

## **ANNEX XV RESTRICTION REPORT**

**PROPOSAL FOR A RESTRICTION** 

#### **SUBSTANCE NAME:** Certain Cr(VI) substances

- EC NUMBERS: 215-607-8, 231-801-5, 236-881-5, 234-190-3, 231-906-6, 232-143-1, 232-140-5, 231-889-5, 246-356-2, 232-142-6, 234-329-8, 256-418-0, 233-660-5
- CAS NUMBERS: 1333-82-0, 7738-94-5, 13530-68-2, 10588-01-9, 7778-50-9, 7789-00-5, 7789-00-6, 7775-11-3, 24613-89-6, 7789-06-2, 11103-86-9, 49663-84-5, 10294-40-3

**DOSSIER SUBMITTER: European Chemicals Agency** 

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#### **ABOUT THIS REPORT**

This report consists of a restriction proposal prepared in accordance with the requirements laid down in Annex XV of REACH Regulation.

It consists of a summary of the proposal itself, a main report setting out the key evidence justifying the proposed regulatory actions and Appendices with more detailed information and supporting analysis.

The report has been reviewed for confidential information and any such information has been redacted.

### **CHANGE VERSION HISTORY**

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1.0	Annex XV restriction report and Appendices submitted to ECHA	11 April 2025

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## LIST OF ACRONYMS AND ABBREVIATIONS

Acronym	Meaning		
A&D	Aerospace and Defence sector		
ADCR	Aerospace and Defence Chromate Reauthorisation Consortium		
AfA(s)	Application(s) for REACH Authorisation		
AI	Artificial intelligence		
BAT	Best Available Techniques		
BOEL	Binding Occupational Exposure Limit		
bw	Body weight		
CES	Combined exposure scenario		
CfE(s)	Call(s) for Evidence		
CJEU	Court of Justice of the European Union		
Cr(III)	Trivalent chromium		
Cr(VI)	Hexavalent chromium		
CrO <sub>3</sub>	Chromium trioxide		
CTACSub2	Chromium Trioxide Authorisation Consortium (2 <sup>nd</sup> submission group)		
DU	Downstream user as per REACH Art. 66		
EASA	European Union Aviation Safety Agency		
ECDF	Empirical Cumulative Distribution Function		
ECHA	European Chemicals Agency		
EEA	European Economic Area (EU Member States + Iceland, Liechtenstein and Norway)		
ELR	Excess lifetime risk (of cancer)		
ELV	Emission limit value		
ESA	European Space Agency		
EU	European Union		
k, m, bn, tn	Thousand, million, billion, trillion		
LoD, LoQ	Limit of detection, limit of quantification		
LV	Limit value (for worker exposure)		
MAC	Marginal abatement cost		
MoD	Ministry of Defence		
OCs	Operational conditions		
P50, P90	Median, 90 <sup>th</sup> percentile		
PPE	Personal protective equipment		
RMMs	Risk management measures		
RPE	Respiratory protective equipment		
SVHC(s)	Substance(s) of very high concern		
tpa	Metric tonnes per year		
TWA	Time weighted average		
UC	Use category		
VSC	Value per statistical case		
WTP	Willingness-to-pay		

# **Executive summary**

Hexavalent chromium (hereafter abbreviated as Cr(VI)) substances are carcinogens that are widely used in the EU. With the exception of barium chromate, all economically relevant Cr(VI) substances are currently regulated under the Authorisation title of REACH, which requires users of these substances of very high concern to either apply for an authorisation or be covered by an authorisation granted to an actor up the supply chain. Since 2015, ECHA has received several hundred applications for authorisation (AfAs) of Cr(VI) uses. This has far exceeded the expectations held at the time of the inclusion of these substances in Annex XIV of REACH and has resulted in challenges for regulators and companies alike. It is taking too long to assess and decide on all the AfAs received, to implement adequate risk management, and in the meantime has hampered the proper functioning of the internal market. On 27 September 2023, the European Commission therefore requested ECHA to prepare an Annex XV restriction dossier for certain Cr(VI) substances that are currently subject to authorisation, with the aim of eventually removing these substances from Annex XIV and adding them to Annex XVII of REACH.

For methodological reasons, the assessment undertaken for this Annex XV restriction report starts from the assumption that the Cr(VI) substances have been removed from Annex XIV of REACH. However, this assumption is purely theoretical as currently the authorisation requirement still applies to these substances and the assessment presented in this report does not pre-empt any future decision on their removal from Annex XIV of REACH.

The investigation shows that over the years the authorisation requirements have brought down occupational exposure to Cr(VI) to levels that are overall compatible with the recent opinion of the Advisory Committee on Safety and Health at Work on the setting of limit values for non-threshold carcinogens. However, there are some companies in the EU that exceed the 'upper risk level' recommended by this Committee. Based on this evidence, priority action seems justified. Moreover, there is evidence that some companies release significant amounts of Cr(VI) to air and water. In the long term, and in the absence of an alternative regulatory regime of comparable scope and stringency, the removal of the Cr(VI) substances from Annex XIV would further weaken the protection of workers and the general population in the EU from the carcinogenic properties of Cr(VI).

This Annex XV restriction proposal seeks to address the identified risk by restricting the use of the following Cr(VI) substances: chromium trioxide, acids generated from chromium trioxide and their oligomers including chromic and dichromic acid, sodium dichromate, potassium dichromate, ammonium dichromate, sodium chromate, potassium chromate, dichromium tris(chromate), strontium chromate, potassium hydroxyoctaoxodizincate dichromate(1-), and pentazinc chromate octahydroxide. In addition, the Dossier Submitter found evidence that barium chromate may be a 'regrettable substitute' and therefore proposes to restrict certain uses of this substance as well. A restriction under Annex XVII of REACH is assumed to take effect in 2028 and will apply to all uses of these substances in the European Economic Area (EU Member States + Iceland, Liechtenstein, and Norway).

In practice, it is proposed that uses of the Cr(VI) substances will be banned unless (1) they fall in a 'closed list' of six use categories, and (2) users comply with specific scientific limit values for worker exposure and emissions of Cr(VI) to the environment. The levels of these limit values may vary between the six use categories to reflect differences in the achievable exposure levels at workplaces. The Annex XV restriction report presents a detailed impact assessment of three restriction options that differ in the levels of the limit values for both worker exposure to and emissions of Cr(VI) to the environment that companies have to comply with. In order to assess these options, the Dossier Submitter conducted two specific Calls for Evidence (CfEs) and collected evidence from 675 of the  $\sim$ 2 000 companies ( $\sim$ 34 %) that currently use Cr(VI) substances in the EU.

This evidence forms the backbone of the risk and impact assessment presented in this report. The strong reliance on the CfE data is justified by the following arguments. First, the CfEs allowed the Dossier Submitter to collect representative information that is not available in existing AfAs and downstream user notifications. Notably, this concerns the expected responses to specific limit values and the associated compliance or non-use costs. Second, the information available from the AfAs has been compiled over a period of more than ten years and is likely to be out of date. Third, the methodologies of the AfAs vary somewhat and – based on the information available – key figures are not always convertible to a common denominator.

Based on the CfE data and other sources of evidence, the Dossier Submitter considers that all three restriction options defined in Section 2.2.4 of the report are effective in addressing the identified risk and would raise the level of protection in the EU compared to today. However, the most stringent restriction option does not appear to be proportionate to the risk. For this restriction option, the limit values for worker exposure are ten or more times more stringent than the current EU-wide BOEL and the emission limit values are designed to ensure that the excess lifetime cancer risk in the general population is below 1E-6. Compliance with these very stringent limit values is not feasible for the majority of companies and would thus result in prohibitively high costs to society.

The other two restriction options are slightly less effective in reducing cancer risk from Cr(VI) exposure, but they are feasible for the majority of companies and therefore impose significantly lower direct costs on society. Moreover, both options are found to be practical (i.e., implementable, enforceable, and manageable) and monitorable. The choice between these two options depends on the balance between the protection of workers and the general population from Cr(VI)-induced cancer risk and the private and societal costs of complying with lower limit values. This trade-off necessitates value judgments and is therefore beyond the remit of the Dossier Submitter. Instead, the Dossier Submitter has drafted two alternative Annex XVII entries in Section 7 of this report. Based on the evaluation by ECHA's Scientific Committees and the discussions in the decision-making phase, one or the other option may be preferred.

The approach employed by the Dossier Submitter allows permutations of these restriction options to be easily assessed. In fact, the Dossier Submitter presents additional restriction options in Appendix E, including a ban on all uses, a ban on functional uses with decorative character, and a harmonised limit value for worker exposure to Cr(VI) that mimics a binding occupational exposure limit (BOEL). The assessment of these additional options serves two purposes. First, it demonstrates how the methodology can be applied to limit values of the Cr(VI) substances in scope is not proportionate to the risk identified, whereas a harmonised limit value of 1  $\mu$ g Cr(VI)/m<sup>3</sup> (TWA) for worker exposure combined with air and water emission limit values of 2.5 kg/year and 15 kg/year (ensuring that the excess lifetime cancer risk in the general population is below 1E-4) may also be proportionate.

# Report

## **1. Problem identification**

## 1.1. Background

Hexavalent chromium (also known as Cr(VI), chromium (VI) or chromium (6)) refers to chromium in the +6 oxidation state in any chemical compound. Cr(VI) substances rarely occur naturally but are manufactured in significant amounts as they are the basis for materials made from chromium (IARC 2012). Industrial uses of Cr(VI) substances are ubiquitous and include chromate pigments in dyes, paints, inks and plastics; chromates and dichromates as anticorrosive agents in paints, primers and other surface coatings; (di-) chromic acids electroplated onto metal or plastic parts to provide a coating; and various other surface treatments such as the anodization of metal substrates. Cr(VI) can also form during industrial activities such as welding or grinding of chromium metal, where the energy involved in the process oxidises inert chromium to its hexavalent state.

Cr(VI) compounds are classified as carcinogenic, mutagenic and reprotoxic under Regulation (EC) No 1272/2008 (CLP). Of special concern is airborne exposure as the inhalation of Cr(VI) particles can cause lung cancer. Under certain situations, ingestion via drinking water and foods may also be of concern (Xie, Holmgren et al. 2017). Due to these hazard properties, several Cr(VI) substances have been identified as substances of very high concern (SVHCs) and subject to the authorisation obligations under Regulation (EC) No 1907/2006 (REACH).<sup>1</sup>The most widely used of these substances is chromium trioxide (CrO3, also known as trioxochromium) which, when dissolved in an aqueous solution, forms chromic acid that is used in electroplating operations across the EU.

Since 2015, ECHA has received several hundred applications for authorisation (AfAs) of Cr(VI) uses. This has far exceeded the expectations held at the time of the inclusion of these substances in Annex XIV of REACH and has resulted in challenges for regulators and companies alike. It is taking too long to assess and decide on all the AfAs received, to implement adequate risk management, and in the meantime has hampered the proper functioning of the internal market. On 27 September 2023, the European Commission therefore requested ECHA to prepare an Annex XV restriction dossier for certain Cr(VI) substances that are currently subject to authorisation under the assumption that these would be removed from Annex XIV and added them to Annex XVII of REACH.

The scope of the original mandate was to restrict  $CrO_3$  in solid and liquid form (Annex XIV entries #16-17). However, ECHA was also asked to investigate the potential for regrettable substitution of  $CrO_3$  and its acids by other Cr(VI) substances listed in Annex XIV and to propose which substances should be restricted based on the findings of this analysis. During the preparation, ECHA informed the European Commission that there could in fact be a potential for regrettable substitution if the Cr(VI) substances listed in Annex XIV were not regulated as a group. In addition, it was found that several Cr(VI) substances may be used in the same workplace, making it difficult to monitor exposure to individual substances. Therefore, the European Commission decided to extend the deadline for the submission of the Annex XV report until 11 April 2025 to allow for a detailed impact assessment of different restriction options for industry sectors that use several Cr(VI) substances or could substitute between them.<sup>2</sup>

 $<sup>^1</sup>$  Annex XIV of REACH currently contains 14 entries for Cr(VI) substances (entries #10-12, #16-22, and #28-31). Other known Cr(VI) compounds are listed in Table 1.1 of IARC (2012).

<sup>&</sup>lt;sup>2</sup> Both mandates can be found under: <u>ECHA's current activities on restrictions - ECHA (europa.eu)</u>.

The uses of Cr(VI) substances for which ECHA has received AfAs can be broadly summarized into the following six categories:

- 1) Formulation of chromic acids and speciality mixtures made from the Cr(VI) substances in scope, which are subsequently used in other use categories
- 2) Electroplating on plastic substrate, e.g. for the automotive and sanitary sectors, providing both functional and aesthetic characteristics to plated parts
- 3) Electroplating on metal substrate, e.g. for achieving corrosion resistance, hardness, and durability of machine parts
- 4) Use of primers and other slurries (incl. applications by painting, spraying, brushing, or pen), primarily done in the aerospace and defence (A&D) sector
- 5) Other surface treatments, incl. passivation (anodizing, conversion coating), etching, cleansing, and sealing, which typically require no or low current
- 6) Speciality uses as functional additive or process aid, for which only few AfAs were made (for example uses, see Section 1.3.2).

As part of the preparation of this Annex XV restriction proposal, specific information was collected and assessed on the uses of Cr(VI) substances in the EU, the risk to workers and the general population (via the environment) arising from these uses, and the measures already taken by industry to either reduce or eliminate these risks (by substitution or otherwise). To this end, the Dossier Submitter analysed information from processed AfAs, downstream user (DU) notifications (as required by Art. 66 of REACH) and two specific calls for evidence (CfEs) that were held and analysed during the preparation of this restriction proposal.

In its analysis, the Dossier Submitter considered several socio-economic factors, such as the availability of alternatives, their technical performance, marketability, potential risks and costs, as well as the expected impact of a restriction on EU competitiveness, sustainability and waste streams as required by the European Commission's mandate.

On the basis of the information collected, the Dossier Submitter assessed different options for restricting various uses (as defined in Art. 3(24) of REACH) of the following Cr(VI) substances: chromium trioxide, acids generated from chromium trioxide and their oligomers including chromic and dichromic acid, sodium dichromate, potassium dichromate, ammonium dichromate, sodium chromate, potassium chromate, dichromit tris(chromate), strontium chromate, potassium hydroxyoctaoxodizincate dichromate(1-), pentazinc chromate octahydroxide, and barium chromate.

In the following, the Dossier Submitter will summarise the results of its investigation, develop different restriction options, and compare them against the criteria of Annex XV of REACH. Calculations, background information, justification for modelling assumption and exploration of alternative assumptions are relegated to a separate Appendix document.

### **1.2. Substance identity, physical and chemical properties**

#### **1.2.1. Identity of the substances**

Except for barium chromate (EC No 233-660-5), the substances in the scope of this Annex XV restriction proposal (listed in Table 1) have been identified as Substances of Very High Concern (SVHCs) and included in Annex XIV of REACH.

		•	•	•
EC No	CAS No	EC name	Entry No in Annex XIV	Date of inclusion
215-607-8	1333-82-0	Chromium trioxide	16	17 April 2013
231-801-5	7738-94-5	Acids generated from chromium	17	17 April 2013
236-881-5	13530-68-2	trioxide and their oligomers	17	17 April 2015
234-190-3	10588-01-9	Sodium dichromate	18	17 April 2013
231-906-6	7778-50-9	Potassium dichromate	19	17 April 2013
232-143-1	7789-09-5	Ammonium dichromate	20	17 April 2013
232-140-5	7789-00-6	Potassium chromate	21	17 April 2013
231-889-5	7775-11-3	Sodium chromate	22	17 April 2013
246-356-2	24613-89-6	Dichromium tris(chromate)	28	14 August 2014
232-142-6	7789-06-2	Strontium chromate	29	14 August 2014
234-329-8	11103-86-9	Potassium hydroxyoctaoxodizincate dichromate(1-)	30	14 August 2014
256-418-0	49663-84-5	Pentazinc chromate octahydroxide	31	14 August 2014
233-660-5	10294-40-3	Barium chromate	n/a	n/a

Table 1. Substances in the scope of this Annex XV restriction proposal

Table notes: in restriction proposals, different degrees of hydration of the substances identified are always included in the scope.

To avoid regrettable substitution, any salt with a different stoichiometry than the specific substances listed in Table 1 is also meant to be covered by the restriction. For example, the entry Pentazinc chromate octahydroxide  $Zn_5(CrO_4)(OH)_8$  is also meant to cover other substances that are currently not registered under REACH such as:

- Zinc chromate hydroxide Zn<sub>4</sub>(CrO<sub>4</sub>)(OH)<sub>6</sub>, CAS 12017-88-8
- Zinc chromate oxide Zn<sub>2</sub>(CrO<sub>4</sub>)O, hydrate (1:1), CAS 15930-94-6
- Zinc chromate ZnCrO<sub>4</sub>, EC 236-878-9, CAS 13530-65-9

### **1.2.2.** Physicochemical properties

The physicochemical properties of Cr(VI) substances included in Annex XIV of REACH are described in the supporting documents published by ECHA as part of their SVHC identification.<sup>3</sup> The physicochemical properties of barium chromate are summarised in Appendix B.1.1. Cr(VI) compounds are commonly found in solid form as salts, which are used as intermediates in the production of other, more specialised Cr(VI) and Cr(III) compounds. They can be dissolved in water to form aqueous solutions such as chromic and dichromic acids. They can also be included in specialised mixtures used as paints or primers. As Cr(VI) is a highly oxidised form of chromium, its compounds are highly reactive (strong oxidising agents), particularly in biological and environmental systems. Appendix B.1.1 also provides a grouping of the Cr(VI) compounds according to their solubility.

#### **1.2.3.** Justification for grouping

During the preparation, the Dossier Submitter reviewed the information submitted in various AfAs. It was noted that in some applications, different Cr(VI) substances were included for the same or very similar uses, suggesting that the intended technical function could be delivered by different Cr(VI) compounds. This is particularly the case for certain safety-related uses in the Aerospace and Defence (A&D) sector where:

• Chromium trioxide, sodium dichromate, potassium dichromate and dichromium

<sup>&</sup>lt;sup>3</sup> Relevant supporting documents are retrievable from <u>https://echa.europa.eu/candidate-list-table</u>.

tris(chromate) are used in chemical conversion coating

• Chromium trioxide, sodium dichromate, potassium dichromate and sodium chromate are used in anodising sealing

As part of the investigation, information was also reviewed from REACH registrations of Cr(VI) compounds not subject to authorisation. The Dossier Submitter noted that one of the registered uses of barium chromate (EC 233-660-5) is for coatings and sealants in A&D applications. As the existence of this use has been documented in a recent AfA and was confirmed in the CfEs, the Dossier Submitter considers that there is a potential for regrettable substitution if the Cr(VI) substances are not regulated together. In addition, there is evidence that several Cr(VI) substances are used at the same sites. As this has been confirmed in the CfEs, the Dossier Submitter considers that enforceability issues may arise if the Cr(VI) substances are not regulated together.

These conclusions do not hold for the lead chromates included in REACH Annex XIV (entries #10-12). These substances have a distinctly different use profile. In fact, lead chromate (EC 231-846-0) was used as an oxidizer in pyrotechnical devices (one authorisation granted until August 2024, no review report submitted to date), while lead sulfochromate yellow (EC 215-693-7) and lead chromate molybdate sulfate red (EC 235-759-9) were used as pigments, but do not have a valid authorisation. Since no other uses of these substances were identified in the EU, the Dossier Submitter concludes that the above uses should continue to be regulated under the REACH authorisation system.

In light of these considerations, the Dossier Submitter proposes to restrict the substances listed in Table 1 as well as any salt with a different stoichiometry and hydration degree.

#### **1.3. Substance manufacturing, trade and uses overview**

This section provides an overview of the manufacturing, trade and uses of the Cr(VI) substances in the scope of this Annex XV restriction report. It should be noted that there are several other Cr(VI) substances that are registered but currently not regulated under Annex XIV of REACH, including barium chromate. A short summary of these substances is provided in Appendix A.3, but the investigation by the Dossier Submitter suggests that, with the exception of barium chromate, they are unlikely to be used in large quantities in the EU, nor do they seem to be suitable substitutes for the Cr(VI) substances currently listed in Annex XIV of REACH.

#### 1.3.1. Manufacturing, imports and exports

Hexavalent chromium compounds are manufactured from chrome iron ore (chromite, FeCr<sub>2</sub>O<sub>4</sub>), which is mined predominantly in South Africa, Kazakhstan, India, Russia, Türkiye, Finland, and Iran (Koleli and Demir 2016). The ore is crushed and ground to a fine powder, roasted in the presence of soda ash (sodium carbonate, Na<sub>2</sub>CO<sub>3</sub>) and lime (calcium oxide, CaO) to form sodium chromate (Na<sub>2</sub>CrO<sub>4</sub>), and then oxidised to obtain sodium dichromate (Na<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>), which is the most accessible raw material both in terms of quantity and price.



Figure 1. Flowchart of the manufacturing of Cr(VI) and Cr(III) compounds

Source: Modified from <u>https://substances.ineris.fr/substance/1333-82-0#usage\_entity</u>.

Sodium dichromate is subsequently used directly or via different manufacturing steps as the starting material to produce other chromium compounds and pure chromium metal. Figure 1 provides an overview of the processes involved in the manufacturing of Cr(VI) and Cr(III) compounds. A more detailed description of the manufacturing processes can be found in Appendix A.1.

Table 3 provides a summary of the authorisation status of the substances in the scope of this Annex XV restriction proposal (with the exception of barium chromate) as well as their registration information. As can be seen, authorisations for  $CrO_3$  alone have generated close to 1 800 downstream user (DU) notifications in accordance with Art. 66 of REACH.<sup>4</sup> Some of the other Cr(VI) substances are also widely used across the EU. For example, DU notifications for entries #28-31 to Annex XIV (mostly used in the A&D sector) amount to more than 1 200 notifications.

As of December 2024, there were 20 active registrations for the manufacturing of Cr(VI) substances in the scope of this Annex XV restriction proposal. However, closer scrutiny of these registration files revealed that CrO<sub>3</sub> is only imported but not actually manufactured in the EU. For sodium dichromate, one registrant also stated that the substance is only imported. For strontium chromate and barium chromate, there is information of active manufacturing in the EU. In addition, there is evidence on the intermediate use of Cr(VI) substances in the manufacturing of Cr(III) compounds. The REACH Registration data permits calculating approximative volumes of individual substances used in the EU.<sup>5</sup> For the Cr(VI) substances included in Annex XIV, registered volumes have substantially declined since 2010, see Figure 2.

 $<sup>^4</sup>$  It should be noted that the CJEU in Case C-144/21 annulled an authorisation that sought to cover most of the DU notifications for CrO<sub>3</sub> listed in Table 2.

<sup>&</sup>lt;sup>5</sup> Consistent with Eurostat conventions, the Dossier Submitter defines *use volume* as substance quantity manufactured in the EU + substance quantity imported – substance quantity exported.



**Figure 2. Trend in registered tonnages of Cr(VI) substances listed in Annex XIV** *Source: ECHA Registration data, accessed 12-12-2023.* 

For all substances listed in Table 3, registered use volumes in 2022 were down to 60 % of their 2010 quantities. The decline in  $CrO_3$  use was even more pronounced. In fact, its 2022 volume was about half of its 2010 volume. This suggests that companies have found ways to significantly cut their use of Cr(VI) substances by either reducing the volumes used or by ceasing these uses altogether. The latter was achieved by either switching to alternatives or by closing operations in the EU. Although it is difficult to establish causality on the basis of the available data, the evidence suggests that the REACH authorisation requirements have contributed to the phase out of Cr(VI) substances in uses where they were substitutable.

There is no substance-specific information on imports, exports and placing on the market available in Eurostat's Comext database.<sup>6</sup> However, there is tonnage information available on chromium ores and concentrates (PRCCODE 07291910) manufactured in, imported to and exported out of the EU. This information is summarised in Table 2. In 2022, the tonnage of chromium ores and concentrates used in the EU amounted to 127 226 metric tons, which is roughly 6.5 times more than the registered volumes of Cr(VI) substances listed in Annex XIV of REACH. Imports of chromium ores and concentrates are almost three times larger than exports and manufacturing, highlighting the EU market's dependence on raw material imports for uses relevant to this restriction proposal.

Chromium ores and concentrates (PRCCODE 07291910)	Tonnage		
Toppage manufactured	16 000		

Table 2 Tonnage of chromium ores and concentrates used in the EU (2022)

	10 000
Tonnage imported	146 886
Tonnage exported	35 650
Tonnage used (i.e. manufactured + imported – exported)	127 226

Source: Eurostat Comext, accessed 09-02-2024.

<sup>&</sup>lt;sup>6</sup> <u>https://ec.europa.eu/eurostat/comext/newxtweb</u>.

EC No	CAS No	EC name	Tonnage band	Active registrations [1]	Authorised uses [2]	Downstream uses [3]
215-607-8	1333-82-0	Chromium trioxide	1 000-10 000	33 (7)	59	1 782
231-801-5	7738-94-5	Acids generated from chromium	n/a	0	1	0
236-881-5	13530-68-2	trioxide and their oligomers	ny d	U	1	0
			10 000-			
234-190-3	10588-01-9	Sodium dichromate	100 000	22 (1)	28	12
231-906-6	7778-50-9	Potassium dichromate	10-100	12 (1)	9	115
232-143-1	7789-09-5	Ammonium dichromate	n/a	1	4	0
232-140-5	7789-00-6	Potassium chromate	1-10	2 (1)	2	1
231-889-5	7775-11-3	Sodium chromate	1-10	2 (1)	7	194
246-356-2	24613-89-6	Dichromium tris(chromate)	10-100	6 (1)	4	304
232-142-6	7789-06-2	Strontium chromate	1 000-10 000	4 (2)	3	626
234-329-8	11103-86-9	Potassium hydroxyoctaoxodizincate dichromate(1-)	10-100	1 (1)	2	246
256-418-0	49663-84-5	Pentazinc chromate octahydroxide	10-100	2 (2)	4	91
233-660-5	10294-40-3	Barium chromate	10-100	4 (3)	n/a	n/a

Table 3. REACH registration and authorisation status of Cr(VI) substances

#### Source: ECHA CHEM, accessed 01-12-2024.

Table notes: <sup>[1]</sup> Brackets include the number of active registrations for manufacturing in the EU; <sup>[2]</sup> These are uses for which companies have an authorisation themselves. They also include authorisations held by companies whose applications cover DUs, as the same uses are permitted to take place at the authorisation holders' sites; <sup>[3]</sup> The number of DU notifications is counted as follows: each use per site is counted as a separate notification, and the total number of active notifications is reported. So, if there are four uses of a substance at one site, and three (same or different) uses at another site, this is counted as seven notifications; if the same use is notified under different authorisation numbers, it is counted only once. Two notifications for the same substance are considered to be the same if the use name/titles are exactly the same; uses for which the authorisation period has expired and no review report has been submitted are deducted from the counts.

#### 1.3.2. Use overview and substance functions

Cr(VI) substances in the scope of this Annex XV restriction proposal are used widely and in a broad range of utilisations to confer several properties to treated goods and articles. In the following, the Dossier Submitter provides an overview on the use categorisation, the technical function(s) of the substances in scope within each of the use categories as well as the main industry sectors in which these uses take place. Information on these use categories and the sectors in which they take place is compiled from various sources, including REACH registration data, AfAs of various uses of Cr(VI) substances, DU notification data as per Art. 66 of REACH, and information gathered in two targeted CfEs.

Short name	Use category
UC 1   Formulation of mixtures	Formulation of chromic acids and speciality mixtures made from various $Cr(VI)$ substances, which are subsequently used in the other use categories
UC 2   Electroplating on plastic substrate	Electroplating on plastic substrate providing both functional and aesthetic properties to plated parts
UC 3   Electroplating on metal substrate	Electroplating on metal substrate providing both functional and aesthetic properties to plated parts: (a) standard electroplating refers to electroplating shops that plate a multitude of objects for other business sectors; (b) site-critical electroplating refers to speciality electroplating operations near airports, freight ports, steel mills, etc. where electroplating needs to take place onsite
UC 4   Use of primers and other slurries	Use of primers and slurry coating operations (by pen applications, painting, spraying, brushing), primarily in the A&D sector
UC 5   Other surface treatments	Other surface treatments, incl. passivation (anodizing, conversion coating), etching, cleansing and sealing, which require no or low current
UC 6   Functional additives and process aids	Speciality uses as functional additive or as process aid

#### Approach to categorisation

The Dossier Submitter considered different ways to group the diverse uses of the Cr(VI) substances in the scope of this Annex XV restriction proposal in a meaningful way. Early in the investigation, the Dossier Submitter decided to limit the granularity of the use categories in order to keep the risk and impact assessment tractable. This approach has several practical advantages: (1) the users of the Cr(VI) substances in scope have no problem selecting the appropriate category for their use(s) and providing information that is pertinent, (2) the sample sizes per use category are large enough to perform a meaningful analysis, and (3) the legal definition of the use categories will minimise enforceability issues that may arise from a finer granularity.

With this in mind, the Dossier Submitter settled on the six use categories summarised in Table 4, which were grouped primarily on a logic of substitutability. Substitutability here refers to the availability of alternatives that provide similar functional properties as the Cr(VI) substances in scope. This does, however, not imply that such alternatives would be desirable substitutes in terms of their technical feasibility or economic viability because specific functional requirements may not be met, the investments needed for an alternative technology may not be affordable by companies currently using Cr(VI)-based technologies, or there simply is no market for products that require re-specifications by business-to-business customers.

As the functional requirements are often use-specific, this grouping logic will partly overlap with other logics, such as an exposure-based logic. For example, worker exposure and environmental releases of Cr(VI) from formulation activities is determined by very different tasks and processes than that of electroplating. However, a grouping based on exposure, e.g. per exposure band, would have impeded the analysis of compliance costs and posed enforceability issues as it would have meant that companies with different exposure conditions operating in the same sectors would have become subject to different regulatory requirements. For these reasons, the Dossier Submitter discarded an exposure-based grouping approach.

Lastly, the Dossier Submitter did not consider in its categorisation approach the societal desirability of using SVHCs to achieve decorative properties, or the ongoing substitution activities by individual companies or subsectors.

#### Use categories

Since 2015, several hundred AfAs have been submitted for different uses of Cr(VI) substances. For analytical reasons, the Dossier Submitter groups these uses into six use categories (UCs) based on their substitutability, i.e. based on an assessment of the availability and technical readiness of alternatives for specific uses of Cr(VI) substances. The details of this assessment are provided in Appendices E.2 and E.3. Below, the Dossier Submitter provides a summary of the broad information on use (BIU) submitted as part of various AfAs for uses belonging to each use category. Some of these uses, e.g. etching and electroplating, may take place at the same sites, while others (especially those listed under UC 6) are specialised uses at dedicated sites. A mapping of existing AfAs to the different use categories is provided in Appendix A.2.1.

#### UC 1 – Formulation of mixtures

Manufacturing of Cr(VI) substances is outside the scope of this Annex XV restriction proposal, as it takes place mainly outside the EU (although some of the substances listed in Table 1 are also manufactured in the EU). The raw substances are imported and subsequently used to formulate mixtures of Cr(VI) substances in order to enable various surface treatment processes. When such mixtures are used in these processes, the Cr(VI) substances in the mixtures provide a number of key functions including corrosion protection, chemical resistance, adhesion promotion, layer thickness, wear resistance, hardness and temperature resistance. *Key functions achieved: neither the Cr(VI) salts nor their mixtures have a specific function at the formulation stage.* 

#### UC 2 – Electroplating on plastic substrate

Electroplating on plastic substrate refers to the deposition of a chromium layer on the surface of plastic parts via electroplating which is achieved by an etching step in which the substrate is pre-treated and by the subsequent immersion of parts under electric current in specific treatment baths. The plating conveys desirable functional and aesthetic properties to the coated surface. At the time of writing, ECHA had received 11 AfAs falling under UC 2, i.e. their use name (or the submitted broad information on use) indicates that the substrate coated is plastic. Another 13 AfAs cover electroplating of metal or plastic substrate and therefore belong to both UCs 2 and 3. In all cases, the applicant indicated that, in addition to providing functional properties to the parts plated, the use has a decorative character. Another three AfAs cover various surface treatments falling under UCs 2, 3 and 5; in these cases, the decorative character is specifically mentioned for UCs 2 and 3. *Key functions achieved: wear resistance, layer thickness, adhesion of coating on substrate, effect on surface morphology (flexibility to coat complex geometries), aesthetic aspects such as shininess, colour stability, 'touch and feel', etc.* 

#### UC 3 – Electroplating on metal substrate

Electroplating on metal substrate refers to the deposition of a chromium layer on the surface of metal parts via electroplating, which is achieved by immersion of components under electric current in specific treatment baths. The plating conveys desirable functional and aesthetic properties to the coated surface. In several sectors (railways, waterways, heavy duty vehicles, A&D), electroplating with CrO<sub>3</sub> is undertaken in both the production of components and final products as well as in maintenance, repair, and overhaul (MRO)

processes. At the time of writing, ECHA had received 120 AfAs for Cr(VI) substances falling under UC 3, i.e. their use name (or BIU) indicates that the substrate coated is metal. As mentioned in the description of UC 2, another 13 AfAs cover electroplating of metal or plastic substrate and therefore belong to both UCs 2 and 3, and another three AfAs cover various surface treatments falling under UCs 2, 3 and 5. 44 of 136 applications in UC 3 (32 %) indicated that the use has a decorative character in addition to providing functional properties. *Key functions achieved: corrosion resistance, hardness, tribological properties (reduced friction), layer thickness, effect on surface morphology (flexibility to coat/treat complex geometries), aesthetic aspects such as shininess, colour stability, etc.* 

#### UC 4 – Use of primers and other slurries

Slurry coating with CrO<sub>3</sub> is used in both the production of components and in MRO processes. The term 'slurry coating' covers two types of coatings: sacrificial coatings and high temperature (diffusion) coatings. Both types of slurry coatings are chemical, non-electrolytical processes applied by spraying or brushing in industrial settings. The resulting coated articles may contain Cr(VI) in the coating layer. *Key functions achieved: corrosion resistance (incl. "self-healing"), thermal resistance, cyclic heat-corrosion resistance, resistance to humidity and hot water, thermal shock resistance, chemical resistance, erosion resistance and smooth surface finish, adhesion promotion.* 

In addition, primers and speciality coatings containing strontium chromate, pentazinc chromate octahydroxide, potassium hydroxyoctaoxodizincate dichromate and barium chromate are used in the rehaul of aerospace and aeronautical parts (incl. airplanes, helicopters, spacecraft, satellites, etc.) as well as for the maintenance of aerospace infrastructure. *Key functions achieved: corrosion resistance, active corrosion inhibition, adhesion of paint/compatibility with binder system, layer thickness, chemical resistance, temperature resistance (thermal shock resistance), compatibility with substrate or processing temperatures.* 

#### UC 5 – Other surface treatments

Passivation of tin-plated steel (ETP) and electrolytic steel coating (ECCS) using CrO<sub>3</sub> or sodium dichromate are performed at multiple sites across the EU. The treated steel sheets are primarily used as food contact material. During these processes, the surface of steel is covered with an inert layer of metallic chromium and/or Cr(III) oxide. Commonly, ETP and ECCS processes are highly automated and partially contained. *Key functions achieved: oxide growth, sulphide staining and temperature resistance; lacquer adhesion; compatibility with can-making process; compliance with food contact material regulations.* 

Passivation of (non-aluminium) metallic coatings using CrO<sub>3</sub>, sodium dichromate or potassium dichromate is used in both the production of parts and MRO processes. Passivation takes place in industrial settings. When the passivation process is applied to a metallic coating it produces a surface layer containing a compound of the substrate metal and elements from the processing solution. To this end, a Cr(VI) containing solution is applied on the non-aluminium coating forming a passive protective layer on the surface of the non-aluminium metallic coating. The level of protection is proportional to the thickness of the passivation layer. Passivation of non-aluminium metallic coatings is a chemical process which is in most cases carried out by immersion of parts in treatment baths. In some cases, when small parts need touching up, passivation of non-aluminium metallic coatings is carried out by applying the solution with a brush or swab. Passivation may also be used to brighten plated surfaces discoloured by thermal treatment to enhance inspections. *Key functions achieved: corrosion resistance (and active corrosion inhibition), chemical resistance, adhesion to subsequent layer, layer thickness, temperature resistance, electrical resistivity, pre-treatment compatibility.* 

Passivation of stainless steel using  $CrO_3$  or sodium dichromate is undertaken in both the production of parts and MRO processes. Passivation of stainless steel takes place in

industrial settings and involves the removal of embedded iron/steel particles from the substrate, and formation of protective chromium oxide on the surface. It is a chemical, non-electrolytic process which, in most cases, is carried out by immersion of parts in treatment baths. In some cases, when small parts need touching up, passivation of stainless steel is carried out by applying the solution with a brush or pad. The finished products are free of Cr(VI) residues. *Key functions achieved: corrosion resistance, embrittlement/heat treatment, adhesion to subsequent layer. Alternatives must comply with any heat treatment process required to purge hydrogen and must not affect fatigue strength and chemical resistance. In addition, chemical passivation may also be used to produce decorative colours, e.g. for stainless steel plates.* 

Anodising is an electrolytic passivation process and one of the most common surface treatments of aluminium.<sup>7</sup> Anodising is widely undertaken (e.g. in the A&D sector) in both the production of parts and MRO processes. CrO<sub>3</sub> is a key substance in chromic acid anodising (CAA)—an electrolytic oxidation process where the surface of a metal is converted to an oxide, which has desirable functional properties. CAA creates a hard insulating metal oxide layer on the surface of treated parts. The anodising process is typically performed in an immersion bath. Local application (sometimes referred to as brush anodising) is possible using an anodising electrode. *Key functions achieved: wear resistance, corrosion resistance, chemical resistance, adhesion promotion (to subsequent coatings or paint), layer thickness.* 

Anodise sealing with CrO<sub>3</sub>, potassium dichromate, sodium chromate or sodium dichromate is used in both the production of parts and in MRO processes. Anodise sealing is the final step in the anodising process. After anodising, the surfaces of substrates are porous which impacts corrosion resistance. Anodise sealing closes the micropores to improve the resistance of the anodised surface. The process of is carried out by immersing anodised parts in treatment baths. *Key functions achieved: corrosion resistance, active corrosion inhibition, layer thickness, chemical resistance, adhesion promotion (to subsequent layer), positive impact on fatigue life.* 

Chemical (chromate) conversion coating (CCC, aka "chromating") with CrO<sub>3</sub>, sodium dichromate, potassium dichromate or dichromium tris(chromate) is widely done (e.g. in the A&D sector) both in the production of parts and in MRO processes. CCC is a chemical process that removes the native oxide and forms a film containing soluble Cr(VI) as well as salts of the base metal that has desirable properties. CCC is carried out in industrial settings by immersing a metallic part in an aqueous solution containing dissolved chromates together with acid compounds such as sulphuric acid or nitric acid; filling cavities; or as a local treatment on small, localised areas, or for touch-ups/repairs of a metallic surface. Local applications are made by brush, swab, wipe, syringe, or pen. The resulting layer may contain Cr(VI). *Key functions achieved: corrosion resistance including active corrosion inhibition (aka "self-healing"), chemical resistance, adhesion promotion, temperature resistance, layer thickness, electrical resistivity, pre-treatment compatibility, visibility of the coating, impact on fatigue life.* 

Chromate rinsing after phosphating with CrO<sub>3</sub> is used in both the production of parts and in MRO processes. Chromate rinsing after phosphating is a passivation post-treatment process carried out after phosphate conversion coating (phosphating) carried out in industrial settings. It is a chemical, non-electrolytical process which is carried out by immersion of parts in treatment baths. The chromate rinsing after phosphating fulfils two requirements: (i) removal of "drag-out," which comprises liquid and solid residuals from preceding treatment processes which adhere to the substrate. Removal of these residuals ensures they do not deteriorate the substrate; and (ii) passivation/sealing of the

<sup>&</sup>lt;sup>7</sup> Many metals may be electrolytically oxidized or anodised, but in industrial practice the procedure is usually limited to aluminium, magnesium, and titanium (Durney 2000).

phosphate conversion coated surface, carried out at between 70-80 °C, which enhances corrosion resistance. The resulting layer may contain Cr(VI). *Key functions achieved: corrosion inhibition incl. active corrosion inhibition ("self-healing"), adhesion promotion. Additionally, rinsing with Cr(VI) containing solution is also used in the post-treatment (reactive rinse) of shock absorbers for automotive vehicles. In this case, no active corrosion inhibition is provided.* 

Stripping is the process used for the removal of a coating from a base metal or undercoat. The stripping of inorganic finishing with CrO<sub>3</sub> or sodium dichromate is used in both the production of parts and in MRO processes. The stripping of anodised layers, conversion coatings or electroplated surfaces with CrO<sub>3</sub> or sodium dichromate-based solutions removes the surface as part of MRO work or for reworking the surface (when the latter is non-conforming or must be removed for quality testing). Stripping with CrO<sub>3</sub> can also be used as part of a main treatment in order to remove copper plating used to mask new parts in the carburising process. *Key functions achieved: ensure negligible or no effect on the underlying substrate whilst supporting the efficient removal of the inorganic finish.* 

Machining (fettling, drilling, milling, riveting, edging, abrading, grinding or sanding) of Cr(VI)-containing coatings (also known as "self-healing" or "sacrificial" coatings) is a common MRO activity, primarily done in the A&D sector. The purpose of these operations is to prepare aircraft surfaces for repainting to ensure that the new layers of primers and paints adhere properly to the surface and provide optimal protection against environmental elements. *Key functions achieved: removing old coatings, smoothing surfaces, cleaning and evening out edges and joints.* 

Pre-treatments using CrO<sub>3</sub> or sodium dichromate are used in both the production of parts and in MRO processes. These pre-treatment processes are categorised as deoxidation, desmutting and pickling/etching (scale conditioner) where they all serve the same purpose of preparing the surface for subsequent treatment processes. Pre-treatments can be either non-electrolytic, or electrolytic processes using a solution containing Cr(VI) together with acid compounds. Application is typically by immersion. *Key functions achieved: corrosion resistance, adhesion of subsequent coatings (including structural bonding), surface preparation prior to further processing, removal of contaminants/complexes after etching processes, surface roughness modification (removal of mechanically deformed layers/oxides/other compounds from the substrate), selective removal of material to reveal the surface (or imperfections in the material) or to improve surface properties.* 

Surface treatment using CrO<sub>3</sub> to provide an insulation coating for the manufacture of grainoriented electrical steel used in magnetic circuits of electric devices (in particular magnetic cores of high-performance transformers). The coating is typically applied by rollers followed by curing using high temperature. *Key functions achieved: electrical surface resistivity, resistance to humidity and transformer fluids, resistance to tensile load (high tensile stress), resistance to high temperatures, low coefficient of thermal expansion, coating adhesion, machinability, optical surface properties.* 

#### UC 6 – Speciality uses as functional additive or as process aid

Uses as functional additive/processing aid have been applied for by several individual companies. Considering the AfA dossiers in the opinion making phase as well as the authorisations valid at the time of writing and information received during the calls for evidence, the following uses belong to this category:

- Use of potassium chromate or sodium chromate as alkali metal dispenser in the production of photocathodes
- Use of sodium chromate or sodium dichromate as corrosion or scaling inhibitor in cooling or heating systems for various applications

- Use of chromium trioxide or sodium dichromate as catalysts or processing aids in the electrolytic manufacture of different chemicals or ore processing applications
- Use of ammonium dichromate as a photosensitizer in UV lithography process to manufacture micro-structured components (filters, sieves, grids, etc.)
- Use of potassium dichromate as a colour indicator in single-use chemical breathalysers
- Use of barium chromate in pyrotechnic compositions for the defence sector

The evaluation of the chemical safety reports provided as part of the corresponding AfAs suggests that these uses usually result in worker exposures well below 0.5  $\mu$ g Cr(VI)/m<sup>3</sup> TWA. *Key functions achieved: various.* 

#### Main use sectors

Even though registered use volumes have dropped significantly since 2010 (see Figure 2), Cr(VI) substances are widely used across different industry sectors in the EU. Based on Downstream User (DU) notifications for authorisations of Cr(VI) substances, the number of EU-based companies using one or multiple Cr(VI) substances is in the ballpark of 2 000. Many of the companies have reported more than one use, bringing the total number of uses notified close to 4 000.<sup>8</sup> A substantial share of these companies are SMEs which operate throughout the EU and provide surface treatment services to actors in the main use sectors listed below. These so-called 'job platers' often coat 100s or 1 000s of different parts requiring ad hoc process modifications to adapt to the material and geometry of the substrate as well as the performance requirements on the final product.

#### Chemicals

The chemicals sector formulates both proprietary chromium-based mixtures using Cr(VI) substances in combination with other substances or compounds as well as chromic and dichromic acids for use in electroplating baths. The formulation of these mixtures is generally a batch process producing large quantities. While the manufacturing of Cr(VI) substances is outside the scope of this Annex XV restriction proposal, it should be noted that there are some active registrations for the manufacturing of chromium salts in the EU (see Table 3), which is not itself subject to the REACH authorisation obligations.

#### Automotive

The automotive sector uses electroplating technologies – predominantly Cr(VI)-based but in recent years increasingly Cr(III)-based – to deposit metallic chromium layers on metal and plastic parts (see Figure 3 for recent market trends in plating on plastics for the automotive sector). For chrome plating on metal substrate, the thickness of the chromium layer is 2-5  $\mu$ m depending on the intended function; for chrome plating on plastic substrate the typical thickness is 0.2-2  $\mu$ m. Chrome plating in the automotive sector typically involves recirculation of the treatment solutions in a closed loop, high throughput of parts and low process temperatures. It may require pre-treatment processes (etching, stripping, cleaning). The resulting crack-free or micro-cracked chrome coating provides a range of desired properties to the finished article as it enhances wear resistance, hardness, corrosion resistance, look and feel, and tribological properties. Example metal parts that are chrome plated include engine parts; transmission, steering, differential components; shock absorbers, piston rings and rods; fuel injection parts, engine valves, and cylinder heads; belt tongues. Example plastic parts that are chrome plated include brand labels, rims, front skirts, rear view mirrors, radiator grills, gear lever knobs, trim strips, frames.

<sup>&</sup>lt;sup>8</sup> For details, see <u>Downstream uses covered by granted authorisations - ECHA (europa.eu)</u>.



Figure 3. Market trends in plating on plastics for the automotive sector

Source: FGK (German plastic plating industry association), provided by email on 29-11-2024.

#### Household and sanitary appliances

The household and sanitary sector uses chrome plating on plastic, metal, and composite surfaces to deposit a metallic chromium layer with a thickness of 0.2-2.0  $\mu$ m. (In certain utilisations such as "black chrome" plating deposits are up to 5  $\mu$ m thick.) Depending on the surface, specific pre-treatment processes (e.g., etching) may be needed. As the throughput of parts in these sectors is typically high, operations are often partly or fully automated. The resulting metallic chrome coating provides a range of desired properties to the finished article incl. optics and haptics, but also functionalities such as corrosion resistance and durability. Examples of sector-specific chrome coating applications include taps, shower heads, towel rails, mirror frames, parts of kitchen and household machines, chairs and lamp posts, and kitchen furniture.

#### Transportation

The transportation sector (airway, seaway, railway) uses various Cr(VI) substances to coat metal surfaces, thereby delivering a barrier film or layer of complex chromium compounds (see Table 5 for a detailed break up of utilisations and use volumes). Pre-treatment steps applied in these activities include chemical polishing, stripping, deoxidizing, pickling and etching of metals. Main treatment includes processes such as functional chrome plating, conversion coating, passivation and anodizing, and other surface treatments such as use of primers and other slurries(incl. spraying). Post-treatment steps include rinsing, staining and sealing for final surface protection as well as machining operations (fettling, drilling, riveting, edging, abrading, or sanding) during which exposure to Cr(VI) dust may occur. The resulting chromium layer provides a range of desired properties such as corrosion

protection and may provide a base for subsequent painting or bonding. Parts that are typically treated include landing gear and control components; wheel axles, pins, rods of hydraulic actuators; engine parts; wear pads, latches, and bushings; bearing systems; suspension splices; access and freight doors; lightning strike shielding; gallery and lavatory parts; pyrotechnic equipment; interstage skirts; fuselage; cockpit frames; engine intake areas; rotor assembly.

#### Packaging

To supply the packaging industry, steel producers use CrO<sub>3</sub> or sodium dichromate solutions to convert the surface of tin-plated or electrolytically coated steel. This is done mostly in automated passivation processes in which steel sheets are dipped/immersed in a tank or through a series of baths containing solutions in closed or open systems. The result of the surface treatment process is a barrier film which provides a range of desired properties (corrosion protection, adhesive base for subsequent lacquer application, sulphide staining resistance, machinability, and other characteristics required by food safety regulations). Examples of sector specific products include food and beverage cans, cans for oils, crown corks and caps. Non-food examples include twist-off caps and aerosol bottoms and tops.

#### Steel

In the steel industry functional chrome plating with  $CrO_3$  is used to renew equipment such as rollers and rolling mill bearings and forging dies. As these parts are large and heavy, operations tend to take place close to the end use of the equipment and can in many cases be deemed site-critical (since it is economically not meaningful to transport heavy rollers over a longer distance). As for other sectors using functional chrome plating, the process involves depositing a chromium layer on the surface of the part to be coated. However, the plating process is less often automated and usually involves manual operations. Moreover, the coating times in the electroplating bath tend to be longer.

#### Printing

In the printing industry, functional chrome plating with  $CrO_3$  is used to manufacture printing equipment such as mandrels; cylinder jackets; and rotogravure plates / rolls. Often these parts are large and heavy and therefore operations tend to take place close to the end use of the equipment (i.e. plating activities are site-critical). As for other sectors using functional chrome plating the process involves depositing a chromium layer on the surface of the part to be coated. However, the plating process is less often automated and usually involves manual operations.

#### Economic importance of affected industry sectors

The overview of use sectors suggests that Cr(VI) substances are widely used and play a crucial role in the production of goods and the provision of services across the EU. The industrial sectors using Cr(VI) substances generate substantial value added, underscoring their importance to the EU economy. Based on information provided in AfAs for Cr(VI) substance uses and received in the CfEs (see Appendix G), one may assume that:

- the average company/company division using Cr(VI) substances has ~20 directly exposed workers (i.e. workers handling the substances)
- depending on the use category, a typical worker contributes €50k-500k to the annual turnover of their company
- the average profit margin of a company using Cr(VI) substances is ~10 % and the corresponding surplus is typically in the range of €100-500k per year before taxes
- given these figures, the average worker exposed to Cr(VI) generates a surplus in the order of €10k-50k per year.

Applying these assumptions to the ~2 000 companies that currently use Cr(VI) substances in the EU and that have applied for an authorisation or notified a use under a granted authorisation suggests a direct economic surplus of the order of €2bn per year. Considering that ~20 % (corresponding to ~€3.4tn in 2023 according to Eurostat) of the EU's GDP is generated by the manufacturing industry, and recognising the widespread use of Cr(VI) treated parts in all kinds of machinery, the *total* economic value added of Cr(VI) substance uses in the EU goes far beyond the direct surplus and is likely to be one or even two orders of magnitude higher. This is because the non-availability of Cr(VI) substances would have serious knock-on effects in industry sectors such as aviation, automotive, mechanical engineering, steel, etc. which could not – or only at very costs – be mitigated by increased imports from outside the EU.

Uses of Cr(VI) substances	Chromium trioxide (#16-17)	Sodium dichromate (#18)	Potassium dichromate (#19)	Sodium chromate (#22)	Dichromium tris(chromate) (#28)	Strontium chromate (#29)	Pentazinc chromate octahydroxid (#30)	Potassium hydroxy- octaoxodizincate dichromate (#31)
Anodising	<125 tpa							
Anodise sealing	<2.5 tpa	<10 tpa	<12 tpa	<2 tpa				
Passivation of (non-Al) metallic coatings	<15 tpa	<50 tpa	<12 tpa					
Passivation of stainless steel	<8.4 tpa	<17.5 tpa						
Electroplating	<500 tpa							
Slurry coating	<3.5 tpa							
Conversion coating	<125 tpa	<40 tpa	<18 tpa		<3 tpa			
Chromate rinsing after phosphating	<0.6 tpa							
Inorganic finish stripping	<50 tpa	<1 tpa						
Pre-treatments	<25 tpa	<45 tpa						
Primers and speciality coatings						<300 tpa	<1.5 tpa	<15 tpa
Formulation	<600 tpa	<100 tpa	<50 tpa	<2 tpa	<3 tpa	<300 tpa	<1.5 tpa	<15 tpa

#### Table 5. Overview of Cr(VI) uses applied for authorisation by the EU A&D sector

Source: compiled based on information from recent AfAs.

#### 1.3.3. Waste management

The use of Cr(VI) substances generates liquid and solid waste, requiring specific handling, classification and treatment to mitigate health and environmental risks.

#### Wastewater

The use of Cr(VI) substances generates Cr(VI)-containing wastewater, which, if released into the aquatic environment poses risks to humans via contaminated drinking water. Cr(VI)-containing wastewater is generated from replacing bath solutions, rinsing tanks and manual rinsing operations, cleaning of workplace and equipment (e.g., baths, spray booths, touch-up work benches, empty chemical containers, brushes, spray guns), liquids from secondary containment pits, wash water from wet scrubbers, and liquid hazardous waste from laboratory samples. Based on information from AfAs, Cr(VI)-containing wastewater is typically collected and undergoes one or more of the following steps:<sup>9</sup>

- Disposal as hazardous waste by an external waste management company<sup>10</sup>
- Recycling and evaporation in an on-site evaporation system where the residue is then treated as hazardous solid or liquid waste<sup>11</sup>
- Treatment in a reduction facility (typically on-site), where Cr(VI) is reduced to Cr(III) by addition of a reducing agent

The effectiveness of the reduction treatment process can be established by performing control measurements of the residual Cr(VI) content before treated water is discharged to the public sewage system. If the concentration exceeds the permitting limit, the reductive treatment has to be repeated until compliance is achieved. To that end, companies regularly monitor Cr(VI) emissions to wastewater to confirm the effectiveness of the RMMs in place and to identify the need for further measures to reduce Cr(VI) emissions.

#### Solid waste

Cr(VI)-containing solid waste may arise in the form of sludge from the treatment and rinsing baths or from spray booths, filter cake from the filter press (containing Cr(III)), solid residue from the evaporation system for wastewater, and sludge from the reduction/neutralisation process. Other Cr(VI)-contaminated solid waste may include empty chemical containers, filters, used material for touch-up applications (e.g., brushes, swabs, pen sticks), waste from cleaning activities, abrasive material from sanding, contaminated equipment (e.g., heaters, filters, pumps), disposable/ contaminated PPE (e.g., gloves, coveralls, aprons). The information available to the Dossier Submitter suggests that solid waste is typically collected in hazardous waste containers and disposed of by certified external waste management companies. Articles electroplated with Cr(VI) typically do not contain Cr(VI), which is reduced to metallic chromium deposited on the surface of articles. Other types of surface treatment such as "self-healing" coatings do contain Cr(VI) and may contribute to Cr(VI)-contaminated solid waste (e.g. dust from sanding treated parts during MRO activities).<sup>12</sup>

<sup>&</sup>lt;sup>9</sup> Less frequently used systems for treating Cr(VI)-containing wastewater include ion exchange, activated carbon and adsorption followed by filtration.

<sup>&</sup>lt;sup>10</sup> The BREF document for Waste Treatment (<u>EU-BRITE</u>, 2018) indicates that the most common treatments for such hazardous waste are reduction, neutralisation, precipitation and filtration.

<sup>&</sup>lt;sup>11</sup> Closed-loop systems whereby the water is re-circulated into the process cycle and no wastewater releases occur are widely reported amongst companies performing Cr(VI) surface treatments.

 $<sup>^{12}</sup>$  Information provided in AfA dossiers indicate that primers used for such self-healing (or sacrificial) coatings contain <0.01 - 10 % Cr(VI) (w/w).

## 1.4. Risk assessment

### 1.4.1. Classification and Labelling

With the exception of barium chromate, all substances in the scope of this Annex XV restriction proposal have a harmonised classification according to Annex VI of the CLP Regulation, either as a specific entry or under a group entry (see Table 6). In 2020, the Netherlands submitted a proposal for harmonised classification for barium chromate. RAC adopted its opinion on this proposal in 2023 proposing a harmonised classification for Carc. 1B, H350.<sup>13</sup> As the decision to include barium chromate in Annex VI to the CLP Regulation is pending, Table 7 reports the notifications to the ECHA C&L inventory.

### 1.4.2. Hazard assessment

### 1.4.3. Scope

Carcinogenicity is the main hazard associated with exposure to Cr(VI) substances and the reason they are identified as SVHCs. In 2013, ECHA's Committee for Risk Assessment (RAC) established reference dose-response relationships for inhalation exposure to Cr(VI) and lung cancer as well as for oral exposure to Cr(VI) and gastrointestinal cancer.<sup>14</sup> Subsequently, these relationships have been widely used as a reference in AfAs. Similarly, the Dossier Submitter's main focus of the hazard assessment presented in this restriction proposal is on the carcinogenic properties of Cr(VI). While other endpoints might be of relevance, the Dossier Submitter notes that measures that protect against cancer will also be effective against other hazard properties of these substances.

### 1.4.4. Carcinogenic properties

The scientific evidence supporting the carcinogenic properties of Cr(VI) compounds was reviewed in a report by the ETeSS consortium (Expert Team providing scientific support for ECHA)<sup>15</sup> accompanying the abovementioned RAC document. The derived dose-response relationships are summarised below. The Dossier Submitter notes that since RAC's assessment of the reference dose-response relationships for lung and gastrointestinal cancer, the scientific evidence on Cr(VI) cancer potency has advanced (see Appendix B.4.8 for a summary of recent advancements). Irrespective of potency, the driving entity of carcinogenicity of these compounds is the Cr(VI) ion, which is released when the substances solubilise and dissociate. Exposure to Cr(VI) ions may cause lung tumours via inhalation and tumours of the gastrointestinal tract via the oral route. These are local, site-of-contact tumours. There is no evidence that Cr(VI) exposure causes tumours elsewhere in the body.

#### **Dose-response relationships**

Dose-response relationships for lung cancer both in workers and the general public were derived based on (i) human epidemiology data for the respirable particulate fraction, and (ii) linear extrapolation using the meta-analysis by Seidler, Jähnichen et al. (2013) of previous studies on the Baltimore cohort (Park, Bena et al. 2004) and the Painesville cohort (Crump, Crump et al. 2003, Luippold, Mundt et al. 2003). The derivation assumed a background lifetime lung cancer risk of 48 per 1 000 for the EU male population and an 89-year life expectancy, resulting in the following dose-response relationships.

<sup>&</sup>lt;sup>13</sup> <u>Registry of CLH intentions until outcome - ECHA</u>.

<sup>&</sup>lt;sup>14</sup> <u>RAC/27/2013/06 Rev.1</u>.

<sup>&</sup>lt;sup>15</sup> <u>ECHA/2011/01 – SR-11</u>.

EC No	CAS No	EC name	Index number	Harmonised classification
215-607-8	1333-82-0	Chromium trioxide	024-001-00-0	Ox. Sol. 1 (H271); <b>Carc. 1A</b> (H350); <b>Muta. 1B</b> (H340); <b>Repr. 2</b> (H361f ***); Acute Tox. 2 * (H330); Acute Tox. 3 * (H311); Acute Tox. 3 * H311); STOT RE 1 (H372); Skin Corr. 1A (H314); Resp. Sens. 1 (H317); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); STOT SE 3 (H335), C ≥ 1 %
234-190-3	10588-01-9	Sodium dichromate	024-004-00-7	Ox. Sol. 2 (H272); <b>Carc. 1B</b> (H350); <b>Muta. 1B</b> (H340); <b>Repr. 1B</b> (H360FD); Acute Tox. 2 * (H330); Acute Tox. 3 * (H301); Acute Tox. 4 * (H312); STOT RE 1 (H372 **); Skin Corr. 1B (H314); Resp. Sens. 1 (H334); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
231-906-6	7778-50-9	Potassium dichromate	024-002-00-6	Ox. Sol. 2 (H272); <b>Carc. 1B</b> (H350); <b>Muta. 1B</b> (H340); <b>Repr. 1B</b> (H360FD); Acute Tox. 2 * (H330); Acute Tox. 3 * (H301); Acute Tox. 4 * (H312); STOT RE 1 (H372 **); Skin Corr. 1B (H314); Resp. Sens. 1 (H334); Skin Sens. 1 (H317); Aquatic Acute 1(H400); Aquatic Chronic 1(H410)
232-143-1	7789-09-5	Ammonium dichromate	024-003-00-1	Ox. Sol. 2 **** (H272); <b>Carc. 1B</b> (H350); <b>Muta. 1B</b> (H340); <b>Repr. 1B</b> (H360FD); Acute Tox. 2 * (H330); Acute Tox. 3 * (H301); Acute Tox. 4 * (H312); STOT RE 1 (H372 **); Skin Corr. 1B (H314); Resp. Sens. 1 (H334); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
232-140-5	7789-00-6	Potassium chromate	024-006-00-8	<b>Carc. 1B</b> (H350i); <b>Muta. 1B</b> (H340); STOT SE 3 (H335); Skin Irrit. 2 (H315); Eye Irrit. 2 (H319); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
231-889-5	7775-11-3	Sodium chromate	024-018-00-3	<b>Carc. 1B</b> (H350); <b>Muta. 1B</b> (H340); <b>Repr. 1B</b> (H360FD); Acute Tox. 2 * (H330); Acute Tox. 3 * (H301); Acute Tox. 4 * (H312); STOT RE 1 (H372 **); Skin Corr. 1B (H314); Resp. Sens. 1 (H334); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
246-356-2	24613-89-6	Dichromium tris(chromate)	024-010-00-X	Ox. Sol. 1 (H271); <b>Carc. 1B</b> (H350); Skin Corr. 1A (H314); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
232-142-6	7789-06-2	Strontium chromate	024-009-00-4	<b>Carc. 1B</b> (H350); Acute Tox. 4 * (H302); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
231-801-5 236-881-5	7738-94-5 13520-68-2	Acids generated from chromium trioxide and their oligomers	024-017-00-8	<b>Carc. 1B</b> (H350i); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
234-329-8	11103-86-9	Potassium hydroxyoctaoxodizincate dichromate(1-)	024-007-00-3	<b>Carc. 1A</b> (H350); Acute Tox. 4 *, (H302); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
256-418-0	49663-84-5	Pentazinc chromate octahydroxide	024-007-00-3	<b>Carc. 1A</b> (H350); Acute Tox. 4 *, (H302); Skin Sens. 1 (H317); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)

 Table 6. Harmonised classification according to the CLP Regulation 1272/2008

Source: Annex VI to CLP\_ATP20, consulted on 21-03-2025.

EC No	CAS No	EC name	Notified classification <sup>[1]</sup>
233-660-5	10294-40-3	Barium chromate	Acute Tox. 3; Skin Sens. 1; Acute Tox. 2; Resp. Sens. 1; Muta. 1B; Carc. 1A; Repr. 2; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1

#### Table 7. Notified classifications under Art. 40 of the CLP Regulation 1272/2008

Source: ECHA website, consulted on 16-05-2024.

Table notes: <sup>[1]</sup> all hazard classes and categories notified via REACH registration or C&L notification processes.

- Workers. Based on a 40-year working life (8h/day, 5 days/week), an excess lifetime lung cancer mortality risk of 4E-3 per μg Cr(VI)/m<sup>3</sup>
- General population. Based on an exposure for 70 years (24h/day, every day), an excess lifetime lung cancer mortality risk of 2.9E-2 per μg Cr(VI)/m<sup>3</sup>

Dose-response relationships for gastrointestinal cancer were derived based on the analysis by USEPA (2010), which selected the NTP (2008) bioassay in rodents for their assessment as this was a well-conducted lifetime animal study of Cr(VI) carcinogenicity via ingestion. Notably, no adequate studies of Cr(VI) carcinogenicity via the oral route were available. Against a background lifetime intestinal cancer risk of 9-16 per 1 000 for the German population and an 89-year life expectancy, the following unit risk factors were derived.

- Workers. Based on a 40-year working life (8h/day, 5 days/week) and an agederived assessment factor of 1, an excess lifetime intestinal cancer risk of 2.0E-4 per μg Cr(VI)/kg bw/day
- General population. Based on an exposure for 70 years (24h/day, every day), an excess lifetime intestinal cancer risk of 8.0E-4 per μg Cr(VI)/kg bw/day.

The Dossier Submitter notes that the relationship for lung cancer is expressed in terms of excess lifetime *mortality* risk, while the relationship for intestinal cancer is expressed in terms of excess lifetime risk.<sup>16</sup> In the following, the Dossier Submitter will by convention use the acronym 'ELR' to refer to any calculation using the above-mentioned Cr(VI) dose-response relationships. However, it should be noted that an estimate of excess lifetime lung cancer mortality risk has to be scaled by a factor of 1/(1 - lung cancer survival probability) to convert it into a proper estimate of excess lifetime risk of lung cancer.

### **1.4.5.** Reprotoxic properties

In an addendum to the RAC note<sup>14</sup> on dose-response relationships, reproductive toxicity has been assessed for four soluble chromium substances (ammonium dichromate, sodium dichromate, sodium chromate and potassium dichromate) as these substances were included in Annex XIV of REACH also because of their reproductive toxicity (cat. 1B).<sup>17</sup> However, in the context of its work on AfAs RAC has deemed the carcinogenic effects of Cr(VI) more relevant than its reproductive toxicity. Moreover, as noted above, limiting exposure to Cr(VI) to reduce cancer risk will also contribute to protection against reprotoxic effects.

#### 1.4.6. Other hazard properties

Although outside the mandate, the Dossier Submitter notes for completeness that Cr(VI) substances pose an environmental hazard as they negatively affect water, soil and plants. For example, Prasad, Yadav et al. (2021) note that Cr(VI) impedes the metabolic activities of plants, hampers crop growth and yield, and reduces vegetable and grain quality. This being said, the EU RAR (2005) concluded that under typical environmental conditions Cr(VI) quickly reduces to Cr(III), which is of limited environmental concern.

#### 1.4.7. Exposure assessment

This section provides an overview of occupational and environmental exposure to Cr(VI). A detailed analysis is provided in Appendix B.8. Minor uncertainties in the input data and

<sup>&</sup>lt;sup>16</sup> See e.g. <u>IRIS Glossary | US EPA</u>.

<sup>&</sup>lt;sup>17</sup> <u>RAC/35/2015/09</u>.

in the subsequent assessment of Cr(VI) releases to the environment and of direct exposure to Cr(VI) substances in the workplace have been identified by the Dossier Submitter. However, as demonstrated in Section 5, they do not alter the conclusions.

#### **1.4.8. Worker exposure**

Workers may be exposed to Cr(VI) during use of chromium substances both via inhalation and the dermal route. The exposure assessment for workers focuses on inhalation as there are no data to suggest that dermal exposure to Cr(VI) compounds poses a significant cancer risk to humans. Indeed, based on experiences from the AfAs, dermal exposure levels are usually not expected to be high enough to significantly contribute to the overall Cr(VI)-induced health risks. As dermal exposure can be adequately controlled by hygiene practices and risk management measures, it is not further discussed below.

#### Inhalation exposure

The worker exposure assessment for the inhalation route presented below relies on:

- Information received in the first Call for Evidence (CfE#1)
- Information received in the second Call for Evidence (CfE#2)
- The CTACSub2 AfA (Communication Nr. AFA-C-2114679208-38-01/F)<sup>18</sup>
- Information from authorisation downstream users (DU notifications)

The main analysis is based on the information collected in both CfEs for the use categories defined in Section 1.3.2. Information from the two other data sources is used to check the plausibility of and corroborate the CfE data for UC 1, 3, 4 and 5. However, these comparison data sources do not contain information on UC 2 and UC 6. These sources have been selected because they contain relevant data from several hundred sites using Cr(VI) substances that have been systematically collected. This allows for meaningful comparisons to be made between different data sources. From the DU notifications, only information reported via standardised excel templates<sup>19</sup> is used in the analysis to ensure that the data are collected in a similar way. Each source is analysed separately to avoid pseudo-duplications that would result from the same companies and sites reporting in more than one dataset.

#### **Bioavailability**

Epidemiologic and mechanistic studies suggest that the carcinogenic potency of Cr(VI) compounds for the lung is greater for substances with high and slightly solubility than for insoluble compounds.<sup>14</sup> However, it is not possible to quantify the difference in potency for different Cr(VI) compounds with the data currently available. Therefore, the proposed lung cancer risk assessment is done for inhalation exposure to aerosols of highly soluble, slightly soluble and insoluble Cr(VI) compounds, accepting that this approach may overestimate lung cancer risk for exposure to insoluble chromates (see Appendix B.1.1.1 for a grouping of Cr(VI) compounds into different solubility categories).

The size of the particles can also influence the exposure to Cr(VI), as the smaller particles are more likely to enter the deepest part of the lung, the non-ciliated alveoli (respirable

 $<sup>^{18}</sup>$  This AfA was used for triangulation purposes because it contains recent measurement data from  $\sim\!330$  companies that operate in four out of the six use categories defined under Section 1.3.2.

<sup>&</sup>lt;sup>19</sup> <u>https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use</u>.

fraction). The larger particles, "non-respirable fraction" of Cr(VI) inhalation exposure stay in the upper respiratory tract and are cleared by the mucociliary escalator and swallowed. Therefore, this inhalable, non-respirable fraction of Cr(VI) would rather contribute to the cancer risk of the small intestine than the lung. Because the available exposure data is lacking the information on the particle size, the Dossier Submitter assumes that all the inhaled particles are of respirable size and acknowledges that this approach might lead to an overestimation of the actual lung cancer risk.

#### General approach for defining worker exposure scenarios

During the investigation, the Dossier Submitter consulted various data sources, incl. the existing AfAs and the Art. 66 DU notifications for authorisations granted. However, it proved difficult to compile standardised exposure information from these data sources. For this reason, the Dossier Submitter developed a specific survey and collected standardised information on worker exposure in two CfEs. The CfE data served as main data source for assessing worker exposure to Cr(VI), while the information from AfAs and DU notifications were used to triangulate the results. In order to analyse the collected data, the Dossier Submitter took the following approach.

First, a set of relevant tasks for each use category was defined. The relevant tasks were selected based on information provided in the CfEs and their descriptions were complemented by comparing them against the CTACSub2 AfA. In the CfEs, companies were asked to report up to five tasks that contribute most to Cr(VI) exposure of workers at their sites. It is assumed that the reported tasks are the most relevant ones for a given use/use category. The list of relevant tasks per use category as summarised in Table 8 was subsequently used to calculate the combined worker exposure for each use category. Further information about the selection of relevant tasks is provided in Appendix B.8.2.2.1.

Task description	UC 1	UC 2	UC 3	UC 4	UC 5 ETP	UC 5 Other	UC 6
Delivery and storage	Х			Х	Х	Х	Х
Weighing, mixing, diluting of liquids	Х			Х		Х	Х
Weighing, mixing, diluting of solids	Х			Х		Х	Х
Loading/unloading of jigs		Х	Х		Х	Х	Х
Surface treatment by spraying in spray booth				Х		Х	
Surface treatment by brushing, rolling or pen stick				x		Х	
Surface treatment by dipping/immersion		х	х		х	Х	
Concentration adjustment of baths with liquids		х	Х		Х	Х	
Concentration adjustment of baths with solids		х	х		Х	Х	
Rinsing, drying, (self-)curing of parts						Х	
Frequent maintenance activities	Х	х	х	х	Х	Х	Х
Infrequent maintenance activities		х	х			Х	Х
Waste/wastewater management	Х	Х	Х	Х	Х	Х	Х
Sampling and transfer to smaller containers	Х	Х	Х			Х	Х

#### Table 8. Relevant tasks for each use category (UC)

Table notes: The table includes predefined tasks from the CfEs. Tasks in **bold** were always included in the exposure scenario for the respective UC. Other tasks, which did not fit the predefined list of tasks were also reported but are not listed in the table above. However, they were included in the exposure scenario if it was clear from the task description that they are relevant for a given UC. Especially for broadly defined UC 6 many tasks were reported under other tasks. UC 5 is split in two different scenarios, passivation of tin-plated steel (ETP) and other surface treatments. Because other surface treatments include a variety of different utilisations, all tasks were considered relevant for the combined exposure.

In a second step, combined exposure scenarios (CES) were generated for each of the sites that had reported information about the performed uses and exposure measurements, including all tasks relevant for a given use category. Importantly, the CES were calculated solely on the basis of personal measurements at a given site. The exposure calculation for a given site reflects site-specific durations and frequencies of relevant tasks. Where corrections were made to account for the use of respiratory protective equipment (RPE), these are based on the RPE use *at* the given site. The rationale behind this approach is that it is more informative to consider differences between sites than to try and create a generic scenario that covers most of the sites. As a result, the exposure assessment relies on the prevailing Cr(VI) concentration at the workplaces, while the actual source of Cr(VI) has not been considered.

Since the different datasets included different information, there are differences in how the CES were eventually analysed (see Appendix B.8.2.2 for a detailed description). Where possible, the analysis accounted for the number of exposed workers in the estimation of the proportion of sites/workers exceeding a certain combined exposure level. For each use category, an empirical cumulative distribution function (ECDF) was constructed that displays the empirical proportion of sites/workers that are exposed below/above certain limit values (Rheinberger 2021).

Some general assumptions were made for the exposure assessment:

- If task frequencies, durations, measured concentrations and numbers of exposed workers are reported in ranges, the mid value is taken forward in the analysis
- If the effectiveness of OCs and RMMs in reducing exposure is reported as a 'greater than' value or a range, the lowest value is taken forward in the analysis
- If the measured value is below the limit of quantification (LoQ), then the LoQ is taken forward in the analysis
- If the LoQ of a method is unknown, 0.1 µg/m<sup>3</sup> is assumed by default as it reflects the median LoQ of methods used to measure worker exposure (see Appendix B.1.2)
- If >5 exposure values are available for a given task and site, P90 values are used in the analysis; else the maximum value is used as a reasonable worst-case assumption

Based on the above assumptions, typical air concentrations of Cr(VI) can be summarised. Table 9 presents summary statistics of Cr(VI) air concentrations (based on personal measurements) that were reported in the CfEs for each of the use categories. For triangulation purposes, similar summary statistics were compiled using data from the CTACSub2 AfA and the DU notifications for UCs 1, 3, 4 and 5. No comparison was possible for UCs 2 and 6, as no authorisation has been granted that covers downstream uses in these use categories.

Generally speaking, the exposure values for surface treatments in the CTACSub2 AfA are consistently higher than those in the other datasets. Presumably, this is because the purpose of the applicant's data collection was to create a single representative scenario covering all sites. Therefore, worst-case assumptions were made for many parameters used to calculate worker exposure. For example, the applicant assumed that no RPE was used for surface treatment by dipping/immersion, whereas the information received in the CfEs indicates that  $\sim$ 70 % of the relevant sites are in fact using RPE for this task. In addition, the frequency and duration of different tasks reported in the CTACSub2 AfA are typically greater than in the other two datasets (see Appendix B.8.2.2.3 for a detailed comparison).

For UC 4, the exposure values reported in the CfEs are higher than in the other two data sources. This is because in the CfEs more information was received for uses such as spraying in open space, which are not covered by other data sources but result in very high Cr(VI) exposures. In conclusion, the comparison in Table 9 demonstrates that the exposure data obtained through the CfEs are – except for UC 4 – consistent with other exposure data sources. The Dossier Submitter therefore considers that the CfE data provides a credible basis for the purpose of calculating the baseline exposures.

Main data source: CfE#1 and CfE#2 data combined										
	Measure	d concent	ration in a	ir (µg Cr(\	VI)/m³)	Worker exposure (µg Cr(VI)/m <sup>3</sup> )				
Use category	N sites	Min	Max	P50	P90	8h- TWA	8h-TWA corrected for frequency	8h-TWA corrected for frequency and RPE		
UC 1	17	0.067	127.0	0.30	10.98	4.12	1.40	0.09		
UC 2	17	0.016	5.5	0.20	2.40	2.34	0.76	0.14		
UC 3	275	0.003	464.0	0.50	3.51	2.04	1.86	0.65		
UC 4	58	0.002	564.0	1.05	93.50	31.25	16.10	3.21		
UC 5	85	0.005	89.0	0.30	3.00	0.90	1.36	0.39		
UC 6	12	0.030	10.4	0.59	9.67	18.06	1.99	0.21		
Comparison data source: CTACSub2 data										
Measured concentration in air (µg Cr(VI)/m³) Worker exposure (µg Cr								Cr(VI)/m³)		
Use category	N sites	Min	Max	P50	P90	8h- TWA	8h-TWA corrected for frequency	8h-TWA corrected for frequency and RPE		
UC 1	17	0.283	17.06	1.20	4.72	3.96	2.92	1.57		
UC 2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		
UC 3	227	0.001	87304	1.14	9.44	3.58	5.18	4.51		
UC 4	5	0.053	65	6.67	42.34	6.30	6.51	0.23		
UC 5	50	0.077	1000	1.00	8.71	2.86	3.35	2.79		
UC 6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		
		Com	parison da	ita source	: DU notifi	cation da	ta			
	Measure	d concent	ration in a	ir (µg Cr(\	VI)/m³)	Worker	exposure (µg	Cr(VI)/m³)		
Use category	N sites	Min	Max	P50	P90	8h- TWA	8h-TWA corrected for frequency	8h-TWA corrected for frequency and RPE		
UC 1	85	0.001	14 000	0.90	4.80	2.21	1.34	0.27		
UC 2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		
UC 3	472	0.001	679 000	0.99	9.69	2.81	4.26	1.75		
UC 4	266	0.001	1 254	0.63	8.00	2.39	2.50	0.67		
UC 5	36	0.001	20	0.91	3.53	0.98	1.43	0.41		
UC 6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		

	Table 9. Triang	ulation of Cr(	(VI)	air	concentration	and	worker	exposure o	lata
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Table notes: combined worker exposure based on all relevant tasks for a given UC. The exposure values represent the P90 value for the sites performing a given UC. For measured air concentrations, the values are based on the worst-case task per site for a given UC. All data are based on personal sampling; <sup>[1]</sup> if the site was not indicated in the data, measurements from the same site but taken in a different year were treated in the analysis as if they were from a different site.

Machining, sanding and blasting of Cr(VI)-containing coatings are work tasks conducted primarily in the A&D sector to prepare surfaces for (re-)painting. In the logic of this dossier, they therefore belong to UC 5. Exposure information on such tasks is scarce. (No relevant information was obtained in the CfEs.) In Appendix D.1.1.2, the Dossier Submitter has summarised publicly available information from the UK REACH AfA by the ADCR consortium concerning the Cr(VI) exposure potential from machining, sanding and blasting. In closed systems, the measured long-term personal measurements for machining and blasting are in general lower than the exposures reported in Table 9. However, measured exposures for tasks that include sanding are at the same level as those found for UC 4 (based on the CfE data). Measurements that exclusively cover sanding suggest even higher concentrations (P90 = 232  $\mu$ g Cr(VI)/m<sup>3</sup>). However, it should be noted that RPE-corrected exposures were below 1  $\mu$ g Cr(VI)/m<sup>3</sup> for all tasks.

The evaluation of previous AfAs suggests that there is no clear distinction in terms of exposure between metal and plastic plating, or between decorative and functional plating. In decorative plating, the chromium layer tends to be thinner and the bath temperature during plating to be lower compared to functional plating. However, since exposure depends on so many site-specific factors, there is no robust evidence that this would result in lower exposure for decorative plating.<sup>20</sup> Moreover, as decorative plating usually has also a functional purpose, e.g. corrosion prevention, it is scientifically impossible to draw a line between "purely" decorative plating and functional plating with a decorative character.

#### Information on operating conditions and risk management measures

In the CfEs, companies were asked to report for each relevant task the following information concerning the operational conditions (OCs) and risk management measures (RMMs):

- Automation, segregation and containment of the task
- Presence and effectiveness of general ventilation
- Presence and effectiveness of local exhaust ventilation (LEV)
- Use and effectiveness of respiratory protection equipment (RPE)

Figure 4 provides an overview of the presence/absence of different OCs and RMMs for different tasks as reported in the CfEs. Although the Dossier Submitter analysed exposures at sites with and without specific OCs and RMMs, no clear patterns emerged (see Appendix B.8.2.2.2). The Dossier Submitter notes that the same conclusion was reached in the analysis of the so-called "spring data campaign" report provided by ADCR consortium as part of the comments to the draft opinions on their AfA. Indeed, a classic endogeneity problem arises where companies/sites have invested in additional OCs and RMMs if they previously had particularly high exposures. Residual exposures are then statistically indistinguishable from sites with less extensive OCs and RMMs in place, obscuring the relationship between improved measures and exposure.

<sup>&</sup>lt;sup>20</sup> Plating on plastic typically requires an additional pre-treatment step (etching), which is in most cases Cr(VI)-based. Typically, etching and plating are performed by the same group of workers resulting in a longer overall exposure time compared to plating on metal where etching is not necessary.





automation containment LEV

#### Brushing, rolling and pen stick



RPE

segregation ventilation

#### Concentration adjustment with liquids





#### Sampling and transfer



#### Dipping/immersion



#### Weighing liquids



Concentration adjustment with solids



Other tasks



#### Figure 4. Proportion of sites using specific OCs and RMMs for a given task

Source: based on information submitted in response to the CfEs.
Based on information received in the CfEs, the Dossier Submitter notes a high reliance on RPE (see Appendix D.8.2.2.3). As many tasks have a duration of two or more hours (see Table 10), it might not be realistic to assume that workers wear a mask during the entire task. Other OCs and RMMs are used for specific tasks/activities. As such measures are task- and site-specific, they were not included in the CfEs. However, based on a review of existing AfAs, the Dossier Submitter considers that many sites use mist suppressants during electroplating.

There are different kinds of mist suppressants some of which contain PFAS, but the proportion of mist suppressants containing PFAS is unknown as their presence has not been systematically reported in AfAs. Alternatives to PFAS-containing mist suppressants and wetting agents used in chrome plating have been studied in both the PFHxS restriction<sup>21</sup> and the universal PFAS restriction proposals<sup>22</sup>. For chrome plating, these include non-fluorinated chemicals (e.g. alkane sulfonates) as well as other mechanical alternatives (e.g. polypropene balls in bath).

It is noteworthy that, in recent AfA opinions, the RAC has proposed other measures (automation, improved LEV) to reduce worker exposure than the use of (PFAS-containing) mist suppressants. This is likely to have reduced the use of PFAS-containing mist suppressants in the EU chrome plating sector. The Dossier Submitter also notes that LEVs are often, but not always, equipped with an alarm system and/or automatic shutdown of the process in case of malfunctioning of the LEV.

		Frequency	Frequency (times/month)		Duration (h)		
Task	N Sites	Min-Max	P50	P90	Min-Max	P50	P90
Delivery and storage	59	0.005-20	1	4	0.08-6	0.5	1.7
Weighing, mixing, diluting of liquids	66	0.08-90	4	30	0.05-8	0.5	3
Weighing, mixing, diluting of solids	74	0.04-294	2	11.4	0.05-10	0.5	2
Loading/unloading jigs	142	0.3-2310	22	318	0.05-12	1.75	8
Spraying in spray booth	56	1-160	20	30	0.1-10	1	5.5
Brushing/rolling/pen	41	0.02-950	12	90	0.03-7	0.3	2
Dipping/immersion	330	0.06-1600	20	200	0.02-12	2	8
Concentration adjustment w/ solids	167	0.03-40	4	12	0.05-7.5	0.5	1
Concentration adjustment w/ liquids	101	0.06-80	3	20	0.02-5	0.5	2
Rinsing/drying/self-curing	70	0.02-600	30	202	0.01-12	0.5	4
Frequent maintenance activities	195	0.06-500	8	40	0.03-10	0.5	4
Infrequent maintenance activities	114	0.003-30	0.275	2	0.05-40	2	8
Waste management	81	0.0001-220	4	30	0.03-8	1	5
Sampling and transfer to small container	144	0.05-90	4	20	0.02-4	0.2	1
Other tasks	106	0.016-150	18	29.5	0.01-24	1.035	8

Table 10. Frequencies and durations of typical tasks

Source: compiled based on information from the CfEs.

<sup>21</sup> <u>Registry of restriction intentions until outcome - ECHA - Perfluorohexan-1-sulphonic acid, its salts</u> and related substances.

<sup>22</sup> <u>Registry of restriction intentions until outcome - ECHA - Per- and polyfluoroalkyl substances</u> (PFAS).

## 1.4.9. General population exposure

Releases of Cr(VI) to air or water may expose the general population via several routes. Because of the toxicological properties of the target substances, it is important to estimate both the air concentration in the vicinity of the release source and the oral dose to which humans might be exposed via the consumption of drinking water. As shown in Figure 5, the Dossier Submitter applied standard modelling assumptions to convert reported Cr(VI) releases to air and water into general population exposures. All modelling assumptions are reported in Appendix B.8.



## Figure 5. Conceptual model for assessing general population exposure to Cr(VI)

## **Release estimation**

The first step in assessing Cr(VI) exposure of humans via the environment is to gauge the releases from the sites that use the target substances. To inform the environmental exposure assessment, the Dossier Submitter reviewed raw release data submitted as part of the CTACSub2 AfA, raw release data submitted as part of Downstream User (DU) notifications for authorisations of various Cr(VI) substance uses pursuant Art. 66 of REACH, and curated release data provided by industry in response to the CfEs.

To obtain representative estimates of annual Cr(VI) releases to air and wastewater, the Dossier Submitter filtered data from the CTACSub2 AfA covering a total of ~300 sites that use CrO<sub>3</sub>. Similar data were collected in the CfEs for other Cr(VI) substances from 361 sites. (Samples are likely to overlap for some of the use categories.) The reported air and wastewater emissions were disaggregated to the individual use categories.<sup>23</sup> Summary statistics of Cr(VI) releases to both air and water are reported in Tables 11 and 12.

<sup>&</sup>lt;sup>23</sup> While DUs reported on releases of Cr(VI) to air and water, their notifications were often incomplete and it was not possible to assign them to the use categories defined in Section 1.3.2.

		Release	to air (kg/y	<b>'</b> )	Release to water (kg/y)			
	N sites	Min-Max	P50	P90	N sites	Min-Max	P50	P90
UC 1	19	0-8	0.012	0.47	11	0-0.6	0.016	0.3
UC 2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
UC 3	254	0-165	0.107	3.58	114	0-10.8	0.043	1.3
UC 4	5	0.1-7.3	n/a	n/a	2	0.14-0.25	n/a	n/a
UC 5	52	0-165	0.32	8.97	34	0-13.7	0.192	2.6
UC 6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ALL	300	0-165	0.087	3.44	143	0-13.7	0.04	1.47

 Table 11. Cr(VI) release estimation per use category – CTACSub2 data

Source: based on data submitted as part of the AfA by the CTAC Sub2 consortium (2021-2023).

Table 12. Cr(VI) release estimation per use category – CfE data

		Release	to air (kg/y	<b>')</b>	Release to water (kg/y)			
	N sites	Min-Max	P50	P90	N sites	Min-Max	P50	P90
UC 1	13	0-2	0.03	1.5	7	0-1.8	n/a	n/a
UC 2	24	0-26	0.38	2.8	27	0-4.44	0.74	2.46
UC 3	280	0-1000	0.29	4.15	123	0-4 000	0.1	2.22
UC 4	33	0-7	0.087	1	22	0-4.44	0.1	1
UC 5	56	0-57.1	0.25	1.17	41	0-65.3	0.15	2.75
UC 6	5	0-181	n/a	n/a	7	0-303	n/a	n/a
ALL	361	0-1000	0.25	4	183	0-4 000	0.117	2.22

Source: based on information submitted in response to the CfEs.

In the CfEs, the highest releases to air were reported for UC 3 (metal plating) and UC 2 (plastic plating), see Table 12. Across the UCs, the P90 values of annual releases to air range from 1 to 4 kg/year. Data from the CTACSub2 AfA largely confirm the values collected in the CfEs. However, it should be noted that UCs 2 (plastic electroplating) and 6 (functional additives and process aides) were not covered by CTACSub2 and UC 4 (use of primers and other slurries) had a non-representative sample size. This gap was addressed in the CfE#2, which specifically targeted the A&D and plating-on-plastic sectors.

In terms of risk management measures (RMMs), the CSRs submitted as part of the CTACSub2 AfA reported that air releases (for UCs 1, 3, 4 and 5) are collected and passed through a filter or droplet separator/wet scrubber to reduce emissions to air. Across both CfEs, 63 % of sites reported that RMMs such as droplet separators and/or wet scrubbers are in place to limit Cr(VI) releases to air.

Data on releases to water are scarcer than those for emissions to air. For example, only 26 % (n=183) of the sites responding to the CfEs reported data on releases to water. This can be partially explained by the fact that around half of the sites claimed they have no releases to water at all, which seems justified in about half of the cases because companies that made such claims indicated to recirculate water in closed systems. However, the other half did not provide evidence to back up this claim, in which case the Dossier Submitter assumes a weighted average based on the environmental emission pathways in Figure 5.

In the CfEs, the highest releases to water were reported for UC 5 (other surface treatments), UC 2 (plastic plating) and UC 3 (metal plating) with P90 values ranging from 1 to 3 kg/year depending on the use category. Again, data from the CTACSub2 AfA confirm

the values collected in the CfEs. According to both data sources, RMMs such as reduction/neutralisation/precipitation and/or closed systems/water recirculation are widely in place (65 % of sites in the CfE).

#### **Exposure estimation**

The conversion of releases to exposure was performed using the EUSES 2.1.2 model in Chesar 3.7. Appendix B.8.1 provides information on and justification of modelling choices, together with default assumptions for the exposure estimation for inhalation (airborne exposure 100 m from the source) and for oral exposure (via ingestion of drinking water only from local sources directly impacted by site emissions). Routes of exposure covered in the analysis are inhalation (of emissions to air) and oral intake via drinking water and the consumption of fish. Consistent with the assumptions made by most applicants and the corresponding RAC opinions, only a local assessment is considered relevant.

While exposure via inhalation depends on air emissions only, the oral exposure via drinking water and fish consumption is mostly due to wastewater emissions. For the latter, it is important to consider whether wastewater emissions are emitted directly to surface water (after onsite treatment) or sent to a municipal STP and, in such case, whether the sludge is applied to agricultural soil. Where this information is missing, the most conservative scenario (sludge is applied to agricultural soil) was assumed. Unless specified otherwise, all input parameters required by EUSES are taken from the EU RAR (2005).

Tables 13 and 14 report on the inhalation concentration at the point of exposure and the modelled oral dose, again disaggregated for the use categories defined in in Section 1.3.2. and covering the release estimates assessed above. Appendix B.8.1 provides more information on how exposure concentration and doses were estimated.

		Inhalatio	on (µg/m³)		Oral dose (µg·kg <sup>-1</sup> bw·d <sup>-1</sup> )			
	N sites	Min-Max	P50	P90	N sites	Min-Max	P50	P90
UC 1	19	0-6.1E-03	9.3E-06	3.6E-04	11	0-4.6E-03	1.2E-04	2.3E-03
UC 2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
UC 3	254	0-1.3E-01	8.2E-05	2.7E-03	114	0-8.4E-02	3.3E-04	1.0E-02
UC 4	5	0-5.6E-03	n/a	n/a	2	1E-3-2E-3	n/a	n/a
UC 5	52	0-1.3E-01	2.5E-04	6.8E-03	34	0-1.06E-01	9.1E-04	2.0E-02
UC 6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ALL	300	0-1.3E-01	6.7E-05	2.6E-03	143	0-1.1E-01	3.1E-04	1.14E-02

Table 13. Exposure estimation per use category – CTACSub2 data

Source: based on data submitted as part of the AfA by the CTAC Sub2 consortium (2021-2023).

Table 14. Expo	sure estimation	per use category	/ – CfE	data
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		Inhalatio	on (µg/m³)		Oral dose (µg∙ kg⁻¹ bw ∙d⁻¹)			
	N sites	Min-Max	P50	P90	N sites	Min-Max	P50	P90
UC 1	13	0-1.53E-03	2.29E-05	1.14E-03	7	0-7.02E-03	n/a	n/a
UC 2	24	0-1.98E-02	2.90E-04	2.15E-03	27	0-3.44E-02	1.95E-03	1.37E-02
UC 3	280	0-7.63E-01	2.22E-04	3.17E-03	123	0-2.8E+01	6.82E-04	2.86E-02
UC 4	33	0-5.34E-03	6.64E-05	7.64E-04	22	0-3.44E-02	6.56E-04	1.98E-02
UC 5	56	0-4.36E-02	1.90E-04	8.92E-04	41	0-2.77E-01	1.17E-03	2.19E-02
UC 6	5	0-1.38E-01	n/a	n/a	7	0-1.18E+00	n/a	n/a
ALL	361	0-7.63E- 01	1.88E-04	3.05E-03	183	0-2.8E+01	7.0E-04	2.17E-02

Source: based on information submitted in response to the CfEs.

The following high-level findings are worth noting:

- Estimated air concentrations<sup>24</sup> at the point of inhalation (left column of Table 14) are proportional to air releases reported in Tables 11 and 12. P90 values are close to 3 ng/m<sup>3</sup> for all data points, with the highest values found for UCs 3, 2 and 1
- Estimated oral doses of Cr(VI) (right column of Table 14) are linked to the releases to water and almost entirely due to drinking water ingestion. P90 values of oral dose are 0.01-0.03  $\mu$ g/kg bw/d, with the highest values found for UCs 3, 2 and 4
- The drinking water concentrations themselves depend on the wastewater scenario assumed; i.e., whether wastewater (after onsite treatment) is discharged to surface water bodies or sent to the municipal sewage treatment plant (STP), and in the latter case, whether the sludge is applied to agricultural soil or incinerated
- The exposure data gathered in the CfEs are broadly consistent with data from the CTACSub 2 AfA reported in Table 13

## 1.4.10. Risk characterisation

Based on the RAC document<sup>14</sup> establishing dose-response relationships for inhalation and oral exposure to Cr(VI) compounds, the Dossier Submitter considers that the mode of action of these substances is non-threshold. Following Annex I, paragraph 6.4 of REACH, the risks resulting from exposure to non-threshold substances cannot be adequately controlled since no DNEL or PNEC can be determined. For the purpose of characterising the risk of Cr(VI) exposure in this Annex XV restriction proposal, the Dossier Submitter applied the dose-response relationships described in Section 1.4.2 to the exposure information collated in Sections 1.4.8 and 1.4.9. Tables 15-Table 19 report the individual excess lifetime cancer risks that correspond to these exposure data.

The Dossier Submitter recognises that in order to generalise this approach one has to assume that the exposure data obtained from a large sample (i.e., from the CfE) are representative of the Cr(VI) exposures at *all* sites in the EU where the target substances are used. While there is no reason to believe that the sample is strongly biased, it could be subject to selection bias. However, a triangulation with other information sources (existing AfAs, literature values, etc.) suggests that despite some discrepancies the exposure and emission data collected in the CfEs are plausible. Therefore, the Dossier Submitter concludes that the data used in the CfEs can be used to quantify any reduction in exposure to Cr(VI) achieved by the proposed restriction options and provides meaningful input to the impact assessment.

	Individual ELR - Inhalation route									
	N sites	Min-Max	P50	P90						
UC 1	17	3.10E-07 - 3.05E-03	7.56E-06	3.66E-04						
UC 2	17	8.00E-07 - 1.88E-03	6.60E-05	5.66E-04						
UC 3	275	1.90E-08 - 5.40E-01	1.50E-04	2.61E-03						
UC 4	58	8.50E-10 - 3.59E-01	7.07E-05	1.28E-02						
UC 5	85	9.44E-10 - 1.62E-02	4.94E-05	1.58E-03						
UC 6	12	4.80E-07 - 5.01E-03	5.59E-05	8.52E-04						
All	416	8.50E-10 - 5.40E-01	9.23E-05	3.07E-03						

Table 15. Worker ELR per use category – CfE data

*Source: based on information submitted in response to the CfEs; ELR estimated based on combined exposures from relevant tasks corrected for frequency and RPE.* 

<sup>&</sup>lt;sup>24</sup> See the CSRs of the CTACSub2 AfA (Communication Nr. AFA-C-2114679208-38-01/F).

	Individual ELR - Inhalation route								
	N sites	Min-Max	P50	P90					
UC 1	17	1.50E-05 - 1.07E-02	2.46E-04	6.28E-03					
UC 2	n/a	n/a	n/a	n/a					
UC 3	227	1.67E-08 - 1.77E+01	1.61E-03	1.80E-02					
UC 4	5	6.52E-06 - 1.35E-03	1.39E-04	9.04E-04					
UC 5	50	9.17E-06 - 1.56E+00	8.07E-04	1.11E-02					
UC 6	n/a	n/a	n/a	n/a					
All	268	1.67E-08 - 1.77E+01	1.51E-03	1.78E-02					

 Table 16. Worker ELR estimation per use category – CTACSub2 data

Source: based on data submitted as part of the AfA by the CTAC Sub2 consortium; ELR estimated based on combined exposures from relevant tasks corrected for frequency and RPE.

Table 17	. Worker ELR	estimation	per use	category -	DU	notification data
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	Individual ELR - Inhalation route								
	N sites	Min-Max	P50	P90					
UC1	85	3.96E-08 - 2.05E-02	4.00E-05	1.06E-03					
UC2	n/a	n/a	n/a	n/a					
UC3	472	2.83E-10 - 3.17E+00	2.23E-04	7.00E-03					
UC4	266	1.16E-09 - 7.00E-01	3.89E-05	2.67E-03					
UC5	36	1.04E-07 - 2.28E-02	1.29E-04	1.62E-03					
UC6	n/a	n/a	n/a	n/a					
All	1026	2.83E-10 - 3.17E+00	1.25E-04	4.19E-03					

*Source: based on data submitted as part of DU notifications; ELR estimated based on combined exposures from relevant tasks corrected for frequency and RPE.* 

	In	dividual ELR -	- Inhalation	route	Individual ELR - Oral route			
	N sites	Min-Max	P50	P90	N sites	Min-Max	P50	P90
UC 1	13	0-4.36E-05	6.54E-07	3.27E-05	7	0-5.62E-06	n/a	n/a
UC 2	24	0-5.67E-04	8.29E-06	6.13E-05	27	0-2.75E-05	1.56E-06	1.09E-05
UC 3	280	0-2.18E-02	6.35E-06	9.05E-05	123	0-2.25E-02	5.46E-07	2.29E-05
UC 4	33	0-1.53E-04	1.90E-06	2.18E-05	22	0-2.75E-05	5.25E-07	1.59E-05
UC 5	56	0-1.24E-03	5.42E-06	2.55E-05	41	0-2.22E-04	9.38E-07	1.75E-05
UC 6	5	0-3.95E-03	n/a	n/a	7	0-9.45E-04	n/a	n/a
ALL	361	0-2.18E-02	5.38E-06	8.72E-05	183	0-2.25E-02	5.6E-07	1.74E-05

#### Table 18. General population ELR per use category – CfE data

Source: based on information submitted in response to the CfEs.

	Table 19. General	population ELR	estimation	per use	category	- CTACSub2 d	ata
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	Individual ELR – Inhalation route				Individual ELR – Oral route			
	N sites	Min-Max	P50	P90	N sites	Min-Max	P50	P90
UC 1	19	0-1.75E-04	2.67E-07	1.03E-05	11	0-3.69E-06	9.87E-08	1.86E-06
UC 2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
UC 3	254	0-3.62E-03	2.34E-06	7.80E-05	114	0-6.70E-05	2.67E-07	8.08E-06
UC 4	5	0-1.60E-04	n/a	n/a	2	0-1.53E-06	n/a	n/a
UC 5	52	0-3.62E-03	7.07E-06	1.95E-04	34	0-8.49E-05	7.26E-07	1.62E-05
UC 6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ALL	300	0-3.62E-03	1.90E-06	7.50E-05	143	0-8.5E-05	2.5E-07	9.10E-06

Source: based on data submitted as part of the AfA by the CTAC Sub2 consortium (2021-2023).

## **1.5. Justification for EU-wide action**

Cr(VI) substances are among the most potent carcinogens in the workplace. They are used by thousands of workers throughout the EU. The intention of this Annex XV restriction proposal is to adequately control the risks of Cr(VI) substances when they would no longer be regulated under Annex XIV of REACH and to include barium chromate (EC No 233-660-5) in order to avoid regrettable substitution.

A comparison of current excess lifetime risk (ELR) levels as reported in Section 1.4.10 with the recent opinion of the Advisory Committee on Safety and Health at Work on setting limit values for non-threshold carcinogens<sup>25</sup> shows that the median ELR across all UCs is slightly above the recommended "lower risk level" while the P90 value is very close to the recommended "upper risk level". Based on this evidence, priority action is warranted.

In the absence of any other Union-wide regulation of comparable stringency, the removal of these SVHCs from Annex XIV would, in the longer term<sup>26</sup>, weaken the protection of human health in the EU from the carcinogenic properties of Cr(VI). While Cr(VI) exposure and emission limits could be set at national level, this would undermine the EU internal market and contradict other EU legislation such as Directive (EU) 2017/2398, which sets out a binding occupational exposure limit (BOEL) for Cr(VI) across the Union. Similar considerations apply to the environmental releases of Cr(VI).

Finally, it is emphasised that different national requirements pose challenges for supranational companies that use Cr(VI) substances in several Member States and that seek to harmonise worker protection across their operations.

#### Therefore, the Dossier Submitter concludes that EU-wide action is justified.

# **2. Identification of REACH restriction options**

## 2.1. Justification that a restriction is the most appropriate EU action

Having established the need for EU-wide action to manage the risks associated with certain Cr(VI) substances, it is important to note that there already exists relevant Union-wide and national legislation to protect workers and control emissions from industrial sites.

With regard to protection of the general population, industrial emission limit values (ELVs) express the maximum permissible emissions of a substance to air or water over a specified sampling period. Although Annex VI of Directive 2010/75/EU (IED) sets ELVs for total chromium emissions to air and water from waste incinerators, these do not apply to small companies and there is no EU-wide measure for Cr(VI) emissions to the environment. As a result, and in the absence of a dedicated environmental quality standard (EQS) for Cr(VI), permits that set ELVs for sites using Cr(VI) substances vary between EU regions (or may not apply at all). Conversely, a restriction under REACH can establish harmonised ELVs for Cr(VI) substances in scope. Therefore, the Dossier Submitter concludes that a restriction under REACH is the most appropriate EU action to harmonise the protection of the general population.

<sup>&</sup>lt;sup>25</sup> <u>ACSH opinion on limit value setting</u>.

<sup>&</sup>lt;sup>26</sup> In the short term, it is unlikely that companies will significantly reduce the level of worker protection.

With regard to worker protection, Directive (EU) 2017/2398 sets an EU-wide BOEL of 5 µg Cr(VI)/m<sup>3</sup> (time-weighted average) per 8h-workday, applicable from January 2025 onwards. Applying the RAC dose-response function for inhalation exposure to Cr(VI) compounds, the EU BOEL corresponds to an excess lifetime risk of 2 %, which is five times higher than the "upper risk level" and 500 times higher than the "lower risk level" proposed in the recent opinion of the ACSH.<sup>25</sup> Although more stringent BOELs exist at Member State level (see Appendix D.1.2 for an overview), there may be scope for reducing these levels in a harmonised way throughout the Union.

As Cr(VI) substances have many uses that vary both in terms of exposure potential and perceived importance to society, setting one common limit value for all uses could result in a situation where the continuation of site-critical uses (e.g. aircraft repair) would be either impossible or extremely difficult, while the same limit value could be too lenient for uses with low exposure potential (e.g., automated plating of plastic parts). Moreover, for some uses there are known substitutes that could become suitable in the future, whereas for other uses a very strict limit value would implicitly mean a ban in the EU as no suitable alternatives are on the horizon.

An additional advantage of a restriction under REACH is that it provides the flexibility to set scientific limit values (LVs) for worker exposure *per* use category or to ban certain uses altogether.<sup>27</sup> On the downside, setting different regulatory measures for different use categories is more complex and may pose enforcement challenges.

Considering the above reasons, the Dossier Submitter concludes that a restriction under REACH is the most appropriate EU-wide measure to address the identified risk associated with the use of certain Cr(VI) substances.

# **2.2. Identification of REACH restriction options**

# 2.2.1. General approach to designing the restriction options

As described in Section 1.3.2, different use categories/sectors using Cr(VI) substances are characterized by different exposure conditions. Therefore, a set of restriction options (ROs) is developed to control the risks associated with exposure to Cr(VI) for each of the use categories identified. In terms of worker exposure, the design of these restriction options is compatible with the principles of 'hierarchy of prevention and control'<sup>28</sup> as companies will still need to comply with applicable EU and national occupational health and safety legislation<sup>29</sup> when deciding on the set of measures they implement to meet the proposed LVs. Accordingly, companies should address the identified risks through a combination of:

- Elimination/substitution of the substance use where viable alternatives are available
- Engineering controls in the form of risk management measures (RMMs) to comply with specific LVs for exposure
- Administrative controls, e.g. monitoring requirements (air and water measurements, biomonitoring) to ensure that engineering controls are effective in

<sup>&</sup>lt;sup>27</sup> A restriction under REACH would not apply to process-generated exposure to Cr(VI) (e.g. through welding, grinding or scraping of inert chrome layers where Cr(VI) is heat-generated).

<sup>&</sup>lt;sup>28</sup> <u>https://oshwiki.osha.europa.eu/en/themes/hierarchy-prevention-and-control-measures</u>.

<sup>&</sup>lt;sup>29</sup> <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004L0037-20240408</u>.

addressing the risk

• Personal Protection Equipment (PPE) for substance uses (e.g., spraying) for which Cr(VI) exposure cannot be brought down to low levels otherwise

In practice, the proposed restriction options rely on a set of scientific limit values as justified in Section 2.1. Companies that already comply with these scientific limit values can continue their uses; companies that do not comply have to decide how they can best achieve compliance by either substituting, improving risk control or ceasing their uses of Cr(VI) substances altogether. Using information on the anticipated reaction of regulated industry sectors to various LVs and ELVs, the benefits and costs of the proposed options (and permutations of them) can be assessed as described below. Notably, separate assessments are made for workers (see Section 2.2.2) and the general population (see Section 2.2.3).

In the early phase of the investigation for this Annex XV report, other options to restrict the Cr(VI) substances were considered. (A summary of other restriction options can be found in Appendix E.1.) In particular, a ban on the placing on the market of the substances in scope was considered by the Dossier Submitter. However, such a ban did not appear to be proportionate to the risks posed by the Cr(VI) substances, especially if these risks are minimised. More importantly, a ban on placing on the market could have unintended effects as certain of the Cr(VI) substances—in particular CrO<sub>3</sub> and sodium dichromate—in the scope of this Annex XV report are used as transported intermediates to produce various Cr(III) compounds, which then serve as the most promising alternative to certain Cr(VI) substance uses, namely in electroplating. While the Dossier Submitter has no specific information on the subsequent uses of these Cr(III) substances, the knock-on impacts of a ban on the placing on the market of Cr(VI) substances could be considerable.

### 2.2.2. Options for addressing worker exposure

It is not possible to establish a generally applicable correlation between a set of OCs and RMMs and the level of Cr(VI) to which a worker is exposed, nor to prescribe a meaningful set of OCs and RMMs at the level of a given UC. This impossibility results from two factors. First, each site differs in terms of size and use volume, process parameters (electroplating currents, bath temperatures, etc.), existing OCs and RMMs etc. Second, sites that would otherwise have high exposures are likely to have invested more in RMMs than sites with lower exposures, resulting in a classic endogeneity problem. Therefore, the restriction options are developed around scientific LVs of varying stringency for exposure to and emissions of Cr(VI).

Figure 6 illustrates the general approach to defining restriction options based on scientific LVs for worker exposure. The impact assessment is undertaken separately for each of the different use categories to better account for differences in their socioeconomic consequences, but the guiding principle of the approach remains the same. This 'marginal' approach has several conceptual and practical advantages. Most importantly, the work on the evaluation of AfAs has shown that it is not possible to define a generic set of OCs and RMMs that would be predictively effective in limiting the risks of Cr(VI) exposure/emissions. Instead, the duty holder is free to implement the measures that enable them to comply with a given LV at the lowest possible cost. From an economic perspective, this is the most efficient way of ensuring compliance with a restriction option and thus preferred to a prescriptive 'Command and Control' approach (Phaneuf and Requate 2016).



#### Figure 6. Illustration of the approach to defining options for worker exposure

A range of LVs for 8-hour time-weighted average (8h TWA) Cr(VI) exposure is examined. The LVs correspond to the excess lifetime risk (ELR) for fatal cancer *bracketed* by the EU binding occupational exposure limit (BOEL) value<sup>30</sup> for Cr(VI) on the one hand, and the lower risk level of 4:100 000 set in the recent opinion<sup>25</sup> of the ACSH. Applying the RAC dose-response function for Cr(VI) suggests that the corresponding LVs range from 5 down to 0.01  $\mu$ g Cr(VI)/m<sup>3</sup> (8h TWA). To put these LVs into perspective, the highest 8h TWA exposures reported by applicants for authorisation are close to 5  $\mu$ g Cr(VI)/m<sup>3</sup>, whereas the level of detection for Cr(VI) in air is close to 0.01  $\mu$ g Cr(VI)/m<sup>3</sup> (implying that a lower LV could not be monitored). The upper risk level in the recent opinion of the Advisory Committee on Safety and Health at Work corresponds to 1  $\mu$ g Cr(VI)/m<sup>3</sup>. As the current BOEL is 5 times higher, priority action to review the BOEL is indicated.

In practice, the most stringent LV will effectively ban many uses of Cr(VI) substances as compliance would require full automation, whereas the most lenient LV will codify the status quo. For each of the use categories defined in Section 1.3, the socioeconomic impacts, i.e. the expected benefits and costs of complying with the different LVs, will thus be analysed. This will result in a matrix of different use categories and different LVs. Each cell of this matrix will contain the expected impacts of a specific LV on a specific use category. (For additional restriction options, the details of the impact assessment are relegated to Appendix E.1.) Based on this matrix, it is not only possible to propose restriction options that combine a set of LVs for specific use categories; one may also assess permutations of the proposed restriction options.

## 2.2.3. Options for addressing general population exposure

A similar approach is proposed to manage the risks related to Cr(VI) exposure of the general population via emissions to the environment as identified in Section 1.4.3.2. However, some additional steps are needed to convert Cr(VI) emissions to water and air into exposure of people living in the vicinity of plants that use Cr(VI) substances, and ultimately into ELR of cancer in the exposed population. The flowchart in Figure 7 summarises these steps.

<sup>&</sup>lt;sup>30</sup> <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02004L0037-20220405</u>.

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#### Figure 7. Environmental risk assessment pathway

For the worker risk assessment, it is reasonable to assume that there is one principal source of Cr(VI) exposure per worker corresponding to that worker's main task(s). An additional complexity arises in the risk assessment for the general population because the population in any specific area can be exposed to multiple sites that emit Cr(VI) to the same area. To account for the possibility of multiple exposure sources, the Dossier Submitter undertook a spatially explicit analysis of the DU notifications for existing authorisations of Cr(VI) substance uses.

This analysis draws on location information of 1 578 sites that reported downstream uses linked to existing Cr(VI) authorisations and corresponding population statistics from Eurostat available at a 1 x 1 km resolution (details are provided in Appendix D.2). Unfortunately, only 25 % of these sites reported measured emissions to air and water. Therefore, the analysis is subject to some uncertainties related to the representativeness of the reporting sites for the universe of sites using Cr(VI) substances in the EU. Bearing this caveat in mind, the upshot of this analysis can be summarised as follows:

- While ~95 % of the grid cells with Cr(VI)-emitting sites host only one site, some ~5 % of cells host two or more sites, confirming the possibility of multiple exposure sources
- Based on population statistics from Eurostat, the analysis suggests that a mean | P50 | P90 of ~1 600 | ~400 | ~4 000 people live within 1 km<sup>2</sup> of a Cr(VI)-emitting site
- Cr(VI) emissions to air can be converted into individual ELR of lung cancer using common modelling assumptions (see Appendix B.8.1). Applying these conversions to the sites for which air emission data are available suggests that a ELR of 1E-6 | 1E-5 | 1E-4 is exceeded at ~70 % | ~40 % | ~10 % of the sites
- Cr(VI) emissions to water can be converted into individual ELR of intestinal cancer using common modelling assumptions (see Appendix B.8.1). Applying these conversions to the sites for which water emission data are available suggests that a ELR of 1E-6 | 1E-5 | 1E-4 is exceeded at ~55 %| ~30 % | ~5 % of the sites

Based on this analysis, the Dossier Submitter considers that harmonised emission limit values (ELVs) could minimise general population exposure to Cr(VI) and assesses the introduction of a binding ELV that would limit the individual ELR of lung cancer and intestinal cancer in the proximity of Cr(VI)-emitting sites to different target risk levels.

In line with the ALARP principle (Jones-Lee and Aven 2011) and in the absence of accepted EU reference levels for cancer risk, the strictest ELR that the Dossier Submitter considers meaningful in this context corresponds to the general population risk criterion of 1E-6 given in the CARACAL paper (CA/101/2017)<sup>31</sup> on long review periods in REACH authorisations. This paper is particularly relevant in this context, as the impact assessment presented below will consider a similar assessment period. It may be argued that the same criterion should be applied in the context of this REACH restriction.

Using the dose-response relationship for inhalation exposure, a lung cancer ELR of 1E-6 corresponds to annual emissions of ~50 g Cr(VI) to air. As suggested by the analysis above, there is a ~5 % probability that individuals are exposed to more than one relevant exposure source. An ELV of 25 g/y for Cr(VI) emissions to air will almost certainly ensure that no member of the general population bears a lung cancer ELR > 1E-6.

Similar considerations can be made for Cr(VI) emissions to water where, using the doseresponse function for intestinal cancer, a ELV of 150 g/y will ensure that no member of the general population bears an intestinal cancer ELR > 1E-6. For target risk levels of 1E-5 and 1E-4, these ELVs can simply be scaled by a factor of 10 and 100 respectively, see Table 20.

Target ELR of cancer	Implied ELV for air	Implied ELV for water <sup>[1]</sup>
<1E-4	2.500 kg/y	15.00 kg/y
<1E-5	0.250 kg/y	1.500 kg/y
<1E-6	0.025 kg/y	0.150 kg/y

Table 20. Summary of selected ELVs for Cr(VI) emissions to air and water

Table notes: <sup>[1]</sup> based on an averaging of the exposure scenarios documented in Figure 5. Details on the calculation are reported in Appendix B.8.1.

## 2.2.4. Restriction options

The Dossier Submitter assessed three different restriction options that differ in their regulatory stringency across the six identified use categories (but are for the utilisations within a particular use category). Table 21 provides an overview of the proposed restriction options. Other restriction options were initially considered but the Dossier Submitter discarded them as they either failed the proportionality test or posed various enforceability issues.

A brief summary of the proposed restriction options is given below. A detailed analysis of the impacts and their proportionality will be provided in Sections 3.3 to 3.6. A detailed assessment of alternative restriction options is relegated to Appendix E.1. However, the Dossier Submitter stresses that – as described in Section 2.2.1 – the modular design of the restriction options allows the decision maker to modify the restriction options assessed in this Annex XV restriction proposal to account for various policy views.

<sup>&</sup>lt;sup>31</sup> <u>https://echa.europa.eu/documents/10162/17091/ca 101 2017 criteria longer review period afa en.pdf</u>.

Use Category	R01	R02	RO3	
UC 1   Formulation of mixtures	LV: 5 µg Cr(VI)/m <sup>3</sup>	LV: 1 µg Cr(VI)/m <sup>3</sup>	LV: 0.5 µg Cr(VI)/m <sup>3</sup>	
	ELV <sub>air</sub> : 2.5 kg Cr(VI)/y	ELV <sub>air</sub> : 0.25 kg Cr(VI)/y	ELV <sub>air</sub> : 0.025 kg Cr(VI)/y	
	ELV <sub>water</sub> : 15 kg Cr(VI)/y	ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	
UC 2   Electroplating on plastic substrate	LV: 1 µg Cr(VI)/m³	LV: 0.5 μg Cr(VI)/m³	LV: 0.1 µg Cr(VI)/m³	
	ELV <sub>air</sub> : 2.5 kg Cr(VI)/y	ELV <sub>air</sub> : 0.25 kg Cr(VI)/y	ELV <sub>air</sub> : 0.025 kg Cr(VI)/y	
	ELV <sub>water</sub> : 15 kg Cr(VI)/y	ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	
UC 3   Electroplating on metal substrate	LV: 5 μg Cr(VI)/m³	LV: 1 µg Cr(VI)/m³	LV: 0.5 μg Cr(VI)/m³	
	ELV <sub>air</sub> : 2.5 kg Cr(VI)/y	ELV <sub>air</sub> : 0.25 kg Cr(VI)/y	ELV <sub>air</sub> : 0.025 kg Cr(VI)/y	
	ELV <sub>water</sub> : 15 kg Cr(VI)/y	ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	
UC 4   Slurry coating operations [1]	LV: 5 μg Cr(VI)/m³	LV: 0.5 μg Cr(VI)/m <sup>3</sup>	LV: 0.1 µg Cr(VI)/m <sup>3</sup>	
	ELV <sub>air</sub> : 2.5 kg Cr(VI)/y	ELV <sub>air</sub> : 0.25 kg Cr(VI)/y	ELV <sub>air</sub> : 0.025 kg Cr(VI)/y	
	ELV <sub>water</sub> : 15 kg Cr(VI)/y	ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	
UC 5   Other surface treatments	LV: 5 μg Cr(VI)/m³ ELVair: 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.25 kg Cr(VI)/y ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	LV: 0.1 µg Cr(VI)/m³ ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	
UC 6   Functional additives/process aids	LV: 1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.25 kg Cr(VI)/y ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	LV: 0.1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	

Table 21. Overview of the proposed restriction options

Table notes: <sup>[1]</sup> all LVs are expressed as 8h-TWA, <sup>[2]</sup> the impact assessment assumes that the use of more effective RPE will be a common response to comply with the LV.

## **Restriction option 1 – RO1**

This restriction option sets the least stringent LVs and ELVs. The evidence gathered during the preparation of this Annex XV restriction proposal suggests that ~90 % of the companies operating in each of the six use categories already comply with the LVs for worker exposure *and* the ELVs for environmental emissions. In other words, this restriction option would be a step towards slightly better standards for occupational and environmental health and safety at minimal compliance costs. The benefit of the options would mainly be related to setting harmonised standards across the EU.

## **Restriction option 2 – RO2**

This restriction option provides for more stringent LVs and ELVs. The evidence gathered during the preparation of this Annex XV restriction proposal suggests that ~62 % of the companies operating in each of the six use categories already comply with the LVs for worker exposure, and around half of them already comply with the ELVs for environmental emissions. This restriction option would therefore reduce the prevailing Cr(VI) exposure of both workers and the general population by eliminating the largest sources of Cr(VI) exposure, whilst allowing many operators to continue their uses under safer conditions.

### **Restriction option 3 – RO3**

This restriction option includes the most stringent LVs and ELVs. The evidence gathered during the preparation of this Annex XV restriction proposal suggests that ~32 % of the companies operating in each of the six use categories already comply with the LVs for worker exposure, and ~23 % of them already comply with the ELVs for environmental emissions. This restriction option would therefore require substantial investments in RMMs by the majority of companies using Cr(VI) substances in the EU. A significant proportion of companies (~30 %) indicated that they would cease operations involving the use of Cr(VI) substances in the EU in response to this restriction option.

## 2.3. General considerations for setting transition periods

For an effective implementation and enforcement, a minimum transition period is needed to allow sufficient time for affected actors to adapt their operations to and comply with the conditions set out in Annex XVII of REACH. This restriction proposal is unique in that it seeks to restrict substances that are currently listed in Annex XIV of REACH (plus barium chromate) and for which substitution and risk control efforts have been underway for at least a decade. Accordingly, there are a number of considerations in determining the optimal transition period that relate to the current progress in phasing out the use of Cr(VI) substances in the EU.

A longer transition period may significantly reduce the non-use cost, i.e. the cost of no longer using Cr(VI) substances, especially if the transition period coincides with the remaining lifespan of the production capital. However, a longer transition period also means a longer continuation of the status quo. There is no reason to expect that companies would reduce existing risk control efforts in response to a longer transition period. Given the unique situation where the regulatory regime is intended to be changed from Annex XIV to Annex XVII of REACH, a longer transition period thus implies a longer period during which the use of Cr(VI) substances are less strictly regulated.

A shorter transition period, on the other hand, will make substitution even less attractive since premature retirement of production capital or investments into meeting the conditions imposed by the restriction coincide with investments in developing suitable alternatives. There is additional pressure for companies that have long term contracts for the supply of certified parts; a shorter transition period may hamper their competitiveness compared to actors outside the EU that can ensure the long-term availability of products and services according to the requirements of their customers.

If a company is in the process of substituting its use of a Cr(VI) substance, there is no reason to assume that it will also invest in risk control; conversely, if a company is investing in RMMs to comply with the conditions imposed by the restriction, it is doing so because it has no intention to substitute. In other words, risk control and substitution efforts are, economically speaking, substitutes, each crowding out investment in the other.

Based on these considerations, the Dossier Submitter proposes a **uniform transition period of 18 months** for all restriction options and all use categories, which should provide sufficient time for companies to upgrade their RMMs if they do not yet meet the relevant limit values. The Dossier Submitter acknowledges that this relatively short transition period will not encourage substitution efforts. If promoting substitution were the main objective of this Annex XV restriction proposal, the transition period would need to be longer than five years to allow for the technical maturity of alternatives, the recertification of products using these alternatives, etc. On balance, and given the risk of a persistent regulatory loophole, the proposed 18-month period seems most appropriate.

## **2.4. General considerations on the proposed limit values**

The proposed limit values for worker exposure and emissions of Cr(VI) to air and water have been determined based on the dose-response relationships set out in Section 1.4 and the target risk levels reported in Table 22. While the Dossier Submitter notes that there is no single acceptable risk standard in EU legislation, some of the Member States (e.g. Germany, the Netherlands) know 'acceptable risks' for both workers and the general population. The Dossier Submitter emphasises that the proposed LVs for worker exposure are 8h time-weighted averages, meaning that short term exposures exceeding these LVs are still permissible under the proposed restriction options as long as substance users comply with EU OSH legislation. Similar peak exposure considerations are not relevant for the proposed ELVs.

Use category	R01	RO2	RO3
UC 1   Formulation of mixtures	ELR <sub>w</sub> : 2E-2	ELRw: 4E-3	ELRw: 2E-3
	ELR <sub>GP_air</sub> : 1E-4	ELR <sub>GP_air</sub> : 1E-5	ELR <sub>GP_air</sub> : 1E-6
	ELR <sub>GP_water</sub> : 1E-4	ELR <sub>GP_water</sub> : 1E-5	ELR <sub>GP_water</sub> : 1E-6
UC 2   Electroplating on plastic substrate	ELR <sub>W</sub> : 4E-3	ELR <sub>W</sub> : 2E-3	ELR <sub>W</sub> : 4E-4
	ELR <sub>GP_air</sub> : 1E-4	ELR <sub>GP_air</sub> : 1E-5	ELR <sub>GP_air</sub> : 1E-6
	ELR <sub>GP_water</sub> : 1E-4	ELR <sub>GP_water</sub> : 1E-5	ELR <sub>GP_water</sub> : 1E-6
UC 3   Electroplating on metal substrate	ELR <sub>w</sub> : 2E-2	ELRw: 4E-3	ELRw: 2E-3
	ELR <sub>GP_air</sub> : 1E-4	ELR <sub>GP_air</sub> : 1E-5	ELR <sub>GP_air</sub> : 1E-6
	ELR <sub>GP_water</sub> : 1E-4	ELR <sub>GP_water</sub> : 1E-5	ELR <sub>GP_water</sub> : 1E-6
UC 4   Use of primers and other slurries	ELR <sub>W</sub> : 2E-2	ELR <sub>W</sub> : 2E-3 <sup>[1]</sup>	ELR <sub>W</sub> : 4E-4 <sup>[1]</sup>
	ELR <sub>GP_air</sub> : 1E-4	ELR <sub>GP_air</sub> : 1E-5	ELR <sub>GP_air</sub> : 1E-6
	ELR <sub>GP_water</sub> : 1E-4	ELR <sub>GP_water</sub> : 1E-5	ELR <sub>GP_water</sub> : 1E-6
UC 5   Other surface treatments	ELRw: 2E-2 ELR <sub>GP_air</sub> : 1E-4 ELR <sub>GP_water</sub> : 1E-4	ELRw: 2E-3 ELR <sub>GP_air</sub> : 1E-5 ELR <sub>GP_water</sub> : 1E-5	ELRw: 4E-4 ELR <sub>GP_ai</sub> r: 1E-6 ELR <sub>GP_water</sub> : 1E-6
UC 6   Functional additives/process aids	ELRw: 4E-3 ELR <sub>GP_air</sub> : 1E-4 ELR <sub>GP_water</sub> : 1E-4	ELRw: 2E-3 ELR <sub>GP_ai</sub> r: 1E-5 ELR <sub>GP_water</sub> : 1E-5	ELRw: 4E-4 ELR <sub>GP_air</sub> : 1E-6 ELR <sub>GP_water</sub> : 1E-6

Table 22. Correspondence between limit values and excess lifetime risks

Table notes:  $ELR_W =$  individual cancer excess lifetime risk to workers;  $ELR_{GP\_air} =$  individual cancer excess lifetime risk to the general population via emissions to air;  $ELR_{GP\_water} =$  individual cancer excess lifetime risk to the general population via emissions to water; <sup>[1]</sup> the impact assessment assumes that the use of more effective RPE will be a common response to comply with the LV.

# **3. Impact assessment**

# 3.1. Scope and approach

This Annex XV restriction report proposes to restrict the use of certain Cr(VI) substances currently listed in Annex XIV of REACH as well as barium chromate (EC No 233-660-5), which is considered a possible 'regrettable substitute' for some of these Cr(VI) substances. The restriction is assumed to enter into force in 2028 (the base year for this impact assessment) and will apply to those uses of these substances in the European Economic Area (EU Member States + Iceland, Liechtenstein and Norway) that are currently covered by the REACH authorisation process. In practice, this means that the manufacture of mixtures containing the Cr(VI) substances (also known as formulation) is within the scope of the restriction, but the manufacture of the actual Cr(VI) substances themselves is not.

Activities where exposure to Cr(VI) substances results from physical or chemical modification of the surface of articles that do *not* contain Cr(VI) themselves (e.g. by grinding, scraping or welding) are not covered by this proposal, as they are outside the scope of the restriction title of REACH. However, the restriction does apply to so-called "self-healing" or "sacrificial" coatings, which contain Cr(VI) but are sealed by a stable chromium oxide layer so that exposure to Cr(VI) can only occur when the surface is modified (e.g. by sanding during MRO activities).

The general approach to assessing the socio-economic impacts of this Annex XV restriction proposal relies on different scientific limit values for exposure to and emissions of Cr(VI) and compares the benefits of implementing such measures against their economic consequences. The impact assessment is specific for each use category and based on a quantitative comparison of the expected health benefit from reducing Cr(VI) exposure of workers and the general population on one hand and the welfare costs accruing from compliance with different restriction options on the other.

Specifically, the following impacts will be assessed:

- Restricting the use of certain Cr(VI) substances reduces the risk of lung and intestinal cancer in the population at risk. As carcinogenesis is an inherently stochastic process, a reduction in exposure represents a statistical benefit that cannot be quantified for an identifiable individual but must be understood in a population context (Hammitt and Treich 2007). The benefit of restricting the use of certain Cr(VI) substances is thus measured in terms of reduced cancer burden in the EU.
- Restricting the use of certain Cr(VI) substances gives rise to two categories of private costs. The first category comprises 'compliance costs' incurred by companies to improve their risk management measures (RMMs) and operational conditions (OCs) in order to limit worker exposure to and control emissions of Cr(VI) to water and air. The second category relates to the phase-out of the substance use and may entail costs for substitution, recertification, shutdown and relocation. Such 'non-use costs' also include the premature retirement of production capital, e.g. when equipment can only be resold at a significant loss (Ramey and Shapiro 2001).
- Additional welfare impacts occur whenever the restriction of a substance entails benefits or costs that are born primarily by society. For example, the cease of Cr(VI) uses in the EU may result in unemployment spells that have detrimental effects on the health of laid-off workers (Wilson and Walker 1993), but may (marginally) reduce the societal cost of cancer treatment; products that use alternative technologies may entail a consumer surplus loss and harbour risks themselves, but consumers may value the fact that products were produced under safe working conditions; importing products using Cr(VI) substances from outside the EU entails an additional carbon footprint, but this may be internalised through the EU's Carbon Border Adjustment Mechanism.

For assessing these impacts, the Dossier Submitter adopts a marginal approach that compares the societal cost of lowering the exposure/emission by one unit to the expected societal benefit in terms of the associated reduction in cancer risk per individual exposed. At the optimal level, the marginal cost equals the marginal benefit, i.e. the cost of reducing exposure by one additional unit is lower (higher) than the corresponding benefit.





Source: ECHA (2013).

Figure 8 illustrates this logic, assuming that the marginal benefit of abatement is constant since every unit of risk reduction is deemed equally valuable. In contrast, the marginal cost of abatement is steadily increasing, reflecting that it becomes increasingly costly to abate an additional unit of exposure as one moves along the safety production function.

The cost of achieving a given level of exposure/emission can be divided by the achieved exposure reduction, yielding the marginal cost of reducing exposure by one unit. This marginal abatement cost measures how costly it is for a company to achieve target exposure level given some level of output (Klepper and Peterson 2006). To make the marginal abatement costs comparable across companies of different size and output, the reported costs are further normalised by the number of directly exposed workers (based on information obtained in the CfEs).

The resulting normalised marginal abatement cost corresponds to the cost of a marginal reduction in Cr(VI) exposure per exposed worker. Following this approach, costs are expressed as the marginal cost per worker over an assessment period of 20 years. Benefits can be broken down in a similar way. All benefits and costs of complying with a given LV are annualised using a 3 %-discount rate in line with the EU Better Regulation Guidelines.

## 3.1.1. Information sources

Although abundant information on uses of Cr(VI) substances is available from both AfAs and Art. 66 notifications for downstream uses of granted authorisations, the use of this information would have several drawbacks: (1) the information was gathered at different points in time; therefore, relying on this information risks using outdated information with regard to exposure conditions, adoption of alternatives, etc.; (2) some companies were part of multiple AfAs covering the same/similar uses or provided the same information as part of an AfA and as part of a DU notification; therefore, relying on this information risks double counting; and (3) highly relevant information such as the expected response to specific limit values and the corresponding costs of compliance or non-use have not been gathered as part of the AfA work; therefore, relying on this information risks obscuring the real impacts on companies affected by this Annex XV restriction report.

For these reasons, the impact assessment presented below relies heavily on stakeholder engagement. The Dossier Submitter gathered extensive information on the cost of reducing exposure to Cr(VI) in the two targeted CfEs. Specifically, the Dossier Submitter reached out to: (i) companies that had submitted an AfA for one or more Cr(VI) substances, (ii) companies that had notified downstream uses in accordance with Art. 66 of REACH, (iii) lead registrants for all Cr(VI) substances in the scope of the proposal as well as various industry associations. These stakeholders were made aware of the targeted CfEs held during the preparation of the proposal and a total of 675 companies using Cr(VI) substances provided company-specific information on the anticipated response to and the costs of complying with different limit values. (See Appendix G.1 for more information on participation in the CfEs.) As these correspond to one third of all companies expected to be using Cr(VI) substances in the EU, the CfE data permits assessing the impacts of different restriction options on the basis of representative, up-to-date and harmonised information.

## **3.1.2.** Compliance costs

The stricter the LVs and ELVs a company has to comply with, the more it needs to invest in order to lawfully continue using Cr(VI) substances. To gauge realistic compliance costs, companies were asked in the CfEs to provide compliance cost estimates for different LVs. Other inputs into the cost analysis were compiled from various AfAs of different Cr(VI) substance uses and unit cost estimates recommended by SEAC.

#### Costs related to abating Cr(VI) exposure in the workplace

Companies in the CfEs provided both the expected investment cost and the annual operating cost for the additional RMMs needed to comply with the different LVs. When companies reported ranges of cost estimates, the Dossier Submitter used the mean of the lower and upper value as central estimate. The investment cost was assumed to account for an assessment horizon of 20 years. The reported increase in annual expenditure, i.e. the operating costs, was multiplied by the annuity factor that corresponds to this horizon and discounted at a rate of 3 % as recommended by the Better Regulation Guidelines. The sum of both investment and operating cost represents the total technical compliance cost accruing to each company over the assessment period.

To allow for a meaningful comparison between small, medium and large companies, the cost estimate was divided by the number of directly exposed workers, i.e. costs are measured in  $\in$  per exposed worker. In a next step, the Dossier Submitter converted the total cost per worker into a marginal abatement cost (MAC) per worker and unit of exposure reduction. To this end, absolute cost figures were divided by the reduction in exposure to Cr(VI) that would result from moving to the next stricter LV. For example, moving from 5 µg/m<sup>3</sup> to 1 µg/m<sup>3</sup> would result in an exposure reduction of 4 µg/m<sup>3</sup>, whereas moving from 1 µg/m<sup>3</sup> to 0.5 µg/m<sup>3</sup> would result in an exposure reduction of 0.5 µg/m<sup>3</sup> and so on. By marginalising the cost estimates in this way, the resulting marginal abatement cost is directly comparable to the marginal benefit of reducing Cr(VI) exposure, and the associated risk, by one unit per worker.

In order to work with the marginal abatement costs indicated in the CfEs, the Dossier Submitter estimated for each use category the relationship between reduction in exposure and marginal abatement costs using a panel regression model where the abatement cost at each LV is company specific (see Appendix E.3 for details). Figure 9 depicts the results of this analysis. For all use categories, the marginal cost for abating worker exposure is very low down to an exposure value of ~1.5  $\mu$ g/m<sup>3</sup>, meaning that moving from exposure levels between 5 and 1.5  $\mu$ g/m<sup>3</sup> can be achieved at minimal costs. At 1  $\mu$ g/m<sup>3</sup>, the marginal abatement cost is  $\in$ 5 000-20 000 per worker and  $\mu$ g/m<sup>3</sup>, depending on the use category.

Some caution should be exercised when comparing these estimates for the different use categories. For example, UC 4 (use of primers and other slurries) has a lower marginal abatement cost than the plating uses (UCs 2 and 3). In the CfEs, many companies operating in UC 4 clarified that they would rely on improved PPE to comply with strict LVs. In comparison, most plating companies indicated that they would invest in technical risk control measures. The reliance on PPE keeps the marginal abatement costs for UCs 4 and 5 (other surface treatments) at a relatively low level even at strict LVs, whereas for electroplating on metal substrate (UC 3) the marginal abatement cost per worker per  $\mu$ g/m<sup>3</sup> approaches  $\leq$ 100k at a LV of 0.5  $\mu$ g/m<sup>3</sup>.

To derive the total abatement cost for reaching different LVs, the marginal cost curves per use category are integrated from the baseline exposure to the relevant LVs. The marginal abatement cost curve is a function representing the derivative of the total cost of abatement at different levels of exposure. It indicates the additional cost incurred by an additional unit of abatement. As integration is the inverse operation of differentiation, integrating a marginal abatement cost curve over an exposure interval will provide the total cost of achieving this exposure reduction. More details on the estimated marginal cost functions and the definite integrals are reported in Appendix E.3.



#### Figure 9. Marginal abatement cost (MAC) curves for different use categories

*Figure notes: each dot represents a cost reported by companies participating to the CfEs. Source: estimated based on information submitted in response to the CfEs.* 

### Costs related to abating Cr(VI) emissions to the environment

As set out in Section 2.2.4, the proposed restriction options include ELVs for water and air to reduce the general population risk of Cr(VI) exposure via emissions to the environment. Depending on the stringency of the ELVs, a higher or lower share of companies will have to invest in improving their abatement technology. The stricter the ELV, the greater will be both the abatement efficiency required to comply and the proportion of companies that are not in compliance.

Based on the CfEs, the Dossier Submitter estimates that under RO2 about half of the companies using Cr(VI) substances in the EU will need to invest to reduce their releases to air, and ~15 % will need to invest to reduce their releases to the water. Of the companies that will have to invest, the majority (74 %) will have to cut releases to air by less than 90 %; another 20 % will have to cut releases to air by 90-99 %, and the remaining 5 % will have to make cuts of more than 99 %. A similar picture emerges for releases to water (Table 23).

The BAT reference document (Brinkmann, Santonja et al. 2016) for common wastewater and waste gas treatment in the chemical sector lists possible abatement techniques for release reduction, including their expected abatement efficiency for different particle types. For air releases, common techniques include scrubbers, aerosol/droplet separators, mist filters and fabric filters. For wastewater, common techniques include neutralisation, chemical reduction, filtration, coagulation and flocculation, and sedimentation.

Compliance status	RO1	RO2	RO3	Compliance cost [1]
Releases to air				
Already comply with ELV	87 %	50 %	23 %	€0
Need to cut releases by $<$ 90 %	11 %	38 %	27 %	€250k
Need to cut releases by 90-99 %	2 %	10 %	38 %	€680k
Need to cut releases by >99 $\%$	0 %	2 %	12 %	€1.1m-1.6m
Releases to water				
Already comply with ELV	96 %	85 %	56 %	€0
Need to cut releases by <90 $\%$	2 %	11 %	29 %	€250k
Need to cut releases by 90-99 $\%$	2 %	2 %	11 %	€680k
Need to cut releases by >99 %	0 %	2 %	4 %	€1.1m-1.6m

Table 23. ELV compliance rates and costs to companies

*Table notes:* <sup>[1]</sup> *per site over the 20-year assessment period.* 

Source: based on information submitted in response to the CfEs.

Although the BAT reference document provides indicative cost estimates for abatement techniques, these estimates are not directly applicable to Cr(VI) emissions. For example, relatively inexpensive fabric filters are reported to have a very high abatement efficiency for some particulate matter. However, Cr(VI) releases to air are usually in the form of aerosols, and fabric filters would not be effective in limiting them. Just selecting the most cost-effective techniques indicated in the BAT reference document would therefore drastically underestimate the total compliance costs to be incurred by the regulated companies. Instead, the Dossier Submitter used cost estimates from a previous Annex XV restriction dossier on five cobalt salts<sup>32</sup>, which are also used in electroplating and therefore comparable to the Cr(VI) substances in the scope of this Annex XV restriction proposal.

In that case, the Dossier Submitter had assumed, and SEAC had verified, that an average scrubber unit would require an investment of  $\leq 100k-500k$  and would incur operational costs of  $\leq 10k-100k$  per year. As the abatement techniques for cobalt salts and Cr(VI) substances are very similar, at least for plating uses, it stands to reason that the costs are also comparable. In order to verify this assumption, the Dossier Submitter asked companies in the CfEs to provide information on the expenditures they had made in the last 10 years to reduce Cr(VI) release to water and air. The average cost reported in the CfEs for measures to reduce emissions to both air and water was close to  $\leq 500k$  over 10 years, which corresponds to average abatement efficiencies of 99.9 % for air and 99 % for water releases, respectively.

The Dossier Submitter combined these unit cost estimates with the compliance status reported in Table 23 to derive indicative costs for complying with different ELVs over the 20-year assessment period. Previous expenditures to reduce Cr(VI) releases to air and water, indicated in the CfEs, were in the same order of magnitude. Therefore, investment costs of  $\in$ 100k and operational costs of  $\in$ 10k per year were assumed to achieve a 90 % reduction in releases; investment costs of  $\in$ 200k and operational costs of  $\in$ 10k per year were assumed to achieve a 99 % reduction in releases; investment costs of  $\in$ 200k and operational costs of  $\in$ 400k and operational costs of  $\in$ 10k per year were assumed to achieve a 99.99 % reduction in releases. This analysis assumes that the relative cost of reducing emissions is independent of absolute release volumes, meaning that after taking measures with an abatement efficiency of 90 %, 10 % of the initial releases remain. A further 90 % reduction brings down the residual releases to less than 1 % of the initial releases, etc. In practice, this implies a loglinear abatement cost curve.

<sup>&</sup>lt;sup>32</sup> See <u>https://echa.europa.eu/documents/10162/c0886fbb-e182-51aa-c51b-e217b6022334</u>.

## 3.1.3. Non-use costs

Not all companies are able or willing to comply with the proposed LVs, resulting in different non-use costs. The two main types of non-use costs relate to the closure/relocation of businesses and the substitution of Cr(VI) substances. It follows that non-use costs and compliance costs are mutually exclusive. If a company invests in additional OCs and RMMs and is therefore able to comply with a given LV, it will continue to use the substance and there are no non-use costs; vice versa, if a company stops using the substance, there are no compliance costs, as it will then not invest in additional OCs and RMMs.

## **Closure/relocation**

From a societal point of view, closures and relocations will have similar impacts due to the premature retirement of tangible and intangible productive assets. SEAC has agreed on a general approach to costing such impacts, whereby the societal cost of non-use is estimated on the basis of the expected loss of future profits that would result from the cessation of operations in the EU.<sup>33</sup> Where large parts of an entire sector are affected by closure/relocation, this means that suitable alternatives are generally *not* available and one would thus not expect that profit gains by alternative producers could offset profit losses in the regulated sector.

Following this line of reasoning, the Dossier Submitter assumed profit losses over 4 years for the most stringent RO3 to capture the consequences of closures/relocations in the EU. The situation is different for RO1 and RO2, where a large proportion of companies are already compliant or have indicated that they could be compliant after investing in additional RMMs. The Dossier Submitter expects that compliant companies could gain at least parts of the market share. Following the SEAC approach, the Dossier Submitter has assumed profit losses for 2 years for companies that cannot comply with the LVs proposed under RO1 and RO2.

The producer surplus losses of companies that intend to close/relocate were estimated based on (i) the annual revenues reported by companies in the CfEs, (ii) the proportion of turnover at stake in case of closure/relocation, and (iii) an average profit margin of 10 % based on experiences from previous AfAs. It should be noted that, in the context of AfA, *closure* as a non-use scenario typically refers to the complete closure of business at the relevant site. In this case, 100 % of the turnover generated at the site would be lost.

In the recent CTACSub2 AfA, however, companies made a distinction between complete and partial closure (or complete and partial relocation), where partial closure refers to the closure of the Cr(VI)-related business activities only. In case of a partial closure, the turnover at stake is considerably lower than 100 %. Complete closure and/or relocation was the most common response to non-use indicated by ~50 % of companies (n  $\approx$  150) covered by the CTACSub2 AfA; partial closure/relocation was indicated by ~35 % of companies (n  $\approx$  110) as best response to non-use. For the purpose of assessing the impacts on these use categories, the most conservative assumption of turnover at stake is therefore 50 %. The least conservative assumption is that 85 % (i.e., 50 % + 35 %) of the turnover is at stake. However, if a company continues to operate despite the closure of their Cr(VI)-related activities, it is likely that the remaining business is not directly dependent. Combining the available full/partial closure rates reported in the CfEs for UCs 3 and 4 suggests that ~60 % of turnover would be lost in case of non-use in these use categories. The same assumption is made for UC2.

For companies operating in UC 5, partial closure or relocation was the most common response to non-use (indicated by  $\sim$ 70 % of companies); complete closure/relocation was

<sup>&</sup>lt;sup>33</sup> <u>https://echa.europa.eu/documents/10162/0/afa\_seac\_surplus-loss\_seac-52\_en.pdf</u>.

indicated by 10 % of companies as best response to non-use. For the purpose of assessing the impacts of various restriction options in this use category, the most conservative assumption of turnover at stake is therefore 10 %, and the least conservative assumption is that 80 % of the turnover is at stake (10 % + 70 %). Combining these rates, and the assumption that in the case the company is able to continue their operation, it is likely that larger share of the turnover is generated by non-Cr(VI) activities, a 30 % central estimate is applied in this use category. For UC 6, only 25 companies responded to the CfEs. However, given companies in UC 6 are typically large companies with a wide variety of operation, and not all activities are related to Cr(VI), it seems plausible to assume a similar share of turnover at stake as for UC 5.

Based on these considerations, closure/relocation costs were calculated separately for each use category. The resulting loss of profit discounted over the assessment period of 20 years ranges from €300k (€600k for RO3) per exposed worker (for the ETP use in UC 5) to €600k (€1.3m for RO3) per exposed worker (in UC 4). UC 6 comprises a large variety of uses, use sectors and use conditions. Some of the uses in this category are done by very large companies with only a few exposed workers. Since these uses typically feed into other production activities, the resulting profit loss over the assessment period of 20 years is very large (up to €1-2m per exposed worker).<sup>34</sup>

## Substitution/recertification

Rather than closing/relocating operations that use Cr(VI) substances, some companies have indicated that their best response to a specific LV would be to switch to alternative technologies or substances. The proportion of companies that indicated substitution was their best response to regulation varied considerably by use category. It was lowest for UC 3, electroplating on metals, where less than 10 % of companies that did not comply with a specific LV would substitute rather than relocate or close down operations. At the other end of the spectrum, 30 % of companies in UC 5 indicated that they would substitute their uses in case they could not comply with an LV, suggesting that in this use category substitution potential is greater.

As summarised in Appendix E.2, there is a wealth of information available on potential alternatives to Cr(VI) substances from existing AfAs and the corresponding consultations. The available information suggests that implementing substitutes often requires significant investment. Costs accrue not only for new equipment, but in many cases research and development work is needed to achieve relevant quality standards. Substitutes may require (more) physical space and/or involve production downtime with subsequent loss of output. In addition, the variable costs of some of the shortlisted alternatives are significantly higher due to more expensive raw materials, increased energy demand, the need for more process steps or an increase in the workforce required to run the production process.

While qualitative information on the cost of substitution is abundant, quantitative estimates of these costs are relatively scarce. To address this gap, a specific question in CfE#2 asked companies to provide estimates of these costs. The question was addressed to suppliers of alternative substances or technologies and to companies that were already using an alternative and therefore had data on the actual (rather than the expected) costs of their substitution efforts. Respondents were asked to specify the alternative they had adopted, and to provide information on both the investment costs and the variable costs (relative to current variable costs). A full summary of the substitution costs reported in the CfE results is reported in Appendix E.3.

<sup>&</sup>lt;sup>34</sup> The Dossier Submitter notes that, because the profit margin assumption is maintained globally, these profit loss estimates are a function of average company size per use category.

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A total of 95 responses to that question were received. Out of these responses, 26 responses (27 %) were from companies that were using alternatives. However, 15 out of these 26 respondents pointed out that (i) the alternative they were using was still in a testing or validation phase, (ii) there were performance issues compared to the use of Cr(VI) substances, or (iii) the alternative could only partially replace the Cr(VI) substance(s). Six responses (6 %) were from suppliers of alternative technologies, whereas 39 responses (41 %) were received from companies that provided information on the difficulty to develop or transition to alternatives. The rest of the responses (25 %) were either from sector associations or other stakeholders wanting to provide information on alternatives.

Considering all responses with quantitative estimates, the mean (median) investment cost per line is ~€4.4m (~€3.5m); when expressed as investment cost per exposed worker, the mean (median) cost is close to €340k (€270k). Based on information received from companies that have at least partially substituted Cr(VI) substances, the lion share of these costs relates to the installation of a new production line.

Companies also compared the relative operating costs of their best alternative to the corresponding Cr(VI)-based technology. The responses show a mixed picture with estimates ranging from large reductions to drastic increases in operating costs. Both the mean and median operating costs for alternatives are more than double those of the Cr(VI)-based technology. However, these results should be interpreted with caution, as there are large differences between respondents.

Companies that had already switched to alternatives estimated on average that their operating costs increased by ~10 %, whereas companies that indicated difficulties in substitution claimed operating costs would more than triple. This contributes to high variance within a small number of observations. On this basis, it is difficult to conclude on a reliable estimate of the increase in operating costs related to the substitution of Cr(VI) substances in different use categories. Therefore, the Dossier Submitter decided to consider only substitution-related *investment* costs, noting that this approach results in a lower bound estimate of *total* substitution costs.

## 3.1.4. Additional welfare costs

In addition to private costs that accrue to the users of Cr(VI) substances, the proposed restriction will entail costs borne by society that are briefly summarised below. It should be noted that these welfare costs will be incurred mostly in the case of non-use, while intended compliance with the LVs and ELVs contributes to higher costs related to RMMs and release mitigation measures, as discussed earlier.

### Unemployment

Closure/relocation will entail temporary unemployment in the EU. Since the job losses associated with the closure/relocation of operations in the EU are a direct consequence of the restriction decision, this is a relevant welfare cost. In order to quantify the unemployment impact, the Dossier Submitter followed SEAC's approach for valuing job losses.<sup>35</sup> First, the number of jobs lost due to the restriction need to be established. To this end, the CfE#1 asked companies to provide estimates of both the number of workers associated with Cr(VI) substance uses, and their total workforce. A conservative assumption is that the jobs directly associated with the Cr(VI) substance uses would be lost, i.e. workers that are currently engaged in Cr(VI) substance uses would be made redundant.

<sup>&</sup>lt;sup>35</sup> <u>https://echa.europa.eu/documents/10162/13555/seac\_unemployment\_evaluation\_en.pdf</u>.

The approach considers the following components: the value of productivity loss during the period of unemployment, the costs of job search, hiring and firing, the impact of being unemployed on employment prospects and earnings, and the value of leisure time during the period of unemployment. Dubourg (2016) provided numerical examples of how these components can be quantified. A rule of thumb that emerges from these examples is that the welfare cost of a lost job corresponds to ~2.7 times its annual pre-displacement wage. Although there is some variation (driven by different unemployment rates and ease of finding a job) in this multiplier across the EU, it is used in this Annex XV restriction proposal. Combining the multiplier with an estimate of the EU27 average annual gross earnings of €45 800 (Eurostat 2024) results in a welfare cost of €124k per lost job (i.e. per directly exposed worker).

## **Consumer surplus loss**

Consumer surplus losses are expected where regulation negatively affects the availability, quality (following the adoption of more expensive technologies) or price (following imports or adoption of more expensive technologies) of goods currently produced with the use of Cr(VI) substances. Although such impacts cannot be excluded in the short term, the import of Cr(VI)-treated articles is likely to mitigate any major effects on consumers. The exception to this conclusion relates to uses of Cr(VI) substances in the maintenance of aircraft, railways and other means of transportation where non-availability could have a major impact on consumers. Whether such adverse effects materialise will ultimately depend on the response of the EU industry to the restriction. In the impact assessment, they will be considered in qualitative form (see Section 3.5).

## **Carbon footprint**

Irrespective of whether companies cease their Cr(VI) substance uses altogether or relocate outside the EU, the reduction in the supply of Cr(VI)-treated articles will need to be compensated to meet EU consumer demand. If and where alternatives are available, their capacity could theoretically be expanded to meet this excess demand. However, as there are no legal means to prevent Cr(VI)-treated articles from being imported into the EU, it is likely that a large part of this demand will be met by non-EU producers as their use of Cr(VI)-based production technologies is superior in terms of both price and quality.

There are at least two ways in which an increase in imports could have a negative impact on the carbon footprint: (1) energy systems outside the EU tend to be more carbon intensive (IPCC 2022), and (2) finished goods have to be transported into the EU. While carbon intensity has not been quantified in any of the existing AfAs, there are some examples of how applicants have included carbon emissions from the transport of goods in their analysis. For example, the Association of European Producers of Steel for Packaging (APEAL) (ECHA 2025) argued that if its members could no longer use  $CrO_3$  and sodium dichromate for the passivation of electrolytic tinplate (ETP) and electrolytic chromium coated steel (ECCS), a part of the market would be supplied with ETP/ECCS treated steel produced in Asia. The environmental externality of importing this steel into the EU was quantified by calculating the  $CO_2$  emissions per year expected from transporting the freight from Asia to Europe and converting the resulting emissions into a monetary equivalent using the social cost of carbon.

While SEAC considered this methodology to be sound, it should be pointed out that steel is covered by the EU's Carbon Border Adjustment Mechanism (CBAM) meaning that this carbon footprint is already internalised. This said, there is evidence that imports of other coated articles from third countries are taking place (e.g., for electroplated plastic parts – UC 2), which are not covered by the CBAM. For some uses in UCs 4 and 5, the articles themselves are means of transportation (aircraft) and their maintenance may be at least partially integrated into regular flight schedules. If maintenance can no longer be carried out on site, it is likely that this will have a negative impact on carbon emissions.

As this discussion demonstrates, quantifying the carbon emissions associated with increased imports of Cr(VI)-treated articles is complex and subject to many assumptions and uncertainties. For this reason, the Dossier Submitter has decided not to present a quantitative analysis but maintains that a negative impact on the carbon footprint can be expected if finished articles are imported instead of being produced in the EU.

## Impacts on SMEs

Introduced in the latest revision Better Regulation Guidelines, the 'SME test' seeks to analyse the effects of upcoming EU legislative proposals on small and medium-sized enterprises (SMEs). By assessing the costs and benefits of policy options to SMEs, the test is meant to promote the 'think small first' principle and to improve the business environment. It consists of four steps: (1) identification of affected businesses; (2) consultation of SME stakeholders; (3) assessment of the impact on SMEs; (4) minimising negative impacts on SMEs. Around 2/3 of the companies answering the CfEs were SMEs. Based on comparing the reactions of the SMEs to the different LVs, there is little or no difference in the responses between SMEs and the larger enterprises (see Appendix E.5).

### **Risk of alternatives**

It is important to note that most, if not all, of the identified alternatives to the Cr(VI) substances covered by this restriction proposal use substances that are not benign. Since a widespread adoption of alternatives in response to the proposed restriction options seems unlikely based on the information obtained during the preparation of this report, the Dossier Submitter refrains from presenting a detailed comparative risk assessment. The impact assessment will ignore any potential risk trade-offs associated with regrettable substitution (see Maertens, Golden et al. (2021) for a discussion of the root causes of regrettable substitution) and will therefore overestimate the *net* benefit of reduced exposure to Cr(VI).

## 3.1.5. Benefits

When companies comply with stricter LV and ELV values, there is a benefit for the exposed population (workers and the general public) in terms of reduced cancer ELR. The dose-response functions for oral and inhalation exposure to Cr(VI) imply a linear relationship between reductions in exposure and reductions in the expected statistical cases of cancer. This linearity assumption (see Crump, Hoel et al. (1976) for a justification) translates into a constant marginal benefit of reducing Cr(VI) exposure by one unit.

### Willingness-to-pay values

The benefits expected from reduced exposure to Cr(VI) can be monetised using the value per statistical case of fatal and non-fatal cancer, respectively. SEAC recently updated its reference values for valuing both fatal cancer and cancer morbidity.<sup>36</sup> The lower (higher) reference value for a premature death due to cancer is  $\leq 4.7m$  ( $\leq 6.6m$ ), while the derived value for cancer morbidity corresponds to  $\leq 540k$  (both expressed in  $\leq 2024$ ). As discussed in Section 1.4.2, the dose-response relationship for inhalation exposure to Cr(VI) translates into a reduction in fatal lung cancer cases. While the survival chances of lung cancer patients are not good, they have improved in recent years. According to the European Cancer Information System, patients diagnosed with lung cancer have a 5-year survival probability (correcting for competing causes of death) of 15 % on average across EU countries. This means that for every fatal lung cancer case caused by exposure to Cr(VI) compounds, one would in principle expect to also avoid 0.18 non-fatal cases of lung cancer.

<sup>&</sup>lt;sup>36</sup> <u>https://echa.europa.eu/documents/10162/17229/seac\_reference\_wtp\_values\_en.pdf</u>.

By adding the monetised value of the statistically expected number of non-fatal cases  $(0.18 * \in 540 \text{k} \approx \in 100 \text{k})$ , the total welfare value of one avoided lung cancer fatality amounts to  $\in 4.8$ -6.7m per statistical fatality avoided (including a co-benefit of 0.18 non-fatal lung cancer cases that are statistically avoided for each prevented case of fatal lung cancer.) For intestinal cancer associated with oral exposure to Cr(VI), the logic is slightly different as the dose-response relationship is expressed in incidence rather than mortality risk. According to the European Cancer Information System, the average 5-year survival probability of intestinal cancer (correcting for competing causes of death) is 59 %. Therefore, the total welfare value of avoided intestinal cancer risk can be approximated by a weighted average of the values of fatal and non-fatal cases, i.e. the lower and higher bound WTP values per statistical case amount to  $\in 2.9m$  and e 4.1m, respectively.<sup>37</sup> Table 24 succinctly summarises these key valuation metrics.

Valuation metric	Lower bound WTP	Higher bound WTP
Value per statistical case of lung cancer [1]	€4.8m	€6.7m
Value per statistical case of intestinal cancer	€2.9m	€4.1m
Marginal benefit of a 1 $\mu$ g/m <sup>3</sup> reduction in Cr(VI) per worker exposure over 20y	€9 600	€13 400
Marginal benefit of a 1 kg reduction in Cr(VI) emissions to air per individual exposed over 20y	€31	€42
Marginal benefit of a 1 kg reduction in Cr(VI) emissions to water per individual exposed over 20y	€3	€4

## Table 24. Key valuation metrics

Table notes: <sup>[1]</sup> includes the co-benefit of 0.18 non-fatal lung cancer cases that are statistically expected to be avoided per fatal lung cancer case avoided.

Source: calculated based on SEAC WTP reference values, see also Appendix E.4.

### Marginal benefits to workers and the general population

Multiplying the value of statistical case (VSC) of fatal lung cancer as reported in Table 24 by the unit risk factor (i.e. the contribution of  $1 \mu g/m^3$  TWA to the ELR of fatal lung cancer) and making adjustments to reflect the 20-year assessment period yields marginal benefit estimates of €9 600-13 400 per worker and unit risk reduction. Similarly, the VSC of lung or intestinal cancer in the general population can be marginalised, i.e. the values can be expressed per worker and unit risk reduction. If a company that is currently emitting Cr(VI) to air and water ceases to do so (through RMMs, substitution, relocation or closure), the benefit of non-use will extend to the general population in the vicinity of the site. Using the modelling assumptions described in Section 2.2.1, the marginal benefit of a 1 kg reduction in Cr(VI) emissions per exposed individual over the 20-year assessment period is equivalent to €31-42 for exposure to air and €3-4 for exposure to water, respectively.<sup>38</sup>

The advantage of this marginal approach is that it is fully consistent with the WTP values reported in Table 24, while allowing for a straightforward analysis and sensitivity testing. For instance, if different assumptions are made on the population exposed to Cr(VI) air emissions around the average emitting site, this will simply result in multiplicative shifts. One can thus immediately see which assumptions are driving the benefit of reducing Cr(VI) exposure in the EU and which assumptions are less relevant in that regard.

<sup>&</sup>lt;sup>37</sup> 0.59\*€4.7m + 0.31\*€540k = €2.9m and 0.59\*€6.6m + 0.31\*€540k = €4.1m.

<sup>&</sup>lt;sup>38</sup> Unit risk factors for worker exposure assume 40 years of exposure, while unit risk factors for general population exposure assume 70 years of exposure. In order to gauge effects over the 20-year appraisal period, marginal benefit estimates have thus been scaled by factors of 20/40 and 20/70, respectively.

## **3.2.** Baseline and response to the proposed restriction options

This section presents the baseline and the expected reaction of actors in the relevant supply chains and society as a whole to each of the three proposed restriction options. For methodological reasons, the Dossier Submitter assumes as a starting point that the Authorisation obligations no longer apply to the Cr(VI) substances in scope. However, this assumption is purely theoretical as these substances are currently still subject to authorisation and the assessment presented in this report does not pre-empt any future decision on their removal from Annex XIV of REACH. The Dossier Submitter emphasises that this Annex XV restriction proposal does *not* assess the socio-economic impacts of removing the Authorisation obligations.

While many companies have made investments during the preparation of their AfA to improve worker protection and control emissions, these are largely fixed costs. Moreover, they would continue to be subject to the EU CMR Directive 2004/37/EC, the EU-wide BOEL for worker exposure to Cr(VI) and to certain local and national emission limit values for Cr(VI). Therefore, it seems highly unlikely that, in the short time, companies would reduce the current level of worker protection and emission control.

### 3.2.1. Baseline

Based on the AfAs, DU notifications, active registrations, and CfEs, the Dossier Submitter estimates that there are currently  $\sim$ 2 000 sites in the EU that frequently use one or more Cr(VI) substances in their operations. (Section 1.3 succinctly summarises the use sectors and categorises the uses.) The same sources indicate that alternative substances or technologies for specific utilisations of Cr(VI) substances exist or are in various stages of development for all of the use categories defined in Section 1.3.2.

#### General information about sites using Cr(VI) substances

To quantify the total impacts of the restriction options for all use categories covered by the restriction, the Dossier Submitter has estimated (i) the number of companies in the EU that (legally) use Cr(VI) substances, (ii) the corresponding number of lines, and (iii) the number of directly exposed workers. The exact number of companies operating in each of the use categories is unknown, however, because the DU notifications lack precise use descriptions or because the available use descriptions are not aligned with the use categories defined in this report.

For the impact assessment, the Dossier Submitter assumed that there are 2 000 companies, which are distributed over the use categories according to the proportions of responses to the CfEs. While this assumption is subject to some uncertainty, the Dossier Submitter highlights that 685 companies—more than one third—participated in the CfEs, suggesting a broad representativeness of the sample. Several of the participating companies have reported multiple uses and/or multiple lines.

Based on information from the AfAs and DU notifications, there is an average of 13.1 directly exposed workers per line and an average of 1.5 lines per site ( $\sim$ 3 500 in total). Combining these estimates with the number of exposed workers per line, one finds that the total number of workers directly exposed to Cr(VI) substances in the EU is close to 46 000. Table 25 summarises these assumptions.

Figure 10 shows empirical cumulative distribution functions (ECDFs) of exposures (8h-TWA corrected for frequency with and without RPE) for each of the use categories. The ECDFs allow to directly read off the proportion of sites that are currently not in compliance with the LVs proposed in Section 2.2.4. Combined with the numbers of directly exposed workers from Table 25, this allows estimating the benefits of lowering worker exposure to Cr(VI).

Use category	Number of companies	Number of lines	Number of directly exposed workers
UC 1   Formulation of mixtures	73	128	1 700
UC 2   Electroplating on plastic substrate	96	168	2 200
UC 3   Electroplating on metal substrate	1 191	2 084	27 300
UC 4   Use of primers and other slurries	233	407	5 300
UC 5   Other surface treatments	344	602	7 900
UC 6   Functional additives/process aids	63	111	1 500
Total	2 000	3 500	45 900

Table 25. Assumptions about companies, lines and directly exposed workers

Source: based on information submitted in AfAs, DU notifications and in response to the CfEs.

As all benefits and costs have been normalised per directly exposed worker, changing the assumptions regarding the number of companies, lines or directly exposed workers per line will have a direct impact on the aggregated benefits and costs over the EU, but will keep the proportion between the two the same.

Although the combined exposures in Figure 10 are an accurate representation of the exposure conditions in the six use categories, the information was not directly used for the quantification of health impacts. Instead, the Dossier Submitter relied on the reported compliance of the CfE respondents with a given LV. The reason for relying on reported compliance rather than a company's calculated combined exposure is purely analytical.

- Reported compliance and combined exposure come from the same companies/sites and should therefore be consistent
- However, small deviations between reported compliance and combined exposure are possible because of different assumptions made in the exposure calculation
- Reported compliance with a given LV is integral to a company's best response to a given restriction option (see the discussion in Section 3.2.2)
- Using the combined worker exposure instead of the reported compliance risks breaking the link between the options a company has to respond to a given LV
- The consequences of using the discrete compliance response instead of the calculated combined exposure in the impact assessment are small (see Appendix D.1.3 for a comparison)
- If anything, the approach taken by the Dossier Submitter errs on the side of caution, i.e. it underestimates current compliance and overestimates the health benefits of imposing a given LV
- To illustrate, if a company's combined exposure is 3 μg/m<sup>3</sup> (8h TWA), then imposing a LV of 1 μg/m<sup>3</sup> would result in an exposure reduction of 2 μg/m<sup>3</sup>; relying instead on the reported compliance suggests that the company's combined exposure is somewhere between 1 and 5 μg/m<sup>3</sup> (8h TWA), so imposing a LV of 1 μg/m<sup>3</sup> would result in a maximum exposure reduction of 4 μg/m<sup>3</sup>

Panel A. Frequency-corrected exposures

Panel B. Frequency- and RPE-corrected exposures



#### Figure 10. Empirical cumulative distribution functions of combined worker exposure

Figure notes: black dots are reported exposure values per use category; red lines are fitted curves based on bootstrapping; grey areas are 95% confidence intervals. Source: based on information submitted in response to the CfEs.

## General information about existing alternatives

To better understand the general availability, technical feasibility and economic viability of alternatives to Cr(VI) substances for the use categories defined in Section 1.3.2, the Dossier Submitter undertook a comprehensive review of the information provided over the last ten years as part of the AfA process. Specifically, the information was used to distil an overview of those alternatives that were shortlisted or identified as most promising for the replacement of Cr(VI) substances. Where review reports to existing authorisations have been submitted, the most recent information was used. This sometimes meant discarding potential alternatives that had been identified in the original AfA, but that were subsequently dismissed in the review report.

Where meaningful, the Dossier Submitter complemented the information with:

- Data submitted to ECHA in the CfEs and in bilateral discussions with stakeholders
- Data submitted as part of the DU notifications related to granted authorisations<sup>39</sup>
- Information from the literature and from workshop reports

While a detailed overview of alternatives is provided in Appendix E.2, the conclusions from the available information can be summarised as follows. Cr(VI) substances offer a wide range of functionalities, they are compatible with a wide range of substrates and many of the existing technical processes using Cr(VI) substances allow the treatment of parts of different sizes and geometries. Because of this versatility, companies using Cr(VI) can often serve a wide range of sectors using relatively standardised technologies. The technical functionalities of the different applications of Cr(VI) substances have been developed over decades and have reached industrial maturity (Boldizzoni 2008). The sectors and value chains using (complex) articles that benefit from the functionalities provided by various uses of Cr(VI) substances have had time to fully develop, integrate and become efficient.

Against this background, a switch to alternatives represents a multivariable equation that is often difficult to solve. From the perspective of technical functionality alone, an alternative substance that offers a similar functional versatility and can be applied using the same (or very similar) technology represents the best case. In this scenario, any disruption from switching to the alternative to the user of the substance, and by extension to the user of the (complex) article produced with Cr(VI) substances is marginal. If, on the other hand, the alternative offers only a part of the required function or can only be applied with a completely different technology, the disruption in the supply chain will be significant. This may entail situations where Cr(VI) substance users would not only have to modify their existing production process but may have to install additional lines/facilities for surface treatment in order to continue serving their customer base.

Between these two extremes, all sorts of combinations are possible. However, regardless of the complexity of the situation, where substitution will occur it is likely to require:

- changes to the technical facilities, which can be time consuming and costly
- training of staff to adapt to differences in chemistry, process, technology etc.
- a process to ensure customer acceptance, which can be time consuming, costly and in certain sectors (e.g. A&D) subject to very strict recertification procedures

<sup>&</sup>lt;sup>39</sup> See <u>Downstream uses covered by granted authorisations - ECHA</u>.

It should also be noted that the risk of the identified alternatives has not been assessed, although the hazard classifications of promising alternatives have been compared with those of the Cr(VI) substances, and high-level conclusions have been reached as to whether a specific alternative is less hazardous than the Cr(VI) substance it is intended to replace. The Dossier Submitter reiterates that hazard is not equal to risk and therefore it is difficult to determine whether an alternative is safer than the incumbent substance without knowing the specific conditions of use. A good example are Cr(III)-based technologies, which are the most frequently mentioned alternative for most of the uses of Cr(VI) substances for which AfAs have been received to date.

In October 2022, ECHA hosted a 'Workshop on the implications of the use of Cr(III) substances in functional plating with decorative character'.<sup>40</sup> Although the event was focused on a particular use, some of the elements discussed were of a generic nature. One of these elements relates to the hazard properties of Cr(III) and of common additives such as borates. The workshop report concluded that the "Cr(III) hazard classification may change as a consequence of the EU substance evaluation going forward; the hazard properties of borates are well known and fulfil the SVHC criteria."

In late 2022, ECHA published an 'Assessment of regulatory needs' for 'Simple chromium compounds'.<sup>41</sup> The assessment concludes that substances commonly used in Cr(III)-based electroplating and other surface treatments such as chromium chloride (EC 256-852-0) and dichromium tris(sulphate) (EC 233-253-2) are skin sensitisers. In addition, data is being generated to assess their potential for reproductive toxicity and endocrine disruption.

Other common alternatives identified by stakeholders working towards the substitution of Cr(VI) substances are also classified for different hazards, and some of these have a harmonised classification according to Annex VI of the CLP Regulation. For example, nickel plating has been identified as a potential alternative to Cr(VI)-based electroplating. However, the process uses nickel compounds that have harmonised classifications for Carc. 1A, H350i, Muta. 2, H341, Repr. 1B, H360D (among others).

In any case, there are indications that substitution of Cr(VI) substance uses is ongoing. Indeed, companies applying for authorisation often explain that they have already substituted Cr(VI) substances in uses where they have found suitable alternatives. This has also been confirmed by data submitted as part of DU notifications for granted authorisations, in the CfE#2 which had a specific section on the substitutability of Cr(VI) substances, as well as in bilateral discussions with stakeholder organisations. Finally, substitution has also contributed to the reduction in consumption of Cr(VI) substances used in the EU (see Section 1.3.1).

Some examples of successful or ongoing substitution projects can be summarised as follows.

• One company reported in the CfE#2 to use thermal spray coatings for wear protection and reduction of sliding friction on specific parts of valves and rotating components. It explained that such coatings are characterised by residual porosity in their microstructure. For this reason, thermal spray coatings are acceptable in applications where the medium in contact with the valves is not very corrosive. However, their performance is insufficient in more demanding applications

<sup>&</sup>lt;sup>40</sup> <u>https://www.echa.europa.eu/-/workshop-on-implications-of-use-of-trivalent-chromium-in-functional-plating-with-decorative-character</u>.

<sup>&</sup>lt;sup>41</sup> <u>https://echa.europa.eu/documents/10162/1f5bd7fc-977b-923f-3b2c-85ce20216553</u>.

- One company reported in their DU notification to use a Cr(VI)-free acidic treatment for the passivation of stainless steel for one of their customers. However, it explained that for other customers it has to continue using a Cr(VI)-based passivation process as this is required by customers
- In bilateral contact with the Dossier Submitter, FGK (the German industry association for plating on plastics) provided information on the plating-on-plastics market for automotive applications. According to this information, the sector has started to substitute Cr(VI)-electrolytes by Cr(III)-electrolytes and is working toward developing chrome-free etching processes. This is consistent with information submitted by individual companies in their AfA
- In bilateral contact with the Dossier Submitter, one global aircraft manufacturer reported that it had qualified alternatives to Cr(VI) substances in electroplating on metal substrates, surface treatments including anodising and conversion coating, pre- and post-treatment uses including cleaning, etching and sealing (UCs 3 and 5). The same company has also identified and is in the process of qualifying alternatives for Cr(VI) substances in various primers (use category 4). ASD Europe (Aerospace, Security and Defence Industries Association of Europe) commented that this was interesting information, but that they had not heard of such an advance
- In bilateral contact with the Dossier Submitter, ACEA (European Automobile Manufacturers' Association) explained that uses of Cr(VI) substances in primers, paints, coatings and sealants (UC 4) stopped due to the ban of chromates in automotive components by the End-of-Life Vehicles Directive (Directive 2000/53/EC), which is currently under review. In many applications, chromate-free materials including thick- and thin-film processes with zinc flanges or zinc-nickel are now used instead of Cr(VI) substances that were commonly used in the past. ACEA noted that there is an exemption for legacy spare parts where repair-asproduced is required

The Dossier Submitter would like to emphasise that the overview of alternatives provided in Appendix E.2 was compiled primarily based on AfAs submitted by (groups of) companies that wish to *continue* using Cr(VI) substances in order to serve their customers. While some stakeholders may consider the state of development of potential alternatives provided by these companies to be biased, virtually all of these AfAs were scrutinised by ECHA's Scientific Committees as part of the opinion-making process and most of them by the REACH Committee as part of the decision-making process. This scrutiny has led to authorisations in almost all cases. The Dossier Submitter therefore considers that the information is applicable in the context of this Annex XV restriction proposal. Lastly, it should be noted that the information submitted in response to the CfEs supports the Dossier Submitter's assessment of the overall state of substitution.

# **3.2.2.** Response to the proposed restriction options

While the primary objective of the authorisation process under REACH is to ensure that SVHCs are progressively replaced by suitable alternatives where these are economically and technically viable, many companies struggle to substitute key uses of Cr(VI) substances for both technical and economic reasons. Given the lack of technological readiness and performance of alternatives to Cr(VI) substances in key applications, another objective of REACH is to ensure that the risks from their continued use are properly controlled (until suitable substitutes are found).

In response, the Dossier Submitter has developed three restriction options (see in Section 2.2.4) that propose different scientific limit values for both worker exposure and general

population exposure via emissions to the environment. To predict the likely responses of duty holders to the three restriction options and to assess the impacts of adopting one of these options, the Dossier Submitter reviewed information from existing AfAs, DU notifications, and responses to two targeted CfEs. Based on this information, a large proportion of companies intend to invest in RMMs to comply with the proposed LVs.

However, not all companies are able or willing to invest. If a company chooses not to implement RMMs, they will either have to cease operations that use Cr(VI) substances in the EU or switch to an alternative. The profit-maximising firm will be willing to invest in RMMs until the marginal cost of doing so equals the marginal loss of profit from avoiding the last unit of exposure (or release). However, it should be remembered that there are also costs to society from non-use. For example, plant closures or the adoption of alternative production technologies and associated downtime periods can result in (temporary) unemployment. While some of these costs may be offset by gains to competitors in the EU who are complying, the impact assessment needs to consider the net cost to society of abating the 'last unit' of exposure/emission. In other words, the full welfare impact of restricting the use of Cr(VI) substances includes both the private impacts (costs and benefits) to the regulated industry and the impacts (costs and benefits) of non-use borne by society.

## **Eliciting intentions to substitute**

A key assumption the Dossier Submitter is making in this respect is that companies respond rationally to regulation. This implies that they will choose the response that results in the lowest cost to them in the long run. For this reason, the Dossier Submitter conducted two CfEs asking companies using Cr(VI) substances in the EU in which use category they operate, whether they already comply with a specific LV and, if not, whether they would be willing to invest in RMMs in order to comply. Based on the answers of companies that indicated their willingness to invest in RMMs, private marginal abatement cost curves were constructed for each use category as described in Section 3.1.2. Companies for whom compliance costs are prohibitively high will not invest in RMMs. Instead, one has to account for the cost of their non-use. In general, the willingness to invest in RMMs is a function of the specific LV itself. The more stringent the LV, the higher the compliance cost, and the more likely it is that the cost of non-use will be lower than the investment required to comply with the LV. Taken together, this results in a complex pattern of responses to different LVs.

Figure 11 summarises the responses indicated by Cr(VI)-substance using companies that participated in the CfEs. As can be seen, most of the responding companies already comply (88 %) or could invest to comply (8 %) with a LV of 5  $\mu$ g/m<sup>3</sup> (8h TWA). This result is not surprising since the CfEs were conducted only a few months before the EU-wide BOEL was lowered to 5  $\mu$ g/m<sup>3</sup> (8h TWA) in January 2025.<sup>42</sup> As the LV becomes more stringent, fewer companies are already in compliance or could invest in additional RMMs. At a LV of 1 | 0.5 | 0.1 | 0.01  $\mu$ g/m<sup>3</sup> (8h TWA), 6 % | 15 % | 31 % | 56 % intend to cease operations that use Cr(VI) substances, while 3 % | 6 % | 9 % | 13 % intend to replace them with alternative substances or technologies. At the most stringent LV of 0.01  $\mu$ g/m<sup>3</sup> almost 70 % of companies indicate that they would cease operations using Cr(VI) substances, whereas 30 % would continue to operate, relying heavily on the use of personal protective equipment. While a detailed breakdown of company reactions per use category is provided in Appendix E.3, the use-category specific reactions are not significantly different from those shown in Figure 11.

<sup>&</sup>lt;sup>42</sup> Non-use costs accruing to companies that indicated they cannot comply with the BOEL were ignored as these costs cannot be attributed to a restriction under REACH.

#### ANNEX XV RESTRICTION REPORT - CERTAIN CR(VI) SUBSTANCES



Reaction of n=685 companies to various scientific LVs

Figure 11. Reaction of Cr(VI) substance users to various scientific LVs

Source: based on information submitted in response to the CfEs.

How does this compare with information from existing AfAs? Substitution to safer alternatives (where these are economically and technically viable) is a key objective of the REACH authorisation title. As part of their AfA, applicants have had to demonstrate that they did not have a viable alternative at the time of applying and, in many cases, provide a plan for future activities directed at substitution. On the basis of these 'substitution plans,' it can be concluded that – with the exception<sup>43</sup> of the passivation of tin-plated steel (ETP) – applicants did not find drop-in alternatives to Cr(VI) substances. Even in cases where applicants identified an alternative that could be suitable for a specific utilisation (e.g. electroplating on plastic substrates), other utilisations in the same use category (e.g. etching) would still have to be performed using Cr(VI) substances. A more detailed breakdown of the evidence gathered from existing AfAs is provided in Appendix E.2.

The CfE responses provide further evidence that substitution is not the main compliance strategy for the majority of EU companies that responded to the CfEs. For example, at the most stringent LV of 0.01  $\mu$ g/m<sup>3</sup>, only 13 % of companies report that they would substitute, while more than half of them would cease operations (see Figure 11). The questions in the CfE#1 were carefully worded to avoid any incentive for strategic responses. One may question the incentive compatibility of the questions and/or the honesty of companies in general. In order to ensure accuracy of and reduce noise in the responses, the Dossier Submitter included a so-called 'Bayesian truth telling' mechanism in the CfE#2. This mechanism asks respondents to not only provide their own best response to a given LV, but also to predict the responses of other companies in their sector. The more accurately a respondent predicts the market response, the more weight their own response is given in the analysis. Under mild conditions, a truthful response is then the best strategy (Cvitanić, Prelec et al. 2019).

Although the Bayesian truth-telling mechanism was only included in the CfE#2, the Dossier Submitter emphasises that there are no clear incentives to downplay the substitution

<sup>&</sup>lt;sup>43</sup> During the investigation, the Dossier Submitter received new information from the metal packaging industry that calls into question the fast substitution of Cr(VI) substances for ETP and ECCS, see Appendix G.4 for details.

potential of Cr(VI) uses in response to the CfE questions. If a company can implement RMMs to comply with a given LV at an affordable cost, it should say so and gain a competitive advantage over companies that cannot. Similarly, if a company has an alternative to which it could switch, it should declare that substitution is its best response and gain a competitive advantage over companies that cannot. The analysis of the Bayesian truth-telling mechanism supports this view as no clear bias is found. If anything, companies whose best response is substitution exaggerate the substitution potential of other actors in the market. A more detailed description of the Bayesian truth-telling mechanism is presented in Appendix E.3.

The Dossier Submitter has used the insights gained from the CfEs to analyse companies' most likely response to the three restriction options for each of the use categories. It should be reiterated that this analysis will only be accurate if the responses to the CfEs are reliable and representative. Although the Dossier Submitter has made every effort to ensure the reliability and representativeness of the responses received through the CfEs, it cannot be excluded that there is some selection bias, i.e. that companies with certain characteristics have chosen not to respond to the CfEs. Nor can it be excluded that some companies responded dishonestly. In that regard, the Dossier Submitter notes that the distributions of combined exposures in Figure 10 are in fair agreement with the reported compliance status of companies participating in the CfEs (see also Appendix D.1.3.). While this does not preclude strategic responses, it suggests that the CfEs responses are generally honest.

## **Response to RO1**

Table 26 collects the information to determine the expected response to RO1. For worker exposure, RO1 mimics the baseline situation in 2025 where companies using Cr(VI) substances have to comply with an EU-wide BOEL of 5  $\mu$ g/m<sup>3</sup> TWA, except for UC 2 (electroplating on plastic substrate) and UC 6 (functional additives and process aides), for which a lower LV of 1  $\mu$ g/m<sup>3</sup> TWA is proposed.

Use category	Relevant LVs and ELVs	ļ	Already complian	ıt	Invest in RMMs	Close/ relocate	Substitute
		Worker	Air	Water			
UC 1	LV: 5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	100 %			0 %	0 %	Not relevant
UC 2	LV: 1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	79 %			18 %	2 %	1 %
UC 3	LV: 5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	100 %			0 %	0 %	Not relevant
UC 4 [1]	LV: 5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	100 %			0 %	0 %	Not relevant
UC 5	LV: 5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	100 %			0 %	0 %	Not relevant
UC 6	LV: 1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 2.5 kg Cr(VI)/y ELV <sub>water</sub> : 15 kg Cr(VI)/y	80 %			8 %	8 %	4 %
Total		98 %	87 %	96 %	2 %	0 %	Not relevant

Table 26. Su	mmary of the	e expected	response to	R01
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Source: based on information submitted in response to the CfEs.
The stricter LVs for these two UCs will not have a major impact as most companies in these use categories that participated in the CfEs indicated that they either already comply or could comply with this LV. For the other use categories, no response to RO1 is expected. If individual companies cannot comply with the proposed LV or would need to invest in RMMs in order to comply, these consequences would already be entailed by compliance with the BOEL and would therefore not be impacts induced by RO1.

RO1 proposes ELVs for releases to air and water of 2.5 kg/y and 15 kg/y, respectively. Both ELVs are aligned with a target ELR of 1E-4. Based on the responses to the CfEs, 87 % of companies already comply with the ELV for releases to air, 11 % would need to cut releases by less than 90 %, and 2 % would need to cut releases by 90-99 %. Similarly, 96 % of companies already comply with the ELV for releases to water, 2 % would need to cut releases by less than 90 %, and 2 % would need to cut releases by 90-99 %.

### **Response to RO2**

Table 27 collects the information to determine the expected response to RO2, which aims to eliminate the largest sources of Cr(VI) exposure while allowing most operators to continue their uses under safer conditions. Based on the CfEs, 62 % of companies already comply with the LVs set under RO2, and 25 % indicate that they could comply by investing in additional RMMs. When aggregating across all use categories, the non-use rate is 14 %.

Based on the CfEs, the lowest levels of compliance are found for UC 2 (45 %) and UC 4 (38 %). For UC 2, almost all companies reported that with further investment in RMMs they could meet the LV of  $0.5 \ \mu g/m^3$ ; only 5 % of companies in this use category indicated non-use in response to RO2. For UC 4, however, compliance with the LV of  $0.5 \ \mu g/m^3$  appears to be more challenging. Exposures in this use category are the highest based on the available exposure data (see Table 9). Almost 41 % of companies responded that they could not meet the LV of  $0.5 \ \mu g/m^3$  even if they invested in additional RMMs.

Use category	Relevant LVs and ELVs	Ļ	Already complian	t	Invest in RMMs	Close/ relocate	Substitute
		Worker	Air	Water			
UC 1	LV: 1 μg Cr(VI)/m³ ELVair: 0.25 kg Cr(VI)/y ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	72 %			21%	6 %	1 %
UC 2	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.25 kg Cr(VI)/y ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	45 %			50 %	5 %	1 %
UC 3	LV: 1 μg Cr(VI)/m³ ELVair: 0.25 kg Cr(VI)/y ELVwater: 1.5 kg Cr(VI)/y	70 %			24 %	5 %	1 %
UC 4 [1]	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.25 kg Cr(VI)/y ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	38 %			22 %	27 %	14 %
UC 5	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.25 kg Cr(VI)/y ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	54 %			22 %	17 %	7 %
UC 6	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.25 kg Cr(VI)/y ELV <sub>water</sub> : 1.5 kg Cr(VI)/y	64 %			20 %	10 %	6 %
Total		62 %	49 %	85 %	25 %	10 %	4 %

#### Table 27. Summary of the expected response to RO2

Table notes: <sup>[1]</sup> the impact assessment assumes that the use of more effective RPE will be a common response to comply with the LV.

Source: based on information submitted in response to the CfEs.

The companies that stated they could invest further in RMMs (~20 %) can be categorised by the type of foreseen improvement. Companies that would rely on more effective RPE estimated costs that were one to two orders of magnitude lower than those that would rely on automation. Based on data from recent AfAs, most companies in UC 4 can achieve TWA exposures below 0.5  $\mu$ g/m<sup>3</sup> by using more effective RPE. However, without RPE, compliance with this LV is virtually impossible. The Dossier Submitter speculates that not all companies in the CfEs were aware that the use of more effective RPE was a permissible compliance strategy and that this may have inflated the non-use rate for UC 4.

RO2 proposes ELVs for releases to air and water of 0.25 kg/y and 1.5 kg/y, respectively. Both ELVs are aligned with a target ELR of 1E-5. Based on the responses to the CfEs, 49 % of companies already comply with the ELV for releases to air, 38 % would need to cut releases by less than 90 %, 11 % would need to cut releases by 90-99 %, and 2 % would need to cut releases to water, 11 % would need to cut releases by less than 90 %, 2 % would need to cut releases by 90-99 %, and 2 % would need to cut releases by 90-99.9 %.

### **Response to RO3**

Table 28 collects the information to determine the expected response to RO3. On this basis, the Dossier Submitter will quantify both the costs and benefits of RO3, which includes the most stringent LVs and ELVs to lower exposure to Cr(VI) across the board and phase out uses in some of the use categories. Based on the CfEs, 32 % of companies already comply with the LVs set by RO3, and 39 % indicate that they could comply by significantly investing in additional RMMs. When aggregated across all use categories, the non-use rate is 29 %. 22 % of the companies indicated they would close down their Cr(VI) operations in the EU in response to RO3, while 7 % would try to substitute. However, a closer look at the responses of the latter group suggests that most companies have not (yet) found a suitable alternative.

Use category	Relevant LVs and ELVs	Already compliant			Invest in RMMs	Close/ relocate	Substitute
		Worker	Air	Water			
UC 1	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	48 %			38 %	11 %	3 %
UC 2	LV: 0.1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	11 %			53 %	28 %	9 %
UC 3	LV: 0.5 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	37 %			44 %	17 %	2 %
UC 4 <sup>[1]</sup>	LV: 0.1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	19 %			16 %	42 %	23 %
UC 5	LV: 0.1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	27 %			30 %	29 %	13 %
UC 6	LV: 0.1 µg Cr(VI)/m <sup>3</sup> ELV <sub>air</sub> : 0.025 kg Cr(VI)/y ELV <sub>water</sub> : 0.15 kg Cr(VI)/y	32 %			48 %	13 %	7 %
Total		32 %	22 %	56 %	39 %	22 %	7 %

### Table 28. Summary of the expected response to RO3

Table notes: <sup>[1]</sup> the impact assessment assumes that the use of more effective RPE will be a common response to comply with the LV.

Source: based on information submitted in response to the CfEs.

Based on the CfEs, the lowest levels of compliance are found for UC 2 (11 %) and UC 4 (19 %). For UC 2, 53 % of the companies reported they could meet the LV of 0.1  $\mu$ g/m<sup>3</sup> with significant investment in RMMs, while 37 % of the companies in this use category indicated non-use in response to RO3. For UC 4, compliance with the LV of 0.1  $\mu$ g/m<sup>3</sup> appears to be even more challenging. Exposures in this use category are the highest based on the available exposure data (see Tables 11-14). 65 % of companies responded that they could not meet the LV of 0.1  $\mu$ g/m<sup>3</sup> even if they invested in additional RMMs. The indicated intentions to substitute are highest for UCs 2, 4 and 5 (with the same caveat about the non-availability of suitable alternatives applying), but the main difference between RO2 and RO3 is that a much larger proportion of companies will cease their Cr(VI) activities in the EU.

RO3 proposes ELVs for releases to air and water of 0.025 kg/y and 0.15 kg/y, respectively. Both ELVs are aligned with a target ELR of 1E-6. Based on the responses to the CfEs, 22 % of companies already comply with the ELV for releases to air, 27 % would need to cut releases by less than 90 %, 38 % would need to cut releases by 90-99 %, 11 % would need to cut releases by 99-99.9 %, and 2 % would need to cut releases by >99.9 %. Similarly, 56 % of companies already comply with the ELV for releases to water, 29 % would need to cut releases by less than 90 %, 11 % would need to cut releases by 90-99 %, 2 % would need to cut releases by 99-99.9 %, and 2 % would need to cut releases by 90-99.9 %, 2 % would need to cut releases by 99-99.9 %, and 2 % would need to cut releases by 99-99.9 %.

### 3.3. Risk reduction and human health impacts

As all restriction options impose binding LVs and ELVs that are as strict or stricter than the baseline exposure/release levels, there will be health benefits for both workers and the general population living in the vicinity of the emitting sites. Importantly, the preceding analysis assumes that all companies operating after January 2025 are compliant with the BOEL. The benefits resulting from stricter LVs/ELVs (per restriction option) are estimated using the methodology described in Section 3.1.5 and summarised in Table 29. Additional considerations on the estimation are provided in Appendix E.4, while assumptions on the environmental risk assessment are provided in Appendices B.8.1 and D.2.

Health benefits	R01	RO2	RO3
Lung cancer, worker exposure	€35m	€711m	€916m
Lung cancer, general population exposure	€236m	€291m	€304m
Intestinal cancer, general population	€60m	€70m	€76m
Total benefits (NPV) over 20y-assessment period	€331m	€1.07bn	€1.30bn
Total benefits (annualised)	€22m	€72m	€87m

 Table 29. Monetised health benefits of the proposed restriction options

### **Response to RO1**

The expected health benefits of implementing RO1 for directly exposed workers are limited to UC 2 and UC 6 since the proposed LVs for the other use categories are the same as the baseline exposure. As shown in Figure 11, the majority of companies (~80 %) in UCs 2 and 6 already comply with the LVs imposed by RO1. Almost all of the companies that do not currently comply with these LVs have indicated that investing in RMMs is their best response to the restriction. Workers in companies that invest in RMMs will have a lower exposure once the RMMs are implemented. Their reduction in exposure is expected to equal the difference between the BOEL and the proposed LVs.

Applying the marginal benefit per exposed worker as reported in Table 24 to non-compliant companies and their directly exposed workers results in a total benefit to workers of ~€35m over the 20-year assessment period. Similarly, the benefits to the general population can be monetised by applying the marginal benefit estimate for a 1 kg reduction in Cr(VI) emissions to air/water reported in Table 24. The average reduction in releases to air/water due to the ELVs imposed by RO1 is estimated to be 16 kg/123 kg per year. These reductions occur at 14 %/4 % of the 2 000 Cr(VI)-emitting sites in the EU. As explained in Section 2.2.3, the average population of the 1x1 km<sup>2</sup> grid cells hosting sites that have notified Cr(VI) uses according to Art. 66 of REACH is 1 600 people. Combining these assumptions suggests that the total benefit of RO1 for the general population amounts to ~€252m (reduction in releases to air)/€64m (reduction in releases to water) over the 20-year assessment period.

However, it might be argued that not everyone living in a 1x1 km<sup>2</sup> grid cell around a site is exposed to Cr(VI) air emissions. Assuming a relevant exposure radius of 500m around the stack, the local population at risk has to be scaled down by a factor of  $\pi/4$ .<sup>44</sup> This decreases the expected benefit of reducing Cr(VI) releases to air to ~€198m. The Dossier Submitter notes that a similar downscaling is not warranted for reductions in Cr(VI) releases to water because the main exposure pathway is via drinking water, see Appendix B.8.1.2.2. The uncertainty analysis presented in Section 5 further explores the sensitivity of the benefit estimates to assumptions about the relevant exposure radius.

### **Response to RO2**

Health benefits to directly exposed workers from implementing RO2 are expected in all use categories. As shown in Figure 11, the compliance rates with the LVs of RO2 range from 38 % to 72 %, depending on the use category. As mentioned above, the main compliance strategy of companies under RO2 is to invest in improved RMMs. The reduction in exposure of workers in companies that invest in RMMs is expected to equal the difference baseline exposure and the proposed LVs.<sup>45</sup> Applying the marginal benefit per exposed workers results in a total benefit to workers of ~ $\in$ 532m over the 20-year assessment period.

Directly exposed workers of companies that stop using Cr(VI) substances in response to RO2 will also benefit from a reduction of Cr(VI)-induced cancer risk.<sup>46</sup> In contrast to RO1, RO2 will result in a substantial proportion of companies closing down, relocating or substituting. Worker exposure to Cr(VI) at these sites will be reduced to zero. However, as explained in Section 3.1, if in each use category a significant proportion of the market continues to operate in EU, then this reduction in exposed workers is expected to be at least partially offset by staff growth at the compliant sites. Therefore, a conservative assumption is that the reduction in exposure across the EU corresponds again to the difference between the baseline levels and the proposed LVs. Combining this assumption with the numbers of workers at the sites that indicate to cease the use of Cr(VI) substances in response to RO2 results in a total benefit to workers of €179m over the 20-year assessment period.

As before, the benefits to the general population can be monetised by applying the marginal benefit estimate for a 1 kg reduction in Cr(VI) emissions to air/water reported in Table 24. The average reduction in releases to air/water due to the ELVs imposed by RO2

<sup>&</sup>lt;sup>44</sup> More generally, the scale factor equals  $\pi r^2/l^2$ , where r is the relevant exposure radius and l is the length of the grid cell hosting the site. If r = 500m and l = 1 000m, then  $r^2/l^2 = 0.25$ .

<sup>&</sup>lt;sup>45</sup> Baseline exposure is assumed to be at the level of BOEL if the company does not comply with any of the LVs, or at the level of the previous LV that the company complies with.

<sup>&</sup>lt;sup>46</sup> These benefits may be partially or fully offset by health risks related to the workers' new tasks.

is estimated to be 5 kg/40 kg per year. These reductions occur at 51 %/15 % of the 2 000 Cr(VI)-emitting sites in the EU. As explained in Section 2.2.3, the average population of the 1x1 km<sup>2</sup> grid cells hosting sites that have notified Cr(VI) uses according to Art. 66 of REACH is 1 600 people. Combining these assumptions suggests a total benefit of RO2 for the general population of ~€290m (reduction in releases to air)/€70m (reduction in releases to water) over the 20-year assessment period. The benefits of reduced Cr(VI) air releases to air. Assuming a relevant radius of 500m decreases the expected benefit of reducing Cr(VI) releases to air to ~€244m.

#### **Response to RO3**

Health benefits to directly exposed workers from implementing RO3 are expected in all use categories. As shown in Figure 11, the compliance rates with the LVs of RO2 range from 11 % to 48 %, depending on the use category. As mentioned above, the main compliance strategy of companies under RO3 is to close down/relocate Cr(VI)-related activities in the EU. The reduction in exposure of workers in companies that invest in RMMs is expected to equal the difference baseline exposure and the proposed LVs.<sup>47</sup> Applying the marginal benefit per exposed worker reported in Table 24 to non-compliant companies and their directly exposed workers results in a total benefit to workers of ~ $\in$ 571m over the 20-year assessment period.

Directly exposed workers of companies that stop using Cr(VI) substances in response to RO3 will also benefit from a reduction of Cr(VI)-induced cancer risk.<sup>47</sup> RO3 will result in an even larger proportion of companies closing down, relocating or substituting. Worker exposure to Cr(VI) at these sites will be reduced to zero. Therefore, it is no longer assumed that remaining sites in the EU could offset the health benefits induced by RO3. Instead, a conservative assumption is that the reduction in exposure at sites that no longer use Cr(VI) substances corresponds to the difference between the baseline levels and zero exposure. Combining this assumption with the numbers of workers at the sites that indicate to cease the use of Cr(VI) substances in response to RO3 results in a total benefit to workers of  $\sim$ €346m over the 20-year assessment period.

As before, the benefits to the general population can be monetised by applying the marginal benefit estimate for a 1 kg reduction in Cr(VI) emissions to air/water reported in Table 24. The average reduction in releases to air/water due to the ELVs imposed by RO3 is estimated to be 4 kg/15 kg per year. These reductions occur at 78 %/44 % of the 2 000 Cr(VI)-emitting sites in the EU. As explained before, the average population of the 1x1 km<sup>2</sup> grid cells hosting sites that have notified Cr(VI) uses according to Art. 66 of REACH is 1 600 people. Combining these assumptions suggests that the total benefit of RO3 for the general population amounts to ~€305m (reduction in releases to air)/€76m (reduction in releases to water) over the 20-year assessment period. The benefits of reduced Cr(VI) air releases to air. Assuming a relevant radius of 500m decreases the expected benefit of reducing Cr(VI) releases to air to ~€255m.

### **3.4. Economic impacts**

As all restriction options impose binding LVs and ELVs that are stricter than the baseline exposure/release levels, there will be economic costs for companies to limit Cr(VI) exposure of both workers and the general population via emissions to the environment. These costs are quantified in Table 30, using the methodology described in Section 3.1.

<sup>&</sup>lt;sup>47</sup> Baseline exposure is assumed to be at the level of BOEL if the company does not comply with any of the LVs, or at the level of the previous LV that the company complies with.

Economic costs	R01	RO2	RO3
Compliance cost, worker exposure	€3m	€160m	€752m
Compliance cost, environmental releases	€127m	€520m	€1.37bn
Additional welfare costs related to non-use	€191m	€2.55bn	€9.9bn
Total costs (NPV) over 20y- assessment period	€320m	€3.2bn	€12bn
Total costs (annualised)	€21m	€215m	0.8€bn

 Table 30. Economic impacts of the proposed restriction options

### **Response to RO1**

For worker exposure, RO1 mimics the baseline situation in 2025 where companies using Cr(VI) substances have to comply with an EU-wide BOEL of 5  $\mu$ g/m<sup>3</sup> TWA. Based on evidence obtained in the CfEs and from existing AfAs, the Dossier Submitter additionally proposes to lower the LV for UC 2 and UC 6 to 1  $\mu$ g/m<sup>3</sup> TWA in order to account for the fact that companies operating in these two use categories have generally speaking lower worker exposure than companies in the other use categories. As these LVs are more stringent than the BOEL, economic consequences due to the compliance with the LV proposed under RO1 are only expected for these two use categories.

As shown in Figure 11, ~80 % of the companies operating in UC2 and UC 6 are already complying with the proposed LV of 1  $\mu$ g/m<sup>3</sup> TWA. Almost all of the companies in UC 2 that are currently operating above this LV indicated that they would invest into RMMs to comply with RO1. For UC 6, the best response of non-compliant companies is more evenly distributed between investment, closure/relocation and substitution. The marginal abatement cost curves derived in Section 3.1.2 are used to gauge the compliance costs for those companies that intend to invest in RMMs. The total cost to comply with the LV of 1  $\mu$ g/m<sup>3</sup> is estimated to be ~€6 700 per directly exposed worker for UC 2, and ~€1 800 per directly exposed worker for UC 6. When multiplied by the expected number of directly exposed workers in both UCs, the compliance costs amount to ~€2.7m for UC 2 and ~€0.2m for UC 6, respectively. The total compliance cost of RO1 is estimated at ~€3m.

The estimated non-use rates for UC 2 and UC 6 are 3 % and 12 %, respectively. This suggests that only a small number of companies would stop using Cr(VI) substances in response to this option. In case of non-use, round about two thirds of the affected companies would either close down or relocate while one third intend to substitute. The non-use costs are weighted according to the reported rates of closure/relocation and substitution, and include the expected loss of producer surplus, the expected cost of unemployment and the expected cost of substitution (see Section 3.1.2).

For UC 6, the estimated non-use cost per exposed worker is three orders of magnitude higher than the estimated abatement cost per worker. This makes the aggregated results very sensitive to the non-use rate, which is based on only three companies that reported in the CfEs that their optimal response to the proposed LV would be to cease the use of Cr(VI) substances. While somewhat uncertain, the corresponding non-use cost for UC 6 amounts to €166m over the 20-year assessment period. Most likely, this cost is an overestimate caused by small sample bias (based on 25 answers in the CfEs, out of which 3 reported non-use). For UC 2, 3 % of companies (based on 38 answers in the CfEs, out of which 1 reported non-use) reported non-use as their optimal response to RO1 and the estimated non-use cost is  $\sim$ €25m.

Concerning general population exposure, RO1 proposes ELVs for releases to air and water of 2.5 kg/y and 15 kg/y, respectively. As explained in Section 3.1, around 13 % of all companies using Cr(VI) substances need to invest in more effective abatement technologies for releases to air and 4 % of companies need to invest in more effective abatement technologies for releases to water. At the EU level, this corresponds to ~260 companies that would need to reduce their releases to air, and around 90 companies that would need to reduce their releases to water. Table 23 reports the expected abatement costs at company level. The corresponding total compliance costs over the 20-year assessment period are ~€86m for air releases and ~€41m for water releases.

#### **Response to RO2**

The economic costs are aggregated in a similar way for RO2. With an aggregate rate of 25 %, investment in additional RMMs is the most common response to the LVs proposed under RO2. Scaled to the EU level, this means that ~500 companies across the different use categories would need to invest in order to comply with RO2. The marginal abatement cost curves derived in Section 3.1.2 are used to estimate the compliance costs for those companies that intend to invest in RMMs. The total cost to comply with the proposed LVs ranges from €5 300 for UC 6 to €25 000 for UC 2 per directly exposed worker. For metal plating (UC 3), the largest use category within the scope of this restriction, the cost is €13 000 per directly exposed worker, while for both UC 4 and UC 5 the cost is ~€12 000, provided that the use of RPE is allowed to meet the LV of 0.5  $\mu$ g/m<sup>3</sup> for UC 4. When multiplied by the expected number of directly exposed workers in all UCs, the compliance costs over the 20-year assessment period are €3m (UC 1), €23m (UC 2), €86m (UC 3), €29m (UC 4), €18m (UC 5) and €2m (UC 6). The total compliance cost of RO2 is estimated at €160m.

At the aggregate level, the non-use rate under RO2 is 14 %, with 10 % of companies either relocating or closing down and 4 % trying to substitute their Cr(VI) substance uses. The costs of non-use are weighted costs based on the closure/relocation rate and the substitution rate, respectively. The non-use costs are weighted according to the reported rates of closure/relocation and substitution, and include the expected loss of producer surplus, the expected cost of unemployment and the cost of non-use is at least one order of magnitude higher than the technical compliance cost for all use categories, even if only direct costs incurred by the companies are considered and the social cost of unemployment is ignored.

At the use category level, the reported non-use rates for RO2 range from 6 % for electroplating (UC 2 and UC 3) to over 40 % for UC 4, which includes spraying, painting and use of primers and other slurries. However, it seems likely that the non-use rate in UC 4 would be significantly lower if investment in more effective RPE is assumed to be a compliance response. In fact, based on the exposure data collected in the CfEs, most companies in UC 4 already comply with the proposed LV if the effectiveness of RPE is considered in the exposure assessment.

Since the cost of non-use is so much higher than the cost of abatement for the LVs proposed under RO2, the optimal response of companies should be to invest in more effective RMMs whenever technically/financially feasible. It cannot be excluded that some of the companies that have reported non-use as their optimal response to RO2 may find ways to technically meet the LVs, especially if investment in more effective RPE is assumed to be a compliance response.

Based on the reported non-use rates, the welfare cost of non-use for RO2 amounts to  $\sim \in 3.6$ bn over the 20-year assessment period. By use category, the non-use costs are highest for UC 4 ( $\in 1.4$ bn) and UC 3 ( $\in 1$ bn). However, given the uncertainties mentioned above, it is possible that these cost figures, at least for UC 4, are an overestimate. If the

compliance rates (with RPE) given in the CfEs are applied to UC 4, and assuming that half of the non-compliant companies could comply with additional investment in RPE, the non-use costs for UC 4 would be ~ $\in$ 340m and the total welfare costs of non-use over the 20-year assessment period would fall to ~ $\in$ 2.55bn.

Concerning general population exposure, RO2 proposes ELVs for releases to air and water of 0.25 kg/y and 1.5 kg/y, respectively. As explained in Section 3.1, around 51 % of all companies using Cr(VI) substances need to invest in more effective abatement technologies for releases to air and 15 % of companies need to invest in more effective abatement technologies for releases to water. At the EU level, this corresponds to ~1 000 companies that would need to reduce their releases to air, and ~310 companies that would need to reduce their releases to water. Table 23 reports the expected abatement costs at company level. The corresponding total compliance costs over the 20-year assessment period are ~€390m for air releases and ~€133m for water releases.

### **Response to RO3**

For RO3, the aggregation of costs differs slightly from that of RO1 and RO2. Almost a third of the companies participating in the CfEs indicated that their best response to the LVs proposed under RO3 is non-use. As explained in Section 3.1.2, if a large part of the EU market were to disappear, it cannot be assumed that the remaining companies would take over these market shares. Therefore, under RO3, long-term negative effects on the EU market have to be expected and the welfare costs of non-use have to account for producer surplus losses over a four-year period rather than a two-year period as under RO1 and RO2 (where some shifts of profits from one EU producer to another are to be expected).

While the non-use rates for RO3 are significantly higher than for RO2, investment in additional RMMs is still the most common response to the LVs proposed under RO3. The aggregate investment rate of 39 % corresponds to ~800 companies at the EU level across the different use categories that would be affected. The marginal abatement cost curves derived in Section 3.1.2 are used to estimate the compliance costs for those companies that intend to invest in RMMs. The total cost to comply with the proposed LVs ranges from €12 400 for UC 6 to €73 000 for UC 2 per directly exposed worker. For metal plating (UC 3), the largest use category within the scope of this restriction, the cost is €50 500 per directly exposed worker, while for both UC 4 and UC 5 the costs are €25 000 and €29 000 per directly exposed worker, provided that the use of RPE is allowed to meet the LV of 0.1  $\mu$ g/m<sup>3</sup> for UC 4. If a company already complies with some of the earlier LVs, the abatement cost of reaching those LVs is deducted from the abatement cost of the company. When multiplied by the expected number of directly exposed workers, the compliance costs over the 20-year assessment period are €15m (UC 1), €70m (UC 2), €525m (UC 3), €76m (UC 4), €57m (UC 5) and €7m (UC 6). The total compliance cost of RO3 is estimated at €750m.

At the aggregate level, the non-use rate under RO3 is 29 %, with 22 % of companies either relocating or closing down and 7 % trying to substitute their Cr(VI) substance uses. The costs of non-use are weighted costs based on the closure/relocation rate and the substitution rate, respectively. The non-use costs are weighted according to the reported rates of closure/relocation and substitution, and include the expected loss of producer surplus, cost of unemployment and cost of substitution (see Section 3.1.2). The Dossier Submitter notes that the cost of non-use is at least one order of magnitude higher than the technical compliance cost for all use categories, even if only direct costs to affected companies are considered and the social cost of unemployment is ignored.

At the use category level, the reported non-use rates for RO3 range from 14 % for formulation (UC 1) to over 65 % for UC 4, which includes spraying, painting and use of primers and other slurries. The plating uses have non-use rates of 37 % (UC 2) and 19 % (UC 3), respectively. Again, it seems likely that the non-use rate in UC 4 would be significantly lower if investment in more effective RPE were assumed a compliance

response. In fact, based on the exposure data collected in the CfEs, almost 70 % of the companies in UC 4 already comply with the proposed LV if the effectiveness of RPE is considered in the exposure assessment. Based on the reported non-use rates, the welfare cost of non-use for RO3 amounts to ~€12.5bn over the 20-year assessment period. By use category, the non-use costs are highest for UC 3 (€5.3bn) and UC 4 (€3.5bn). However, given the uncertainties mentioned above, it is possible that these cost figures, at least for UC 4, are an overestimate. If the compliance rates (with RPE) given in the CfEs are applied to UC 4, and assuming that half of the non-compliant companies could comply with additional investment in RPE, the non-use costs for UC 4 would be ~€820m and the total welfare costs of non-use over the 20-year assessment period would fall to ~€9.9bn.

Concerning general population exposure, RO3 proposes ELVs for releases to air and water of 0.025 kg/y and 0.15 kg/y, respectively. As explained in Section 3.1, around 78 % of all companies using Cr(VI) substances need to invest in more effective abatement technologies for releases to air and 44 % of companies need to invest in more effective abatement technologies for releases to water. At the EU level, this corresponds to ~1 600 companies that would need to reduce their releases to air, and ~900 companies that would need to reduce their releases to water. Table 23 reports the expected abatement costs at company level. The corresponding total compliance costs over the 20-year assessment period are ~€960m for air releases and ~€410m for water releases.

# **3.5. Other impacts**

Sections 3.3 and 3.4 have quantified the monetizable impacts expected from the implementation of any of the three restriction options identified in Section 2.2. However, the proposed restriction options entail other impacts that the Dossier Submitter could not quantify. These include the consumer surplus loss entailed by higher prices, lower quality or non-availability of products, the carbon footprint caused by increased imports of Cr(VI) treated goods and products, as well as impacts on the competitiveness of SMEs in the EU, including of companies that have in recent years substituted Cr(VI) substances and would potentially benefit from strict measures on uses of Cr(VI) substances. More generally, the Better Regulation Guidelines list a catalogue of impacts to be screened. From this catalogue, the Dossier Submitter has screened the impacts most relevant in the context of this Annex XV restriction proposal and assessed them in Table 31.

Impact category <sup>[1]</sup>	RO1	RO2	RO3	
Climate	0	-		
Working conditions, job standards and quality	+	++	++	
Public health & safety and health system	+	++	++	
Conduct of business	0	-		
Position of SMEs	0	-		
Sectoral competitiveness, trade, and investment flows	0	-		
Functioning of the internal market and competition	0	-	-	
Employment	0	-		
Consumers and households	0	0	-	
Innovation (productivity and resource efficiency), research (academic and industrial)	0	0	-	
Resilience, technological sovereignty, open strategic autonomy, security of supply	0	-		

*Table notes:* <sup>[1]</sup> '--' significant negative impact, '-' mild negative impact, 'o' no or marginal impact, '+' mild positive impact, '++' significant positive impact.

*Source: adapted from Chapter 3 of the Better Regulation Toolbox; scoring applies to the 'key questions' listed in Section 4 of Chapter 3.* 

The upshot from this analysis is that the non-quantified impacts of RO1 are expected to be limited. This is because most companies already comply with the relevant LVs and ELVs. Under RO2, around 10 % of the companies in the EU would either close down or relocate. This could have a slightly negative impact on the carbon footprint, both in terms of increased freight transport and a more carbon-intensive energy mix in the countries to which relocation would take place. Under RO3, around 22 % of companies would either close down or relocate, and, assuming increasing imports, the negative impacts on the EU's carbon footprint would be more significant.

The working conditions for exposure to Cr(VI) are set under RO2 such that the maximum ELR is 4E-3, corresponding to 2E-3 for the 20-year assessment period. This is in line with the recent opinion of the Advisory Committee on Safety and Health at Work on the setting of limit values for non-threshold carcinogens. For the general population, the highest ELR for RO2 is 1E-5. For RO3, the target risk levels are an order of magnitude lower.

On the basis of the CfE responses, the Dossier Submitter considers that the reactions of SMEs to the LVs are almost identical to those of larger companies in all restriction options. About 66 % of the companies participating in the CfEs are SMEs, while about 20 % are micro-enterprises. Although the optimal responses to the LVs proposed under RO2 are almost identical for SMEs and larger companies, their financial constraints will make it somewhat more difficult for them to invest in additional RMMs. For example, based on information provided by FGK to the Dossier Submitter, many companies in UC 2 are already operating under fierce price competition. The picture is different for the ELVs proposed under RO2 and RO3, where the less a company is using Cr(VI) substances, the easier it is for them to comply with the proposed requirements, and therefore the impact of these requirements on SMEs and micro-enterprises is expected to be less than for larger companies.

It is foreseeable that RO2 will have a negative impact on sectoral competitiveness, trade and investment flows. For RO3, these impacts would be more drastic. Many of the companies concerned, especially SMEs, operate on tight profit margins and the necessary investment in further RMMs could either be difficult to finance or the increase in operating costs could result in companies becoming unprofitable. This is particularly relevant if achieving the proposed LV requires structural changes to processes, e.g. requiring the construction of a new line or even a new factory, which is more likely for the LVs proposed under RO3 than under RO2. These concerns are also reflected in the reported non-use rates of 14 % for RO2 and 29 % for RO3.

In terms of impact of a restriction on companies that have switched to Cr(III)-based and other alternatives in recent years, RO1 is likely to make it most difficult for them to recoup their investment, while RO3 could be seen as most protective of their investment. However, the Dossier Submitter notes that it is unclear how competitive these alternatives are compared to products treated with Cr(VI) substances outside the EU and subsequently imported as finished goods. At least in electroplating on plastics, the available evidence (see Figure 3) does not suggest that Cr(III)-based plating would replace Cr(VI)-based plating.

While competition with third countries may increase, there are also clear benefits for the functioning of the internal market. In particular, a restriction will create a set of common standards for both LVs and ELVs across the Union. This is a major step forward in harmonising environmental and occupational health and safety standards and will create a level playing field for all users of Cr(VI) substances. It will also foster business certainty by providing a clear regulatory outlook for the use of Cr(VI) substances.

In terms of unemployment, RO2 will have a temporary impact on workers employed by companies whose optimal response is to cease operations in the EU. At a minimum, the

directly exposed workers at each of the sites reporting non-use as their optimal response to the restriction would be made redundant. For RO2, this would affect ~6 000 workers. However, based on information in recent AfAs, in some use categories many or even most companies in the EU could cease their activities that do not involve direct exposure to Cr(VI) substances. Consequently, the number of workers made redundant could be much higher than 6 000. For RO2, cascading effects along the supply chain are possible, but they are not expected to be very significant. In fact, based on the CfEs, the Dossier Submitter assumes that most of the affected companies would continue operating in the EU. Therefore, a part of the induced unemployment may be offset by an increase in employment in companies that do comply with the LVs. For RO3, the number of workers made redundant would be in the order of 13 000; large-scale offsetting would not be feasible as demand would mostly been met through imports from third countries.

Under RO3, consumers could be slightly affected by both a deterioration in the quality of products and their price/availability on the EU market. A large part of the current production would likely be relocated outside the EU. However, some of the affected products could possibly be produced with slightly less efficient technologies. However, the reported substitution rates are marginal – 4 % for RO2, and 7 % for RO3 – suggesting that most of the demand will be met by imported articles, raising questions about environmental conditions in third countries, especially low-income countries, as well as the strategic autonomy of the Union. For example, if food cans were to be made from steel not treated with Cr(VI), this could have a negative impact on the shelf life and could lead to dependence on foreign production of canned food.

All restriction options could have a deterrent effect on innovation and investment in R&D in the EU, as only a small fraction of companies have indicated that their optimal response under a Cr(VI) restriction would be to find a substitute (with most companies instead seeking to comply with the proposed LVs and ELVs). The dossier submitter sees two opposing forces affecting the level of innovation and investment as a result of this proposed Annex XV restriction. Companies would have more business certainty if the regulation was clear and the prevailing regulatory uncertainty was removed. This could lead to a rebalancing of the current situation and, in the long term, to an increase in R&D investment in the sectors concerned, e.g. through automation of tasks with high exposure potential. Thus, the regulatory certainty provided by a REACH restriction may stimulate innovation related to current processes.

At the same time, all restriction options would reduce the incentive to invest in finding alternatives, as companies would instead invest in complying with the proposed limits. It is therefore likely that the proposed restriction options would have a negative impact on process innovation/substitution in the short and medium term. However, one might argue that if the use of Cr(VI) substances is controlled to a level where the risk to workers and the general population is sufficiently low, such innovation is not efficient and capital is better invested elsewhere.

RO1 and RO2 would allow the EU to keep know-how and services within the Union that may be deemed critical for strategic reasons. In terms of resilience, sovereignty, open strategic autonomy and security of supply, the most critical UCs are 3, 4 and 5, as these are directly linked to major industrial and transport activities that contribute substantially to the prosperity of the Union. The reported non-use rates for these UCs under RO2 are 6 %, 41 % and 22 %, respectively. However, for UC 4, if companies are allowed to use RPE to reach the proposed LVs, the non-use rate is expected to be significantly lower. There may be some concern about the reported non-use rate of 22 % for UC 5, where e.g. speciality surface treatments are used in the maintenance and repair of aircraft. If these services were hampered by stringent regulation and had to be outsourced to third countries, this could have a serious negative impact on the resilience of the EU aerospace sector as a whole.

For RO3, the impact would be more pronounced as the reported non-use rates for UCs 3, 4, and 5 are 19 %, 65 %, and 43 %. Under these conditions, it might not be possible to keep all aircraft maintenance within the EU and spare parts for many important sectors would have to be imported. While a significant proportion of Cr(VI) substance uses would cease under RO3, this option could provide some opportunities for EU companies that use alternative substances and technologies. However, as the operating cost of such companies tend to be somewhat higher, it is unclear how competitive they are compared to third country providers that continue to offer Cr(VI)-treated parts and products.

Other impacts on third countries, developing countries and international relations could occur under RO2 and more so under RO3. As it is expected that some companies will relocate their activities outside the EU if either RO2 or RO3 is implemented, this would lead to increased use of Cr(VI) substances outside the EU implying that the risks associated with these activities would be transferred to third countries and, in the case of less stringent worker protection legislation than in the EU, resulting in a higher global cancer burden than under the status quo—a leakage effect known to create 'pollution havens' (Phaneuf and Requate 2016).

### 3.6. Proportionality assessment

The proportionality of the restriction options will be assessed on the basis of the impacts reported in Sections 3.3 to 3.5. The benefits and costs of restricting the use of certain Cr(VI) substances will also be assessed from the point of *standing* in cost-benefit analysis (Boardman, Greenberg et al. 2022) as it can be more meaningful to assess the benefits and costs for different groups of beneficiaries/cost bearers instead of looking at the aggregate net benefit only. This ensures that distributional concerns are duly reflected in the proportionality assessment, which considers impacts over a 20-year assessment period. The assessment is carried out for each restriction option as the objective is to assess whether and under what conditions a given option can be considered proportionate, rather than to compare the options and identify the most proportionate. The latter task would be policy prescriptive.

#### **Response to RO1**

RO1 proposes to impose stricter LVs than the BOEL for UCs 2 and 6. The resulting health benefits for directly exposed workers are estimated at ~€35m, equivalent to approximately 6 statistical cancer cases avoided over a 20-year assessment period. The corresponding compliance cost, i.e. the cost of installing more effective RMMs, is estimated at ~€3m. RO1 also proposes ELVs that would be imposed for all use categories. The health benefit associated with these ELVs would be ~€296m, while the cost of more effective release control for the companies concerned is estimated at ~€127m. From these figures it can be concluded that compliance with the LVs and ELVs proposed under RO1 is proportionate for those companies for which it is technically possible to reduce Cr(VI) exposure of workers and Cr(VI) emissions to air and water.

Based on the responses to the CfEs, some companies in UCs 2 and 6 would close down their Cr(VI)-related operations if they had to comply with LVs stricter than the BOEL. The reported non-use rates are 3 % for UC 2, and 12 % for UC 6 (with the caveat that there were only 24 companies in the CfEs belonging to the latter use category). If these rates are applied to companies that did not participate in the CfEs, the total cost of non-use would be around €191m, highlighting that non-use is a costly and economically undesirable outcome of restricting the use of Cr(VI) substances. There is, however, reason to believe that the costs of non-use may be exaggerated as the responses to the CfEs indicate that the abatement costs are at least two orders of magnitude lower than the costs associated with closure/relocation. Consequently, there is a strong incentive for companies to meet the LVs by implementing additional RMMs.

Although the CfEs emphasised that truthful responses are in the best interest of participating companies, they represent only about one third of the affected companies in the EU. There may be a selection bias, with companies most concerned about the continuation of their business being more likely to participate in the CfEs than those less concerned. At the extreme, if all companies that would close/relocate in response to a stricter LV had participated in the CfEs, the total cost of non-use would be only 1/3 of the cost estimate above (while the total compliance costs would need to be multiplied by a factor of three).

As mentioned above, directly exposed workers stand to incur a health benefit of ~€35m under RO1. This benefit may then be compared to the restriction-induced unemployment by applying the non-use rates reported in the CfEs. The comparison suggests an estimate of ~230 jobs lost and an aggregate cost of unemployment of ~€29m. From the perspective of the directly exposed workers, RO1 is therefore proportionate. The quantified impacts of RO1 are summarised in Table 32. With regard to non-quantified impacts (see Section 3.5), RO1 is a step towards better standards for occupational and environmental health and safety. All aspects considered, and paying due attention to worker safety, the Dossier Submitter concludes that RO1 is a proportionate restriction option.

### **Response to RO2**

RO2 proposes to impose stricter LVs than the BOEL for all use categories. The resulting health benefits for directly exposed workers are estimated at ~ $\in$ 710m, equivalent to approximately 120 statistical cancer cases avoided over the 20-year assessment period. The corresponding compliance cost, i.e. the cost of installing more effective RMMs, is estimated at ~ $\in$ 160m. However, based on the responses to the CfEs, 14 % of all companies would close down their Cr(VI)-related operations, if they had to comply with the LVs imposed under RO2 and 30 % of the latter would try to substitute. Considering substitution intentions and correcting for the possible use of RPEs in UC 4 when extrapolating the non-use rate to companies that did not participate in the CfEs, the total cost of non-use would be ~ $\in$ 2.54bn. This highlights that non-use is a costly and economically undesirable outcome of restricting the use of Cr(VI) substances.

There is reason to believe that the costs of non-use may be somewhat exaggerated. Based on the responses to the CfEs, the abatement costs are two orders of magnitude lower than the costs associated with closure or relocation. In addition, if a non-negligible fraction of competitors have to exit the market, that creates opportunities for the companies that can comply with the conditions imposed under RO2. Consequently, there is a strong incentive for companies to meet the LVs by implementing additional RMMs if they can.

Although the CfEs emphasised that truthful responses are in the best interest of the participating companies, they represent only about one third of affected companies in the EU. There may be a selection bias, with companies most concerned about the continuation of their business being more likely to participate in the CfEs than those less concerned. At the extreme, if all companies that would close/relocate in response to a stricter LV had participated in the CfEs, the total cost of non-use would be only 1/3 of the cost estimate above (while the total compliance costs would need to be multiplied by a factor of three).

As mentioned above, directly exposed workers stand to incur a health benefit of about  $\in$ 720m under RO2. This benefit may then be compared to the restriction-induced job loss by applying the non-use rates reported in the CfEs. Doing so leads to an estimate of ~3 500 jobs lost (~4 600 without correcting for the possibility to use RPE in UC 4) and an aggregate cost of unemployment of ~ $\in$ 430m. However, the Dossier Submitter expects that some of the affected jobs would move to EU companies that can comply with the conditions of RO2 and thus stay in the market. The net impact of RO2 on employment is therefore likely to be smaller.

Notwithstanding the worker benefits, many companies would have to close down or make substantial investments to find alternatives that are safer.<sup>48</sup> The estimated producer surplus loss resulting from RO2 is ~€2.12bn. Although this figure may be somewhat exaggerated due to a possible selection bias in the CfEs, it is likely that, based on standard cost-benefit reasoning, RO2 is not proportionate. This is because the aggregate net benefits to workers are not going to offset the costs incurred by the companies using the Cr(VI) substances. Ultimately, the question of proportionality boils down to distributional preferences—if impacts on workers are given more weight in the decision than impacts on businesses, then RO2 could still be considered proportionate.

RO2 proposes ELVs that would be imposed for all use categories. The health benefit associated with these ELVs would be in the ballpark of ~€360m, while the cost of more effective release controls for the companies concerned is estimated at ~€520m. These figures suggest that compliance with the ELVs proposed under RO2 is not proportionate in terms of standard cost-benefit considerations.

Table 32 summarises the quantified impacts of RO2. With regard to non-quantified impacts (see Section 3.5), RO2 entails both positive and negative ones. There are slightly negative impacts expected in terms of carbon footprint; business profitability; position of SMEs; sectoral competitiveness, trade and investment flows; employment; and resilience, technological sovereignty, open strategic autonomy and security of supply. However, there are significant positive impacts expected in terms of setting more effective standards for working conditions, job standards and quality; public health & safety and health systems.

Taking all aspects into consideration, and paying due attention to worker safety, the Dossier Submitter notes that RO2 may be a proportionate restriction option, if the decision maker places more weight on the health and safety of workers compared to the detrimental impacts on employment and the economy. The distributional aspects are discussed in section 5.2.2. with a partial sensitivity analysis. The Dossier Submitter therefore concludes that RO2 may be proportionate.

### **Response to RO3**

RO3 proposes the most stringent LVs of the assessed restriction options for all use categories. The resulting health benefits for directly exposed workers are estimated at ~€920m, equivalent to approximately 150 statistical cancer cases avoided. However, only ~€571m (63 %) of these benefits would accrue to workers in companies that can comply with the LVs by investing into more effective RMMs, whereas ~€346m of benefits would accrue to workers made redundant.<sup>49</sup> The compliance cost incurred by companies to comply with the LVs, i.e. the cost of installing more effective RMMs, is estimated at ~€750m. This cost has to be compared to the health benefits of workers in companies that can comply, while the health benefits of workers made redundant has to be compared to the cost of non-use, which is around €10bn.

Based on the responses to the CfEs, 29 % of companies would close down their Cr(VI)related operations, if they had to comply with the LVs imposed under RO3 and 25 % of the latter would try to substitute. Considering substitution intentions and correcting for the possible use of RPEs in UC 4 when extrapolating the non-use rate to companies that did not participate in the CfEs, the total cost of non-use would thus be ~€9.89bn. This highlights that non-use is a costly and economically undesirable outcome of restricting the use of Cr(VI) substances.

<sup>&</sup>lt;sup>48</sup> Appendix E.2 provides more details on the safety of known alternatives.

<sup>&</sup>lt;sup>49</sup> The Dossier Submitter notes that unemployment may entail substantial health costs too, which in theory would have to be deducted from the health benefits to the workers that are made redundant.

Even for RO3, there is some reason to believe that the costs of non-use may be exaggerated. Based on the responses to the CfEs, the abatement costs are at least one order of magnitude lower than the costs associated with closure or relocation. In addition, as a significant fraction of competitors have to exit the market that creates opportunities for the companies that can comply with the conditions imposed under RO3. Consequently, there is a strong incentive for companies to meet the LVs by implementing additional RMMs if they can. This said, the compliance cost for meeting the LVs imposed under RO3 are 2-5 times higher than under RO2, highlighting the difficulty of achieving these stringent limit values. The Dossier Submitter concludes that while the non-use rate under RO3 may be somewhat lower than reported, it would still be high, with the potential to create knock-on consequences for the EU economy.

As mentioned above, directly exposed workers stand to incur a health benefit of ~€920m under RO3. This benefit may then be compared to restriction-induced job loss by applying the non-use rates reported in the CfEs. Doing so leads to an estimate of ~8 400 jobs lost (~10 100 without correcting for the possibility to use RPE in UC 4) and an aggregate cost of unemployment of ~€1.04bn. Even if some of the affected jobs would move to EU companies that can comply with the conditions of RO3 and thus stay in the market, a large fraction of these jobs would be lost permanently. As a significant part of EU companies would cease their Cr(VI)-related operations in the EU, the Dossier Submitter expects that cascading impacts would ripple through the supply chains and this might result in even more jobs being lost.

It is foreseeable that a significant number of companies would have to close down or make substantial investments to find alternatives that are safer.<sup>49</sup> The estimated direct producer surplus loss resulting from RO3 is ~8.85bn. However, in the case of RO3, cascading impacts through the supply chains could result in even greater producer surplus losses. Based on standard cost-benefit reasoning, RO3 is thus not proportionate. In addition, RO3 imposes ELVs that are one order of magnitude stricter than those under RO2. The health benefit of complying with these ELVs would be in the ballpark of ~€380m, while the cost of more effective release controls for the companies concerned is estimated at ~€1.37bn. Again, these figures suggest that compliance with the strictest ELVs is not proportionate.

The quantified impacts of RO3 are summarised in Table 32. With regard to non-quantified impacts (see Section 3.5), the negative ones would be far more significant than under RO2. Specifically, there are significant negative impacts expected in terms of climate impacts; business profitability; position of SMEs; sectoral competitiveness, trade and investment flows; employment; and resilience, technological sovereignty, open strategic autonomy and security of supply. There are also mild negative impacts in terms of consumers and households; functioning of the internal market; and innovation and research. On the benefit side, there are significant positive impacts in terms of setting more effective standards for both working conditions, job standards and quality; and public health & safety and health systems.

Taking all aspects into consideration, the Dossier Submitter notes that RO3 could only be seen as proportionate if the decision maker places the greatest emphasis on the health and safety of workers while ignoring the adverse effects on employment and the economy. Such preferences are unlikely to be welfare enhancing. In terms of cost-benefit reasoning, they would imply that the value society places on avoiding one Cr(VI)-induced lung cancer is more than an order of magnitude higher than the value it places on avoiding one lung cancer caused by smoking. This seems neither logical nor consistent with the Better Regulation Guidelines. Therefore, the Dossier Submitter concludes that RO3 is not proportionate in the meaning of Annex XV of REACH. By extension, any restriction option that would impose even stricter LVs or ELVs cannot be considered proportionate.

### ANNEX XV RESTRICTION REPORT - CERTAIN CR(VI) SUBSTANCES

### Table 32. Proportionality assessment

Impact category	R01	RO2	RO3
Workers (LV compliance), monetised health benefit	€24m	€532m	€571m
Workers (redundant), monetised health benefit	€11m	€179m	€346m
Population at the vicinity of sites, health benefit	€296m	€360m	€380m
Total monetised benefits over 20y-assessment period	€331m	€1.07bn	€1.30bn
Workers (redundant), monetised cost of unemployment	€21m	€433m	€1.04bn
Companies, abatement cost, workers	€3m	€171m	€750m
Companies, abatement cost, releases	€127m	€520m	€1.37bn
Companies, costs of non-use	€170m	€2.12bn	€8.85bn
Total monetised costs over 20y-assessment period	€314m	€3.23bn	€12.01bn
Net benefit	€10m (= €331m-€314)	-€2.17bn (= €1.07bn-€3.24bn)	-€10.71bn (= €1.30bn-€12.01bn)
Summary of key impacts assessed qualitatively	RO1 is a step towards better standards for occupational and environmental health and safety but has no significant negative impacts that deserve mentioning.	RO2 entails both positive and negative impacts; on the benefit side, there are positive impacts for health (workers and the general public); mild negative impacts are expected in terms of climate, SMEs, business profitability & competitiveness. In terms of worker protection, the health benefits are expected to be larger than the estimated cost of regulation-induced unemployment.	RO3 entails more significant negative impacts outweighing the positive impacts; while health benefits for workers and the general public are notable, they are to be balanced against significant negative impacts for the EU economy (SMEs, competitiveness, unemployment, knock-on impacts), climate (increase in GHG) and resilience and sovereignty.
Dossier Submitter's conclusion	Proportionate	May be proportionate	Not proportionate

# 4. Practicality and monitorability

## 4.1. Implementability and manageability

EU industry sectors using Cr(VI) substances have for a long time (i) been aware of the hazard properties of these substances, (ii) taken measures to comply with REACH authorisation decisions and other legislation meant to protect workers and the general population, (iii) monitored Cr(VI) exposure of workers and emissions to the environment, and (iv) undertaken R&D efforts to find alternative substances and technologies to eventually replace their uses of Cr(VI) substances.

There are no drop-in substitutes in any of the identified use categories to the Cr(VI) substances covered by this Annex XV restriction proposal. However, several alternatives have been identified for parts of the product portfolios in each of the use categories considered (cf. Appendix E.2). In general, these alternatives appear to offer lower performance compared to the Cr(VI) substances or are not yet technologically mature. In most cases, identified alternatives appear to be less hazardous but not benign. Moreover, the adoption of any of these alternatives requires significant investments and is likely to raise production costs by 10-20 %. Therefore, the Dossier Submitter concludes that, with or without regulatory pressure, the widespread adoption of substitutes for the Cr(VI) substances covered by this restriction proposal is unlikely to happen as long as imports of Cr(VI)-treated articles from third countries cannot be prevented.

For these reasons, the Dossier Submitter has assessed three restriction options that differ in terms of the stringency of the proposed LVs and ELVs. With some investment, compliance with the limit values proposed under RO1 and RO2 within the proposed 18month transition period appears feasible for the majority of companies. Compliance with RO3 may be more challenging as a significant proportion of actors may not be able to afford the investments required to comply with the most stringent set of limit values. The impact on such actors, including the consequences of their exit from the market, has been assessed in Section 3. The impact assessment suggests that RO3 is feasible, if the decision maker is willing to accept the negative consequences that this option entails for SMEs.

In terms of manageability, the Dossier Submitter argues that demonstrating compliance with the LVs and ELVs proposed under the different restriction options should not be a major challenge for companies using Cr(VI) substances, as they already have to report on worker exposure and emissions to the environment under existing legislation and should therefore know what is required of them. There are detailed instructions for testing for compliance with the limit values in the EN 689:2019 standard (for more details see Appendix E.6). For calculating emissions to the environment, the ECHA Guidance contains relevant information on environmental exposure assessment in Chapter R.16.<sup>50</sup>

# 4.2. Monitorability and enforceability

Due to their toxicity, Cr(VI) compounds have long been regulated in the EU and beyond. As a result, sampling and analytical methods have been developed, consolidated and are available in internationally recognised and validated standards. The fate of Cr(VI) has been studied in virtually all matrices: water, soil, wastes, workplace air, air emissions, cement, packaging, toys, leather, textiles and food/drinking water. In the EU, several legislative frameworks and analytical standards have been established to facilitate the regulation of the presence and use of Cr(VI). At the same time, enforcement authorities have gained experience in interpreting monitoring data and their contextual information.

<sup>&</sup>lt;sup>50</sup> <u>https://echa.europa.eu/documents/10162/17224/information\_requirements\_r16\_en.pdf</u>.

In general, test methods are available to verify compliance with the restriction conditions. Appendix B.1.2 provides an overview of the analytical methods that can be used for the determination and quantification of Cr(VI) in the matrices that are relevant in the context of this restriction proposal, i.e. emission monitoring (industrial air and wastewater emission matrices) and occupational exposure monitoring (workplace air matrix).

The Dossier Submitter stresses that Cr(VI) particles are highly reactive and easily reduced to Cr(III) in the ambient environment. It is therefore important that sampling procedures, including sample preservation, pre-treatment and treatment, are followed to ensure the quality of the monitoring results. This has become even more important as the accuracy of analytical methods for detecting Cr(VI) in all matrices has improved in recent decades (Gomez and Callao 2006) and the limit of quantification (LoQ) for Cr(VI) in air is now generally in the order of  $0.01 \,\mu\text{g/m}^3$  (ISO 16740:2005).

All LVs and ELVs proposed in the restriction options defined in Section 2.2.4 are enforceable in the sense that sampling and analytical methods exist to ensure that the concentration levels proposed can be accurately measured. However, as mentioned above, Cr(VI) is easily reduced to Cr(III) in the ambient environment. As the level of Cr(VI) in the matrix sampled decreases, the sampling time that is required to obtain an adequate sample increases. While levels of  $0.2 \ \mu g/m^3$  in ambient air are routinely sampled and analysed, a lower LoQ will also require more care in all steps of the sampling, storage and analytical procedures.<sup>51</sup> This is particularly relevant for the lowest LV proposed.

Although these elements are not in themselves enforceability constraints, they do have an impact on the cost of monitoring. General information on the cost of monitoring campaigns was collected through an AI-based search (see Appendix B.1.2.3 for details). The results suggest that the unit cost per monitoring campaign for Cr(VI) exposure varies widely across the EU and is determined by several factors such as the size of the workplace, the complexity of the monitoring required, the frequency of sampling, and the specific methods used. A comprehensive workplace air monitoring campaign costs between  $\in$ 5 000 and  $\in$ 15 000. For the monitoring of Cr(VI) releases to air and water, the cost per campaign ranges from  $\in$ 5 000 to  $\geq$ €15 000, depending on the setup and complexity of the analysis. However, as companies are already required to frequently measure exposure and emissions of Cr(VI) under existing legislation, the welfare-relevant costs attributable to the proposed restriction are limited to the additional costs of having to use analytical methods with a lower LoQ than today.

As a general requirement, the Dossier Submitter proposes that—following the proposed transitional period of 18 months—principles similar to those currently used in the implementation of monitoring programmes established under the AfA process would apply to demonstrate compliance with the LVs and ELVs. Monitoring of occupational inhalation exposure to Cr(VI) and of Cr(VI) emission to air and water should be conducted at least once per year. Monitoring programmes should be based on relevant standard methodologies or protocols, be representative of the OCs and RMMs used at the site and cover tasks that are representative of a typical exposure scenario. They must have a sufficiently low LoQ to demonstrate compliance with the LVs and ELVs and ELVs proposed.

To demonstrate compliance over time, the measurements should be sufficient to capture any potential increase in worker exposure to Cr(VI) or in Cr(VI) emissions to the air and water. The monitoring data (incl. contextual information about the tasks performed during the sampling) are to be made available to enforcement authorities. Based on the information above and the substance identification provided in Section 1.2, the Dossier Submitter does not foresee any difficulties for enforcement authorities to understand which

<sup>&</sup>lt;sup>51</sup> See <u>https://www.acgih.org/chromium-and-inorganic-compounds</u>.

substances are covered by this Annex XV restriction proposal. The Dossier Submitter therefore concludes that companies will be able to monitor Cr(VI) exposure and emissions, and enforcement authorities will be able to ensure compliance with the LVs and ELVs in a consistent, efficient and practical way in all EU Member States.

# 5. Uncertainties and sensitivity analysis

In this section, the Dossier Submitter undertakes a sensitivity analysis to assess how uncertainties pertaining to the key assumptions of the impact assessment presented in Section 3 affect the estimation of benefits and costs of the restriction options. The sensitivity analysis presented below is based on ECHA's 'Guiding principles for uncertainty analysis in Annex XV Restriction Reports'<sup>52</sup>. For this analysis, the Dossier Submitter compiled a list of uncertainties (see Table 33) that are associated with the inputs (data, estimates, other evidence) and/or the methodologies (statistical methods, calculations, models, expert judgement) used in the assessment.

Discussed in	Identified uncertainties							
Discussed in	#	Description of uncertainty	Input	Methodology				
Section 3.1.1	1	Abatement cost per directly exposed worker	Х	Х				
Section 3.1.1	2	Release abatement cost per company	Х					
Section 3.1.2	3	Turnover % at stake	Х					
Section 3.1.2	4	Turnover of the companies in the UCs	Х	Х				
Section 3.1.2	5	Profit margin	Х					
Section 3.1.2	6	Number of years over which producer surplus loss is accounted for		х				
Section 3.1.2	7	Closure/relocation rate vs. substitution rate	Х					
Section 3.1.2	8	Substitution cost per line	Х					
Section 3.1.2	9	Substitution related change in operational costs	Х					
Section 3.1.3 10 As		Assumption that only directly exposed workers are unemployed in case of non-use		Х				
Section 3.1.3	Section 3.1.3 11 Number of directly exposed workers in the EU		Х					
Section 3.1.4	12 Willingness-to-pay values		Х					
Section 3.1.4	13	Size of general population living in the vicinity of sites	Х					
Sections 3.2-3.6	14	14 Compliance / Investment / Non-use rates for different LVs						
Sections 3.2-3.6	15	Compliance rate for different ELVs	Х					
Sections 3.2-3.6 16 Companies can mitigate releases without affecting the non-use rates			х					
Sections 3.2-3.6 17		Number of companies and lines in the EU	Х					
Section 3.6	18	(Distributional) weighting of impacts		Х				
Section 1.4.3.1	19	Solubility and particle size not considered in risk assessment	Х	х				
Section 1.4.3.1 20 CfE data: only five most exposure relevant to reported		CfE data: only five most exposure relevant tasks reported	Х					
Section 1.4.3.1	Section 1.4.3.1 21 Indirect exposure for bystanders is not considered in the exposure scenarios		Х	х				
Section 1.4.3.1	22	Representativeness of the exposure data	Х					
Section 1.4.3.1	Section 1.4.3.1 23 CfE data: reported durations for RPE use unrealistically long		Х	х				
Section 1.4.3.1 24 DU notifications: task and use description are not harmonised, reporting is partially incomplete		DU notifications: task and use description are not harmonised, reporting is partially incomplete	Х					
Section 1.4.4	25	RAC dose-response relationships might overestimate cancer risk at low exposure levels	Х					

#### Table 33. Identified uncertainties

<sup>&</sup>lt;sup>52</sup> <u>Guiding principles uncertainty analysis</u>.

A preliminary screening of the uncertainties in Table 33 with respect to their contribution to the overall uncertainty in the impact assessment let the Dossier Submitter prioritise the items listed in Table 34.

Identified uncertainties	Priority	Description
Uncertainty related to the abatement costs (#1, 2)	1	The investment and operational costs that companies need to invest to be able to comply with the proposed LVs and ELVs are subject to uncertainty. For the LVs, the exposure abatement costs are estimated based on estimates by companies in the CfEs. For the ELVs, the release abatement costs are estimated based on a log- linear relationship between the cost and the abatement efficiency. Both uncertainties play a key role in the proportionality assessment.
Uncertainty related to producer surplus loss (#3, 4, 5, 6, 8, 9)	1	All of these uncertainties are important to estimating the producer surplus loss in case a company relocates or closes. The producer surplus loss is calculated by applying a profit margin of 10 % (#5) to the turnover figures reported in the CFE (#4). Although >30 % of companies reported their turnover, there is uncertainty in the turnover distribution of the remaining companies. How much of the turnover is at stake when a company closes its Cr(VI)-related operations (#3) is estimated by applying turnover-at-stake rates from the CTACSub2 AfA. The resulting figure is multiplied by the number of years (#6) that the producer surplus losses are expected to last. Some producer surplus loss is expected to happen even if a company substitutes (#9) as they face higher operational costs and have to bear one-time costs (#8).
Company reactions to LVs and ELVs (#7, 14, 16, 17)	1	Reactions are based on the CfE data which represents >30 % of users of Cr(VI) substances in the EU. Compliance, investment and non-use rates (#14) for different LVs determine the costs of different LVs. If a company already complies, no costs or benefits are expected. However, if the company does not comply and states that they would invest, the costs are determined by estimating their abatement costs. If the company states that they would cease the use of Cr(VI) substances, they can either close/relocate or substitute to other substances. The reactions to different LVs and the corresponding costs are based on CfE data (and verified by exposure data from other sources), so are the compliance rates for ELVs (#15). The better a company already complies with the proposed ELVs, the lower (higher) are the abatement costs (benefits). It is assumed that the proposed ELVs would not have an impact on the non-use rates (#17). This assumes that companies that have chosen non-use as their best response to a proposed LV are the same as those that would select non-use as the best response to a proposed set of ELVs. The substitute in case they cannot comply with the LVs.
Health benefits (#12, 13, 18, 25)	1	The benefits in terms of reduced Cr(VI) exposure are monetised. For that, the exposure is converted into excess lifetime cancer risk using a dose-response relationship (#25). The number of people exposed at the workplace is based on CfE figures and can be effectively matched with the reduction in exposure in each company. However, in the case of amount of general population in the vicinity of the sites (#13), DS distribution of general population living in the vicinity of the sites. Applying the same amount of people for each site can either underestimate or overestimate the benefits. Once the number of statistical cases is derived, the estimate is multiplied by the statistical value of a case (#12). It is possible to attribute a higher weight (#18) to these benefits compared to producer surplus losses for two main reasons: (i) the workers have typically a lower income than the capital owners that bear a large proportion of the costs, and (ii) the decision-maker might prioritise health-benefits to other types of impacts; (i) is something that can be handled based on a scientific framework, while (ii) should be reflected in the policy choices later in the process.

 Table 34. Prioritised uncertainties

Unemployment impacts (#10)	2	Currently, it is assumed that only directly exposed workers would be unemployed in the case of non-use. For RO1 and RO2, this is aligned with the approach taken for profit loss calculation, since it is expected that after a short period, most of the capital (including human capital) is put to use in either within the sector in other companies, or in other parts of the economy. However, for RO3, it can be assumed that cascading impacts through supply chain could result into higher unemployment figures. This is discussed in Section 3.5. A quantitative estimate is hard to put forward without macroeconomic modelling, and even in the absence of such analysis, it would only affect RO3 in a way that it would make it less proportionate.
Number of companies and workers in the EU (#11, 17)	3	The impacts have been normalised by the number of directly exposed people/number of lines. While there is a level of uncertainty related to the aggregate number of workers and lines in the EU, any change in the estimate would scale both the benefits and the costs by the same factor.
Uncertainty related to exposure of the workers (#19, 20, 21, 22, 23, 24)	3	Overall, the current level of exposure of the workers is reflected in the compliance rate of companies to different LVs reported by the companies. Where needed, these compliance rates were verified by the exposure data. The uncertainty related to the exposure data is discussed in Section 1.4.3 and Appendix B.8.2.3.

Based on the identified uncertainties and the corresponding prioritisation, the uncertainty analysis is divided into two parts – a quantitative uncertainty analysis (Part A), which is done using Monte Carlo simulations and a qualitative uncertainty analysis (Part B) where the impacts of different methodological assumptions and possible distributional weights are discussed, see Table 35. Part C of the uncertainty analysis described in the ECHA Guiding Principles<sup>52</sup> is discussed in the specific sections on worker exposure (3.3) and other impacts (3.5).

#	Identified uncertainties	Part of the uncertainty analysis
1, 2	Uncertainty related to the abatement costs	Part A
3, 4, 8, 9	Uncertainty related to the profit losses	Part A
7, 14	Company reactions to LVs and ELVs	Part A
12, 13	The health benefits	Part A
5,6	Profit margin & Number of years of profit losses	Part B
15, 16	Compliance (non-use) rate for ELVs	Part B
18	Distributional weighting of impacts	Part B
25	The dose-response relationship	Part B
11, 17	Number of companies in the EU	Part B
10	Unemployment impacts	Part C
19 - 24	Uncertainty related to exposure of the workers	Part C

 Table 35. Treatment of identified uncertainties

### 5.1. Quantitative uncertainty analysis

Monte Carlo analysis is a probabilistic method that lends itself to assessing the robustness of results in a regulatory impact assessment as it helps quantifying the impacts of various uncertainties. It does so by simulating a wide range of possible outcomes based on the variation in key input variables. The variables analysed in the quantitative uncertainty analysis (Part A) are listed in Table 35. For each of them, the Dossier Submitter specified a probability distribution, reflecting plausible ranges of values. These distributions are derived from data, literature, expert judgment, or a combination of these sources. By running thousands of simulations, one can visualise the probability of different regulatory outcomes and thereby informs policymakers about key uncertainties in the assessment and displays which conclusions are likely to hold even in face of uncertainty. Table 36 provides a summary of the assumed distributions for key parameters, and the reasoning behind these assumptions.

#	Uncertain Variable	Distribution	Justification
1	Abatement cost (workers)	Lognormal	The distribution for each UC was derived from the estimated marginal abatement cost curves and the modelled errors. To derive the minimum and maximum values of abatement costs, 95 % confidence intervals were applied to the estimated parameter values.
2	Release abatement per company	Uniform	For the release abatement cost at different required efficiencies, a range between 50 % and 150 % of the central estimate was applied. A uniform distribution is a typical assumption when there is no information on the most likely value, but a reasonable estimate of the minimum and maximum values.
3	Turnover % at stake	Triangular	Data from CTAC Sub2, closure and relocation rates for 12 uses, mapped to UC 1-6. Where data was sparse (UC4, one observation) or absent (UC 1,6), conservative assumptions were made. Lower bound assumes 0 % profit loss for partial closure, and higher bound 100 %. Triangle distribution to have more probability mass on the lower end of the range.
4	Turnover of the companies in each UC	Beta-Pert	The Beta-PERT distribution was chosen to represent the sample statistics combined with expert opinion. The data from CfEs were used to derive minimum, maximum, mean and most likely values. Beta-PERT was adjusted to exclude outliers, and to adjust for a possible sample bias towards larger companies with a higher participation rate at the CfEs.
7	Closure/relocation rate vs. substitution rate	Triangular	The range is based on the analysis of truthfulness of the substitution rates (Appendix E.3). Applying the weights to plating uses UC2 and UC3 will slightly raise the closure/relocation rate at the expense of substitution rate. The weighted substitution rate is used as the minimum value for UC2 and UC3. Higher probability mass assigned for the rates reported by the companies.
8	Substitution cost per line	Lognormal	The substitution cost data includes around 90 observations. A log-normal distribution was the best fit for the data.
9	Substitution related change in operational costs	Triangular	Due to higher operational costs, some producers could incur profit losses also in the case of successful substitution. The higher bound of 50 % is applied, while a triangle distribution ensures higher probability of values closer to 0.
12	Willingness-to-pay values	Triangular	The VSL values applied in the U.S. have been slightly higher compared to EU values. Also, the health care related costs were included, while only representing a fraction (1-2 %) of the statistical case of cancer. The PPI-corrected values from the US and an addition of 2 % of health care costs was used as a higher bound, while triangle distribution allowing a higher probability for the EU values.
13	General population in the vicinity of the sites	Discrete	The population nearby each site is unknown to the DS. However, DS has a dataset including the people in the vicinity of the sites in general. This data was used to derive key percentiles. Each site's population is drawn randomly from these values with probabilities assigned based on their empirical distribution.
14	Compliance rate, investment rate and non-use rate for different UCs and LVs	Triangular	The compliance rate, investment rate and non-use rate all sum up to 1, as companies need to select one of them as the most likely reaction for each LV. The data represents around 40 % of the companies. The minimum can be calculated thus as 40 % of the current non-use rate. Triangle distribution was applied to ensure higher probability mass for lower non-use rates, reflecting a possible selection bias.

Table 36. Distributional choices for uncertain parameters

### 5.1.1. Sensitivity analysis for RO1

A Monte Carlo simulation was run with the statistical software @RISK to assess the sensitivity of the NPV of RO1 to key uncertainty parameters listed in Table 36. The simulation was run 100 000 times resulting in the NPV distribution depicted in Figure 12. The mean of the NPV distribution is €66m, which is slightly higher than the central estimate reported in Section 3.6. The 90 % confidence interval ranges from -€112m to €274m, which confirms that for RO1, the expected benefits and costs are approximately equal, with a slightly higher probability of a positive NPV. The factor explaining most of the variance in the simulated NPV is the assumed size of the population living in the vicinity of sites with high Cr(VI) emissions. This factor explains ~65 % of the total variance. The sensitivity to this factor has to be seen in the context of the benefits and costs of establishing ELVs compared to the limited benefits and costs brought about by the most lenient LVs. Other important factors contributing to the variance in the NPV are the value per statistical cancer case (18 % of the variance), and the estimate of the non-use rate in UC 6 (10 % of the variance).



Figure 12. NPV distribution for RO1

Source: own simulation with @RISK.

### 5.1.2. Sensitivity analysis for RO2

A Monte Carlo simulation was run with the statistical software @RISK to assess the sensitivity of the NPV of RO2 to key uncertainty parameters listed in Table 36. The simulation was run 100 000 times resulting in the NPV distribution depicted in Figure 13. The mean of the NPV distribution is - $\in$ 2.2bn, which is almost exactly the central estimate reported in Section 3.6. The 90 % confidence interval ranges from - $\in$ 3.8bn to - $\in$ 1.1bn, which confirms that, based on the net benefit criterion only, RO2 cannot be considered proportionate. (It should be pointed out that even under the most extreme realisations of the simulation (very low aggregate turnover and very low percentage of that at stake), the right tail of the NPV distribution does not attain positive values.) The cost of non-use explains most of the variance in the simulated NPV. Indeed, the factors that affect the producer surplus loss (aggregate turnover of the UCs, and the percentage of turnover at stake in case of non-use) explain ~65 % of the total variance. Other important factors contributing to the variance in the NPV are the non-use rate (17 % of the variance), and the assumed size of the population living in the vicinity of sites with high Cr(VI) emissions (10 % of the variance).





Source: own simulation with @RISK.

### 5.1.3. Sensitivity analysis for RO3

A Monte Carlo simulation was run with the statistical software @RISK to assess the sensitivity of the NPV of RO3 to key uncertainty parameters listed in Table 36. The simulation was run 100 000 times resulting in the NPV distribution depicted in Figure 14. The mean of the NPV distribution is -€13.1bn, which is even less proportionate than the central estimate reported in Section 3.6. The 90 % confidence interval ranges from - €23.2bn to -€6.4bn, which confirms that RO3 cannot be considered proportionate. (Even under the most extreme realisations of the simulation, the right tail of the NPV distribution does not attain values larger than -€3bn.) The cost of non-use explains most of the variance in the simulated NPV. Indeed, the factors that affect the producer surplus loss (aggregate turnover of the UCs, and the percentage of turnover at stake in case of non-use) explain ~75 % of the total variance. Another important factor contributing to the variance in the NPV is the non-use rate (12 % of the variance). The other parameters in the simulation jointly explain ~13 % of the variance.



### Figure 14. NPV distribution for RO3

Source: own simulation with @RISK.

# 5.2. Partial sensitivity analysis and qualitative uncertainty analysis

### 5.2.1. Methodological assumptions

### 5.2.1.1. Profit losses

The Dossier Submitter has applied the standard methodology for assessing producer surplus loss as recommended by SEAC.<sup>53</sup> In line with the recommended methodology, the Dossier Submitter calculated the producer surplus loss based on two years of profit loss for companies indicating closure/relocation in response to the limit values under RO1 and RO2, and four two years of profit loss for companies indicating closure/relocation in response to the limit values under RO3. This approach implicitly assumes that after a certain period – and depending on the level of market disruption – the capital used in the affected sectors is reallocated to other investments. The capital can either remain in the sector (e.g., a compliant company stays in the market and increases its production capacity to meet excess demand) or be reallocated to other sectors (e.g., a company invests in an alternative production technology) or economies (e.g., a company relocates and invests in a production facility in a third country).

While this approach is theoretically sound, the question arises as to how long profit losses should be counted in order to approximate the producer surplus loss to EU producers that cannot comply with the proposed limit values. The Dossier Submitter observers that as the periods considered are very short, there is almost no effect of discounting and thus the assumed period acts implicitly as a multiplier. For example, if the Dossier Submitter had assumed three years of profit loss under RO1 and RO2 to account for the time it takes companies to build up their production capacity, the resulting producer surplus loss would have been 50 % higher. It is important to keep this in mind because the cost of non-use is directly proportional to the assumptions made about the profit loss incurred by companies and, as seen in Section 5.1, is a key uncertainty factor in the quantitative uncertainty analysis.

#### 5.2.1.2. Dose-response relationship

The benefits of the restriction options are directly proportional to the achieved reduction in cancer ELR. The ELR in this restriction proposal is based on the reference dose-response relationships for inhalation exposure to Cr(VI) and lung cancer as well as for oral exposure to Cr(VI) and gastrointestinal cancer as established by ECHA's Committee for Risk Assessment (RAC) in 2013.54 These dose-response functions assume strict linearity between exposure and statistically expected cancer cases. RAC has acknowledged that these functions might overestimate cancer ELR at exposure levels below 1  $\mu$ g Cr(VI)/m<sup>3</sup>. Applied to a population at risk, the potential overestimation in ELR will result in a potential overestimation of statistical cancer cases among that population and thus in a potential overestimation of the benefit of restricting the use of Cr(VI) substances in scope. Because of the linear relationships between exposure and statistically expected cancer cases and between the reduction in statistically expected cancer cases and the benefit of the restriction, it is straightforward to see that any global change in the assumed slope of the dose-response function propagates linearly through the risk and impact assessments presented in this Annex XV report. If, instead, a kink in the dose-response relationship at  $1 \mu g Cr(VI)/m^3$  (8h TWA) is assumed, this would reduce the expected benefit expected of RO2 and RO3, but not of RO1 (as all LVs required under RO1 are above this kink).

<sup>&</sup>lt;sup>53</sup> <u>https://echa.europa.eu/documents/10162/0/afa\_seac\_surplus-loss\_seac-52\_en.pdf</u>.

<sup>&</sup>lt;sup>54</sup> The Dossier Submitter has conducted a short review of the scientific literature and concluded that despite conflicting evidence, the dose-response relationships used by RAC are still fit-for-purpose as no other, generally accepted, dose-response functions for Cr(VI) are available (see Appendix B.4.8).

### 5.2.2. Distributional weighting

Distributional weights can be used in socio-economic analysis to account for (income) disparities. In practice, this is done by giving priority to low-income individuals to reflect societal equity preferences (Nurmi and Ahtiainen 2018). Equity weights are typically calculated as  $w_i = (y_i/\bar{y})^{-\varepsilon}$  where  $y_i$  represents the income of individual *i*,  $\bar{y}$  represents the mean income and  $\varepsilon \ge 0$  represents the inequality aversion of the decision maker and enables them to rebalance costs and benefits of a regulation across different income groups. In the context of this restriction proposal, the distributional weights are relevant to test the proportionality of RO2 as it has impacts on those who directly benefit from better protection and on those who need to bear the cost of better protection.

Therefore, the Dossier Submitter performed a simple simulation in which equity weights are applied to a setting similar to RO2 in which health benefits of €290 million accrue to 50 000 workers (i.e., €5 800 per worker) and aggregate costs of €2.3bn are incurred by 20 000 capital owners (i.e., €115 000 per capital owner). According to Eurostat<sup>55</sup>, the annual income of an average industrial worker in the EU is ~€45 000. For the purpose of the distributional analysis, it is assumed that the mean income of capital owners is four times higher than that of the average worker, i.e. €180 000. In the simulation, income is assumed to be lognormally distributed with a variance that corresponds to a Gini index of 0.3 as found for the EU.<sup>56</sup> Iterative  $\varepsilon$ -testing for this setup finds a break-even point of  $\varepsilon \approx$  1.5. Since the economics literature typically suggests  $\varepsilon$  values in the range of 0.5 to 2 (see Nurmi and Ahtiainen, 2018 for a review), this sensitivity analysis suggests that, under plausible equity preferences, RO2 can be considered proportionate.

### 5.2.3. Number of companies and workers

The number of affected companies and the corresponding number of exposed workers and members of the general population is subject to some uncertainty. However, the advantage of the marginal approach pursued by the Dossier Submitter is that it allows for straightforward sensitivity testing. For example, if one maintains different assumptions about the population size exposed to Cr(VI) air emissions around the average emitting site, or about the value per avoided case of lung cancer, or the average number of workers per site, this will simply result in multiplicative shifts of estimates. One can therefore immediately see which assumptions are driving the benefit and cost estimates of reducing Cr(VI) exposure in the EU, and which assumptions are less relevant in that regard.

# 6. Conclusion on appropriate restriction options

Based on the impact assessment presented in Section 3 of this Annex XV report, the Dossier Submitter considers that all three restriction options (RO1, RO2 and RO3) are:

- Targeted to the risks posed by Cr(VI) compounds and effective in reducing these risks
- Practicable, i.e. implementable, manageable and enforceable

<sup>&</sup>lt;sup>55</sup> <u>https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Manufacturing\_statistics -</u> NACE\_Rev. 2&oldid=502915.

<sup>&</sup>lt;sup>56</sup> Lognormally distributed income and Gini coefficient are related through  $\sigma = \sqrt{2\Phi^{-1}((G+1)/2)}$  where  $\sigma$  is the standard deviation of log income, G is the Gini index, and  $\Phi^{-1}$  is the inverse normal CDF.

 Monitorable, i.e. the implementation of the proposed restriction can be duly monitored

However, as discussed in the proportionality assessment in Section 3.6, only RO1 and RO2 appear to be proportionate to the identified risks. Between these two options, RO1 appears preferable based on a standard cost-benefit logic where every actor receives the same consideration. However, if the decision maker weighs the health benefits to workers and the general population exposed to Cr(VI) more than the costs to companies using these substances, then RO2 may be better (see Section 5.2.2).

The Dossier Submitter also notes that the LVs and ELVs imposed by RO1 and RO2 could be mixed. For example, there is nothing to prevent the decision maker from imposing the LVs assessed in this Annex XV report under RO2 and the ELVs assessed under RO1. The consequence of combining the assessed restriction options would be a new restriction option with impacts between those of RO1 and RO2. Appendix E.1 provides the information necessary to assess permutations of the restriction options assessed in this Annex XV report.

# 7. Proposed restriction entry

## 7.1. Wording of the proposed restriction entry

Based on the proportionality assessment presented in Section 3.6, only RO1 and RO2 appear to be proportionate to the identified risks. The Dossier Submitter therefore proposes two alternative restriction entries (Option A and B) to be evaluated by the RAC, SEAC and Forum. This should allow ECHA to provide two duly assessed, consulted and evaluated restriction entries to the Commission at the end of the opinion-making process.

#### Short title

Restriction on the use of certain Cr(VI) substances, on their own or in mixtures.

#### **Scope description**

The text of the proposed entry in REACH Annex XVII has been drafted in Tables 37 and 38 to describe the intention of the Dossier Submitter under RO1 and RO2, respectively. The final legal wording (i.e. the entry in Annex XVII to REACH), including any relevant arrangements that govern the transition from the duties under the Authorisation title to the duties under the proposed restriction, is decided by the European Commission during the decision-making phase. An explanation of the intention of the Dossier Submitter, and the justification for the wording proposed is provided in Section 7.2.

### 7.2. Justification of the wording for the proposed restriction entry

#### Wording of column 1 of Table 37/Table 38 – Designation

See Section 1.2 for a justification of the proposed designation.

#### Wording of paragraphs 1-4 in column 2 of Table 37/Table 38 - Conditions

The wording of the draft restriction entries presented in Tables 37 and 38 reflect the restriction conditions proposed under RO1 and RO2 as these options appear proportionate to the identified risk according to the impact assessment presented in Section 3. In particular,

- paragraph 1 clarifies that all uses of the substances in the designation, including uses of Cr(VI) salts with a different stoichiometry and hydration degree are in the scope of this restriction proposal
- paragraph 2 excludes intermediate uses, e.g. in the manufacture of Cr(VI) and Cr(III) salts. Such uses are also exempt from REACH authorisation obligations
- paragraph 3 provides a list of the uses that make up the use categories assessed in the risk and impact assessment parts of this Annex XV restriction proposal. This is done intentionally to allow for a narrow list of conditionally derogated uses, implying that uses that have been phased out will not be covered by a derogation
- paragraph 4 clarifies that where multiple uses take place and therefore different limit values may apply in theory, the most stringent limit value is relevant unless the user can demonstrate that their uses are strictly segregated. In that case, compliance with the use-specific limit values can be monitored and enforced. The Dossier Submitter considers uses as 'strictly segregated' when workers that perform activities for use A are not exposed to Cr(VI) from use B. The Dossier Submitter considers that in practise this requires both organisational measures (i.e., a worker shall not carry out tasks for both uses within the same shift) and physical segregation (i.e., the uses have to take place in different rooms or are otherwise enclosed).

This approach allows mimicking the coverage of the authorisation requirements and should reassure policy makers that similar or stricter levels of protection are achievable under the restriction title of REACH.

Designation			Conditions of restriction	
EC No 215-607-8 CAS No 1333-82-0	Chromium trioxide as well as any salt with a different stoichiometry and	1.	Substances in the designation shall not be used on their own or in a mixture with a concentration equal or greater than <b>0,01</b> % by weight.	
	hydration degree	2.	By way of derogation, paragraph 1 shall not apply to uses as intermediates within the meaning of Art. $3(15)$ of REACH	
EC No 231-801-5 CAS No 7738-94-5	Chromic acid	3.	By way of derogation, where site-specific Cr(VI) releases are below the emission limit values of <b>2,5</b> kg/Cr(VI)/year to air and <b>15</b> kg Cr(VI)/year to water, paragraph 1 shall not apply under the following use	
EC No 236-881-5 CAS No 13530-68-2	Dichromic acid		<ul> <li>conditions:</li> <li>(i) occupational exposures to Cr(VI) is below the limit value of 5 µg Cr(VI)/m3 (8h time-weighted average) for companies that use the substances:</li> </ul>	
EC No 234-190-3	Sodium dichromate as well as any salt with a different		<ul> <li>to formulate Cr(VI) containing mixtures within the meaning of Art. 3(2) of REACH,</li> <li>is all structure lating to deposit a characterize based</li> </ul>	
CAS NO 10568-01-9	hydration degree		<ul> <li>In electroplating to deposit a chromium layer onto the surface of a metal substrate using an electrolytic solution,</li> </ul>	
EC No 231-906-6 CAS No 7778-50-9	Potassium dichromate as well as any salt with a different stoichiometry and hydration degree	-	<ul> <li>in a mixture to coat objects with a paint or primer,</li> <li>in other surface treatment processes that require no or low currents, including passivation, anodising, conversion coating, chromate rinsing, etching, pickling, stripping, deoxidising, desmutting, cleansing, sealing and insulation coating for the manufacture of grain-oriented electrical steel,</li> </ul>	
EC No 232-143-1 CAS No 7789-09-5	Ammonium dichromate as well as any salt with a different stoichiometry and hydration degree			
EC No 232-140-5 CAS No 7789-00-6	Potassium chromate as well as any salt with a different stoichiometry and		<ul> <li>in the machining of articles that contain Cr(VI) in their coatings.</li> <li>(ii) occupational exposures to Cr(VI) is below the</li> </ul>	
EC No 231-889-5 CAS No 7775-11-3	Sodium chromate as well as any salt with a different stoichiometry and hydration degree		<ul> <li>limit value of 1 µg Cr(VI)/m3 (8h time-weighted average) for companies that use the substances:</li> <li>in electroplating to deposit a chromium layer onto the surface of a plastic substrate using an electrolytic solution,</li> </ul>	
EC No 232-142-6 CAS No 7789-06-2	Strontium chromate as well as any salt with a different stoichiometry and		<ul> <li>as an alkali metal dispenser in the production of photocathodes,</li> <li>as a corrosion or scaling inhibitor in cooling or heating systems for various applications</li> </ul>	
EC No 233-660-5 CAS No 10294-40-3	hydration degree Barium chromate as well as any salt with a different stoichiometry and hydration degree		<ul> <li>as catalysts or processing aids in the electrolytic manufacture of different chemicals or ore processing applications,</li> <li>as a photosensitizer in UV lithography process to manufacture micro-structured components (filters, sieves, grids, etc.),</li> <li>as a colour indicator in single-use chemical breathalysers,</li> <li>in pyrotechnic compositions for the defence</li> </ul>	
EC No 246-356-2 CAS No 24613-89-6	Dichromium tris(chromate) as well as any salt with a different stoichiometry and hydration degree			
EC No 234-329-8 CAS No 11103-86-9	Potassium hydroxyocta- oxodizincate dichromate(1- ) as well as any salt with a different stoichiometry and hydration degree	4.	sector. Unless activities leading to Cr(VI) exposure are <b>strictly segregated</b> , a site operating in two or more of the use categories named in paragraph 3, points (i) and (ii), shall comply with the strictest relevant limit value.	
EC No 256-418-0 CAS No 49663-84-5	Pentazinc chromate octahydroxide as well as any salt with a different stoichiometry and hydration degree			

Table 37. Proposed REACH Annex XVII entry, Option A corresponding to RO1

Designation			Conditions of restriction		
EC No 215-607-8 CAS No 1333-82-0	Chromium trioxide as well as any salt with a different stoichiometry and hydration degree	1. 2.	Substances in the designation shall not be used on their own or in a mixture with a concentration equal or greater than <b>0,01</b> % by weight. By way of derogation, paragraph 1 shall not apply to		
EC No 231-801-5 CAS No 7738-94-5	Chromic acid	3.	<ul> <li>uses as intermediates within the meaning of Art. 3(15) of REACH.</li> <li>By way of derogation, where site-specific Cr(VI) releases are below the emission limit values of 0,25 kg/Cr(VI)/year to air and 1,5 kg Cr(VI)/year to water, paragraph 1 shall not apply under the following use conditions:</li> <li>(i) occupational exposures to Cr(VI) is below the limit value of 5 µg Cr(VI)/m3 (8h time-weighted average) for companies that use the substances:</li> <li>— in the machining articles that contain Cr(VI) in their coatings.</li> <li>(ii) occupational exposures to Cr(VI) is below the</li> </ul>		
EC No 236-881-5 CAS No 13530-68-2	Dichromic acid				
EC No 234-190-3 CAS No 10588-01-9	Sodium dichromate as well as any salt with a different stoichiometry and hydration degree				
EC No 231-906-6 CAS No 7778-50-9	Potassium dichromate as well as any salt with a different stoichiometry and hydration degree		<ul> <li>(ii) becomparison of 1 µg Cr(VI)/m3 (8h time-weighted average) for companies that use the substances:</li> <li>— to formulate Cr(VI) containing mixtures within the meaning of Art. 3(2) of REACH,</li> </ul>		
EC No 232-143-1 CAS No 7789-09-5	Ammonium dichromate as well as any salt with a different stoichiometry and hydration degree		<ul> <li>in electroplating to deposit a chromium layer onto the surface of a metal substrate using an electrolytic solution.</li> <li>(iii) occupational exposures to Cr(VI) is below the initial endoted of the surface of the</li></ul>		
EC No 232-140-5 CAS No 7789-00-6	Potassium chromate as well as any salt with a different stoichiometry and hydration degree		<ul> <li>limit value of <b>0,5</b> µg Cr(VI)/m3 (8h time-weighted average) for companies that use the substances:</li> <li>in electroplating to deposit a chromium layer onto the surface of a plastic substrate using an electrolytic solution,</li> <li>in a mixture to coat objects with a paint or primer,</li> <li>in other surface treatment processes that</li> </ul>		
EC No 231-889-5 CAS No 7775-11-3	Sodium chromate as well as any salt with a different stoichiometry and hydration degree				
EC No 232-142-6 CAS No 7789-06-2	Strontium chromate as well as any salt with a different stoichiometry and hydration degree		require no or low currents, including passivation, anodising, conversion coating, chromate rinsing, etching, pickling, stripping, deoxidising, desmutting, cleansing, sealing and insulation coating for the manufacture of		
EC No 233-660-5 CAS No 10294-40-3	Barium chromate as well as any salt with a different stoichiometry and hydration degree		<ul> <li>grain-oriented electrical steel,</li> <li>as an alkali metal dispenser in the production of photocathodes,</li> <li>as a corresion or scaling inhibitor in cooling</li> </ul>		
EC No 246-356-2 CAS No 24613-89-6	Dichromium tris(chromate) as well as any salt with a different stoichiometry and hydration degree		<ul> <li>as a convision of scaling immitted in cooling or heating systems for various applications,</li> <li>as catalysts or processing aids in the electrolytic manufacture of different chemicals or ore processing applications,</li> </ul>		
EC No 234-329-8 CAS No 11103-86-9	Potassium hydroxyocta- oxodizincate dichromate(1- ) as well as any salt with a different stoichiometry and hydration degree		<ul> <li>as a photosensitizer in UV lithography process to manufacture micro-structured components (filters, sieves, grids, etc.),</li> <li>as a colour indicator in single-use chemical breathalysers,</li> </ul>		
EC No 256-418-0 CAS No 49663-84-5	Pentazinc chromate octahydroxide as well as any salt with a different stoichiometry and hydration degree	4.	<ul> <li>in pyrotechnic compositions for the defence sector.</li> <li>Unless activities leading to Cr(VI) exposure are strictly segregated, a site operating in two or more of the use categories named in paragraph 3, points (i), (ii) and (iii), shall comply with the strictest relevant limit value.</li> </ul>		

 Table 38. Proposed REACH Annex XVII entry, Option B corresponding to RO2

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