all existing authorisations be withdrawn but all applications for authorisation should be refused (cf. more details in Appendix E).

As described in more detail in Appendix E, none of the listed measures on their own are practical, or effective means of addressing all the risks and issues posed by CA:C14-17. In addition, some measures are too sector-specific to address the overall risks.

2.2. Approach taken for the impact assessment

2.2.1. Introduction to the impact assessment

The Dossier Submitter conducted an impact assessment of the different REACH restriction options identified in section 2.1.1. The assessment is underpinned by information on uses, releases, availability of alternatives and socio-economic impacts. The Dossier Submitter organised three calls for evidence and conducted multiple interviews and meetings with stakeholder associations and companies to explore the impacts of the various restriction options on different sectors. Specific investigations and sector specific discussions were also organised via two consultants on behalf of the Dossier Submitter between December 2021 and April 2022. Appendix G contains further information on the stakeholder consultations undertaken and the information is referenced in the report. The Dossier Submitter is therefore confident that industry has sent in information on the impacts to its sectors and that other impacts are limited, as no information to the contrary was submitted.

For RO1, RO3, RO4a and RO4b, the Dossier Submitter performed a quantitative assessment of the impacts presented in section 2.3. The remaining options (RO2 and RO4c) – which would only partially address the risks or would not fulfil REACH restriction criteria – were abandoned in the course of the restriction proposal preparation. Specifically, RO2 is not deemed to be enforceable considering that it would not allow the use of articles/mixtures already placed on the EU market. For example, it would not be possible to enforce a ban on the use of OCF products already bought by consumers in the EU. Also, this RO cannot be considered practicable either.

As also indicated in Section 2.1.1.4, the Dossier Submitter considered an additional RO (RO4c), which includes a derogation for metalworking activities, conditional on the implementation of specific risk management measures. However, as detailed in Appendix E, and given the diversity of the metalworking operations, it was not possible to define risk management measures that would be applicable to all uses of metalworking fluids containing CA:C14-17. The two ROs (RO2 and RO4c) are only described qualitatively in Appendix E.

The geographical scope of the impact assessment is the European Union. However, where relevant, impacts expected to occur outside the EU were also considered. Regarding the timeline for the impact assessment, 2024 is assumed to be the first full year of entry into force of the proposed restriction, and a 20-year analytical period was assumed for the impact assessment. Unless otherwise noted, all costs and benefits are discounted at 3 % discount rate and expressed either in Net Present Value (NPV) or in annualised costs considering a 20-year period for the analysis. The 3 % discount rate was applied in line with new recommendations from the European Commission, as set out in the 'Better Regulation Tool-box 2021'(EU Commission, 2021a).

The impact assessment is based on the comparison of RO1, RO3, RO4a and RO4b. The societal costs of the ROs are measured in terms of compliance costs that the sectors affected by the restriction are expected to incur because of the conditions of each restriction option (ROs). The covered costs are one-off costs for searching and testing a feasible alternative and the expected variable costs linked to higher production costs resulting from higher prices of alternative raw materials and other possible changes in the affected formulations. All the one-off costs refer exclusively to the expenses for the research, development and testing of alternatives. None of the stakeholder interviewed by the Dossier Submitter (ECHA market survey) or who participated to the calls for evidence, indicated that the implementation of alternatives would require investments in physical assets.

Where possible, a plausible demand price elasticity and expected price increase of the concerned products were assumed to estimate the consumer surplus loss.

Finally for the impact assessment of all restriction options, and to allow a proper comparison of the ROs against each other, the Dossier Submitter considered the same default parameters/assumptions re. (i) alternatives, and technical solutions availability, costs and risk reduction capacity, (ii) the transition period, and (iii) the admissible

concentration limits. These default parameters and their justifications are further explained in sections 2.2.2 to 2.2.4. In addition, the Dossier Submitter tested these parameters (assumptions) conducting sensitivity analysis. Detailed information is available in section 3.

2.2.2. Conclusions on alternatives and technical solutions

Substances containing CA:C14-17 provide a number of functions to different types of products. Overall, the following three functions appear to be the most relevant, meaning that suitable alternatives have to provide those functions in the same types of products where substances containing CA:C14-17 are currently being used. Specifically, substances containing CA:C14-17 act as:

1. plasticisers, meaning they confer softness and flexibility to the materials to which they are added (Godwin, 2017);
2. flame retardant *"to provide varying degrees of flammability protection"* (Kutz, 2011);
3. extreme pressure additives in metalworking fluids to *"alleviate the dramatic effect of 'dry' friction by preventing destructive metal-to-metal contact in lubrication at high temperature and pressure conditions"* (Bart et al., 2012); and
4. as lubricants.

It is important to note that in the identification of suitable alternatives, one key complexity is that within the same use, substances containing CA:C14-17 can provide different functions and some functions can be more relevant than others, depending on the final (area of) applications of the products. For example within the same product, substances containing CA:C14-17 can act as both plasticisers and flame retardant. When used in PVC cables (the main product category under Use#00), substances containing CA:C14-17 are used as non-flammable secondary plasticisers, that improve the overall flame retardancy of the products.

The main function of substances containing CA:C14-17 in sealants (Use#01) appears to be as plasticiser. Some stakeholders interviewed by ECHA as part of the market survey, reported that the flame retardant function in sealants is of secondary importance for their market.

Different stakeholders have also indicated that – when used in sealants – substances containing CA:C14-17 are also important non-volatile fillers, contributing to the overall durability of the products.

When used in rubber conveyor belts and other rubber goods (Use#02), substances containing CA:C14-17 act as both flame retardant and plasticiser (CFE 1, 2 and ECHA market survey). However, the flame retardant function appears to be the most relevant one (ECHA market survey).

When used in metalworking fluids (Use#03), substances containing CA:C14-17 act as extreme pressure additives by creating a protective film *"on the surfaces of the contact, due to the reaction with the metal of the additives or of their products of decomposition"* (Bart et al., 2012).

Substances containing CA:C14-17 (predominantly EC 264-150-0) are used both as plasticisers and flame retardants in solvent-based intumescent coatings and flame retardant paints (Use#04). When substances containing CA:C14-17 are used in marine and protective coatings, the plasticiser function appears instead to be the most important one. However, some marine coatings – such as those for vessel interiors – need to have low flame spread to increase safety (ECHA market survey).

With regard to leather treatment (Use#05), the substances identified as 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' are added to fatliquor formulations, used to confer softness and waterproofing properties to leather as well as to strengthen its fibre structure.

Regarding other uses, substances containing CA:C14-17 appear also to be used as

plasticisers and flame retardants in Polyurethane rigid foams.²⁴ However, based on information received from the relevant industry association, PU-EUROPE (ECHA market survey), the use of substances containing CA:C14-17 in these products is in the process of being phased out following the listing of some substances containing CA:C14-17 on the Candidate List. The Dossier Submitter notes that one possible alternative mentioned by stakeholders is Tris(2-chloro-1-methylethyl)phosphate (TCPP) (EC 237-158-7) (ECHA market survey).

To search for information on alternatives, the Dossier Submitter reviewed the following documents: the Annex XV dossier for SVHC identification (ECHA, 2021b), UK RMOA (UK Environment Agency, 2019), German RMOA, Dechlorane Plus Annex XV restriction proposal²⁵, RoHS Annex II Dossier for EC 287-477-0 (EU Commission, 2020b) based on the KEMI proposal (KEMI, 2018).

Appendix E lists the alternatives which appear to be able to provide plasticising and/or flame-retardant properties and potential alternative extreme pressure additives. However, as indicated in the tables, some of these alternatives may not be considered suitable based on their hazard profile or their use has been already restricted.

Stakeholder inputs provided in the context of the CfE1, CfE2 and CfE3 were assessed and extensive bilateral exchanges with relevant trade associations and companies (detailed in Appendix G) as well as extensive surveys were also conducted to:

1. gain a better understanding of the technical and economic profiles of the identified alternatives
2. identify (when possible) the most promising alternatives in each of the above-described uses
3. understand the state of technology of the different sectors regarding substitution, as well as the time that different sectors may require to shift to the alternatives.

Therefore, where possible, a short-list of alternatives - technically feasible and available on the market - was identified for each use category. Moreover, price information for the alternatives was collected as part of the assessment of the overall economic feasibility of the alternatives. In the following sections 2.2.2.1 to 2.2.2.7, this information is condensed for each of the main uses.

Finally, the hazard and risk reduction potential of the alternatives available on the market is analysed in sections 2.2.2.8 and 2.3.2.2.

2.2.2.1. Technically feasible and available alternatives for PVC (Use#00)

Substances containing CA:C14-17 are used as secondary plasticisers with flame retardant properties in PVC compounds used for manufacturing different articles, especially low and medium voltage PVC cables.

Secondary plasticisers, also known as 'extenders' are always combined with a 'primary' plasticiser, often phthalates, to add flexibility to the final product. A secondary plasticiser, when added to the polymer alone, does not bring about these changes and may have limited compatibility with the polymer. (Howick, 2021).

A part from these two technical functions, substances containing CA:C14-17 often result in cost savings as they are purchased at a lower price than phthalates (CfE2 #1504) used as primary plasticiser (Howick, 2021).

Considering also that (i) PVC has inherent flame retardant properties due to the presence of chlorine atoms in its molecular formula (Hirschler, 2017), and that (ii) primary plasticisers such as phosphate esters phthalates have also inherent flame retardant properties because they create a charring layer²⁶, and release CO₂ when subject to high heat, it appears that the use of substances containing CA:C14-17 is

²⁴ Polyurethane rigid foams are widely used in construction sector and "main application is thermal insulation of buildings and technical installations" <https://www.pu-europe.eu/>

²⁵ Available at: <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e184a168c4>

²⁶ Charring is a chemical process of incomplete combustion of certain solids when subjected to high heat.

mainly driven by economic reasons to reduce the quantity of 'primary' plasticiser in the formulation and that in certain types of PVC compounds the use of substances containing CA:C14-17 can be simply removed.

It should nevertheless be noted that in case the primary plasticiser would be a non-halogenated phthalate ester, then substitution of substances containing CA:C14-17 by such a phthalate only would result in a lower flame retardancy of the PVC compound (CfE1 #1356).

Based on the inputs provided by stakeholders in response to the calls for evidence and ECHA market survey, several technically and economically suitable alternatives – both alternative substances and technologies (e.g. compounds based on alternative polymers) appear to be available on the market.

Some stakeholders indicated that substances containing CA:C14-17 were simply removed from some PVC formulations because PVC has inherent flame-retardant properties. Such a 'removal' seems possible in cases where PVC does not need to pass stringent fire test requirements. E.g. PVC cables of class "D"²⁷ need to comply with less stringent fire performance requirements when compared to cables of class "A" (ECHA Market Survey and Hirschler (2017)).

The '*Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)*' lists an extended number of alternatives to 287-477-0 (EU Commission, 2020b). Some of them appear to be able to provide both functions; however, most of them are either plasticisers or flame retardants but not both. Also, PINFA lists in its '*Innovative and Sustainable Flame Retardants in Building and Construction*' report several alternative flame retardants for PVC cable compounds and other halogenated polymers (Pinfa, 2017).

Regarding the flame retardant properties, several alternatives are identified in the two mentioned reports including:

- Antimony trioxide (ATO) (EC 215-175-0)
- Aluminium (tri-)hydroxide (ATH) (EC 244-492-7)
- Magnesium (di-) hydroxide (MDH) (EC 215-170-3)
- Zinc Hydroxystannate (EC 404-410-4)
- Triphenyl phosphate (EC 204-112-2)
- Phosphorus and nitrogen-based flame retardants.

It should be noted that antimony trioxide acts rather as a synergist than as a flame retardant. Synergists enhance the flame retarding properties of other substances in a formulation. In PVC, synergists like antimony trioxide enhance the inherent flame retardance properties of PVC (chlorine atoms).

EC 264-150-0 (containing less than 0.1 % of CA:C14-17) was also identified as an alternative, potentially able to provide both functions (secondary plasticiser and flame retardant). However, the longer the carbon chain length of the raw material (n-alkane), the higher is the viscosity of the final chlorinated product (chloroalkane). This means that, for a given density (same chlorine content), EC 264-150-0 will have a higher viscosity when compared to EC 287-477-0. To reduce the viscosity of EC 264-150-0, the content of chlorine – which gives flame retardancy properties – needs to be reduced (typically: 6-8 % w/w of chlorine content less), meaning that EC 264-150-0 might not be able to provide the same flame retardant properties as EC 287-477-0 (ECHA market survey).

Other potential alternatives – fire retardant plasticisers – have been indicated by stakeholders, such as phosphate esters (CfE1 #1345). In addition to alternative chemicals, several halogen free compounds for cables were identified by the Dossier Submitter in the above mentioned PINFA report, among which:

- EVA Ethylene vinyl acetate copolymers (EVA or EVM)
- Linear Low Density Poly-ethylene (LLDPE)
- TPE (thermoplastic elastomers).

²⁷ https://eur-lex.europa.eu/eli/reg_del/2016/364/oj

The Dossier Submitter also identified several players on the market offering halogen free flame retardant (HFFR) cable compounds, which confirms the commercial availability of these alternative technologies.

PVC compounds producers interviewed by the Dossier Submitter (ECHA market survey) indicated that substitution of substances containing CA:C14-17 is possible with little impact on the production costs of PVC compounds.

The Dossier Submitter also gathered information on the availability of alternatives from PVC Forum, the Italian Association representing the main Italian producers of PVC compounds and PVC converters. The association indicated that the PVC industry has been active to phase out substances containing CA:C14-17 and that potential alternatives – e.g. combinations of plasticisers and flame retardants - are available. However, one company interviewed by the Dossier Submitter indicated that the substitution of substances containing CA:C14-17 appears to be challenging in specific types of cables, which need to comply with the more stringent fire performance requirements set out in Regulation (EU) No 305/2011²⁸.

The company in question explained that the alternatives they have tested so far (EC 264-150-0 included) were not able to pass the EN 50399 tests required for C_{ca} types of cables²⁹. The Dossier Submitter nevertheless notes that substitution with a synergist (cf. above) may help to reach the more stringent fire standard requirements.

Overall, the Dossier Submitter concludes that technically feasible alternative substances or technologies are available, even though substitution may lead to a slight increase in production costs of PVC compounds. The impact on costs will be further described in the specific section on the assessment of impacts (cf. section 2.3.1).

The Dossier Submitter notes that the feasibility of substitution/removal may differ between different types of PVC compounds. For example, substitution/removal appears to be more feasible in PVC compounds used for manufacturing cables with lower fire performance requirements (e.g. in compounds used for manufacturing 'Eca' class of cables), while substitution appears to be technically more challenging in PVC compounds used for manufacturing 'Cca' cables that need to pass more rigorous fire resistance tests. For example, one company interviewed by the Dossier Submitter indicated that they simply removed substances containing CA:C14-17 (specifically EC 287-477-0) from the compounds they produce. A second company indicated that they could remove substances containing CA:C14-17 (specifically EC 287-477-0) from some compounds, while for others they were testing the available alternatives.

2.2.2.2. Technically feasible and available alternatives for adhesive and sealants (Use#01)

Technically feasible alternatives should provide the sealants with the different functions currently provided by substances containing CA:C14-17, meaning that any suitable alternative³⁰ should act as plasticiser, flame retardant and filler, as well as meet a number of physico-chemical criteria (see e.g. CfE1#1335, CfE1#1357).

When considering substitution in:

- *One-component foams (OCF), 'alternatives should be non-reactive to isocyanates and meet certain criteria in terms of viscosity, hydrophobicity, solubility etc., in order to be chemically compatible to PU prepolymer system inside the OCF can'* (ECHA market survey). These and additional performance requirements such as the ability of the alternative to act as an emulsifying agent and meet the required shelf-life criteria were described by other stakeholders (CfE1#1363)

²⁸ Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC <https://eur-lex.europa.eu/eli/reg/2011/305/2021-07-16>

²⁹ Commission Delegated Regulation (EU) 2016/364 of 1 July 2015 on the classification of the reaction to fire performance of construction products pursuant to Regulation (EU) No 305/2011 of the European Parliament and of the Council, [EUR-Lex - 32016R0364 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/eli/reg/2016/364/2021-07-16)

³⁰ This can include a combination of chemicals.

- For insulating glass (IG) polysulfide sealants, any suitable alternative needs to be compatible with the polysulfide polymer technology, provide good adhesion, mechanical properties and UV stability to the sealant and have a very low migration potential (CfE1#1335).

Based on inputs provided by stakeholders in response to the calls for evidence (CfE1#1353, CfE 1#1357, etc.), ECHA market survey (cf. Appendix G), literature (Wei et al., 2015), and the online catalogues of chemical suppliers (Lanxess, "Additives for polyurethanes"³¹), the substitution efforts in this sector are taking place and potential alternatives appear to be available on the market. Also, a number of stakeholders shared with ECHA the conclusions from internal tests carried in an effort to identify a suitable replacement.

Some of the main technically available alternatives in one-component polyurethane foams (OCFs) are:

1. Tris(2-chloro-1-methylethyl)phosphate (TCPP) (EC 237-158-7)
2. Paraffin waxes and Hydrocarbon waxes, chloro (LCCPs) (EC 264-150-0)³²
3. Triethyl phosphate (TEP) (EC 201-114-5)
4. Tricresyl phosphate (TCP) (EC 215-548-8)

With regard to polysulfide sealants, some benzoates (e.g. Oxydipropyl dibenzoate (DPGDB) (EC 248-258-5)³³, phthalates (e.g. Di-"isononyl" phthalate (DINP) EC 249-079-5) and some special grades of (EC 264-150-0) appear to be among the main potential substitutes (CfE2#1471).

Some stakeholders stressed that the substitution of substances containing CA:C14-17 is challenging because:

- The alternatives appear not always to be able to adequately meet one or more of the above required functions (ECHA market survey)
- Several issues were identified with some potential alternatives, such as "*viscosity, unproven thermal performance and unproven adhesion*" (CfE1#1363); and
- Some alternatives may negatively impact the foam stability of OCFs.

It should be also noted that formulators of sealants tend to offer customised solutions for their customers, meaning that any new formulation using an alternative or a combination of alternatives need to be tested against customer requirements before being able to conclude on the suitability of an alternative.

Finally, the potential alternatives appear to be more expensive compared to the price of EC 287-477-0 (CfE1#1353, CfE1#1335, ECHA market survey) and require the same concentration, meaning that the production costs for these products are expected to be higher in case of substitution. Moreover, one of the major producers of OCFs in the EU stressed that EC 287-477-0 cannot be replaced by a drop-in alternative and that an overall product reformulation is needed (ECHA market survey). This was also confirmed by another stakeholder interviewed by the Dossier Submitter (ECHA market survey). Based on the bilateral exchanges undertaken with some of the main producers of OCFs in the EU, the Dossier Submitter concludes that technically and economically feasible alternatives are available to replace substances containing CA:C14-17 in OCFs, acknowledging however that a drop-in alternative appears not to be available, that product reformulations are needed, and that the overall substitution costs (and impacts on sealant prices) might be significant.

Alternative plasticisers in insulating glass (IG) polysulfide sealants appear to be also available, even though the price difference compared to substances containing CA:C14-

³¹ See https://pla.lanxess.com/fileadmin/user_upload/Additives/Additives_for_polyurethanes_A4_05-2018.pdf.

³² Only EC 264-150-0 containing less than 0.1 % CA:C14-17 with PBT and/or vPvB properties can be considered as an alternative.

³³ <https://www.dibenzoateplasticizers.com/sale-13958939-polysulfide-sealant-phthalate-free-plasticizers-benzoate-ester-plasticizers.html> , <https://www.ataman-chemicals.com/en/products/dipropylene-glycol-dibenzoate-1403.html>

17 can be significant (ECHA market survey).

The Dossier Submitter also identified potential alternative technologies to polyurethane foams, such as mineral wool and pre-compressed tapes (ECHA market survey).

The association representing the European adhesive and sealant industry – FEICA – however indicated that mineral wool needs to be manually inserted and pressed into a joint. Application of this alternative technology requires hours of manual labour compared to a few minutes required for installing an OCF product. Moreover, the association stressed that long-term insulation performance inside a joint with (thermal) movement is unclear as this product does not guarantee the seamless filling capacity as OCF products do.

Pre-compressed tapes may also be considered as substitutes, according to FEICA.

However, the association explained that the quality of workmanship is much more critical than for OCFs and that insulation values are typically lower when compared to OCFs.

Finally, as further detailed by the association – in case of poor workmanship - the insulating function of pre-compressed tapes could fail altogether.

Several alternatives, among which tris(2-chloro-1-methylethyl)phosphate (TCPP, EC 237-158-7), appear to be suitable to replace substances containing CA:C14-17 in rigid polyurethane foams (ECHA market survey). Substitution is expected to be completed before the entry into force of the restriction with no additional impacts on the industry.

This was also confirmed by PU-Europe, the European association representing the polyurethane (PUR / PIR) insulation industry, which however indicated that the alternatives are more expensive compared to EC 287-477-0 and that they consider EC 287-477-0 as *“the most cost-efficient substance for the same level of performance”*.

2.2.2.3. Technically feasible and available alternatives for rubber (Use#02)

Substances containing CA:C14-17 provide anti-firing properties to rubber conveyor belts and other rubber articles used in underground activities such as mining (CfE2#1474, ECHA market survey). Contrary to PVC, pure rubber is flammable.

Based on the inputs received during the calls for evidence and bilateral exchanges with the stakeholders from the rubber industry, substitution activities in this sector are ongoing and for most of the products are in the final stage.

Regarding the specific category of rubber conveyor belts used for underground activities, a technically feasible alternative needs to meet several European standards, including:

- ‘Conveyor belts for use in underground installations - Electrical and flammability safety requirements’ (EN14973³⁴)
- ‘Conveyor belts for general purpose use. Electrical and flammability safety requirements’ (EN12882³⁵).

Based on inputs collected from stakeholders through the ECHA market survey, it appears that the main EU-based companies (between 5 and 10) in the rubber conveyor belt sector³⁶ are currently using EC 287-477-0 or EC 264-150-0, and that those currently using EC 287-477-0 are primarily focusing their substitution efforts towards EC 264-150-0 (e.g. EC 264-150-0, C22-30).

However, as also highlighted by the EU sealants and adhesive sector, it appears that EC 264-150-0 has some technical limitations when compared to EC 287-477-0, notably in terms of its high viscosity. Despite this, EC 264-150-0 appears to be the closest alternative to EC 287-477-0 used in rubber conveyor belts from a technical perspective (ECHA market survey).

In addition to EC 264-150-0, a stakeholder interviewed by the Dossier Submitter indicated that flame retardants based on phosphates – among which phenol,

³⁴ <https://www.en-standard.eu/une-en-14973-2016-conveyor-belts-for-use-in-underground-installations-electrical-and-flammability-safety-requirements/>

³⁵ <https://www.en-standard.eu/bs-en-12882-2015-conveyor-belts-for-general-purpose-use-electrical-and-flammability-safety-requirements/>

³⁶ For underground activities.

isopropylated, phosphate (3:1) (EC 273-066-3) and tricresyl phosphate (TCP) (EC 215-548-8) – may be considered as technically feasible substitutes.

ETRMA – the association representing the European industry producing tyre and rubber goods – indicated that a transition period of 24 months (until 2026) would be needed considering the industry's substitution status and the current challenges in acquiring raw materials (including substitutes to substances containing CA:C14-17) (CfE2 #1484).

The association also indicated that "*where the final product has strict conditions for use in terms of fire resistance and safety, in example, underground mining or transport, the use of EC 287-477-0 could be substituted with Long Chain Chlorinated Paraffins (EC 264-150-0)*" and that "*for other uses of EC 287-477-0, other alternatives are available*" (ECHA market survey). Regarding EC 264-150-0, the Dossier Submitter notes that the industry's association submission does not however discuss the possible presence of CA:C14-17 in EC 264-150-0, while being aware that the substance might also be covered by the restriction (ECHA Market Survey).

The Dossier Submitter concludes that technically and economically feasible alternatives for this use are available. Specifically, the Dossier Submitter notes that EC 264-150-0 appears to be considered among the alternatives identified by the rubber sector. However, in line with the restriction's conditions, EC 264-150-0 can only be considered an alternative if the concentration of CA:C14-17 with PBT and/or vPVB properties is below 0.1 %.

2.2.2.4. Technically feasible and available alternatives for metalworking fluids (Use#03)

Substances containing CA:C14-17 are used as extreme pressure (EP) additives in certain types of metalworking fluids used in heavy duty metal working operations, such as '*deep drawing*', '*broaching*' and '*fine blanking*'. EP additives act by creating a protective film on the surface of the contact because of the additive's reaction with the metal or because of their products of decomposition (Frene et al., 1997).

Among the potential alternatives, the Dossier Submitter identified phosphorus and sulphur-based additives.

A list of identified alternatives is reported in Appendix E.

Specific advantages of sulphur and phosphorus-based EP additives are that they are not corrosive to carbon steels.³⁷ Products and tools can be degreased in normal industrial cleaning processes and there are no special requirements or additional costs for the disposal of oil waste as these substances are not identified as SVHC (ECHA market survey).

Sulphurised olefins and fatty acid esters appear suitable to replace substances containing CA:C14-17 in some applications using oil-based fluids, but difficulties have been encountered when using them in water-based fluids, as these are less stable and form malodorous sulphur compounds when degrading (ECHA market survey).

The S-olefins appear not to be suitable for direct substitution as they lack the lubricity and cutting performance at lower temperatures, and they have to be used in combination with other substances (ECHA market survey). S-esters/fats appear to have better lubricity than the olefins but are generally more odorous. However, it seems that this alternative may be used in less demanding applications where CA:C14-17 is present in the metalworking fluids in low concentrations. A combination with other substance is generally required (ECHA market survey).

Critically, the temperature needed to 'activate' sulphur is higher than that required to activate the chlorine-form chloroalkanes. Moreover, these EP additives have been found unsuitable for certain materials such as stainless steel, titanium, and copper as these have very stable oxide coatings, so they do not react with these additives. Also, sulphur-based additives cannot be used for copper alloys in electrical terminals as they are corroded by sulphur (ECHA market survey).

³⁷ <https://www.sciencedirect.com/topics/engineering/carbon-steel>

Phosphate esters were also indicated as potential alternatives that could be used in combination with other EP additives to substitute substances containing CA:C14-17 in certain applications, but some of them are already under investigation for Persistent, Bioaccumulative and Toxic (PBT) properties (ECHA market survey).

Several stakeholders (CfE1#1332 and ECHA market survey) indicated that substitution already occurred in processes where that was possible and that today substances containing CA:C14-17 are only used in heavy duty metalworking operations where alternatives appear not to be available yet. These niche applications seem to account for no more than 5 % of the overall metalworking processes (CfE1#1332)³⁸.

This was confirmed by several users and formulators of metalworking fluids (ECHA market survey).

Respondents to the ECHA market survey reported that less demanding machine processes can generally be performed using widely available alternatives such as sulphur-based EP additives, phosphorus-based additives, polymeric esters, or over-based sulfonates. It appears that even some more demanding operations can be performed using selected single additives from this list or a synergistic combination thereof. One formulator estimated that for >95 % of metalworking operations it is possible to replace substances containing CA:C14-17 by synergistic combinations of organic sulphur compounds (e.g. polysulfides/ sulfur carriers) either in combination with overbased calcium sulfonates, polymeric esters, phosphor-organic compounds or succinimides (ECHA market survey).

However, it seems that for some processes and materials it has not so far been possible to replace substances containing CA:C14-17 in metalworking fluids and this seems particularly the case of very heavy-duty applications and hard materials such as stainless steel and titanium that are resistant to reaction with EP additives other than chloroalkanes (ECHA market survey). Based on the inputs collected from various stakeholders, substitution appears to be technically challenging in oil-based fluids with higher concentrations of substances containing CA:C14-17 that are used for the most demanding metalworking operations (ECHA market survey).

A formulator stated that sulfur and phosphorous based additives are much weaker in anti-wear performance when compared to substances containing CA:C14-17. This observation was confirmed by another formulator reporting that when sulfur- and phosphorous-containing EP additives are used, a greater volume of metalworking fluids is required during processing. Moreover, when sulfur and phosphorous-based additives are used, the stability of the metalworking fluids seems to be lower leading to a higher frequency of oil changes (ECHA market survey).

Finally, a number of stakeholders reported that the production of certain products, specifically metals used in the aerospace and automotive industries, require higher quality metalworking fluids that cannot currently be formulated using alternatives to CA:C14-17 (CfE2#1480).

EC 264-150-0 is also considered as potential alternatives, having however a major disadvantage in terms of high viscosity when the trend in neat oils is to move to lower viscosities. Also, in water soluble metalworking fluids, the high viscosity of EC 264-150-0 leads to formation of sticky deposits where evaporation rates are high (ECHA market survey).

Based on other sources, substitution in heavy duty working operations (like fine blanking or broaching) might nonetheless be feasible, even though *"to replace chlorinated paraffins in metalworking applications, its often necessary to combine two or even more additives like sulfur or phosphor-based chemistry, overbased sulfonates or polymeric esters to fulfil the wide band of requirements of heavy duty metalworking processes like fine blanking or broaching. Sometimes also the machine setup, machining speed, tool coatings and other production parameters need to be adjusted to keep the tool life and*

³⁸ In the submission the stakeholder in question referred to chlorinated paraffins, without providing a specific substance identifier/s.

machining precision on the desired level” (Lanxess submission to the POP Risk Profile).³⁹ The response from Lanxess suggests that the substitution of the remaining uses of substances containing CA:C14-17 in metalworking fluids is more complex and requires more time. The main reason is that alternatives need to be tested and adjusted directly in the field due to the singularity and sometimes uniqueness of the remaining metalworking operations: standard tests in the laboratory reproducing the conditions of the metalworking application do not always exist.

Based on the available information, the Dossier Submitter concludes that potential alternatives appear to be available, noting however that at this stage, it is not certain whether they are technically able to replace the substances containing CA:C14-17 in all metalworking fluids used and in particular in heavy duty working operations. These products seem to be used in less than 5 % of metalworking processes (CfE1#1332).

2.2.2.5. Technically feasible and available alternatives for paints and coatings (Use#04)

Substances containing CA:C14-17 (notably EC 287-477-0) are used in the manufacturing of marine and protective coatings (ECHA market survey). In this use the main function of EC 287-477-0 is as plasticiser and possible alternatives are non-chlorinated plasticisers (ECHA market survey). One company indicated that the alternative they had identified is EC 264-150-0 with chain length C18-20 and containing approximately 1 % of CA:C14-17 (ECHA market survey). The Dossier Submitter however notes that – in line with the scope of the restriction – this substance cannot be considered as a viable alternative.

Further information on this use and on the availability of alternatives was collected by the Dossier Submitter in bilateral exchanges with the marine and protective coating producers.

Based on the information provided by coating producers, it appears that substitution is ongoing, technically and economically feasible alternatives are available, and some of the major players in the market have already phased out the use of substances containing CA:C14-17 in marine and protective coating formulations (ECHA, market survey).

EC 264-150-0 (with chain lengths C22-30) is widely used as fire retardant and plasticiser in fire retardant paints and solvent-based intumescent coatings.⁴⁰ Because the concentration of CA:C14-17 is expected to be below 0.1 % in EC 264-150-0 (with carbon chain lengths between C22 to C30), companies operating in this sector are not expected to look for any alternative because of this restriction. Also, in case some companies are currently using EC 264-150-0 with CA:C14-17 concentrations above 0.1 %, these are expected to shift to EC 264-150-0, containing CA:C14-17 in a concentration below 0.1 %.

2.2.2.6. Technically feasible and available alternatives for leather (Use#05)

With the exception of the two substances identified as: a) ‘Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified’ and b) ‘Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified’, which are used in fatliquors, the use of other substances containing CA:C14-17 appears to be minor in the textile sector (CfE2, #1496). TEGEWA, the German association of producers of textile, paper and leather, indicated that the use of substances containing CA:C14-17

³⁹ Response to the invitation for information following the decisions adopted by the Persistent Organic Pollutants Review Committee at its seventeenth meeting (POPRC-17) on Chlorinated paraffins with carbon chain lengths in the range C14–17 and chlorination levels at or exceeding 45 per cent chlorine by weight: available at: [Annex E CP Submission \(pops.int\)](#)

⁴⁰ Intumescent coatings are used to protect steel substrates of constructions exposed to fire and work by increasing in volume when exposed to heat.

in textile (as flame retardants and waterproofing agents) is no longer state of the art in Europe and that in most textile applications, the use of these substances has been already phased out.

Regarding the two substances used in fatliquors, the Dossier Submitter identified some alternatives, among which:

- Phosphorous esters and
- Sulphited / Sulphated fatty acid esters (De Rosa-Giglio et al., 2020).

Moreover, different types of natural fatliquors appear to be available on the market, such as fatliquors based on coconut, soya, fish oil, lanoline, lard oil, sulphated neatsfoot oil (De Rosa-Giglio et al., 2020).

The Dossier Submitter notes that while companies may produce many types of fatliquors, the discussed substances appear to be used in fatliquor products that need to provide a particularly high degree of softness to leather, as well as water and tear resistance (ECHA market survey).

In particular, the alternatives would need to be tested against the following parameters:

- Odourless
- Light fastness
- Stability to oxidation
- Polar affinity with the leathers due to chlorine
- Compatibility with natural fatliquors
- Excellent in-depth greasing action
- Excellent distribution of natural fat in the skin
- Qualitative constancy
- Improvement of the mechanical characteristics of the leather (anti-tear) (ECHA market survey)⁴¹.

It is unclear whether the alternatives identified above by the Dossier Submitter would provide the same performance to leather in terms of softness, resistance and waterproofness and a drop-in alternative for the two above-mentioned substances could not be identified at this stage by the Dossier Submitter (ECHA market survey). However, product reformulation appears to be possible, as also indicated by some stakeholders interviewed by the Dossier Submitter (ECHA market survey).

For example, COTANCE, the association representing the European leather industry, indicated that the industry would need between two and five years to reformulate products (also considering the time for the testing and requalification process with customers), if a substitution was required. Also, a fatliquor producer directly contacted by the Dossier Submitter indicated that product reformulation would take 4-5 years. (ECHA market survey). Other stakeholders indicated that product reformulation might take 5 (or more) years and that it is not certain that the substitution will be successful and that the reformulated products will meet the necessary requirements (ECHA market survey).

Dossier Submitter however notes that there is no certainty that a substitution will be required for this sector as a result of this restriction.

This is due to the fact that, based on the information the Dossier Submitter received from the various calls for evidence, it appears that CA:C14-17 with PBT/vPvB properties may be present in 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' in concentration varying between below 0.1 % and up to ca. 10 % (cf. Appendix B.1). Some companies using or producing this substance indicate indeed that the presence and concentration of CA:C14-17 with PBT/vPvB properties depends on the grade of the feedstock (presence of C14-17) used to produce EC 269-145-7 and on the amount of alkane that would be chlorinated but not sulfonated.

The presence and the origin of CA:C14-17 with PBT/vPvB properties in 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' (and in EC 269-145-7) can

⁴¹ These are the criteria identified by the Dossier Submitter through the ECHA market survey. The list might not be exhaustive.

therefore be linked to the presence of the C14-17 chain length in the alkane/alkene feedstock used to produce EC 269-145-7. The presence and concentration of CA:C14-17 (with PBT/vPvB properties) in the fatliquoring substance 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' may vary depending on the starting material, the manufacturing conditions, and the manufacturer of EC 269-145-7. Some users of the fatliquoring substance 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' confirmed that they would already fulfil the potential restriction conditions because the substance they use already contains <0.1 % of CA:C14-17 (and therefore <0.1 % of the chloroalkanes with PBT/VPvB properties). These users also confirmed that their suppliers of EC 269-145-7 are indeed already using an alkane/alkene feedstock with <0.1 % of C14-17 chain length.

Based on the above information, the Dossier Submitter considers that:

- 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' containing < 0.1 % of CA:C14-17 with PBT and/or vPvB property could be an alternative to 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' containing \geq 0.1 % of CA:C14-17 with PBT and/or vPvB property and that
- Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' containing < 0.1 % of CA:C14-17 with PBT and/or vPvB property could be an alternative to Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' containing \geq 0.1 % of CA:C14-17 with PBT and/or vPvB property.

Therefore, no impacts on the leather sector are expected as a result of this restriction because:

1. companies currently using the substances containing <0.1 % of CA:C14-17 will continue to do so under the restriction scenario, and
2. companies that may be currently using the substances containing more than 0.1 % of CA:C14-17 are expected to shift to compositions containing <0.1 % of CA:C14-17.

In line with the two assumptions above, the impact assessment did not quantify the impacts for this sector. If the industry does not consider the two assumptions plausible, the sector is invited to provide relevant comments and supporting evidence during the Annex XV report consultation.

Considering the above uncertainties – on whether the substitution would be required as a result of the restriction – the Dossier Submitter estimated the potential economic impacts on this sector (as part of the uncertainty analysis), assuming that the concentration of CA:C14-17 with PBT and/or vPvB properties cannot be reduced below 0.1 %, meaning that all the volumes of 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' would need to be replaced. The economic impacts were assessed for two scenarios:

- The leather sector is granted a two-year transition period; or
- The leather sector is granted a five-year transition period.

The industry's behavioural responses and the approach in quantifying the economic impacts under the above two scenarios are reported in Appendix F.

2.2.2.7. Technically feasible and available alternatives for paper (Use#06) and other uses (Use#07)

Considering that the use in paper appears to be obsolete, the Dossier Submitter concludes that alternatives are available and are already implemented by industry. To confirm this assumption, the Dossier Submitter contacted the relevant EU confederation, CEPI (Confederation of European Paper Industries), and no relevant use was reported by the organisation.

Regarding other potential uses (e.g. lubricants for applications other than heavy duty metal forming operations falling under Use#03), the Dossier Submitter considers that alternatives to substances containing CA:C14-17 are available. For example, in many metal forming operations alternatives are available and have already replaced substances containing CA:C14-17 (Nilsson et al., 2005). This is consistent with information that the Dossier Submitter collected through the calls for evidence and the sector-specific market survey.

Finally, and based on the information that the use of substances containing CA:C14-17 is relevant only for certain types of heavy-duty metal forming operations, the Dossier Submitter considers that technically and economically feasible alternatives are available in other categories of lubricants (such as 'general lubricants', which might be used in kitchen appliances, chain bicycles, etc.).

2.2.2.8. Hazard and risk of alternatives

The Dossier Submitter identified ~ 70 potential different alternatives from a literature review, stakeholders' consultations and the ECHA market survey.

In general, the alternatives available are better than the substances to be restricted from a human health and environmental standpoint (cf. Appendix E).

Based on the information available in the ECHA C&L inventory, and PACT, there is indeed no potential human health or environmental hazard identified for most of the alternatives listed in Appendix E.

For example, among the alternatives mentioned in section 2.2.2.1: aluminium (tri-)hydroxide (ATH)(EC 244-492-7), magnesium (di-) hydroxide (MDH) (EC 215-170-3) and zinc hydroxystannate (EC 404-410-4) do not have a harmonised classification and no potential hazards are suspected neither for human health or the environment.

For some substances, potential hazards are suspected for human health. For example some substances are classified as Carc. Cat. 2 (e.g. antimony trioxide (ATO) (EC 215-175-0)⁴²), and others are under regulatory scrutiny due to endocrine disruption suspicion (e.g. triphenyl phosphate (EC 204-112-2), tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)(EC 237-159-2), 1,1'-[ethane-1,2-diylbisoxo]bis[2,4,6-tribromobenzene] (EC 253-692-3), 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (EC 201-236-9) or CMR concerns.

With regard to tris(2-chloro-1-methylethyl) phosphate (TCPP) (EC 237-158-7) and TDCP (EC 237-159-2), the substances are to be restricted according to the Restriction Roadmap,⁴³ with the potential submission date still to be decided. Carcinogenic, mutagenic and toxic for reproduction are the identified concerns.

Trixylyl phosphate (EC 246-677-8) was included on the REACH Authorisation List in 2020.

Finally, some substances are currently under regulatory scrutiny, e.g. 1,1'-[ethane-1,2-diylbisoxo]bis[2,4,6-tribromobenzene] (EC 253-692-) or under assessment due to PBT and/or vPvB concerns. For example, phenol, isopropylated, phosphate (3:1) (EC 273-066-3) is currently under Substance Evaluation by Netherlands⁴⁴, and EC 264-150-0 may be subject to an updated assessment by the UK Environment Agency to evaluate its PBT and/or vPvB potential (UK, 2021).

Terphenyl, hydrogenated (EC 262-967-7) was identified as SVHC due to its vPvB properties, and a restriction proposal was submitted in 2022.

An overview of the hazard profile of the identified alternatives and their regulatory status is reported in Appendix E.

⁴³ [DocsRoom - European Commission \(europa.eu\)](https://docsroom.ec.europa.eu/)

⁴⁴ [PBT assessment list - ECHA \(europa.eu\)](https://pbt.echa.europa.eu/)

2.2.3. Transition period

A transition period of a certain duration may be needed to avoid disproportionate socio-economic impacts immediately after the restriction enters into force.

A ban without a transition period (TP) would mean an immediate closure of activities along the value chain as there is currently not enough capacity in the EU production of some of the alternatives to absorb the existing market volume for all uses in the scope of the proposed restriction. In addition, sufficient time is needed for some companies to investigate the substitution with new alternatives, also considering that no 'one fits-all solution' is available for all the different applications. As indicated in section 2.2.2, substances containing CA:C14-17 can provide different functions in a wide range of products and the setting of a TP needs to factor the time that companies might need to test the different alternatives, reformulate and validate all the affected products.

A TP is also needed to provide time to relevant/interested laboratories not yet organised, for planning, choosing equipment, staffing and training to guarantee sufficient laboratory quality standards and ensure the accuracy of test results when performing the most advanced analytical methods.

ETRMA indicated that a TP until 2026 would be needed considering the industry's current challenges (due to the geo-political situation on the European continent) in accessing raw materials including substitutes to substances containing CA:C14-17 (CfE2 #1484). Based on these elements, and considering the information gathered during the ECHA market survey on the experience of some companies that already substituted substances containing CA:C14-17 in certain types of uses, a uniform TP of 2 years has been investigated for all ROs except for RO4b and RO5.

The 2-year TP is considered long enough to allow the entire use/consumption of stocks of the substances and mixtures. Consequently, uses of substances and mixtures at industrial sites and by professional should cease once the 2-year transition period is over.

Under RO4b a 2-year, TP is considered for all sectors except the metalworking fluid sector, for which a 7-year TP is foreseen. A 7-year TP is akin to the standard review period granted in the frame of authorisation applications where such a time span is considered as sufficient for industry to undertake the necessary research and development and substitute SVHC. In addition, during the ECHA market survey, several stakeholders from the metalworking sector indicated that a TP between two and ten years (on average six years) would be needed to substitute the substances containing CA:C14-17 in the remaining metalworking applications. The request for a longer TP was justified by the uniqueness of the remaining process (essentially heavy-duty metalworking), and the necessity to test directly substitutes in those workshops where the substances containing CA:C14-17 are currently used (Lanxess submission to the POP Risk Profile, and ECHA Market Survey).

Finally, regarding RO5, the Dossier Submitter is proposing a shorter transition period of 6 months, as the requirements associated with RO5 are purely administrative (update of the registration dossier, transfer of information in the supply chain), and should already be made for the substances in the Candidate List which represent the biggest share (in term of tonnage) of substances containing CA:C14-17. The proposed 6-month TP is consistent with the Commission implementing Regulation EU 2020/1435,⁴⁵ which clarifies that Registrants shall update their registration dossier within 6 months once new information on hazard and risk are identified, and within 3 months when reporting a change in the composition of the substances registered.

⁴⁵ COMMISSION IMPLEMENTING REGULATION (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

2.2.4. Concentration limit

For all ROs assessed, the Dossier Submitter is proposing a unique concentration limit of 0.1 % (w/w) for restricting the presence of CA:C14-17 with PBT and/or vPvB properties in substances, mixtures and articles.

The proposed 0.1 % limit is consistent with the conclusions of the Member State Committee on the SVHC identification of 'MCCP' (cf. section 1.4.2), which stated that substances containing CA:C14-17 could be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if CA:C14-17 with PBT and/or vPvB properties are present in a concentration \geq 0.1 % (w/w) (ECHA, 2021a). It is also consistent with the ECHA PBT guidance (section R.11.4.1), which states that if registered substance contains constituents (in this case congeners) meeting the PBT and/or vPvB criteria in concentration above 0.1 % (w/w), then the relevant compositions meet the PBT and vPvB criteria (ECHA, 2017b).

With regard to mixtures, the 0.1 % concentration limit proposed is consistent with the current provisions on PBT and vPvB substances in REACH. For example, REACH Articles 14(2)(f), 31(3)(b) and 56(6)(a)⁴⁶ apply the same concentration limit for PBT and vPvB substances in mixtures to trigger various obligations under REACH.

Finally, the 0.1 % limit is also the limit triggering obligations for PBT and vPvB substances in articles under REACH Article 7(2)(b), and under Article 9(1)(i) of the Waste Framework Directive 2008/98/EC.

During the ECHA market survey, the 2nd and 3rd calls for evidence, and the Registrants' survey, stakeholders did not raise any issue with the proposed limit indicating that a concentration of 0.1 % of CA:C14-17 could be achieved in substances, mixtures, and articles.

Stakeholders, and in particular some registrants, indicated that a concentration limit below 0.1 % in substances may be difficult to achieve for some chloroalkanes due to the (unintentional) presence of C14-17 chain length in the feedstock used to produce chloroalkanes with a carbon chain length longer than C18 (cf. Appendix B.1).

It should be noted that during the restriction dossier preparation, the Dossier Submitter investigated also the possibility to set a lower concentration limit than 0.1 % for mixtures and articles. Maximum concentrations of 0.01 %, 0.005 % and 0.001 % CA:C14-17 with PBT and/or vPvB properties in mixtures and articles were tested (cf. Appendix E). Based on the simulation reported in Appendix E, the Dossier Submitter concluded that in order to apply the same restriction conditions to both imported and EU-produced mixtures and articles, a concentration limit of 0.005 % might be set for CA:C14-17 with PBT and/or vPvB properties in mixtures and articles. However, the simple simulation reported in Appendix E does not take into account the diversity of uses and concentration ranges of substances containing CA:C14-17 in mixtures and articles. In addition, due to a lack of data on imported articles, the Dossier Submitter could not estimate the associated costs and impacts in terms of release reduction when lowering the concentration limit. The Dossier Submitter could therefore not conclude on the appropriateness and proportionality of a concentration limit lower than 0.1 %.

With regard to the proposed 0.1 % concentration in mixtures and articles, the Plastics Recyclers Europe association indicated that a "low limit" of < 10 % may be difficult to achieve for recycled articles (e.g. recycled PVC cables into road equipment) considering the concentration of CA:C14-17 usually reported in cables (CfE3 #1522).

Some possibilities could exist to reduce the CA:C14-17 content in recycled PVC through dilution with virgin PVC or other materials (e.g. a filler). However, while economically questionable, and technically allowed, such a dilution would become impossible once the substances would be listed under the POPs Regulation. Indeed, Article 7(3) of the EU Regulation 2019/1021 on persistent organic pollutants prohibits the recycling or reuse of POP substances for substances listed in Annex IV to the POPs Regulation which sets

⁴⁶ Article 14(2)f: CSR duties for PBT/vPvB substances in mixtures

Article 31 (3)b: requirement for safety data sheet for PBT/vPvB substances in mixtures

Article 56(6)(a): authorisation requirement for PBT/vPvB substances in mixtures

limits for the recycling or re-use. Nevertheless, until the POP process is finalised, and the Annex VI to POP is amended, substances containing CA:C14-17 may not be a concern for recycling as soft PVC articles containing CA:C14-17 should already be treated as waste, and not recycled due to the concomitant presence⁴⁷ of phthalates in the same articles that are identified as SVHC and restricted⁴⁸ under REACH (e.g. DEHP, DBP, BBP, DIBP).

2.3. Impact assessment of restriction options (RO1, RO3, RO4a, RO4b and RO5)

2.3.1. Economic impacts

This section assesses quantitatively the societal costs of the following restriction options: RO1, RO3 and RO4a and RO4b (RO2 and RO5 are qualitatively assessed in Appendix E and section 2.3.1.7, respectively). The different restriction options are described in section 2.1.1, and a summary of the proposed restriction options is provided in Table 11. To determine the societal costs of each RO, economic impacts were quantified separately for the relevant sectors before proceeding with the overall aggregation at RO level. The economic impacts – as described in the following sections – are based mainly on the costs for replacing EC 287-477-0, because this is the substance for which some information on substitution costs were provided by stakeholders that contributed to the calls for evidence or that responded to the ECHA market surveys⁴⁹.

In addition, considering that this substance accounts for most of the tonnage used and the available information on substitution costs was extrapolated to cover the whole tonnage of substances that may contain CA:C14-17 in a concentration above 0.1 %, the Dossier Submitter expects that the below quantified economic impacts provide a good approximation of the societal costs of this restriction.

The conditions of the four ROs examined imply that substances containing CA:C14-17 will no longer be placed on the EU market after 2026 and the most likely response of the producers of PVC compounds and cables (Use#00), sealant & adhesive (Use#01), rubber goods (Use#02), paints and coating (Use#04) will be to shift to the available alternatives during the TP.

As described in section 2.2.2, several possible alternatives – among which EC 264-150-0 – were identified for each sector. EC 264-150-0 was indicated as one of the potential alternatives in some of the above uses, notably in rubber products requiring high flame retardant properties (e.g. conveyor belts for underground activities). However, as also discussed in section 2.2.2, EC 264-150-0 can only be considered a potential alternative if the concentration of CA:C14-17 with PBT and/or vPvB properties is below 0.1 %.

The Dossier Submitter considers it plausible that some sectors may decide to shift to EC 264-150-0 containing CA:C14-17 with PBT and/or vPvB properties below 0.1 % and that in parallel the substance producers may decide to change the supply source and specifications of their feedstock if they currently produce EC 264-150-0 containing CA:C14-17 with PBT and/or vPvB properties above 0.1 %.

For PVC as well as for the rubber and coating sector, the compliance cost model (cf. SEA guidance) was applied because reliable information on the possible price effects on the final goods of the restriction was not available.

Direct estimation of the expected consumer loss was however possible for sealant & adhesive products as some information was available on the baseline volumes sold of the products affected and an approximate price increase – resulting from substitution – could be estimated based on information from the relevant stakeholders (ECHA market

⁴⁷ Substances containing CA:C14-17 are used as secondary plasticiser in soft PVC.

⁴⁸ Annex XVII entry 51

⁴⁹ Stakeholders from the leather sector also provided information on the economic impacts of the restriction in case substitution would be needed for Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'. These impacts are described in Appendix F.

survey, CfE1#1357).

Industry response and economic impacts of the four sectors affected are expected to be very similar under RO1, RO3, RO4a and RO4b. This is because under all ROs the proposed TP of 2 years is deemed to be sufficient for phasing out the use of substances containing CA:C14-17 in the concerned uses.

Regarding the metalworking fluids sector (Use#03), the industry response is expected to differ under RO4a when compared to RO4b or RO1 (and RO3), because a specific derogation is considered under RO4a for the latter sector, while under RO4b a longer TP of 7 years is proposed for this use.

A TP of 2 years is considered not to be sufficient for the metalworking sector to shift to an alternative, meaning that it is possible that - under RO1 and RO3 - the production of metalworking fluids with substances containing CA:C14-17 will cease in the EU because of the restriction. The Dossier Submitter therefore considers that the most likely response of the EU metal forming sector is to halt those operations that are assumed to be dependent on the use of metalworking fluids based on substances containing CA:C14-17 or to relocate the impacted activities outside the EU. The assumption on the most likely response of this sector is based on the information that the Dossier Submitter gathered through a sector specific survey, the findings of which indicate that the average time required by this sector to shift to an alternative is approximately 6 years (as also reported in section 2.2.3).

The Dossier Submitter assumed that 5 % of all metalworking processes would be affected by the restriction, based on information reported by some stakeholders that over the last two decades there has been a move away from chlorinated additives in metalworking fluids in up to 95 % of metalworking operations that used them previously. It was also reported that metalworking fluids containing CA:C14-17 are only used where this is technically necessary for heavy duty applications (ECHA market survey).

The impacts on this sector under RO1 and RO3 were estimated in terms of profit losses along the supply chain for three different categories of actors (producers of extreme pressure additives based on CA:C14-17, producers of metalworking fluids, and companies performing metal processes using metalworking fluids based on substances containing CA:C14-17).

Under RO4a, no impacts are expected for this sector considering the proposed derogation.

Finally, under RO4b, economic impacts for this sector are estimated in terms of compliance costs because this option assumes that, during the TP of 7 years, affected operations will shift – at a certain cost – to a suitable alternative.

Because of data constraints, the impact assessment did not cover the impacts on other potential remaining uses (such as the use in lubricants). However, the Dossier Submitter assessed the impacts on sectors that account for approximately 98 % of substance volumes used. Therefore, any additional impact, which might affect other uses falling under this category, is expected to only marginally alter the cost-effectiveness ratios of the examined restriction options.

Below, the Dossier Submitter presents a use-specific account of the expected impacts.

2.3.1.1. PVC (Use#00)

The use of substances containing CA:C14-17 appears to have been already phased out in most PVC applications (e.g. in PVC tubes, pipes, flooring, etc.). The main remaining use seems to be in PVC compounds used for manufacturing PVC cables (ECHA market survey). For the purpose of this impact assessment, it is therefore assumed that all volumes of substances containing CA:C14-17 are used in the production of PVC compounds for PVC cables.

PVC compounds are a combination of polymers and additives. When formulated using plasticisers, the compounds are called P-PVC (flexible material): "*PVC compounds are*

commonly used in low voltage wire & cable (up to 10 kV), telecommunication lines, automotive wires other electrical wiring".⁵⁰

The main producers of PVC compounds for cables produce also the cables. However, some companies may only produce PVC compounds to supply manufactures of PVC cables (ECHA market survey). Based on interviews with stakeholders from the PVC sector, the Dossier Submitter notes that substitution appears to be economically and technically feasible (ECHA market survey). In case of a restriction, affected companies will shift to the available alternatives. Based on this, the response to the restriction by the PVC industry – shift to the available alternatives – is expected to be same under all ROs assessed.

Different substitution options are available to PVC compound producers (ECHA market survey):

1. removal of substances containing CA:C14-17,
2. replacement of substances containing CA:C14-17 with EC: 264-150-0 (containing <0.1 % CA:C14-17), and
3. replacement of substances containing CA:C14-17 with a combination of alternative plasticisers and flame retardants).

Some stakeholders that already phased out substances containing CA:C14-17 indicated that their production costs did not increase, while others indicated that the costs slightly increased because of the substitution (ECHA market survey).

No significant impacts on the prices of PVC cables were reported by those firms that had completed substitution or expected by those engaged in substitution activities. The Dossier Submitter takes this as indication that no significant impacts on consumers will result from the proposed restriction. Moreover, the Dossier Submitter notes that any assessment of the impact on cable prices would not be meaningful as the price per metre of cable ranges from €0.5 to over €120 depending on the cable quality (ECHA market survey).

The Dossier Submitter estimated the compliance costs for the producers of PVC compounds⁵¹ as a close proxy for the social cost of the proposed restriction. Even though compliance costs are focused on the supply side only, they can reasonably capture the most relevant welfare effects of regulations that have only minor impacts on the behaviour of producers and consumers.

In line with the information provided by relevant stakeholders on the available alternatives, the estimation of compliance costs is based on the following assumptions⁵²:

- 25 % of the tonnage of substances containing CA:C14-17 will be removed from PVC compounds formulations without replacement (expected to occur in PVC compounds for less demanding applications in terms of fire performance),
- 25 % of the tonnage of substances containing CA:C14-17 will be replaced by other alternatives (e.g. combination of flame retardant and plasticisers).
- 50 % of the tonnage of substances containing CA:C14-17 will be replaced by EC 264-150-0 (containing <0.1 % CA:C14-17).

When substances containing CA:C14-17 are simply removed from PVC compound formulations, an increase in production cost in the range of 2-4 % could be expected, because of the need to adapt other components in the formulations (ECHA market survey), while when the substances are replaced by alternatives, an increase in the production costs in the range of 10 % was assumed by the Dossier Submitter.

The total estimated costs include one-off R&D and testing costs of approximately €120 million for all affected companies – up to 400 across the EU – and an annual increase in variable costs of approximately €30 million.

⁵⁰ [PVC compounds for Wires & Cables \(vitahco.com\)](http://vitahco.com)

⁵¹ That can also produce cables or supply producers of cables.

⁵² The Dossier Submitter relied on the information provided by stakeholders to predict the possible industry's reaction. However, the percentages had to be assumed by the Dossier Submitter given data constraints.

It is also assumed that one-off costs to shift to an alternative will occur during the TP, while the increase in the variable costs is expected to start only at the end of the 2-year transition period. In any case, these assumptions do not have a large effect on any cost estimate given the short duration of the TP analysed.

Yet, the Dossier Submitter notes that the overall testing costs might differ among the affected companies. Therefore, as part of the sensitivity analysis, the Dossier Submitter recalculated all cost-effectiveness ratios based on a three-times higher estimate of one-off costs.

All calculations and the main assumptions made are described in Appendix E.

The Dossier Submitter estimated a total compliance cost of €580 million (NPV – 20-year time period) for this sector.

2.3.1.2. Adhesives & Sealants (Use#01)

To assess the impacts for this use, it is assumed that 80 % of the volumes of substances containing CA:C14-17 are used in OCFs and that 20 % of the volumes are used in insulating glass (IG) polysulfide sealants. This assumption aims to reflect the information that the Dossier Submitter collected through the different calls for evidence and the market survey, according to which the OCF appears to be the main sealant product category where substances containing CA:C14-17 are used, followed by polysulfide sealants.

In addition, substances containing CA:C14-17 were identified in some types of tapes and adhesives used in construction, aerospace, and automotive applications (ECHA market survey, CfEs). Impacts on the adhesive and tape sector were not assessed separately, on the basis that volumes of substances containing CA:C14-17 used in these sub-sectors are expected to be minor compared to the volumes used in OCFs and IG sealants.

Also, some of the major companies producing adhesives and tapes for the automotive and aerospace sector indicated that they do not use substances containing CA:C14-17 in their products (ECHA market survey). Finally, by considering that all volumes are used in OCFs and IG sealants (so by overestimating the costs for these two sub-sectors), the assessment can be expected to capture the impacts on possibly remaining sub-uses.

Impacts for the rigid polyurethane sector were also not assessed on the basis that PU Europe indicated that alternatives are available and the restriction is not expected to have any significant impact on the sector. So, for this sector it is assumed that transition to an alternative will be completed before the entrance into force of this restriction.

Approximately 667.7 million cans of OCFs were manufactured globally in 2018 (with EMEA⁵³ accounting for 55 % of the global production⁵⁴). These products play an important role for the energy efficiency of buildings and are thus crucial in the transition towards a low carbon economy.

The concentration of substances containing CA:C14-17 in OCFs is in the range of 10-30 %⁵⁵. Considering that 37 thousand tonnes of substances containing CA:C14-17 are assumed to be used per year in the EU in these types of products, it is estimated that approximately 250 million cans (containing 750 ml of OCF product) are produced per year in the EU, with an estimated market value of approximately €2 billion.

The concentration of substances containing CA:C14-17 in insulating glass sealants is likewise in the range of 10-30 %. Considering that approximately 9 thousand tonnes of substances containing CA:C14-17 are assumed to be used per year in the EU, it is estimated that around 50 million kg of sealants (containing substances containing CA:C14-17) are produced per year in the EU, with an estimated market value of approximately €200 million.

Based on inputs received from stakeholders, the Dossier Submitter notes that the substitution activities are being conducted by the relevant industry to reformulate the

⁵³ Europe, the Middle East and Africa

⁵⁴ <https://www.fapu.de/index.php/en/presentations/epuj-01-02-2015/global-overview-of-the-spray-polyurethane-foam-spf-and-1-component-foam-ocf-markets>

⁵⁵ Additional concentration ranges for different types of sealants are also reported in Appendix E.

sealants that contain substances containing CA:C14-17. It is therefore assumed that the producers of OCFs and insulating glass sealants will continue their R&D efforts until a suitable alternative has been implemented. Therefore, the Dossier Submitter assumes that the sealant industry's response – and thus the economic impacts – are the same under all ROs assessed.

The impact of the restriction for this sector was calculated in terms of consumers surplus loss. A consumer surplus loss occurs in the restriction scenario considering that sealants reformulated with alternatives are expected to be more expensive because of the higher price of alternative plasticisers and because of the need to adapt other raw materials in the sealant formulation.

Based on information of the substitution costs (ECHA market survey and CfE1#1357), the Dossier Submitter estimated that the affected products might experience a price increase between 10-13 % compared to the baseline scenario. (This calculation assumes an average price of €8 per 750 ml-can of OCF and of €4.5 per kg of IG sealants in the baseline scenario.)

The consumer loss was calculated, by considering three possible price elasticities (0, 1 and 0.5). Detailed calculations are reported in Appendix E. For the purpose of this impact assessment, the Dossier Submitter used the central estimate. The total consumer loss was estimated to be €3.2 billion (NPV – 20-year time period).

2.3.1.3. Rubber (Use#02)

The assessment of impacts for this sector is based on the information provided by ETRMA (CfE#1484) and information collected by the Dossier Submitter (ECHA market survey).

While volumes used in each category of rubber products concerned by the restriction are not available, it is the Dossier Submitter's understanding that rubber goods used in underground activities represent one of the main product categories for this use. ETRMA also indicated that "*most of the general rubber goods – GRGs - free of EC 287-477-0 are in the final steps for finalisation and commercial distribution*" (ETRMA, CfE2 # 1484).

The impact assessment for this sector relies on information provided to the Dossier Submitter by companies producing rubber conveyor belts and so assumes that all volumes relevant for this use are used in these types of products. The Dossier Submitter notes that other types of rubber goods (such as tubes) might be affected by the restriction. However, no information was provided by the stakeholders for any other type of rubber good that could be factored in the assessment of economic impacts.

Considering separate categories of rubber articles affected by this restriction would not significantly impact the estimates of substitution costs because similar alternatives are expected to be suitable for other rubber articles requiring high flame retardant properties, and alternatives are expected to be used in similar concentrations as substances containing CA:C14-17.

The Dossier Submitter also notes that some companies producing rubber conveyor belts have already started R&D activities to substitute substances containing CA:C14-17 and consider EC 264-150-0 (with carbon chain lengths C22-30) as the alternative of choice for rubber products requiring high flame retardant properties (ECHA market survey).

In addition to EC 264-150-0, several phosphate-based flame retardants were identified as potential alternatives in rubber conveyor belts by some stakeholders interviewed by the Dossier Submitter (ECHA market survey). For other types of rubber products alternative flame retardants also appear to be available and, as indicated by ETRMA, the industry is in the phase to finalise the substitution activities.

Considering the information provided in the calls for evidence and inputs provided by conveyor belt producers, the Dossier Submitter expects that the latter are likely to shift to EC 264-150-0 (containing <0.1 % of CA:C14-17), whilst acknowledging that other alternatives are also available. The same behavioural response – shift to EC 264-150-0 (containing <0.1 % of CA:C14-17) – is expected by the affected industry under all ROs assessed.

The impacts for this sector were calculated in terms of compliance costs and assuming that the demand for these types of goods is not sensitive to changes in the price. All calculations and additional assumptions are reported in Appendix E.

Considering that substitution is still ongoing, it is also assumed that additional one-off costs to shift to an alternative will occur during the 2-year TP. The increase in variable costs is assumed to start at the end of the TP.

The estimation of one-off costs is based on the following assumptions:

1. The costs for verifying product compliance with the relevant EN standards range between €6 000-30 000 per product (ECHA market survey, CfE2#1474)
2. The number of affected companies producing rubber conveyor belts for underground activities in the EU is between 5 and 10 (ECHA market survey)
3. Each company would have to test approximately 5 to 10 products (ECHA market survey).⁵⁶

The Dossier Submitter notes that the number of products as well as the overall costs might differ among the affected companies. Therefore, the Dossier Submitter recalculated as part of its sensitivity analysis all the costs-effectiveness ratios, after multiplying the estimated one-off costs by a factor of 3.

In addition to one-off costs during the TP, a permanent increase in production costs is expected due to the higher price of alternatives. These incremental annual costs assume that substances containing CA:C14-17 are replaced by LCCP (264-150-0) with a concentration of PBT/vPvB congeners below 0.1 %. While the price of 264-150-0 is reported to be approximately 1.25-1.5 times the price of EC 287-477-0 (currently used by the interviewed companies), a price difference of 100 % (i.e. two times higher price) is assumed to account for potential additional costs that may result because of the need to adapt other components in the rubber mixture.

Further, it is assumed that the same quantity of rubber articles will be produced and that producers of rubber products will be able to pass on most of the substitution costs to their customers. When assessing the price elasticity for this product category, the Dossier Submitter evaluated the market features of this sector and noticed that companies producing rubber conveyor belts are usually located near mining sites because the transport of these rubber goods is very costly and logistically complex. Considering this, it is reasonable to assume that in the specific geographical areas where the mining sites and the producers of rubber conveyor belts are located, the demand for conveyor belts is not price sensitive and that producers of rubber conveyor belts would be able to pass on most of the compliance costs to companies engaged in mining activities.

The total cost for this sector in terms of one-off costs and variable costs – was estimated to be €54 million (NPV – 20-year period).

2.3.1.4. Metalworking fluids (Use#03)

As indicated in section 2.3.1, the impacts on the metalworking fluids sector are expected to differ under the considered restriction options.

Under RO1 (and RO3), the additives suppliers, producers of metalworking fluids, and the metalworking sector (relying on these metalworking fluids) are expected to incur profit losses. This response is expected on the basis that the 2-year TP is deemed too short for the sector to identify, test and shift to suitable alternatives.

The additives suppliers are expected to incur profit losses due to the impossibility to continue to supply substances containing CA:C14-17 to the metalworking fluids producers (€300 000 per year), metalworking fluids producers will incur profit losses for having to halt the production (and thus the sales) of metalworking fluids with substances

⁵⁶ Regarding the testing, the Dossier Submitter understands that the companies would not have to test all products, but only a share. For example, the rubber conveyor belts the companies produce can be grouped according to their thickness in 3 (or more groups). They would have to test few products from each category.

containing CA:C14-17 (€5 million per year) and the metalworking sector will incur profit losses from not being able to supply metal parts, the forming and/or the cutting of which requires the use of metalworking fluids with substances containing CA:C14-17 (€250 million per year). The metalworking operations affected by the restriction are therefore expected to cease in the EU and some companies may decide to relocate these activities outside the EU.

In line with the SEAC paper on producer surplus⁵⁷, profit losses were considered over 4 years and the total profit loss – annualised over 20 years – was estimated at €70 million per year. The Dossier Submitter applied a default period of 4 years of profit loss because the availability of alternatives in this sector resembles to a no-SAGA (suitable alternative available in general) case.

The total cost of RO1 (and RO3) in terms of profit losses for this sector were estimated to be €1 billion (NPV – 20-year period).

Under RO4a the metalworking fluids sector is not expected to be impacted, so the RO4a is equivalent to the baseline scenario for this sector.

Under RO4b, the metalworking fluid sector is expected to shift to a non-chlorinated paraffin-based alternative during the 7-year TP. The one-off costs (reformulation and testing) were estimated to be €90 million for the producers of metalworking fluids and the increase in annual operating costs was pegged at €12 million (expected to start after the 7-year transition period). In the calculation of the incremental variable costs, the Dossier Submitter applied three different methods to verify the consistency across the different pieces of information and the data collected from stakeholders that participated in the calls for evidence and ECHA market survey. In all three cases, the quantified annual costs were in the range of €12 million per year. Detailed calculations are reported in Appendix E.

The total compliance costs under RO4b (one-off costs and incremental variable costs) were estimated to be approximately €200 million (NPV – 20-year time period).

2.3.1.5. Paints and coatings (Use#04)

Substances containing CA:C14-17 are used in fire retardant paints and solvent-based intumescent coatings and some types of marine and protective industrial coatings (e.g. chlorinated rubber coatings).

Based on inputs provided by different stakeholders, the Dossier Submitter notes that companies from the intumescent and flame retardant paint coating sector are using EC 264-150-0 (with carbon lengths in the range of C22-C30). British Coating Federation (BCF) also indicated that they are unaware of any company using EC 287-477-0 in solvent borne intumescent coating products. The same was confirmed by several companies that were interviewed by the Dossier Submitter (ECHA market survey). Because the concentration of CA:C14-17 is expected to be already below 0.1 % in EC 264-150-0 (with carbon chain lengths within the range from C22 to C30), the companies in this sector are not expected to be impacted by restriction. Also, it is assumed that in case some companies are currently using EC 264-150-0 with concentrations of CA:C14-17 above 0.1 %, they can shift without major costs to EC 264-150-0 containing CA:C14-17 in a concentration below 0.1 %.

Based on this information, it is assumed that under all ROs companies operating in the flame retardant paint and intumescent coating sector will continue to use EC 264-150-0 containing CA:C14-17 in a concentration below 0.1 %. Therefore, no impacts are expected for this sector.

Regarding marine and protective coating sector, many companies appear to have already phased out the use of substances containing CA:C14-17. One of the major producers of protective and marine coatings indicated that alternative plasticisers (non-chlorinated paraffin-based) are available on the market for these applications (ECHA market survey). The Dossier Submitter therefore assumes that substitution in this sector will be completed during the 2-year TP, meaning that the same behavioural response is

expected under all ROs assessed.

Also, one of the major global producers of paints and coatings – that already replaced EC 287-477-0 in marine coating formulations – indicated that typically a company might require up to two years to reformulate the products (ECHA market survey).

According to the information provided by stakeholders, the main impacts relate to testing costs (internal and external testing that will be carried out in the restriction scenario to verify the compliance of products with the relevant product requirements and EN standards). A possible increase in variable costs because of substitution was not indicated as a relevant factor by the companies operating in this sector.

The total cost of the restriction on this sector was estimated at €10 million (NPV – 20-year period). The estimate considers that potentially 50 companies in the EU may be affected by the restriction, and that each of them would have to incur testing costs of around €200 000. Additional information is available in Appendix E.

The Dossier Submitter notes that the overall costs might differ among the affected companies. Therefore, as part of its sensitivity analysis, the Dossier Submitter recalculated all the costs-effectiveness ratios of the four restriction options after multiplying by a factor of 3 all the estimated one-off costs.

Considering the value added of the coating of articles (containers/boats/steel constructions) and that marine and protective coatings are highly technical and differentiated products, it may be assumed that demand is not very sensitive to price increases and that the coating producers will be able to pass on most of the substitution costs (through price increases of paints/coatings), while maintaining their sales volumes.

2.3.1.6. Leather (Use#05)

As indicated in 2.2.2.6, none of the restriction options is expected to affect the leather sector and it is assumed that companies operating in this sector will keep using the two substances ('Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified') with concentration of CA:C14-17 with PBT and/or vPVB properties below 0.1 % in the production of fatliquors.

It is also assumed that in case companies are currently using the two substances but in concentrations of CA:C14-17 with PBT and/or vPVB properties >0.1 %, they will shift to substances with concentrations of CA:C14-17 with PBT and/or vPVB properties below 0.1 %, before the entrance into force of this restriction.

To address this potential uncertainty, the Dossier Submitter assessed, as part of its sensitivity analysis, the economic impacts for this sector under two possible scenarios:

1. The sector is in the scope of the restriction. In line with information collected from stakeholders (ECHA market survey), this scenario assumes that a 2-year TP might not be sufficient for the industry to reformulate all the affected products.
2. The sector is in the scope of the restriction, and a longer TP of 5 years (to test and shift to an alternative) is proposed for this sector. This would give sufficient time to companies for reformulating products currently containing 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' or 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'.

It is important to note that both scenarios implicitly assume that the concentration of CA:C14-17 with PBT and/or vPvB properties in the two substances cannot be reduced below 0.1 % so that companies would have to search for alternatives.

The Dossier Submitter considered it appropriate to test these alternative two scenarios as part of its sensitivity analysis because, based on available information, it cannot be concluded with certainty whether the sector is in the scope of the restriction. In other words, it cannot be concluded with certainty that the concentration of CA:C14-17 with PBT and/or vPvB properties cannot be reduced below 0.1 % in the two substances.

2.3.1.7. Total economic impacts of RO1, RO3 and RO4a, RO4b and RO5

The overall economic impacts for each of the ROs are reported in Table 12. The expected impacts under RO1 and RO3 are almost the same; the only difference between the two is that under RO3, there would be also profit losses (in the range of €300 000 per year⁵⁸) due to the impossibility of the substance producers to keep manufacturing for export. Under RO4a, which includes a permanent derogation for the metalworking fluid sector, all the profit losses that this sector could experience under RO1 and RO3 would be avoided. In practice, RO4a would be equivalent to the baseline scenario for this sector. The impacts of RO4b are equal to the impacts expected under RO4a plus some substitution costs for the metalworking fluid sector, which is expected to shift to an alternative over a 7-year TP.

There are no additional costs for industry associated to the complementary measures (RO5) as the requirements set in RO5 are already existing under REACH, and there is no prescriptive format proposed by the Dossier Submitter regarding the obligations to inform the supply chain.

In addition to the above cost estimates, annual enforcement costs of €110 000 per year are included for the duration of the analytical period of 20 years. The Dossier Submitter considered it appropriate to double the default enforcement costs of €55 000 to reflect the fact that the analysis to identify the presence of the above congeners are expected to be more expensive compared to standard testing costs.

Table 12. Total economic impacts of the restriction options (NPV and annualised values)

Restriction option (RO)	Total costs, NPV – 20-year analytical period) €	Annualised costs Cover 20 years
RO1	€4.9 billion	€330 million
RO3	€4.9 billion ⁵⁹	€330.3 million
RO4a	€3.9 billion	€260 million
RO4b	€4.1 billion	€270 million

With regard to affordability considerations, it is not possible to conclude with certainty to which extent the above restriction options can be considered affordable for each of the affected actors.

The substances containing CA:C14-17 are used across different sectors and within each sector there might be both large companies as well as small and medium enterprises. It is often reasonable to expect that restrictions are more affordable for larger companies that have larger financial capacities than they are for small and medium enterprises.

However, none of the interviewed stakeholders indicated that the proposed restriction would not be affordable, even though they all indicated that substitution would involve some testing costs, alternatives are more expensive compared to substances containing CA:C14-17, and they would require some time after the entrance into force of the restriction to shift to the available alternatives (ECHA market survey). Therefore, the affordability for EU actors depends on the length of the TP. Based on the inputs collected

⁵⁸ Annualised value, estimated on the basis that approximately 5 % of the volume of manufactured substances containing CA:C14-17 is exported outside the EU, the price of substances containing CA:14-17 is approximately 1.06€/kg and that the profit margin of the sector is 12 %. 12 % is the average gross operating rate (2016-2020) of the economic activity: "Manufacture of other chemical products n.e.c. [C2059]". Data were extracted on 21/04/2022 13:30:35 from Eurostat Database.

⁵⁹ Rounded value. The difference between the two options (RO1 and RO3) is approximately €300 000 (annualised value, as reported in 3rd column), equivalent to approximately 4 million over the 20-year period.

from relevant stakeholders (ECHA market survey and CfEs), a 2-year TP is expected to be sufficient for all but the metalworking fluid sector to transition to suitable alternatives. Regarding the impacts on consumers (see also section 2.3.1.2), consumer surplus losses are expected under all ROs considered because the reformulation costs are expected to impact the price of OCFs and insulating glass sealants. Consumer losses assumed in the calculation of the cost-effectiveness ratios were derived assuming a price elasticity of 0.5⁶⁰, meaning that volumes sold would be lower when compared to the baseline scenario. This also means that for some consumers the price increase - expected to be in the range of 11 %-13 % - would be considered unaffordable and so a 6 %-7 % drop in the sales could be expected as a result of the restriction⁶¹.

2.3.2. Human health and environmental impacts (effectiveness)

PBT/vPvB substances give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse even when releases cease. Currently, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way, e.g. by derivation of risk characterisation ratios. Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore a proxy for risk.

In addition to their release reduction potential, the effectiveness of each RO may be appreciated by looking at the risk reduction potential of the alternatives to substances containing CA:C14-17.

2.3.2.1. Release reduction potential

For each of the ROs assessed in quantitative terms (RO1, RO3, RO4a and RO4b), the Dossier Submitter calculated the total avoided emissions of CA:C14-17 in the environment over 20 years in comparison with the baseline.

Table 13 summarises the estimates of the avoided emissions for each RO.

The Net Present Values (last column in the table) were calculated by discounting the avoided releases (central estimate, as reported in the fourth column) by applying a discount rate of 3 % over 20 years. The Net Present Value of releases is only used for calculating the cost effectiveness of each RO.

Similarly to the total costs estimates, the benefits of the ROs – in terms of avoided releases – were indeed discounted to calculate the cost-effectiveness ratios of the different ROs reported in section 2.4. The avoided releases were discounted considering that it is more desirable to reduce the emissions as early as possible. Also, if emissions are not discounted but costs are, future emission reductions are considered as valuable as emission reductions today, while future costs are less valuable than costs today. The Dossier Submitter also notes that the only impact of not discounting the avoided releases would be to reduce the cost-effectiveness ratios, meaning that this alternative approach would not have any implications on the overall conclusions on the examined restriction options in terms of proportionality (cf. also section 3).

Significant emission reductions (ca. 90 %) are envisaged from each ROs. However, emissions will not be completely prevented as the use and disposal of articles containing CA:C14-17 with PBT and/or vPvB will continue when they are disposed of, and releases from substances, mixtures and articles containing CA:C14-17 with PBT and/or vPvB in concentrations below the limit of 0.1 % w/w will continue after the restriction enters into force, and after the transition periods have elapsed.

⁶⁰ The Dossier Submitter also tested how the consumer surplus might change when applying a demand price elasticity of -1 and when assuming a rigid demand, with demand price elasticity of 0. The consumer surplus loss was estimated under these two additional scenarios, considering that the Dossier Submitter could not identify any specific study on the price elasticity for these types of products. Additional details are reported in Appendix E.

⁶¹ The Dossier Submitter also calculated consumer loss, assuming a price elasticity of 0 as well as a price elasticity of 1, to assess how changes in this parameter might impact the quantification of economic impacts for this sector.

Table 13. CA:C14-17 release reduction associated to RO1, RO3, RO4a and RO4b over the 20-year period used for the impact assessment

	Remaining CA:C14-17 releases to the environment (lower and upper estimate) ^[1]	CA:C14-17 releases reduction compared to the baseline (lower and upper estimate) ^[2]	CA:C14-17 releases reduction compared to the baseline (central estimate) ^[3]	Net present value (NPV, 3 %) of avoided releases (central estimate) ^[4]
Baseline (i.e. no EU action)	104 000- 126 000 tonnes	-	-	-
RO1 (i.e. ban on placing on the market)	11 000 - 13 000 tonnes	94 000 -113 000 tonnes i.e. 90 % reduction compared to the baseline	103 000	74 500 tonnes
RO3 (i.e. ban on manufacturing and on placing on the market)	10 000 - 13 000 tonnes	94 000 -113 000 tonnes i.e. 90 % reduction compared to the baseline	103 000	74 500 tonnes
RO4a (i.e. RO1 with a derogation for the metalworking fluid uses)	11 000 - 17 000 tonnes	93 000 -108 000 tonnes i.e. 89 – 86 % reduction compared to the baseline	101 000	73 000 tonnes
RO4b (i.e. RO1 with a longer transition period for the metalworking fluid uses)	11 000 - 14 000 tonnes	94 000 – 112 000 tonnes i.e. 90 – 89 % reduction compared to the baseline	102 700	73 900 tonnes

Note: [1] values rounded to the nearest thousand
 [2] values rounded to the nearest thousand
 [3] for RO1, RO3 and RO4a, values are rounded to the nearest thousand and for RO4b value has been rounded to the nearest hundredth
 [4] net present value of avoided releases is used only to calculate the cost effectiveness ratios of the different ROs

With regard to RO5, it is not possible to quantify the effect of the proposed measures and their release reduction potential. If considered on their own, the measures proposed under RO5 would probably have a limited impact on the risk reduction potential of the proposed restriction. Nevertheless, considered as complementary measures, RO5 could support the proposed restriction as it could also be considered as a complementary effective tool for risk management by influencing consumer, professional, and industrial behaviour. In addition to drawing attention, the proposed measures must improve knowledge by making the users of the substances aware of the hazard, consequences and how to avoid the risks associated with PBT and vPvB substances. This could be achieved by updating the relevant registration dossiers (to indicate the PBT or vPvB status) and by communicating in the supply chain the presence of CA:C14-17 with PBT and/or vPvB properties using brief explicit messages (LAUGHERY and WOGALTER, 2014). RO5 is also instrumental when it comes to the enforcement of the restriction proposal (cf. sections 2.1.1.5 and 2.3.4.2).

2.3.2.2. Risk reduction potential from alternatives

Detailed information on human health and environmental hazards of all the technically and available alternatives is presented in Appendix E and summarised in section 2.2.2.8. Multiple alternatives (~70) to substances containing CA:C14-17 were identified and in general their hazard and risk profile – from both a human health and an environmental

perspective – is better. There is indeed no potential human health or environmental hazard identified for most of the alternatives listed in Appendix E. However, it is important to note that some of the alternatives are currently suspected to be carcinogenic, with ED, PBT/vPvB properties, or might become subject to regulatory actions under REACH in the future. If industry would decide to replace substances containing CA:C14-17 by one of these substances, and if the hazard of these substances would be confirmed, then the risk reduction capacity of the proposed restriction would therefore be a bit lower than the net risk reduction capacity of the proposed restriction if industry would select a technically feasible and available alternative with no identified hazard or concerns. Currently, it is not possible to pre-empt the hazard conclusions for these alternative substances as assessments, and evaluation are currently on-going. Finally it is important to note that the Dossier Submitter proposal to restrict the presence of CA:C14-17 constituents (congeners) having PBT and/or vPvB properties, rather than a list of substances will avoid regrettable substitution and prevent future release of CA:C14-17 with PBT and/or vPvB properties.

2.3.3. Other impacts

With regard to social and wider economic impacts, and considering that the phasing out of substances containing CA:C14-17 appears to be technically and economically feasible, the Dossier Submitter foresees no major effects on employment. This said, some job losses could occur among the producers of substances containing CA:C14-17, considering that, because of the restriction, the output produced would be lower and so some employees could be made redundant. For example, one company producing substances containing CA:C14-17 indicated that they would have to lay off between 5 and 20 employees (CfE1#1487).

However, considering that technically and economically feasible alternatives are available, it is likely that the producers of alternatives might need to hire new employees to meet the growing demand and increase their production capacity.

The Italian Federation of the chemical industry indicated that due to the restriction, 100 jobs could possibly be lost in Italy along the entire supply chain (CfE1#1358). The association also pointed out that in Italy the PVC sector consisting of 50 producers of flexible PVC would be affected the most, with an increase in production costs in the order of tens of millions of euros. As indicated in section 2.2.2.1, the Dossier Submitter estimated that the cost of the restriction is expected to exceed €500 million for the whole EU PVC sector (NPV over 20 years). However, none of the companies that already phased out substances containing CA:C14-17 or are in the phase of testing alternatives indicated in the interviews that jobs were or are expected to be lost as a result of the restriction (ECHA market survey).

Regarding the rubber sector, the industry did not indicate that the proposed restriction would lead to job loss in this sector but that a TP of two years (until 2026) would be important for allowing a smooth transition to available alternatives.

No job losses are expected in the paint sector either. The Dossier Submitter contacted the European Brussels association for paint (CEPE) to ask for inputs to the second call for evidence. However, the organisation decided not to provide inputs but encouraged the national members to do so. No submissions were received to the call for evidence by any of the national paint associations.

The Dossier Submitter therefore also contacted the Dutch Association for paint (VVF), which indicated that EC 287-477-0 is not used anymore by their members representing 90 % of the paint industry in the Netherlands. The Italian Association for Paint (Assovernici), which was directly contacted by the Dossier Submitter, indicated that substances containing CA:C14-17 are still used by some Italian paint companies (ECHA

market survey). However, as indicated by the association, economic considerations linked to substitution play a minor role because these substances are used in small concentration in the paint/coating formulations. Considering also that no major economic impacts are expected on this sector, the Dossier Submitter concludes that no job losses are expected among the companies that will have to phase out the substances containing CA:C14-17 from their paint/coating formulations⁶².

One sector where job losses may be expected is the metalworking fluid sector under RO1 (and RO3), considering that the economic activities relying on the use of substances containing CA:C14-17 might have to be halted as a result of the restriction.

As indicated in section 2.3.1.4, the production of metalworking fluids relying on substances containing CA:C14-17 as well as the heavy-duty metal forming operations that employ these specific types of metalworking fluids may have to cease in the EU. Based on information collected from relevant stakeholders a TP of two years is not expected to be sufficient for companies to identify, test and shift to an alternative (ECHA, market survey).

The Dossier Submitter notes that, in the EU, 92 % of companies in the metalworking sector have less than 50 employees⁶³. Considering also companies with up to 249 employees, this share increases to 99 %. Therefore, potential job losses under RO1 (and RO3) would be mainly incurred by small and medium companies in the metalworking sector.

2.3.4. Practicability, enforceability and monitorability

2.3.4.1. Practicality (implementable and manageable)

The restriction options RO1, RO3, RO4a and RO4b are all considered implementable and manageable for the different actors in the supply chain: manufacturers, importers, downstream users, recyclers and waste operators.

By knowing and identifying the carbon-chain lengths of the feedstock used to manufacture chloroalkanes, REACH registrants and manufacturer/importers of chloroalkanes (whatever the tonnage) can identify the substances and compositions that would fall in the scope of the restriction proposal and modify the specifications of the feedstock accordingly. This approach already exists in practice and is consistent with the recommendations from the ECHA guidance on the identification of UVCB substances (ECHA, 2017).

As far as the downstream users are concerned, alternatives to substances containing CA:C14-17 are available, technically and economically feasible (cf. section 2.2.2). The Dossier Submitter notes however that at this stage, it is not certain whether the available alternatives are technically able to replace the substances containing CA:C14-17 for some heavy-duty metalworking operations.

There is no general drop-in one-for-one replacements for substances containing CA:C14-17 in all identified uses, but multiple potential alternatives were identified for each use and technical function. The alternatives appeared to be more costly than substances containing CA:C14-17, but still affordable. In terms of hazards and risks associated with alternatives, the analysis of alternatives looked at both human health and environmental hazard and risks (cf. section 2.2.2.8). The identified alternatives varied in regard to their relative environmental and human health risks: for some there are indeed concerns about ED, PBT/vPvB properties. Nevertheless overall alternatives appeared less

⁶² According to the association it is not clear whether alternatives – other than 264-150-0 – are available. Information on alternatives provided by other stakeholders is reported in 2.2.2.5

⁶³ Eurostat database, Industry by employment size class (NACE Rev. 2, B-E) [SBS_SC_IND_R2__custom_2700812]. NACE code: C255. Data extracted on 12/05/2022.

hazardous and risky than substances containing CA:C14-17. In addition, the reformulation, substitution, and transition to alternatives are feasible if sufficient transition time is given to Industry.

For most of the uses, there are already alternatives available on the market that are free from CA:C14-17 (ECHA Market Survey and BfR (2022)).

The provisions from RO5 are also considered practical considering that (i) the suppliers of substances including the Registrants should already have available information and analytical techniques in place to identify the composition of the substances they are placing on the market⁶⁴, and that (ii) the Dossier Submitter does not impose a format to make available the information to the authorities. For example, Registrants could update their registration dossier once new information becomes available: this is already a Registrant's duty according to REACH Article 22. For the other substance suppliers (e.g. the one placing the substances in quantity below one tonne per year) with no registration duty, the information and analytical techniques in place to identify the composition of the substances could be shared with the enforcement authorities upon request.

Secondly, with regard to the obligations to inform the supply chain, the Dossier Submitter does not impose nor prescribe any specific format to transfer the PBT and/or vPvB information down the supply chain. It is indeed left to the company placing on the market the substances, mixtures or articles to decide what is the most practical way for them to inform their customers about the presence and concentration of CA:C14-17 with PBT and vPvB properties (e.g. via a safety data sheet, label, product technical sheet, etc.).

RO5 implementation, and in particular the suppliers' obligations, and supply chain communication obligations could be facilitated and substantiated by the voluntary implementation of certification schemes in the affected sectors of use (voluntary action from the relevant sectors). Certification schemes already exist in various domains to communicate information in the supply chain for example 'recycled plastics traceability certification', 'EUCertPlast', but also 'EcoCert', 'Ecolabel', to name a few, but also measures and private initiatives set in the frame of the New Legislative Framework (NLF)⁶⁵ which aim at improving market surveillance and boost the quality of conformity assessments. For example, the NLF framework establishes close cooperation between public authorities and market operators: an important role exists for the bodies, which can be private entities, responsible for the assessment of conformity with the requirements of an EU regulation.

With regard to the recycling and waste life-cycle stages, the proposed restriction is also considered practical. Indeed 'on-line' analysis already exists to detect the presence of chlorine and therefore the presence of chloroalkanes in different types of waste streams. So these waste streams can be separated and sent for specific treatment. For example on-line ED-XRF (X-ray fluorescence or X-ray fluorimeter analysis), and hand-held XRF already exist and are capable of separating chlorine-containing plastics from other types of plastics/polymers. Hand-held X-ray fluorescence can be used for the measurement of total chlorine with a limit of quantification (LOQ) of 30 mg Cl / kg according to the DIN standard EN 16424⁶⁶ on characterisation of waste. Even if difficult to know without detailed analysis⁶⁷ of the waste composition, should substances containing CA:C14-17 be

⁶⁴ REACH Annex VI requirement for Registrants, and general responsibility of suppliers to know about any hazard properties of the substances, mixture or articles components they are placing on the market.

⁶⁵ https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

⁶⁶ EN 16424 Characterization of waste — Screening methods for the element composition by portable X-ray fluorescence instruments (hand-held or portable bench top XRF spectrometers). The software must be adapted for interactions from specific matrix. Reference materials are available among other for Br, Cl and Sb (concentration of 1 000 mg/kg).

⁶⁷ XRF is not sufficient to measure CA:C14-17 content and laboratory confirmation using advanced methods would be required to attribute the chlorine content to CA:C14-17. A first screening using XRF would thus need to be complemented with a sample being taken and sent for advanced

the only source of chlorine in the relevant waste (which would be difficult to know), this LOQ would be sufficient to detect and separate the restricted substances from the recycle stream. Of course, as the chlorine content in the relevant waste detected with XRF cannot be automatically attributed to substances containing CA:C14-17, this would lead to an over rejection of material from the potential recycling. This is already the case for the detection of 'SCCP' in recycling facilities according to EU Commission (2021b). It should be noted that XRF online analysis are commonly applied as a screening step in recycling facilities to detect and separate chlorine containing substances (EU Commission, 2021b). In addition, several standards already exist and are also relevant for the waste sorting and recycling of WEEE, and ELV PVC for examples such as CENELEC EN/TS 50625, IEC 62321-3-1:2013. Finally the ED-XRF analysis and standards are already applied in the waste treatment of other chloroalkanes such as SCCP which are very similar in term of structure (and in used applications) to substances containing CA:C14-17.

2.3.4.2. Enforceability

RO1, RO3, RO4a, RO4b, and RO5 are enforceable, and the scope of the proposed restriction options are clear and unambiguous.

The Dossier Submitter notes nevertheless that the definition of the derogation for metalworking fluid (encompassed in RO4a and RO4b) would deserve further clarifications and description given that metalworking may include a broad range of metals and metalworking techniques.

The enforcement of the ban on placing on the market of substances, mixtures and articles containing CA:C14-17 with PBT and/or vPvB properties (RO1, RO3, RO4a and RO4b) could be foreseen using one of the following methods:

- Manufacturer/Producer/Downstream User industrial site inspections
- Spot checks of imports (e.g. by the customs)
- Retailers site inspections
- Retailers/social media website inspections

The enforcement could be performed either with:

- Laboratory testing to check the absence/presence of the restricted congener groups, or with
- Paper or document-based inspection: i.e. verification of paper records such as registration dossier, inventory records (purchased goods, sold goods, source of supply, material composition, SDS content, technical documentation etc.).

Laboratory testing

With regard to the laboratory testing, the Dossier Submitter acknowledges that developments of methods for the analysis of chloroalkanes encountered in the past a number of challenges.

However, based (i) on recent literature review, (ii) on the comments received during the first call for evidence launched in the context of the SVHC identification process, and based (iii) on discussions held with EU laboratory experts, it appears evident that advanced techniques enabling a sufficient selectivity in the identification and quantification of groups of congeners having the same carbon chain length and chlorination level (i.e. CA:C14-17) are emerging, and are nowadays available to detect and quantify CA:C14-17. These techniques often combine enhanced chromatographic separation (as two-dimensional GC (GC×GC)) and high mass resolution (as time-of-flight mass spectrometry), minimising interferences between chloroalkane congeners and other organo-halogen compounds (cf Appendix B).

It should also be recognised that the most recent scientific research has increased the understanding of analytical processes and obtained results, providing the opportunity to

analysis in a laboratory – if one would need to quantify the presence of CA:C14-17. Such a quantification is not needed to eliminate substances from the recycling streams.

better control the accuracy of the determination despite the presence of different degree of chlorination and of interferences, in particularly for environmental samples.

For example, following the results of the inter-laboratory comparison by van Mourik et al. (2018) essentially focusing on short chain chloroalkanes, the same research group cooperates since 2019 in the project 'Development of reference standards for the analysis of chlorinated paraffins (CPs)'⁶⁸ funded from the Eurostar-2 joint programme aiming at filling the gap of suitable standards for the analysis of chloroalkanes and substances containing chloroalkanes. At present reference standards for the analysis of chloroalkanes exists or are under development for all CA:C14-17 intended to be restricted (cf. Appendix B).

Robust and validated analytical procedures can currently be further investigated by the production of a wider number of analytical standards intended for quantification of various congeners according to carbon chain length and chlorine content, and of better quality (well-characterised and with purity fully assessed) as well as the development of certified materials.

As described in Appendix B, the increased number of available standards for different group of congeners (ranging from short to long chain of carbons) and of certified reference materials, is of the utmost relevance for an accurate quantification of CA:C14-17 also to reduce the uncertainty with the identification and quantification of congeners with a limited number of chlorine atoms. The use and availability of such standards is beneficial when using both low resolution methods and high resolution methods. The Dossier Submitter is also describing in Appendix B a laboratory testing strategy that could be used by the enforcement authorities to enforce the proposed restrictions RO1, RO3, RO4a and RO4b.

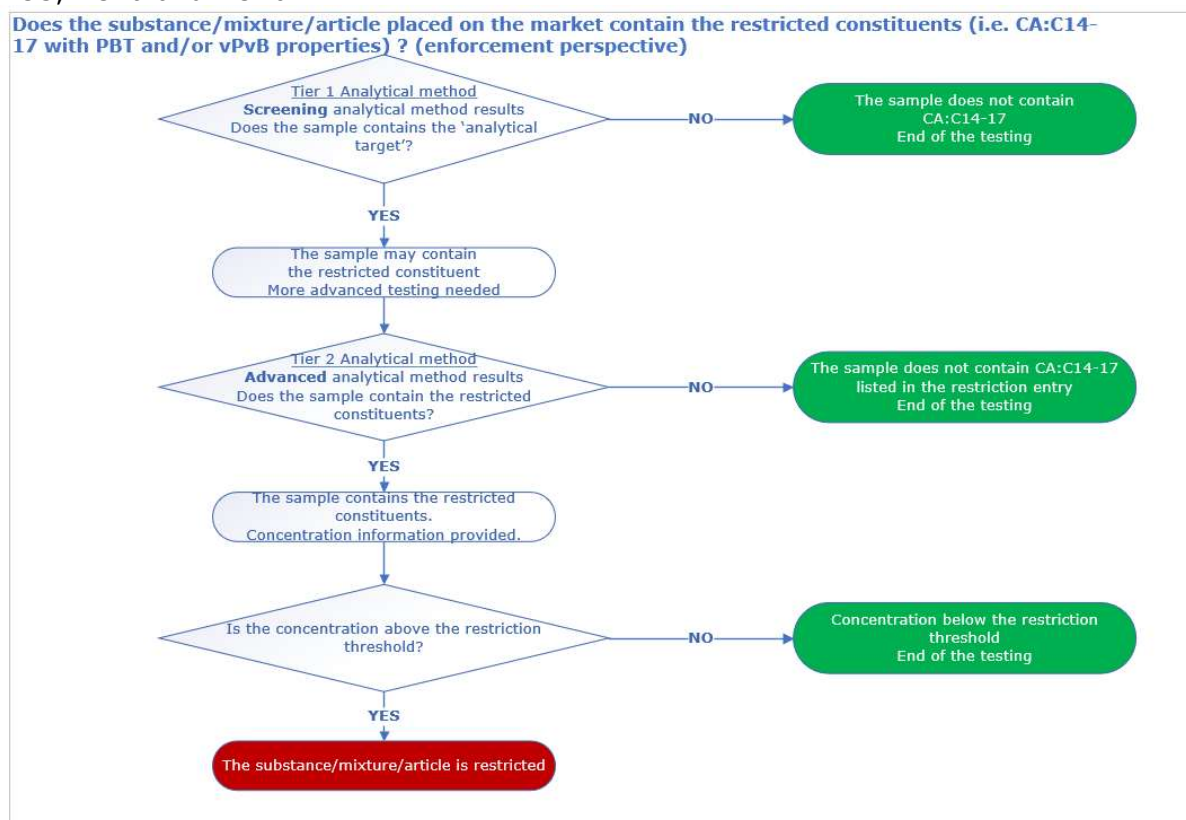


Figure 1. Proposed tiered approach for enforcement

The proposed tiered approach is based on the following key principles that are further detailed in Appendix B:

⁶⁸ <https://www.era-learn.eu/network-information/networks/eurostars-2/eurostars-cut2013off-11/development-of-reference-standards-for-the-analysis-of-chlorinated-paraffins-cps>

- Screening methods could be used to confirm the absence of chloroalkanes (and therefore the possible presence of CA:C14-17 with PBT and/or vPvB properties)
- High resolution analytical methods are suitable to confirm the presence of CA:C14-17 of concern and to quantify the individual carbon-chlorine congeners
- The proposed limit value of 0.1 % exceeds by far the limit for detection of the identified analytical methods which makes the proposed concentration limit practical, and enforceable as well
- Recent availability of new analytical standards, allowing an appropriate identification and quantification of congeners
- Publication of International Standards for analytical procedures by ISO⁶⁹ (applicable to both screening and advanced analytical methods)
- Publication of analytical procedures described and peer-reviewed in scientific literature (applicable to both screening and advanced analytical methods).

The practicality of the proposed tiered approach is also supported by the results from the survey toward the EU enforcement laboratories conducted by the Dossier Submitter in March and April 2022 (cf. Appendix B). Out of the 18 respondents from ten different EU countries, about half of the laboratories have already experience in sampling and analysing the presence of chloroalkanes (essentially short chain ones). All the laboratories responding to the survey indicate that they have screening analytical methods in place (cf. Appendix B for the list of proposed screening methods), and ~ 55 % have also advanced detection methods and instruments available (cf. Appendix B for the list of advanced methods). In addition, some respondents indicate in the survey that they can sub-contract to private laboratories analysis in case of lack of capacity or technology in their own laboratories.

Finally, it should also be noted that standardised laboratory methods for measuring other types of chlorinated alkanes, such as short chain chloroalkanes (e.g. 287-476-5), have been developed in response to the POP restriction on short chain chlorinated paraffins. For example, validated ISO methods (ISO 22818:2021, ISO 18219-2:2021, ISO 18219-1:2021) have been developed and are focused on the quantification of short- and medium-chain chloroalkanes.

Even though different, because requiring different analytical standards, the enforcement of the legal duties associated to short chain chloroalkanes (e.g. 287-476-5) could be achieved in the past. Between October 2017 and December 2018, 15 EU member states carried out indeed a pilot enforcement project. The project⁷⁰ investigated the presence of substances of very high concern (SVHC) in articles placed in the European market. Of 682 inspected products, 12 contained SCCPs above 0.1 % (w/w). At that time, the pilot project was a test for the compliance with Article 7(2) of REACH (obligation to notify ECHA of the presence of SVHC in articles) and Article 33 of REACH (obligation to provide information on the presence of the SVHC in articles down the supply chain).

Nevertheless the pilot projects proved that EU enforcement authorities had the analytical methods and instrument to detect the presence of short chain chloroalkanes in articles.

Paper inspection

Paper or document-based inspection could be performed independently or in complement to a laboratory testing inspection. This could include verification and cross-checking of various documents such as registration dossier, information requested to be made available under RO5, inventory records (purchased goods, sold goods, source of supply, material composition), but also SDS, label, or technical documentation contents, etc.

Document-based inspection could be performed at manufacturing sites, importer and only-representatives offices, but also at downstream and suppliers' sites (office, workshop or website).

During previous consultations on other restriction proposal (e.g. restriction proposal on microplastics), Forum has indicated that document-based enforcement can only build

⁶⁹ The International Organization for Standardization

⁷⁰ Cf. https://echa.europa.eu/documents/10162/13577/sia_pilot_project_report_en.pdf/f9fc153b-a322-43be-1ba1-44f4e5cb02c8

upon obligatory documentation.

In the proposed restrictions, during and after the transition period, document-based inspection is enabled and facilitated thanks to the obligations set in RO5. Indeed suppliers of chloroalkane substances, including registrants of substances potentially containing CA:C14-17 are obliged to conclude on and indicate the PBT and vPvB status of the compositions they place on the market, or make available or provide information and justification in case the composition contains less than 0.1 % of CA:C14-17 with PBT and/or vPvB properties. So inspectors can verify the consistency and compliance between the composition and the PBT/vPvB properties reported by the suppliers, and the information available in the supply chain.

The document-based inspection will also be facilitated by the provision of a list of substances that may contain CA:C14-C17 either as a separate list (e.g. published on ECHA website) or as an Appendix to the Annex XVII restriction entry (cf. section 2.5). The provision of this list would help the enforcement authorities to target the inspection of some substances suspected to contain CA:C14-17 with PBT and/or vPvB properties.

2.3.4.3. Monitorability

The restriction options RO1, RO3, RO4a, RO4b and RO5 are all considered monitorable. The effectiveness of the proposed restriction could indeed be monitored:

- Via the monitoring and content (registered compositions, tonnages and uses) checking of the registration dossiers for some of the substances containing CA:C14-17
- Via a market survey similar to the one undertaken by the Dossier Submitter for the preparation of this restriction proposal
- Via EU or national monitoring campaign of CA:C14-17 in the environment.

Re. the monitoring via the EU or national campaigns, substances containing CA:C14-17 (e.g. EC 288-477-0) are already included in several national monitoring programs both for the environment and the human health as described in Table 14. The monitoring of samples from the biota and the environment is indeed possible using the advanced analytical techniques considered in Appendix B and considering the relevant variation in measurements.

Even though monitoring of CA:C14-17 in the environment is possible, the effect of the restriction may be difficult to measure solely via monitoring campaigns after the entry into force of the restriction proposal due to the PBT, vPvB, and LRT properties of the substances restricted. The concentrations of CA:C14-17 measured in the environment may indeed come from previous sources of releases and uses (e.g. landfill disposal prior to the restriction), as well as from uses and releases outside the EU. Using solely monitoring campaign to monitor the effectiveness of the restriction may therefore not suffice.

Table 14. Examples of existing annual EU monitoring programs

EU country	Monitoring programme	Reference
Norway	Environment contaminants in air and precipitation	https://www.miljodirektoratet.no/publikasjoner/
Norway	Contaminants in coastal waters of Norway	https://www.miljodirektoratet.no/publikasjoner/
Norway	Environmental pollutants in the terrestrial and urban environment	https://www.miljodirektoratet.no/publikasjoner/
Norway	Environmental Contaminants in an Urban Fjord	https://www.miljodirektoratet.no/publikasjoner/
Norway	The Norwegian River Monitoring Programme Priority substances and emerging contaminants in selected Norwegian rivers	https://www.miljodirektoratet.no/publikasjoner/
Norway	Sediments in Norwegian	https://www.mareano.no/en/about_mareano

EU country	Monitoring programme	Reference
	offshore areas	
EU-wide	MISA study on Persistent Organic Pollutants (POPs) in human samples	https://www.miljodirektoratet.no/publikasjoner/2021/mars-2021/persistent-organic-pollutants-pops-in-human-samples-from-the-misa-study-northern-norway/

Source: literature review

2.4. Proportionality to the risk (including comparison of options)

To demonstrate the proportionality to the risk identified, the Dossier Submitter performed an indicative abatement cost approach (cost effectiveness) as suggested by SEAC for the evaluation of restriction proposals and applications for authorisation for PBT and vPvB substances (ECHA, 2014).

Taking into account the PBT/vPvB properties of the CA:C14-17 in the scope of the restriction, the avoided releases are used as a proxy for the benefits of the restriction. According to Table 13, RO1 (and RO3), RO4b and RO4a are anticipated to reduce CA:C14-17 releases to the environment by about 103 000 tonnes, 102 700 tonnes and 101 000 tonnes, respectively (nominal values, central estimates, values rounded to the nearest thousands) over the 20-year period used for the impact assessment, equivalent to 74 500 tonnes, 73 900 tonnes and 73 000 tonnes (when discounted at 3 %). When compared to the baseline release, significant emission reductions (by ca. 90 %) are envisaged from each of the ROs.

The average cost-effectiveness as well as the incremental cost-effectiveness ratios of RO1, RO3, RO4a and RO4b are reported in Table 15. Both costs and benefits (in terms of avoided releases) were discounted over 20 years using a 3 % discount rate.

Table 15. Cost-effectiveness of RO1, RO3, RO4a and RO4b

Restriction option	Total costs (NPV over 20 year)	Total emission Reduction (NPV over 20-year, central estimates)	C/E-ratio €/kg	Incremental change in costs € (NPV over 20 year)	Incremental reduction of kg (NPV over 20 year)	Incremental C/E-ratio €/kg
RO4a	€3.9 billion	73 million kg	53	€3.9 billion	73 million kg	53
RO4b	€4.1 billion	73.9 million kg	55	€200 million	0.9 million kg	222
RO1(and RO3 ⁷¹)	€4.9 billion	74.5 million kg	66	€800 million	0.6 million kg	1 333

The average cost-effectiveness ratio ranges between 53 €/kg and 66 €/kg for the restriction options considered.

The incremental cost-effectiveness ratio, which measures the marginal abatement costs for the releases, is 53 €/kg for RO4a, 222 €/kg for RO4b and 1 333 €/kg for RO1 (and RO3).

Given the similarity of the average cost-effectiveness ratios, the incremental cost-effectiveness ratio is more informative. For example, RO1 and RO3 have an incremental effect of avoiding 0.6 million kg (or 600 tonnes) of emissions over and above that of RO4b, at an incremental cost of 1 333 €/kg.

In the evaluation of the proportionality of the various restriction options, the Dossier Submitter compared the cost/effectiveness ratios of the examined restriction options to those of former REACH actions to avoid PBT(-like) substances.

As can be seen from Table 16, the cost-effectiveness ratios of the examined ROs are well below the cost-effectiveness ratios of recent REACH restrictions (with the exception of the restriction for lead in shots in wetlands).

⁷¹ Given the marginal differences between RO1 and RO3 (in terms of costs and avoided release), the costs effectiveness ratios are almost the same. More precisely, CE ratio of RO1 is 65.91 €/kg, while CE ratio of RO3 is 65.96 €/kg.

Table 16. Cost-effectiveness ratios of recent REACH restrictions

Restriction under REACH	€/kg p.a., central value
Lead in shot in wetlands	9
Lead in PVC	308
D4, D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734
PFOA	1 649

Source: ECHA (2021c)

The Dossier Submitter also notes that a recent study by Oosterhuis and Brouwer (2015) concluded that the available evidence suggests that any regulatory measure involving societal costs of less than €1 000 per kg of PBT emission reduction, have not been rejected on the grounds of proportionality.

While noting important differences in terms of incremental cost-effectiveness ratios and the possibility that cost-effectiveness ratio per sector could differ from the above cost-effectiveness ratio per RO, the Dossier Submitter considers all of the above restriction options to be proportionate, on the basis that the costs of this restriction appear to be in line with the previous restrictions for substances of similar concern and because of the unknown (but potentially significant) damage that the emissions of CA:C14-17 are expected to cause, as they continue to accumulate in the environment.

It is however important to note that under each restriction option, each sector might have a different cost-effectiveness ratio. For example, it is possible that for some sectors the cost-effectiveness ratio of a restriction option could be lower than the above average (as reported in column 4 of the Table 15), or it could be higher in case that a sector accounting for a minor share in terms of the avoided releases, but is expected to bear significant substitution costs.

The Dossier Submitter notes that a separate calculation of cost-effectiveness ratios per sector under each RO, would not change the conclusion on the overall proportionality of the restriction options.

The Dossier Submitter however calculated the sectorial cost-effectiveness ratios for the metalworking fluid sector. A separate calculation for this sector was deemed appropriate by the Dossier Submitter, considering that an important number of companies as well as associations indicated that restriction could have significant negative impacts on the overall sector due to the challenges in replacing substances containing CA:C14-17. The sectorial cost-effectiveness ratios were estimated by the Dossier Submitter at 170 €/kg, and 580 €/kg for RO4b and RO1 (and RO3) respectively. Regarding RO4a, a sectorial cost-effectiveness was not possible to calculate, considering that this restriction option is equivalent to the baseline for this sector.

RO1 and RO3 cost-effectiveness ratio for the metalworking fluid sector is almost nine times higher compared to the cost-effectiveness ratio of 66 €/kg, while the RO4b cost-effectiveness ratio for this sector is three times higher compared to the cost effectiveness ratio of 55 €/kg, as reported in Table 15.

Considering all the elements above, RO1, RO3, RO4a and RO4b are all as cost-effective as previously adopted restrictions on environmental pollutants. Therefore, the Dossier Submitter concludes that the proposed restriction options can be seen as proportionate to the risks associated with CA:C14-17 with PBT and vPvB properties.

2.5. Proposed restriction entries

Based on the impact assessment, the Dossier Submitter considers that the restriction options RO1, RO3, RO4a, and RO4b are all:

- Effective, i.e. targeted to the risks posed by the presence of PBT and/or vPvB constituents, effective in reducing the risks and proportionate to the risks
- Practicable, i.e. implementable, manageable and enforceable
- Monitorable, i.e. the result of the implementation of the proposed restrictions can be duly monitored.

and that RO5 supports and enhances their enforceability, and effectiveness. Considering on one hand the PBT and vPvB properties of the CA:C14-17 to be restricted and the risks arising from the releases of CA:C14-17 to the environment, and considering that the environmental stock of CA:C14-17 with PBT and/or vPvB properties will increase over time if emissions are not minimised, the Dossier Submitter is proposing to put forward a restriction entry that minimises the most the releases in the EU, i.e. a combination of RO3 (ban on manufacturing and placing on the market) with RO5 (complementary measures). This is 'Restriction entry - Option A' (cf. section 2.5.1). As well as informing the decision-making process, this option A could also be useful for the EU to support its position, and contribution in the framework of the on-going discussions for the POP listing of the substances containing CA:C14-17. Indeed, restrictions under the Stockholm Convention focus exclusively on the manufacture of POPs (with exempted uses) and Europe does the same in the corresponding POPs Regulation.

On the other hand, considering that (i) alternatives appear not to be readily available for all Extreme Pressure metalworking fluids applications and (ii) a ban on manufacturing would de facto entail a ban on manufacturing for export which represents max. 0.08 % of the total releases (cf. Table 10), the Dossier Submitter is proposing to put forward a second restriction entry that minimises the releases of CA:C14-17 with PBT and/or vPvB properties in the EU in the same order of magnitude. This is 'Restriction entry - Option B' (cf. section 2.5.2), i.e. a combination of RO4b (i.e. RO1 ban on placing on the market with a longer transition period for metalworking fluids) with RO5 (complementary measures).

The Dossier Submitter is therefore proposing two restriction entries (option A and B) to be assessed by RAC, SEAC and Forum. The Dossier Submitter's intention is to provide, at the end of the opinion making process, the Commission with two proposed restriction entries but also a comparative assessment of other ROs to address the identified risks.

2.5.1. Title and scope of the proposed restriction (option A)

Short title:

Restriction on the manufacturing or placing on the market of chloroalkanes with carbon chain lengths within the range from C14 to C17, on their own, in other substances, in mixtures or in articles.

Scope description:

The text of the proposed entry in REACH Annex XVII has been drafted to describe the intention of the Dossier Submitter. The final legal wording (i.e. to update the Annex XVII to REACH) would be decided by the European Commission during the decision-making phase.

Detailed explanation of the intention of the Dossier Submitter, and the wording proposed is also provided in Section 2.5.3.

Some elements of the restriction entry proposal are presented in square brackets [...]. This is intended to indicate these elements of the conditions of the restriction which are included on the basis of a preliminary conclusion that is subject to a review by the Dossier Submitter and the Committees during the opinion-making phase (i.e. after the consultation).

Table 17. Proposed REACH Annex XVII entry (option A)

Designation	Conditions of restriction
Linear chloroalkanes with the following molecular formulae: C ₁₄ H _{30-y} Cl _y where y = 3 to 11 C ₁₅ H _{32-y} Cl _y where y = 3 to 8	1. a. Substances containing chloroalkanes listed in column 1 shall not be manufactured if the overall concentration of the chloroalkanes listed in column 1 is [equal to or greater than 0.1 % (w/w)]. b. Chloroalkanes listed in column 1 shall not be placed on the market in substances, in mixtures

Designation	Conditions of restriction
C ₁₆ H _{34-y} Cl _y where y = 3 to 8	and in articles if their overall concentration in such substances, mixtures and articles is [equal to or greater than 0.1 % (w/w)].
C ₁₇ H _{36-y} Cl _y where y = 6 to 9	<p>Paragraph 1 shall apply [2 years] after entry into force of the restriction.</p> <p>2. Substances containing chloroalkanes listed in column 1 shall not be used for the formulation of mixtures and production of articles if the [overall concentration] of the chloroalkanes listed in column 1 is [equal to or greater than 0.1 % (w/w)].</p> <p>Paragraph 2 shall apply [2 years after entry into force of the restriction].</p> <p>3. Paragraphs 1 and 2 shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force].</p> <p>4. Paragraphs 1 and 2 shall not apply to reference materials and standards for analytical purposes.</p> <p>5. [Within three months after entry into force of the restriction, the European Chemicals Agency shall publish and maintain on its website an indicative list of identifiers describing substances that may contain the chloroalkanes listed in column 1].</p> <p>6. [Within six months after entry into force] of the restriction, the suppliers of substances containing the chloroalkanes listed in column 1 or, of substances referred to in paragraph 5, shall conclude and identify the substances as PBT and/or vPvB unless they can demonstrate to the Competent Authorities that the overall upper concentration of the chloroalkanes listed in column 1 is [lower than 0.1 % (w/w)], by providing the following information (i) the overall upper concentration level of the chloroalkanes listed in column 1 in the composition(s). The upper concentration level should be determined using representative batches (typically five batches) manufactured according to the same technical specifications by the same manufacturer. The level should be determined using validated analytical methods and statistical calculations, and (ii) a description of the analytical methods used, and the results obtained to derive the overall upper concentration level mentioned above.</p> <p>7. [Within 6 months after entry into force] of the restriction, the supplier placing on the market substances, mixtures, or articles [containing chloroalkanes listed in column 1 or referred to in paragraph 5], irrespective of the concentration, shall inform their downstream users and customers of (i) the presence and overall concentration of the chloroalkanes listed in column 1, and (ii) the appropriate risk management measures and operating conditions to minimise the releases and exposure in case of presence of chloroalkanes listed in column 1.</p>

2.5.2. Title and scope of the proposed restriction (option B)

The differences with option A are identified with a red colour.

Short title:

Restriction on the **placing on the market** of chloroalkanes with carbon chain lengths within the range from C14 to C17, on their own, in other substances, in mixtures or in articles.

Scope description:

Table 18. Proposed REACH Annex XVII entry (option B)

Designation	Conditions of restriction
Linear chloroalkanes with the following molecular formulae: C ₁₄ H _{30-y} Cl _y where y = 3 to 11 C ₁₅ H _{32-y} Cl _y where y = 3 to 8 C ₁₆ H _{34-y} Cl _y where y = 3 to 8 C ₁₇ H _{36-y} Cl _y where y = 6 to 9	<ol style="list-style-type: none"> 1. <ol style="list-style-type: none"> a. REMOVED b. Chloroalkanes listed in column 1 shall not be placed on the market in substances, in mixtures and in articles if their overall concentration in such substances, mixtures and articles is [equal to or greater than 0.1 % (w/w)]. <p>Paragraph 1 shall apply [2 years after entry into force of the restriction].</p> 2. REMOVED 3. Paragraph 1 shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force]. 4. Paragraph 1 shall not apply to reference materials and standards for analytical purpose. 5. [Within three months after entry into force] of the restriction, the European Chemicals Agency shall publish and maintain on its website an indicative list of examples of identifiers describing substances that may contain the chloroalkanes listed in column 1. 6. [Within six months after entry into force] of the restriction, the suppliers of substances containing the chloroalkanes listed in column 1 or, of substances referred to in paragraph 5, shall conclude and identify the substances as PBT and/or vPvB unless they can demonstrate to the Competent Authorities that the overall upper concentration of the chloroalkanes listed in column 1 is [lower than 0.1 % (w/w)], by providing the following information (i) the overall upper concentration level of the chloroalkanes listed in column 1 in the composition(s). The upper concentration level should be determined using representative batches (typically five batches) manufactured according to the same technical specifications by the same manufacturer. The level should be determined using validated analytical methods and statistical calculations. (ii) a description of the analytical methods used and the results obtained to derive the overall upper concentration level mentioned above. 7. [Within 6 months after entry into force] of the restriction, the supplier placing on the market substances, mixtures, or articles containing [substances containing the chloroalkanes listed in column 1 or referred to in paragraph 5], irrespective of the concentration, shall inform their downstream users and customers of (i) the presence and overall concentration of the chloroalkanes listed in column 1, and (ii) the appropriate risk management measures

Designation	Conditions of restriction
	and operating conditions to minimise the releases and exposure in case of presence of chloroalkanes listed in column 1.
	8. [By way of derogation, paragraph 1 shall not apply to substances if placed on the market for use as Extreme Pressure Additives in oil-based metalworking fluids - as defined in DIN 51385 -] [for 7 years after into force.]
	By way of derogation, the concentration limit set under paragraph 1 shall not apply to mixtures placed on the market as oil-based metal working fluids referred to in paragraph 8 - [for 7 years after the EIF].

2.5.3. Justification of the wording for the proposed restriction entries

Wording of the column 1 - Designation

Please refer to sections 1.2.1. and 1.2.2 for the justifications of the proposed wording. The proposed wording is in line with the MSC conclusions on PBT and/or vPvB properties of 'MCCP' congeners. It does not cover 'branched' chloroalkanes. The Dossier Submitter takes note that chloroalkanes may be theoretically also produced from branched feedstocks. Such products are however not placed on the market in Europe. They are generally considered inferior to linear chloroalkanes because they have higher volatility and viscosity that lead to inferior processing and end product performance according to the MCCP consortium (CfE2 #1494).

Wording of paragraphs 1 and 2 in column 2:

Please refer to section 2.1.1.1 (RO1) for the explanations of the proposed ban in paragraphs 1 and 2.

Paragraph 1b applies to both option A and B, and describes the 'ban on placing on the market' of substances, mixtures or articles containing CA:C14-17 with PBT and/or vPvB properties:

- 'chloroalkanes' 'in substances' intends to cover substances containing CA:C14-17 of concern in their composition (as defined above for paragraph 1a. (option A))
- 'chloroalkanes' in 'mixtures' intends to cover mixtures containing CA:C14-17 of concern. These mixtures are formulated using substance(s) containing CA:C14-17 of concern. However, for enforceability and practicality, the proposed ban applies to the presence of CA:C14-17 of concern in the final mixture and not to the content of the substance (containing CA:C14-17 of concern) used in the formulation.
- 'chloroalkanes' in 'articles' intends to cover articles containing CA:C14-17 of concern. These articles are produced using substance(s) containing CA:C14-17 of concern. However, for enforceability and practicality, the proposed ban applies to the presence of CA:C14-17 of concern in the final article and not to the content of the substance (containing CA:C14-17 of concern) used to produce the article.

Paragraph 1a and 2 are specific to option A only and are related to each other as explained below.

Paragraph 1a is about the proposed ban on manufacturing substances containing CA:C14-17, and paragraph 2 aims at underpinning the obligations set in paragraph 1, and in particular the situation where a manufacturer would also be a formulator and/or producer of articles for export (i.e. no placing on the market as such) and would still have in stock substances and mixtures in the scope of the restriction proposal.

In paragraph 1a and 2 (option A only), the term 'Substances containing chloroalkanes' intends to cover substances with restricted CA:C14-17 present as constituents in their composition (including impurities and additives).

The concentration limit in paragraph 1a, 1b and 2 sets the maximum allowed concentration of the restricted CA:C14-17 in substances, mixtures and articles. The concentration limit is applicable to the individual restricted CA:C14-17, or to the sum of

some or all of them. In case of complex object, and as explained above, the maximum allowed concentration limit is applicable to each of the individual articles composing the complex object. Finally, the proposed wording 'overall concentration' reflects the intention of the Dossier Submitter. It clarifies that registrants, and enforcement authorities are not requested to determine the concentration levels of the individual congeners but rather to determine the total amount of chloroalkanes of concern listed in column 1 of the entry.

More details to justify the proposed concentration limits, in particular in term of efficiency and enforceability, are available in section 2.2.4.

Finally, the terms 'substance', 'mixture', 'article', and 'placing on the market' are defined in REACH Article 3. In particular:

- 'article' applies in the same way to restrictions in REACH Annex XVII as to the other aspects of the REACH Regulation as per the European Court of Justice (ECJ) interpretation in its judgement of 10 September 2015 in case C-106/14⁷². In the proposed restriction entry, the term 'article' has the specific meaning set out in Article 3(3) of the REACH Regulation where 'article' is defined as 'an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'. 'Complex objects' are made up of more than one article which meet the criteria laid down in Article 3(3) of REACH, e.g. a bicycle is a complex object made up of several articles, such as handlebar grips, cables, screws, lubricants etc. Complex objects are explained in the ECHA Guidance on requirements for substances in articles. The ECJ, in its judgment, observed that the REACH Regulation does not contain any provisions specifically governing complex products and that consequently, in the absence of specific provisions, there is no need to draw a distinction between articles of their own (e.g. screw) or when incorporated as components of a complex product (e.g. a screw in a bike). Therefore, when incorporated into a complex product, an 'article' remains an article within the meaning of REACH, as long as the article retains its special shape, surface or design, which is more decisive for its function than its chemical composition.
- 'Placing on the market' should be understood as 'placing on the EEA market (i.e. EU + Iceland, Norway and Liechtenstein)' as defined under REACH Article 3(12), i.e. 'supplying or making available, whether in return for payment or free of charge, to a third party. Import is deemed to be placing on the market'.

The 'ban on placing on the market' puts therefore the obligation on all actors in the supply chain who supply or make substances, mixtures, articles available, whether in return for payment or free of charge, to a third party. It includes also the placing on the market via internet.

Wording of paragraphs 3 and 4 in column 2:

Paragraphs 3 and 4 identify uses that would be out of the scope of the proposed ban under paragraph 1 and 2.

It should be noted that SR&D (Scientific Research and Development) is always outside of the scope of restriction as per REACH Article 67(1). Nevertheless as there might be some uncertainties if analytical reference standards would always fall under the SR&D definition, and considering that analytical standard made of pure CA:C14-17 would be needed to enforce the proposed restriction. The Dossier Submitter is proposing to add a specific exemption under paragraph 4 to clarify that reference standards are out of the scope of the proposed restriction.

Second-hand articles and articles already in use (according to the definition of use in REACH Article 3(24)) are also proposed to be out of scope to avoid a recall of articles already in use that contain CA:C14-17. For example, electrical equipment, rubber conveyors which may have a long-life span etc. (cf. section 2.1.1.2).

According to the Forum Guide on Enforcement for Dossier Submitters, there is no need to propose a definition in Annex XVII entries for common words where the normal

⁷² Available at: <http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14>

dictionary definition is sufficient, or where technical terms are used (ECHA, 2016). Therefore no specific definition is proposed for the terms 'articles already in use', 'second-hand article', and 'reference materials and standards for analytical purpose'. Finally, it should be noted that the wording proposed for derogating articles already in use and second-hand articles is similar to existing REACH Annex XVII entries (entry 20 on organostannic compounds, 46a on NPE, 47 on Chromium VI compounds, 72 on skin sensitisers for example).

Wording of paragraph 5 in column 2:

A list of identifiers describing substances that may contain CA:C14-17 with PBT and/or vPvB properties is needed to facilitate the enforcement and the implementation of the requirements in paragraph 6 and 7 of the draft restriction entry (see below).

The Dossier Submitter is therefore proposing to refer to a 'non-exhaustive list of examples of identifiers describing substances that may contain the restricted chloroalkanes'. ECHA could for example develop such a list, keep it up to date, and publish it on the ECHA's website together with other Q&As⁷³ on restriction entries. Referring to this list in the Annex XVII entry makes the list legally binding and therefore enforceable.

Alternatively the list of substances could also be provided as a separate Appendix to the Annex XVII entry as already done for some other existing REACH Annex XVII entries (entry 28, 29, 30, or 43 for example).

The main reasons to include this list of substances on the ECHA website, rather than in the Annex XVII entry itself, is that the content of the list could be more easily modified, reviewed by ECHA, and keep up to date.

Indeed, having the list in Annex XVII, as an Appendix, would require a process for revising the Appendix, i.e. probably a revision made by the Commission or a mechanism defined for ECHA to update the list if needed

The content of the list referred to in paragraph 5 would include:

- An introduction text such as:
'The identifiers listed describe substances that contain or may contain the chloroalkanes listed in column 1 to the Annex XVII entry [# to be specified] in concentration [equal to or greater than 0.1 % (w/w)].
This list of identifiers is provided to facilitate the identification of substances that may fall within the scope of the Annex XVII entry [# to be specified]. The list is not exhaustive and only indicative. The presence and concentration of chloroalkanes listed in column 1 to the Annex XVII entry [# to be specified] depends on the composition of the substance. The presence and concentration of the chloroalkanes is therefore specific to each supplier/manufacturer of the substances.
- A table of substance identifiers: EC number, CAS number and substance name is provided in Appendix B.1 to this document (69 substances).

Wording of paragraphs 6 and 7 in column 2:

Please refer to section 2.1.1.5 (RO5) for the explanations of the proposed conditions.

The requirements set in paragraphs 6 and 7 are similar to a conditional derogation; meaning that a supplier of chloroalkane substances does not need to identify/conclude its substance as PBT and/or vPvB properties if it can prove to the Authorities (i.e. either ECHA, Member States Competent Authorities, or enforcement authorities) that its substance does not contain the CA:C14-17 with PBT and/or vPvB properties in concentration ≥ 0.1 %. The burden of proof is on the supplier's side.

The requirements set in paragraphs 6 and 7 are fair as they apply to all suppliers whatever the tonnage they are placing on the market (i.e. below or above 1 tonne per year).

The requirements apply to 'all substances containing chloroalkanes listed in column 1 or referred to in paragraph 5' – as the list of substance referred to in paragraph 5 may not be exhaustive.

The conditions in paragraph 6 have indeed been deliberately worded to allow flexibility in

⁷³ <https://www.echa.europa.eu/web/quest/support/qas-support/browse>

its application so that the supplier of a substance has the freedom to apply the most efficient and effective means to identify its substance as PBT and/or vPvB criteria or to provide the requested information to the authorities to justify that the concentration of restricted CA:C14-17 is lower than 0.1 %. For example, REACH registrants, in line with REACH Article 22, have the duty to update their registration dossier and provide information in line with REACH Annex VI requirements. On the other hand, suppliers placing on the market substances in quantity below 1 tonne per year do not have to register the substance under REACH but would still need to make available the information to the Authorities in case of enforcement for example.

The conditions in paragraph 7 have also been deliberately worded to allow flexibility in its application so that the supplier of a substance, mixture or article has the freedom to apply the most efficient and effective means to communicate the relevant information to downstream users and/or consumers. No specific format is imposed as explained in section 2.1.1.5.

The information to be shared with the Authorities listed in paragraph 6 have been deliberately worded with the following intention:

- 'Representative batches (typically five batches)': allow the supplier to adapt (and justify) the requirement set in point (i) in case a different number of batches would be considered to be appropriately representing the number of batches manufactured yearly
- 'Same technical specifications by the same manufacturer': implies that the registrants which are importers or only representative should provide the requested information from each manufacturer supplying the registered substance
- 'Validated analytical methods and statistical calculations': the Dossier Submitter does not impose a specific method or calculation. The one chosen by the registrant should nevertheless be validated and described in the registration dossier as per the REACH Annex VI requirements.

The requirement in paragraph 6 and 7 is targeting 'suppliers of substance' as defined in REACH Article 3(32) i.e. "*manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture*". In paragraph 7, the 'suppliers' definition is extended to cover also the suppliers of mixtures and articles as per REACH Article 3(32 and 33), i.e. "*manufacturer, importer, downstream user or distributor placing on the market a mixture*" and "*any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market*".

As explained in section 2.1.1.5 (RO5), there is no concentration limit triggering the requirements in paragraph 7.

Please note finally that the wording 'appropriate risk management measures and operating conditions to minimise the releases and exposure' is similar to the wording in some other existing REACH Annex XVII entries (entry 71 on NMP for example).

Wording of paragraph 8 in column 2 (only applicable for the restriction entry – option B): Paragraph 8 is presented intentionally in brackets as the Dossier Submitter may decide to remove this derogation if not sufficient and substantiated information is received during the Annex XV consultation phase.

As indicated in section 2.4, RO1 (which excludes paragraph 8 in column 2) and RO4a/RO4b (which include paragraph 8) would both be proportionate to the risk. Even though RO4b would be potentially more affordable for the metalworking sector.

The Dossier Submitter recognises that the wording 'metalworking fluids' on its own, even though used in the past in Annex XVII entry 42⁷⁴ for SCCPs, may not be specific enough to allow to set clear boundaries for this derogation. The Dossier Submitter tried therefore to narrow down the scope of this possible derogation based on the comments received during the Annex XV consultation.

The Dossier Submitted is proposing to refer to a commonly agreed definition of oil based metalworking fluids such as the one defined under DIN 51385. Another option would be

⁷⁴ This entry is now removed from REACH Annex XVII.

to add the definition directly in the restriction entry rather than referring to the standard itself.

After the Annex XV consultation, the Dossier Submitter has also clarified that the derogation under paragraph 8 would apply not only to the placing on the market of metalworking fluids, but also on the placing on the market of substances for the EU manufacturing of these mixtures.

After the SEAC Draft Opinion consultation, SEAC may re-evaluate if a derogation or a longer TP (7 years proposed) should be maintained with a clear and narrow scope reflecting the challenges in term of substitution. In addition a review clause could also be envisaged to allow the Commission in the future to re-evaluate the need to maintain a derogation or longer TP for this sector.

3. Assumptions, uncertainties and sensitivity analysis

3.1. Identification of uncertainties

In this section, the Dossier Submitter assesses how uncertainties related to the key assumptions of the impact assessment presented in section 2 would affect the conclusions about the restriction options, and in particular their cost effectiveness. The analysis of uncertainties is based on the EFSA's guidance on uncertainty analysis and the communication of uncertainty in scientific assessment (EFSA, 2018). The key input parameters and assumptions for the exposure assessment and the impact assessment of the different restriction options are summarised respectively in Appendix B.5 Exposure assessment, and Appendix E Impact assessment.

On one hand the releases calculations are subject to a range of input parameters and assumptions such as the substances potentially falling within the scope of the restriction proposal, the annual manufactured and used tonnages, the release factors associated to the different uses, and the efficiency of the RMMs already in place, of the WWTP and waste management, etc.

On the other hand, the cost assessment is essentially driven by one-off cost supported by Industry and the response from some sectors to the restriction options. Indeed, based on the available and provided data, sector/use-specific assessment was considered necessary only for metalworking fluids. While this simplifies the assessment, it does not mean that other sector-specific issues could not exist.

The examination of these key input parameters and assumptions lead to the identification of several key uncertainties, which are reported in Table 19.

All the uncertainties reported in Table 19 are associated with the 'input assessment parameters', except for the uncertainties U10 and U11 which are associated with 'assessment methodology' uncertainties according to the EFSA guidance. Finally all uncertainties in Table 19 are non-standard uncertainties⁷⁵. The uncertainties are further described and analysed in Appendix F.

⁷⁵ i.e. uncertainties that are not addressed by any standardised procedure/assessment element and are thus not covered by any allowances for uncertainties that would be built into the standard procedure (e.g. doubt on the applicability model of default value)

Table 19. Identified key uncertainties

#	Section(s)	Short description of the uncertainty
U1	1.2.2, 2.2.2 and Appendix B.1	Uncertainty on the list of substances potentially affected by the restriction proposal.
U2	1.3.1 and Appendix B.5	Potential overestimate of the tonnages released to the environment.
U3	1.3.1 and Appendix B.5	Uncertainty related to imported mixtures and articles (tonnage, tonnage of CA:C14-17 in imported articles, impact of a lower concentration limit for mixtures and articles)
U4	1.3.1 and Appendix B.5.2	<p>Uncertainty re. the proportion of CA:C14-17 in the Chloroalkanes other than the one listed in the Candidate List.</p> <p>The fraction of CA:C14-17 in the substances EC 264-150-0, EC 269-145-7, 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' may be lower or higher than the estimated 10 % by the Dossier Submitter for the release estimates.</p>
U5	1.4.3 and Appendix B.5.2	Uncertainty on the treatment of the industrial waste. Industrial waste may not all be incinerated/destroyed.
U6	1.4.3 and Appendix B.5.2	<p>Uncertainty on the WWTP effectiveness.</p> <p>According to the registrants, high biodegradation can take place in WWTP (OECD 314B study results submitted by the registrants during the calls for evidence (CfE2 #1527)).⁷⁶</p>
U7	1.4.3 and Appendix B. 5.2	The tonnage split between industrial use and professional/consumer use may be different for Use#01 and Use#04.
U8	Appendix E	For the estimation of the one-off costs, precise data are lacking to identify the exact number of companies that would be affected in each sector and the exact one-off cost that would be borne by each company.
U9	2.3.1.2	Some variances in the prices of sealant producers can be expected.
U10	2.4	The costs effectiveness ratio is based on central estimates of avoided releases. The ratio would differ if upper or lower estimates of avoided releases are considered.
U11	2.4	The costs effectiveness ratio is based on discounted avoided releases, and not on non-discounted avoided releases.
U12	2.3.1.6	There is no certainty on whether the leather sector would be

⁷⁶ The results of the OECD314B study are not considered to be reliable by the Dossier Submitter (cf. Appendix F for more details). However, the Dossier Submitter used the outcome of this study in the sensitivity analysis to estimate an alternative input value for biodegradation that may occur in sewage treatment plants and what could be the consequences of such high degradation for release estimation.

#	Section(s)	Short description of the uncertainty
		affected by the entry into force of the restriction.
U13	2.3.1.4 and 2.4	No information is available to quantify potential impacts of the restriction options (RO1, RO3 and RO4a) on some actors, down the supply chain (e.g. the automotive, aerospace, and other sectors relying on the use of metal parts resulting from processes where substances containing CA:C14-17 are used).

Source: Appendix F

3.2. Sensitivity and influence analysis

In this section, the Dossier Submitter summarises how the identified uncertainties in Table 19 might impact the conclusions on the proportionality of the different restriction options, i.e. cost-effectiveness ratios. The detailed sensitivity analysis is available in Appendix F.

To simplify the assessment of the uncertainties, the Dossier Submitter has grouped in Appendix F the uncertainties according to the following criteria:

- Uncertainties that may impact the releases estimates (baseline and per RO) and therefore the cost effectiveness ratio of the ROs
- Other uncertainties that may impact the cost effectiveness ratio of the ROs
- Uncertainties that cannot be quantified

Whenever possible, the Dossier Submitter conducted first a sensitivity analysis for each identified uncertainty in Table 19. The sensitivity analysis is used to apply different possible inputs parameters (or methodological choices) and then compare the outcomes to the results of the initial assessment. When a quantitative sensitivity analysis was not possible, a qualitative assessment was made based on expert judgement as per the EFSA guidance recommendation (EFSA, 2018).

Finally an influence analysis further considers the effects that the analysed sensitivities could exert on the overall outcomes and conclusions of the restriction proposal, both individually and collectively.

The sensitivity and influence analysis showed that none of the identified individual uncertainty listed in Table 19 (except U11) have a significant effect on the cost effectiveness of the restriction options. 'Significant' impact being defined as an absolute value higher than 10 % compared to the cost effectiveness calculated in this report⁷⁷.

Finally to gain an impression of the joint influence of the uncertainties described in Table 19 and Appendix F the Dossier Submitter carried out a best-case and worst-case analysis to demonstrate how far all the elements together may shift the conclusions on cost effectiveness in one or another direction. The Dossier Submitter took a pragmatic approach and performed this collective influence analysis on one RO only (RO1) rather than making the comparisons for all ROs assessed (RO1, RO3, RO4a and RO4b).

The Dossier Submitter notes that even when considering all assumptions together, the cost-effectiveness ratios of RO1 (43 €/kg - 78 €/kg) remain within the same order of magnitude of the C/E ratio calculated for RO1 in this report (66 €/kg) and are well below the cost-effectiveness ratios of recent REACH restrictions for substances having PBT and/or vPvB properties (cf, Table 16).

In the end, the Dossier Submitter concludes that the individual and collective uncertainties do not impact the conclusions on proportionality for RO1, RO3, RO4a and RO4b.

Finally, despite repeated and targeted contacts with specific sectors (cf. section G), no substantiated information was provided during the one-year restriction preparation on the restriction costs and impacts for specific sectors (e.g. automotive, leather treatment), and uses (Metalworking Fluids). This uncertainty U13 could be reduced if

⁷⁷ i.e 53 €/kg for RO4a, 55 €/kg for RO4b and 66 €/kg for RO1 and RO3

substantiated and detailed impact analysis information, including releases and costs estimates, is received from stakeholders during the Annex XV restriction consultation.

4. Conclusions

This report demonstrates that an action is required on a Union-wide level to address the risks posed by the releases of CA:C14-17 with PBT or vPvB properties, which are present in many substances, mixtures and articles.

The proposed identification of the substances, mixtures and articles to be restricted which is based on the presence of CA:C14-17 with PBT and/or vPvB properties, and the restriction options analysed (RO1, RO3, RO4a, RO4b and RO5) are considered to be balanced, justified and effective as they are (i) targeted to the risk posed by the presence of congeners with PBT and vPvB properties, (ii) capable of reducing the risk (release reduction by ~90 %, and limiting the potential for 'regrettable' substitution) within a reasonable period of time as suitable alternatives⁷⁸ are available for most of the uses, and (iii) proportionate to the risk as considering that the costs of the restriction options appear to be in line with the previous restrictions for substances of similar concern and because of the unknown (but potentially significant) damage that the emissions of CA:C14-17 are expected to cause as they continue to accumulate in the environment.

The analysed restriction options are practical both for industry and enforcement authorities and monitorable, acknowledging that a lot of progress has been made in recent years regarding the analytical detection and quantification of CA:C14-17. Finally, the analysed restriction options ensure a level playing field⁷⁹ for EU manufacturers and companies to compete with foreign produced substances, mixtures and articles.

If no new substantiated information is provided by industry to justify larger impacts on their company/sector in the consultation on the Annex XV report, this indicates that the costs are manageable for industry and that the actual costs of RO1, RO3, RO4a, RO4b (and RO5) may be acceptable for society as a whole.

The scope of the restriction could be extended to other congeners than those with PBT and/or vPvB properties, considering that other CA:C14-17 congeners⁸⁰ could be used as indicators for the presence of congeners of concern.

The REACH restriction process will also help the European Commission to contribute to the scientific documents discussed in the POP Review Committee of the Stockholm Convention and will facilitate the development of the EU position for the Conference of Parties in which the listing of the substances as POP substances will be decided.

⁷⁸ An alternative is a replacement for a substance. The alternative should be able to replace the function that the substance performs. An alternative could be another substance or technology, or a combination of both. Suitable alternatives mean here those alternatives that are technically and economically feasible, available in sufficient quantity and quality, and resulting in an overall reduction of risk to human health or the environment.

⁷⁹ In trade and commerce, level playing field is a concept about fairness, not that each player has an equal chance to succeed, but that they all play by the same set of rules.

⁸⁰ And in particular CA:C14-17 congeners with higher number of chlorines.

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