ANALYSIS OF ALTERNATIVES

and

SOCIO-ECONOMIC ANALYSIS

Non-confidential version

Legal name of applicant: Maschinenfabrik Kaspar Walter GmbH & Co. KG

Submitted by: Maschinenfabrik Kaspar Walter GmbH & Co. KG

Date: February, 2021

Substance: Chromium trioxide

EC No.: 215-607-8

CAS No.: 1333-82-0

Use title: Use 1: Formulation of chromium trioxide-based electrolyte for electroplating process

Use 2: Chromium trioxide based functional chrome plating of cylinders used in the rotogravure printing and embossing industry

Use number: 1 and 2

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FIGURES

LIST OF ABBREVIATIONS

AfA	Application for Authorization
ACIMGA	Italian: Associazione Costruttori Italiani Macchine Per L'industria Grafica, Cartotecnica, Cartaria, Di Trasformazione E Affini (Association of Italian Manufacturers of Machinery for the Graphic, Paper, Papermaking, Printing and Related Machines Industries)
AoA	Analysis of Alternatives
CAS	Chemical Abstracts Service
Cr(III)	Trivalent chromium
Cr(VI)	Hexavalent chromium
CSR	Chemical Safety Report
CTAC	Chromium Trioxide Authorisation Consortium
CVD	Chemical Vapour Deposition
DU's	Downstream Users
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
e.g.	exempli gratia (for example)
ELR	Excess lifetime risk
etc.	Et cetera
EU	European Union
EUR	Euro
GAA	Graphic Arts Association
HV	Vickers Hardness
HVOF	High Velocity Oxygen Fuel
ISP	Intermediate Service Provider
i.e.	id est (that is)
MVE	Man via environment

NPV	Net-Present Value
NUS	Non-Use Scenario
OEM	Original Equipment Manufacturer
PVD	Physical Vapour Deposition
R&D	Research and Development
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAGA	Suitable Alternative Generally Available
SDS	Safety Data Sheet
SEA	Socio Economic Analysis
SVHC	Substance of Very High Concern
UK	United Kingdom
US(A)	United States (of America)
USD	US-dollar
VCM	Value of cancer morbidity
VSL	Value of Statistical Life
WCS	Worker contribution scenario
WTP	Willingness to pay

GLOSSARY

Term	Definition
Adhesion	This term describes the tendency of dissimilar particles or surfaces to cling to one another, for example adhesion of a coating to the substrate.
Alternative	A technology or substance considered and assessed for its suitability to substitute the use of chromium trioxide.
Beta tests	Beta tests are tests carried out under real operating conditions. Normally, they follow laboratory- or small-scale tests.
Cell geometry	The term "cell geometry" refers to the size and shape of the depressions engraved on the surface of a gravure cylinder that carry ink onto the substrate material.
Coating	A coating is a covering that is applied to the surface of an object, usually referred to as the substrate. The purpose of applying the coating may be decorative, functional, or both.
Embossing	Embossing is the process of creating a raised or recessed relief pattern (images or letters) on a material. In embossing, this is accomplished by pressing an engraved gravure cylinder against the material to be embossed, so that the engraved pattern is transferred to the material as a relief.
Electroplating	Electroplating is the process of coating a part or component with a metal via an electrochemical process. An electrolyte-containing bath is normally used. Electrical current is applied to trigger the deposition of ions onto the surface of the part or component to be coated.
Electroplating Unit	A typical equipment for the surface treatment of parts in which the part to be treated is submerged in a galvanic bath containing the required chemicals.
Engraving	Engraving is the general term for a process which involves the transfer of an image onto an image carrier. In rotogravure printing and embossing, the image carrier is a rotating cylinder.
Functional chrome plating	Functional chrome plating is an electrochemical surface treatment process whereby metallic chromium is deposited on the surface of a part or component to enhance properties such as wear and corrosion resistance, hardness, and tribological properties, among others.
Intermediate service provider	Electroplating and engraving companies that provide ready to use gravure and/or embossing cylinders.
Metallic chrome coating	This is the resulting coating layer of the functional chrome plating process.
Printing cell	A printing cell is a cavity in the surface of a gravure cylinder that is filled with ink during the printing process. Ink in the cell is then transferred and deposited on the surface of the substrate.
Rotogravure printing	Rotogravure printing is a printing system in which fluid ink is transferred from cavities or depressions on the surface of a rotating cylinder to a substrate material, for example paper. The design to be printed is etched, lasered or engraved into the surface of the printing cylinder.
Substrate	A material, such as paper, carton, film, foil, textiles to be printed or embossed.
Tribological properties	Tribological properties are those properties related to friction, lubrication and wear of surfaces in relative motion. These properties are important for moving machine parts.

DECLARATION

The Applicant, Maschinenfabrik Kaspar Walter GmbH & Co. KG is aware of the fact that evidence might be requested by ECHA to support information provided in this document.

Also, we request that the information blanked out in the "public version" of the Analysis of Alternatives and Socio-economic analysis is not disclosed. We hereby declare that, to the best of our knowledge as of today (February 5th, 2021) the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature:

Christoph Gschossmann
CEO Maschinenfabrik Kaspar Walter GmbH & Co. KG

Date, Place: February 5th, 2021, Krailling

SUMMARY

Introduction

The Analysis of Alternatives (AoA) and the Socio-Economic Analysis (SEA) form part of the Application for Authorisation (AfA) for the continued use of chromium trioxide in the formulation of chromium trioxide-based electrolytes for electroplating process (Use 1) and in the functional chrome plating of cylinders used in the rotogravure printing and embossing industry (Use 2) submitted by Maschinenfabrik Kaspar Walter GmbH & Co. KG (from here on referred to as K. Walter). K. Walter is a German company with more than 110 years of corporate history dedicated to the design of electroplating units for gravure form manufacture and the development of technologies for the process of system integration tailored to customer requirements.

K. Walter uses chromium trioxide in the formulation of electrolytes used for the electroplating of gravure cylinders, used in rotogravure printing and embossing applications. As an importer of chromium trioxide, K. Walter applies for the continued use of this substance to cover its entire supply chain.

Rotogravure printing is a printing technique based on the transfer of fluid ink from engravings on a gravure cylinder, or roll, to the surface of a substrate, or the material to be printed. An impression cylinder is used to apply pressure from the other side of the substrate and cause ink to be transferred from the engravings on the printing cylinder's surface to the substrate due to the ink's surface tension. Rotogravure is used primarily for long printing runs in applications such as packaging, magazines, catalogues, inserts, flyers, gift-wrap and labels, among many others, achieving fine and clear images.

Embossing is a process by which a relief is created on a substrate, such as paper, flexible polymer foils or textiles. It is usually carried out on an industrial scale in roll-to-roll processes with gravure cylinders. This technique is used for giving a 3D-texture to the embossed surface for both decorative and functional purposes. An example of a decorative application is the embossing of a texture into a protective foil in which the embossing follows the printed image below. In this way, a printed wood look on furniture or flooring can be given the haptics corresponding to the pattern, for example, thus increasing the value of the embossed surface. For technical applications, an example is the embossing of a specific surface pattern that provides anti-slip properties to the surface.

In all rotogravure printing (publication rotogravure, packaging rotogravure and decorative rotogravure printing) and embossing processes the gravure cylinders must be covered with a functional hard chromium layer. It is important that the surface of the cylinders is homogeneous, scratchproof, highly wear resistant, and hard (> 900 HV), as interaction with hard ink particles, with the doctor blade and the substrate causes damage to the cylinder's surface. Figure 25 below shows an overview of the cylinder preparation process.

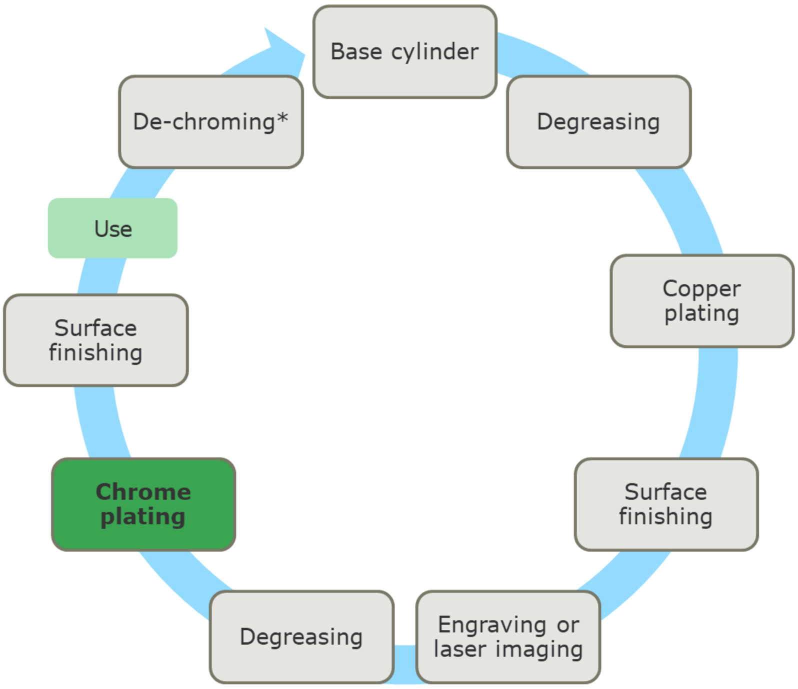

Figure 1: Flow diagram of cylinder preparation process. *De-chroming can refer to either refurbishing or refinishing.

Identification of possible alternatives

K. Walter has developed a triple parallel strategy for substituting chromium trioxide in the manufacture of rotogravure and embossing cylinders. This project is called HelioGreen. It features the development and implementation of the alternative manufacturing techniques Helio® Pearl and HelioChrome® NEO, coupled with the submission of this AfA for the extended use of chromium trioxide until 2032 (a project that K. Walter has named ChromeXtend). HelioChrome® NEO focuses on the development of Cr(III)-based plating as an alternative to the current process and has been ongoing since 2013. Helio® Pearl was started in 2014 and targets the development of polymer-based coatings. Combined, these developments could potentially substitute current applications of K. Walter's customers. For a detailed description of these technologies see section 4.2.

Many of the technical requirements needed to substitute Cr(VI) in the electroplating of gravure cylinders have already been successfully established for Helio® Pearl and HelioChrome® NEO. However, further testing is needed at DU sites to ensure the reliability of these technologies. These tests are expected to start in 2021. Because both alternatives use a different technology than the current Cr(VI)-based method, downstream users will need to implement new plating lines (in the case of substitution HelioChrome® NEO) or new manufacturing lines (when substituting with Helio® Pearl) for replacing the Cr(VI)-based process. Given the large investment costs associated with this transition, it will occur slowly. An assessment of these alternatives can be found in section 4.4.

Information on the length of the review period

K. Walter foresees that at least 12 years will be needed for a complete transition to a Cr(VI)-free alternative. This time includes the technical development of the short-listed alternatives and the time needed by K. Walter to manufacture and distribute the new equipment, as well as the time needed for DUs to evaluate and switch to the new process(es). The technical development of Cr(III)-based electroplating and polymer coatings is already ongoing and runs in parallel.

Further R&D testing will be conducted on both alternatives to ensure the quality and reproducibility of the alternatives. A customer approval phase will follow, in which the alternatives will be tested under real operating conditions at several beta-testing sites (DU sites selected to carry out first tests under real conditions). After these tests, a transition period is needed to substitute all current and potentially future Cr(VI)-based electroplating units operated by K. Walter’s DUs in the EEA. As soon as a new technology will be available for the DUs, it will take several years for K. Walter to manufacture the needed equipment to distribute to its customers, given a limited production capacity and the large number of Cr(VI)-based electroplating units that need to be substituted. Companies who adopt a new process will not directly substitute 100% of their process but will use e.g. a Cr(III)-based electroplating process in parallel to a Cr(VI) process to minimise risks and gain experience with the new technology.

An overview of this R&D plan is shown in Figure 2.

K. Walter therefore applies for a review period of 12 years, comprising the time needed to further develop the main alternatives, to test them at DU sites and to completely switch from the Cr(VI)-dependent process to the new technologies. A detailed derivation of the requested review period is found in section 4.5.

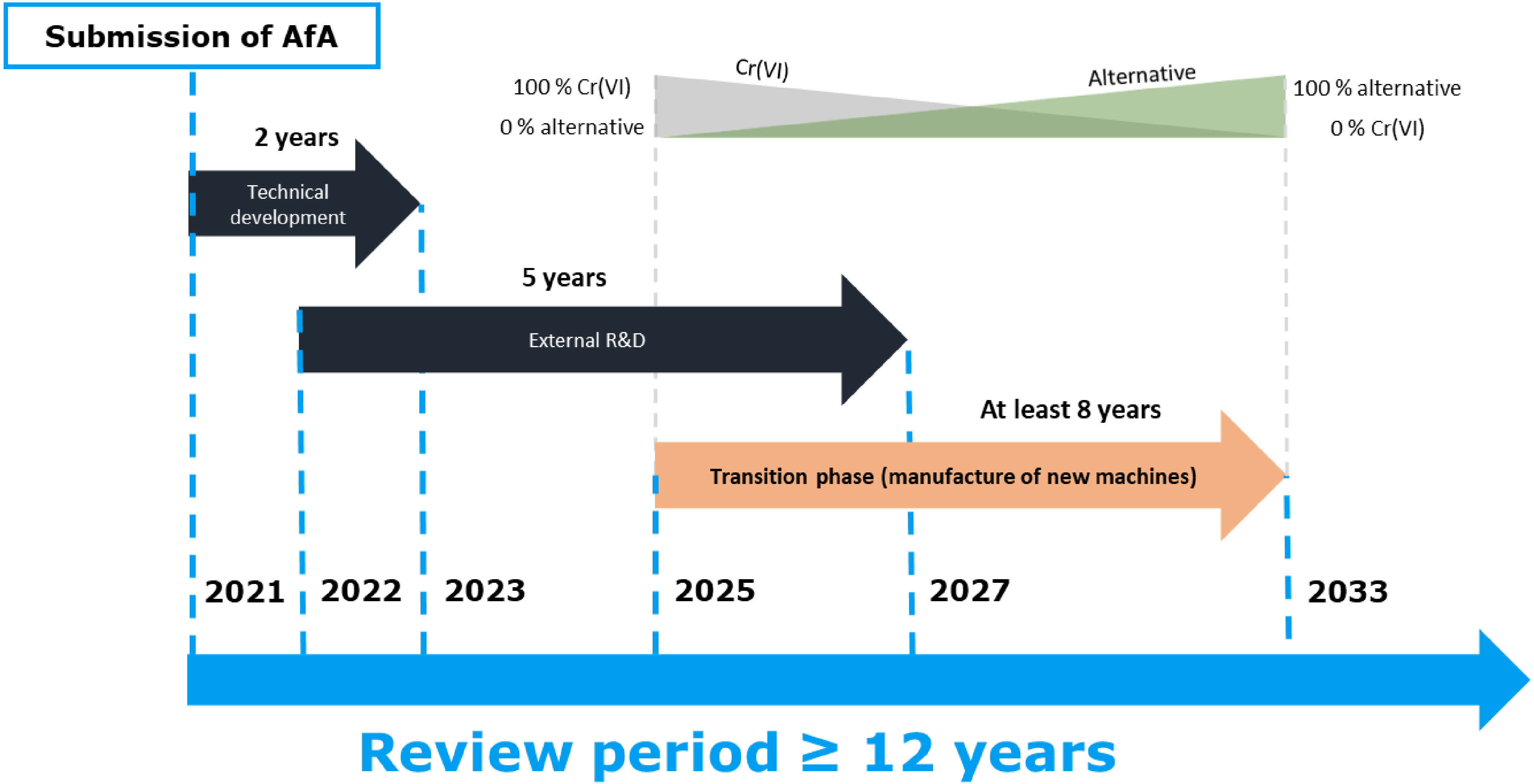

Figure 2: Overview of R&D plan for substitution of Cr(VI)

1 AIMS AND SCOPE OF THE ANALYSIS

1.1 Aims

The following substance is subject to this AoA and SEA:

#	Substance	Intrinsic property(ies)[1]	Latest application date[2]	Sunset date[3]
16	**Chromium trioxide** **CrO_3** EC No: 215-607-8 CAS No: 1333-82-0	Carcinogenic (category 1A) Mutagenic (Category 1B)	21 March 2016	21 September 2017

[1] Referred to in Article 57 of Regulation (EC) No. 1907/2006
[2] Date referred to in Article 58(1)(c)(ii) of Regulation (EC) No. 1907/2006
[3] Date referred to in Article 58(1)(c)(i) of Regulation (EC) No. 1907/2006

Chromium trioxide is categorised as a Substance of Very High Concern (SVHC) and is listed on Annex XIV (substances subject to authorisation) of Regulation (EC) No 1907/2006 as entry 16. This substance meets the criteria of Article 57 (a) and (b) of Regulation (EC) 1907/2006 (REACH) because of its carcinogenic and mutagenic properties. Chromium trioxide is an inorganic salt based on hexavalent chromium (Cr(VI)). Adverse effects are evaluated in detail in the chemical safety report (CSR) of this Application for Authorisation (AfA). The substance was included in Annex XIV in the course of the third recommendation of ECHA for the inclusion of substances in Annex XIV from 20th of December 2011. Furthermore, chromium trioxide is categorised as a non-threshold substance, so the so-called Socio-Economic Analysis (SEA) route is followed.

The applicant, Maschinenfabrik Kaspar Walter GmbH & Co. KG, further on referred to as K. Walter, applies for authorisation to continue the use of chromium trioxide in the formulation of chromium trioxide-based electrolytes for electroplating processes (Use 1) and the chrome plating of printing cylinders used for rotogravure printing and embossing (Use 2). This application covers K. Walter's supply chain in Europe. K. Walter applies for authorisation assuming the role of importer of the substance.

The CSR prepared as part of this AfA is referenced here to provide context for the SEA part of this document.

The aim of this document is:

a) from the Analysis of Alternatives (AoA) side, to demonstrate that no feasible alternatives to chromium trioxide will be available and successfully implemented for the chrome plating of gravure cylinders before 2032 (Use 1 and Use 2);

b) from the SEA side, to demonstrate that the socio-economic benefits associated with the continued use of chromium trioxide by the applicant outweigh the remaining risks to human health associated with prevalent use conditions.

1.2 Scope

K. Walter is an importer of chromium trioxide in the EU. The substance is formulated and sold as an electrolyte for chrome plating applications. This AfA covers the formulation of chromium trioxide and its use by downstream users (DUs) for electroplating of printing and embossing cylinders, also known as gravure cylinders. K. Walter is a manufacturer of plating equipment for gravure cylinders, and supplies customer-specific equipment for different printing segments: packaging, decorative, publication and embossing. The core part of such plating systems is the device for the application of a chromium trioxide-based functional chrome coating on the printing cylinders (the plating units). This coating is required to achieve multiple beneficial performance properties such as high wear resistance and longevity combined with high-quality printing for long printing runs.

The gravure cylinders in scope of this AfA, i.e. requiring a chromium trioxide based functional chrome coating are listed in Table 1 together with information on their specific specifications, characteristics and area of application.

Table 1: Product scope of this AfA

Product	Specification	Characteristics	Area of applications
Cylinder A	Circumference 300 – 1000 mm, Face Length 400 – 1800 mm	Variety of substrates in print run/different surface treatment, high printing speed	Packaging
Cylinder B	Circumference 300 – 2100 mm, Face Length 200 – 2800 mm	Long print runs, special high wear resistance	Decorative
Cylinder C	Circumference 800 – 1500 mm Face length 1800 – 4400 mm	Long print runs, high reproducibility, high printing speed	Publication
Cylinder D	Circumference 300 – 2100 mm, Face Length 200 – 5000 mm	High wear resistance, critical structure (concerning plating)	Embossing

2 CONSULTATIONS

European Rotogravure Association (ERA)

K. Walter is a member of the European Rotogravure Association (ERA). The ERA is actively involved in the authorisation process for the use of chromium trioxide in the rotogravure industry, both at the industry and the regulatory level. The association regularly organizes meetings and conferences among its members to discuss relevant topics, including the authorisation of chromium trioxide, the status of substitution efforts and available alternatives.

Consultations with experts from academia

K. Walter has a long-term cooperation expert in the area of printing technologies to discuss the availability and suitability of alternatives to chromium-trioxide dependent rotogravure printing and embossing, i.e. alternative printing technologies. This discussion provided an overview on the limitations and challenges of alternative printing technologies. The information gathered from these discussions was used for the assessment of potential alternatives (see section 4.2).

Consultations with other companies and research institutes

Over the past years, K. Walter has cooperated with various companies and institutions for the research and development of possible alternatives to chromium trioxide in the rotogravure and embossing applications. These include the Fraunhofer Institute for Surface Engineering and Thin Films IST, the Helmut Schmidt University, [redacted], Interpane AG, Mac Dermid Enthone GmbH, Coventya GmbH and Atotech GmbH**.**

Supply chain mapping and Downstream User Survey

To collect information on the supply chain covered by this AfA, questionnaires were sent to K. Walter's DUs within the EEA addressing critical points of the AoA, SEA and CSR. These questionnaires aimed to collect information on the feasibility and availability of potential alternatives, affected production activity at DU sites and information regarding the baseline scenario and the non-use scenario(s) to calculate socio-economic and human health impacts. These questionnaires were distributed as an online survey available in five languages (Spanish, Italian, French, German and English) starting on February 25th, 2020. K. Walter informed its DUs about this survey and encouraged them to participate. One CSR-related questionnaire was sent per site, while one combined AoA- and SEA-specific questionnaire was sent for each registered legal entity. This is because exposure is site-specific, whereas economic and R&D data can be evaluated at the company level. Hence, the number of AoA/SEA questionnaires sent is lower, considering that a few legal entities had more than one site and therefore had to fill more than one CSR questionnaire but only one AoA/SEA questionnaire. DUs were requested to fill these questionnaires until April 30th, 2020 with two reminders sent before this deadline. Additionally, explanatory videos in Spanish, Italian, French, German and English were prepared and made available to all DUs. These videos aimed to provide instructions on how the questionnaires were to be completed and to help illustrate the authorisation process and its impact on K. Walter's supply chain.

A total of 117 CSR- and 105 AoA/SEA-related questionnaires were sent, covering all DUs of K. Walter in the EEA. These represent a wide range of applications in the publication, packaging, decorative and embossing industries, and include intermediate service providers and printing shops using gravure coating for self-use. The countries covered were Portugal, Spain, France, Belgium, Germany, Italy, Greece, Poland, Austria, Slovakia, Hungary, Croatia, Czech Republic and Romania. Regular data assessments were carried out during the time the surveys were available for the DUs to evaluate response rates and the quality of the responses. DUs whose responses were unclear or incomplete were contacted individually and asked for clarification or further information, even past the response deadline.

A response rate of 75% was obtained for CSR-related questions, i.e. a total of 88 responses. For the AoA and SEA-related questions, the response rates were 70% (74 responses) and 70% (73 responses), respectively. These rates are different because not all DUs answered all sections within the surveys. Importantly, these results also include partially completed questionnaires with incomplete or missing answers. It is possible that some DUs only completed one of both questionnaires (CSR and AoA/SEA). A detailed discussion about the results of these surveys is presented in the following sections.

These activities and proactive engagement with the supply chain have been important to understand the impact of the authorisation requirements for the industry, and to support the preparation of this AfA.

3 APPLIED FOR "USE" SCENARIO

3.1 Definition of the applied for use scenario

Chromium trioxide is used in the production process of printing cylinders in the rotogravure and embossing industry. Rotogravure, shortly referred to as gravure, is a printing process that utilises a cylindrical image carrier in which the printing area is below the non-printing area, using liquid inks that dry through evaporation (1). In all gravure printing processes, the printing cylinders have to be covered with a functional chrome coating. These cylinders are widely used for printing magazines and catalogues and any types of packaging material - especially the flexible packaging material for consumer brand articles. It is further applied in decorative paper or film printing for furniture, flooring and wallpaper (2). Chromium trioxide is also used for embossing cylinders, with which embossed reliefs can be directly created at the end of the printing corresponding to the printed image or on not previously printed substrates. The embossed structure can add a haptic feature to printed products or introduce new functionalities to its substrate.

To further explain the uses covered under this AfA, it is necessary to begin with the supply chain description to demonstrate the interconnectedness of the uses among several actors including the applicant.

3.1.1 Supply Chain

The vertical supply chain in which chromium trioxide is being used originates from the applicant's role as an importer of the substance in the European Economic Area (EEA). Since, the value to society of any intermediary good(s) is based on the value of the final consumer good(s)/service(s) and since upstream impacts are also relevant in this case, the supply chain is considered from import of the substance in the EEA all the way down to production of a consumer good(s)/service(s) and the societal benefit derived from them. The supply chain in this case covers a wide array of actors – upstream and downstream.

Figure 3 depicts a general description of the supply chain for the applicant and its connection to the rotogravure industry.

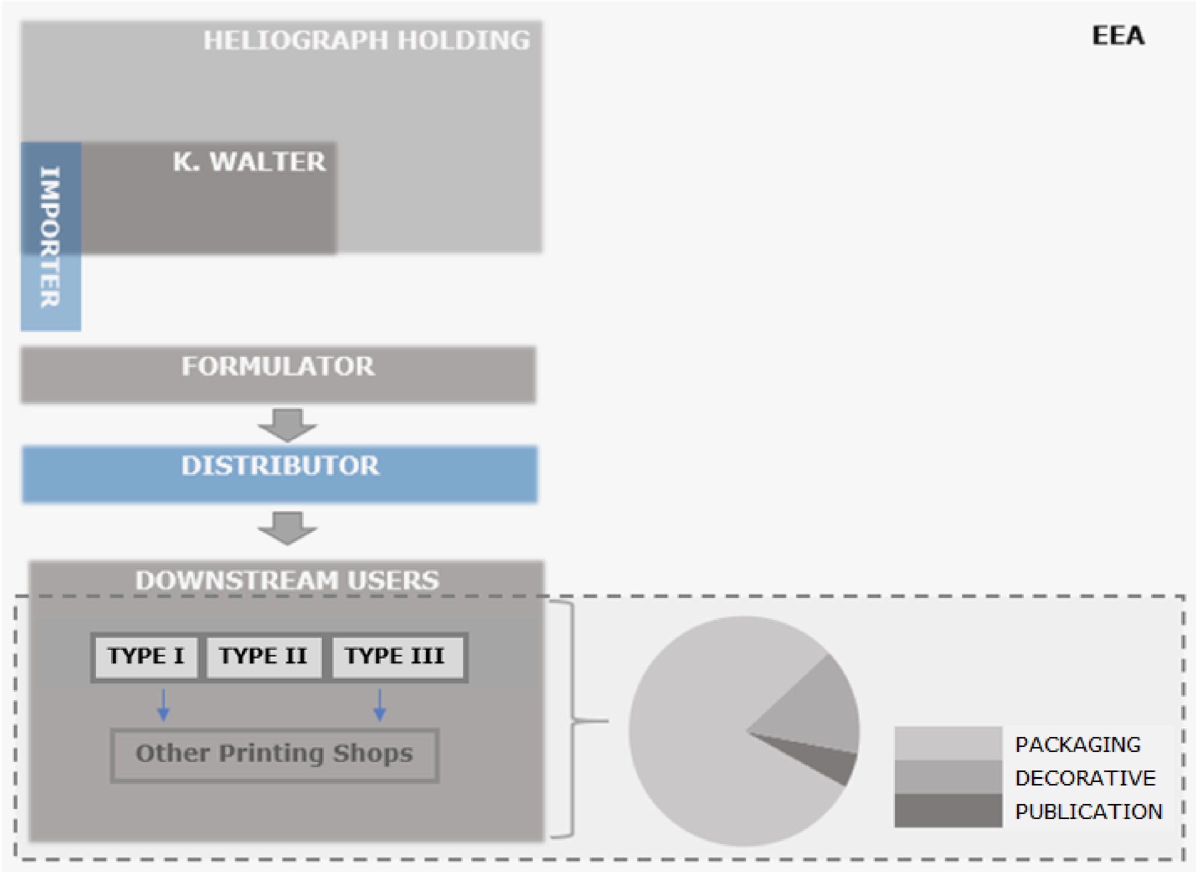

Figure 3: Generalized supply chain for K. Walter

The illustration shows the link between them signifying the (in)direct impacts of this authorisation. Subsequently, an impact of an authorization to K. Walter will certainly have impacts on other members of the supply chain as well. Thus, the actors include:

Importer that purchases chromium trioxide as raw material from outside the EEA and sells it within the EEA. The applicant is responsible for this role in the supply chain.

Formulators that purchase the raw materials from manufacturers/importers of chromium trioxide to form appropriate mixtures or liquid formulations. They develop mixtures or formulations containing chromium trioxide to meet industry specific requirements.

Distributors that purchase chromium trioxide or chromium trioxide formulations from the manufacturer, formulator or importer and deliver it to the customer. The liquid formulations containing chromium trioxide are distributed by the applicant along with its self-manufactured machinery.

Processors or Downstream Users (DUs) that purchase chromium trioxide liquid formulations to electroplate gravure cylinders utilised by printing shops to produce end products like packaging/decorative/publication substrates for use by OEMs in a consumer product further to the end of the supply chain. An example of consumer brands of such an OEM would be Ferrero Rocher or Milka for which the wrapping paper is produced by one of the DUs to which the applicant supplies the liquid formulation containing chromium trioxide as well as the plating units.

In this case and for the ease of analysis later, the downstream users have been divided into three categories as shown in Table 2. Demographics of these downstream users have been further elaborated in section 3.2.3.2.

Table 2: Classification of the downstream users (DUs)

Types of DUs	Description
Type I: Intermediate service provider	Type I DUs are involved in coating gravure cylinders with chromium trioxide mixtures or formulations purchased from the applicant and provide such coated cylinders to printing shops
Type II: Printing company with gravure cylinder manufacturing for self-use	Type II DUs are printing companies that are involved in manufacturing gravure cylinders for self-printing use
Type III: Printing companies with gravure cylinder manufacturing for self-use and intermediate service providers of the self-coated cylinders	Type III is a combination of Type I and Type II such that the company is manufacturing gravure cylinders for self-use and acts as an intermediate service provider of gravure cylinders to other printing companies

The cylinder is coated using the mixture by the intermediate service providers and delivered to printing companies without an own gravure cylinder manufacturing. The DUs are engaged in several printing sectors including publication, packaging, decorative and embossing gravure. The supply chain however does not end here. There is a further dependency of printing firms that do not coat their own gravure cylinders. They rely on Type I and III producers for coated cylinders for their downstream use. Such printing sites/firms, however, are not part of this application and were thus, not included in the survey as they do not directly utilize chromium trioxide in their production activities but would certainly incur indirect impacts as a result of a refused authorization.

The actors of the supply chain depicted in Figure 3 are further elaborated in section 3.2.

Given the structure of the supply chain elaborated above, the applicant, as an importer remains the sole source of supply for chromium trioxide as a raw material for the formulator and chromium trioxide based liquid formulations as well as electroplating units to the downstream users respectively. Based on this inter-dependency of the supply chain on the applicant, an authorization is being requested for the affected production activity segmented into the following two uses -

3.1.2 Use 1 – Formulation

In the first use covered in this AfA, the applicant is applying for authorisation for formulation of mixtures containing chromium trioxide to be used in galvanic equipment to manufacture gravure cylinders for use in the printing and embossing industry. These formulations are prepared by a contracted party and supplied back to the applicant within the EEA to be used by its downstream users for coating gravure cylinders for varied segments in the printing industry.

3.1.3 Use 2 – Downstream users

In the second use covered in this AfA, the applicant is applying for authorization for chromium trioxide based functional chrome plating of printing cylinders used in high-quality printing applications required in the packaging, decorative, publication and embossing industry.

3.2 About the applicant and other stakeholders

3.2.1 Maschinenfabrik Kaspar Walter GmbH & Co. KG

Maschinenfabrik Kaspar Walter GmbH & Co. KG (from here on referred to as "K. Walter") is a German company in the rotogravure sector with more than 110 years of corporate history. The company designs electroplating units for gravure form manufacture and develops technologies for the process of system integration tailored to their customer requirements (3). Since 1906, K. Walter has evolved in its innovative equipment and automation technology garnered with cooperation of companies forming the Heliograph Holding – which is the umbrella organization containing industry expertise, know-how and reliable solutions for electroplating, automation, surface treatment, engraving and laser systems for gravure and more (4).

The applicant operates its production lines in Krailling, a district of Starnberg in Bavaria, Germany (see Figure 4).

Figure 4: K. Walter's site in Krailling

<u>**Financial figures**</u>

Use 1

Financial figures for this use represent the applicant's revenues and subsequent profits from sales of liquid chromium trioxide mixtures or formulations. In 2019 with these products, the annual EBIT reached EUR [redacted] million (see Figure 5). These figures only represent K. Walter's surplus with formulations. Besides this, the formulator's surplus with the use of these formulations has not been included in these estimates. Such information was not available at this time.

Use 2

Financial figures for this use represent the applicant's revenues and subsequent profits from sales of liquid chromium trioxide mixtures or formulations plus the galvanic machines used for plating of gravure cylinders with this formulation. In 2019 with these products, the annual EBIT reached EUR [redacted] million (see Figure 5). These figures represent the EBIT generated from the sales in and outside the EEA.

[redacted]

Figure 5: Annual profits at K. Walter for use 1 and use 2

<u>Number of employees</u>

The applicant employs a total of [redacted] employees, out of which [redacted] employees are directly involved in the manufacture of plating units that are supplied to the applicant's downstream users.

<u>Export outside the EEA</u>

Compared with the distributions within the EEA, the export share of the applicant's gravure cylinder electroplating units and consumables outside the EEA is a relatively small share of the total sales ([redacted]%). It underlines that the applicant has a large reliance on the EEA market.

3.2.2 Heliograph Holding

While the description of the applicant above only covers a small aspect of its widespread roots in the printing industry, its massive contribution can be understood by introducing the umbrella organization – Heliograph Holding comprises seven manufacturing companies including K. Walter. The group is involved not only in the manufacture and handling of gravure cylinders but also in other technologies including laser for engraving and imaging in flexography, letterpress, screen and offset printing, and embossing, finishing, and security applications. The network started around K. Walter and was established as the Heliograph Holding in 2009 (5).

The applicant produces all electroplating units for the group and even acts as a full system retailer (selling all parts for rotogravure cylinder manufacturing process (6)). Therefore, it can be said that the Holding would not benefit from the use of other technologies in case K. Walter is refused an authorisation. Including K. Walter, the brands of the holding are quite well connected and offer each other complementary services and products. Four out of seven brands under the Holding are based in the EEA, each having individual areas of expertise that complement each other (see Table 3).

In the following table, each of the companies' activities and products related to chromium trioxide are described.

Table 3: Brands belonging to the heliograph holdings (6)

EEA		
Name of the brands	**Country of location**	**Main activity**
Bauer	Germany	Manufactures inline transportation and storage systems and input/output stations for automatic gravure cylinder lines.
HELL Gravure Systems	Germany	Provides electromechanical and direct laser engravers for gravure cylinders.
K.Walter	Germany	See section 3.2.1
Schepers Laser Technology	Germany	Manufactures direct laser engravers for universal use in terms of material, roller size, resolution, and application or industry.
Non-EEA		
Name of the brands	**Country of location**	**Main activity**
Ohio Gravure Technologies	USA	Supplies special electromechanical engravers for packaging and decorative engraving.
Daetwyler - Graphics Precision	Switzerland	Handles surface processing equipment for gravure cylinders.
Lüscher Technologies	Switzerland	Not included in the scope of this assessment, because the company does not operate any business related to rotogravure.

In Figure 6, a production flow of the rotogravure cylinders between K. Walter and the members of the holding is described.

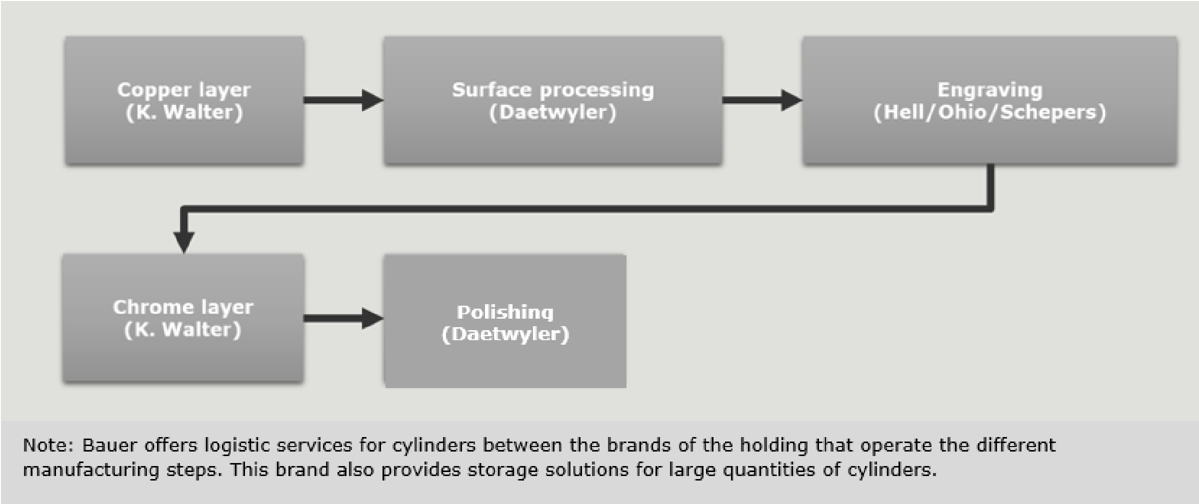

Figure 6: Production flow between K. Walter and the members of Heliograph Holding

It underlines the close connection between all the firms derived from activities requiring chromium trioxide as a raw material to surface processing of gravure cylinders. The activities reach from copper plating to engraving, surface finishing in copper and chrome to all the logistics between these processes all the way to delivery.

Additionally, Heliograph Holding also has subsidiaries across the globe which sell consumables/machines or provide services that involve the use of chromium trioxide and will thus be equally impacted by this authorization.

Table 4 shows the subsidiaries that are located in the EEA and fall under the scope of this assessment.

Table 4: Geographical distribution of subsidiaries belonging to the heliograph holdings in the EEA

Name of the subsidiaries	Country of location
Daetwyler-Hell France S.A.S.	France
Daetwyler-Hell Iberica S.L.	Spain and Portugal
MDC Max Daetwyler GmbH	Germany

Financial figures

Figure 7 represents total annual profits of the Heliograph Holding companies located in the EEA[1] excluding K. Walter, along with their annual profits from the services essential in manufacturing gravure printing cylinders for three consecutive financial years – 2016, 2017 and 2018. In 2018 with these services, the annual turnover reached EUR [redacted] million with an EBIT of EUR [redacted] million. It should be noted that these figures only represent all EEA based firms under the Heliograph Holding except K. Walter. Financial figures for K. Walter have been included separately under section 3.2.1.

[1] It includes Bauer, HELL Gravure Systems, and Schepers Laser Technology.

[redacted]

Figure 7: Annual profit as accrued at the Heliograph Holding manufacturing companies in Germany between 2016 and 2018

Figure 8 represents annual revenues and subsequent profits at the subsidiaries located in the EEA for the activities related to chromium trioxide including the sales of consumables and machines. In 2018 with these products, the annual profit related to the sales from selling only formulations (use 1) reached an EBIT of EUR [redacted] million, whereas the annual profit related to the sales of formulations plus machines (use 2) reached an EBIT of EUR [redacted] million at these brands.

[redacted]

Figure 8: Annual profit as accrued at Heliograph Holding's sales and service subsidiaries located in EEA between 2016 and 2018

<u>Number of employees</u>

Table 5 shows the number of workers dependent on sales of chromium trioxide products employed at three firms under Heliograph Holding in the EEA. Number of employees at K. Walter that are dependent on the use of chromium trioxide are not included here but have been elaborated in section 3.2.1.

Table 5: Number of employees at the brands of the Heliograph Holding excluding K. Walter in Germany[2]

Name of the brands	Number of workers dependent on chromium trioxide
Bauer	[redacted]
HELL Gravure Systems	[redacted]
Schepers Laser Technology	[redacted]
TOTAL	[redacted]

Table 6 shows the number of workers dependent on sales of chromium trioxide products employed at Heliograph Holdings' subsidiaries in the EEA.

Table 6: Number of employees at the sales and service subsidiaries of the Heliograph Holding in the EEA

Name of the subsidiaries	Number of workers dependent on chromium trioxide
Daetwyler-Hell France S.A.S.	[redacted]
Daetwyler-Hell Iberica S.L.	[redacted]
MDC Max Daetwyler GmbH	[redacted]
TOTAL	[redacted]

Table 7: Total number of employees related to use 1 and use 2 at Heliograph Holding (except K. Walter) and Heliograph holdings' subsidiaries

Unit	Number of workers dependent on chromium trioxide
Heliograph Holdings (except K.Walter)	[redacted]
Heliograph Holdings' subsidiaries	[redacted]
TOTAL	[redacted]

Table 7 shows the total number of workers at Heliograph Holdings as well as their subsidiaries.

3.2.3 Downstream users (DUs)

K. Walter further maintains an extended network of DUs throughout the EEA that are dependent on the use of chromium trioxide. They are supplied with formulations of chromium trioxide and galvanic machines/equipment from K. Walter to coat gravure cylinders for use in numerous printing applications spanning over packaging, publication, decorative and embossing industrial segments. This value addition in terms of providing an intermediate product for downstream user makes K. Walter a competent partner for

[2] The number does not include employees at the subsidiaries

gravure cylinder manufacturing equipment (7). Information about DUs was collected via a survey, which allowed the description of these DUs on the basis of these attributes:

- Geographical distribution
- Industrial segment by revenue share
- Size of the firm by revenue share and profit margin related to use 2

The results of the survey have been used to elaborate on these attributes of the downstream users.

3.2.3.1 Use of survey results for the socio-economic assessment

Questionnaires were sent to the 105 DUs within the EEA, of which 73 DUs responded to the SEA questionnaire. The response rate of the SEA survey is therefore estimated to be 70%[3].

3.2.3.2 Downstream users by geographical distribution

Figure 9 below depicts the number of DUs by Member state in the EEA. Since one AoA-/SEA-related survey/questionnaire was sent to one company comprising several legal entities, total number of companies of downstream users that were contacted were taken to be equal to the number of questionnaires circulated. Accordingly, there are 105 DUs[4] corresponding to 117 sites or companies in the EEA. The highest concentration of K. Walter's DUs is in Germany with 29 DUs and the least in Slovakia, Portugal and Belgium with 1 DU each. Figure 9 shows the total number of K. Walter's DUs in the EEA as of December 2020. Please note that in 2021, K. Walter had its first installation in Bulgaria which has not been incorporated in the figure below as all DUs except the DU in Bulgaria were surveyed[5].

[3] The response rate is inclusive of partially complete and complete responses to questionnaires. The partially complete questionnaires either provided information on the applied for use scenario or non-use scenario and corresponding impacts. However, for some DUs, answers to the most-likely non-use scenario were provided without information on corresponding impacts. A quality check of the data was performed to check the robustness and appropriateness of data. Wherever appropriate data was made available in the partially completed questionnaires, it was used to elaborate the characteristics of the downstream users.

[4] 1 DU is equivalent to 1 company having one or more legal entities.

[5] This is due to the fact that the survey was conducted in 2020 and K. Walter had its first installation in Bulgaria in 2021.

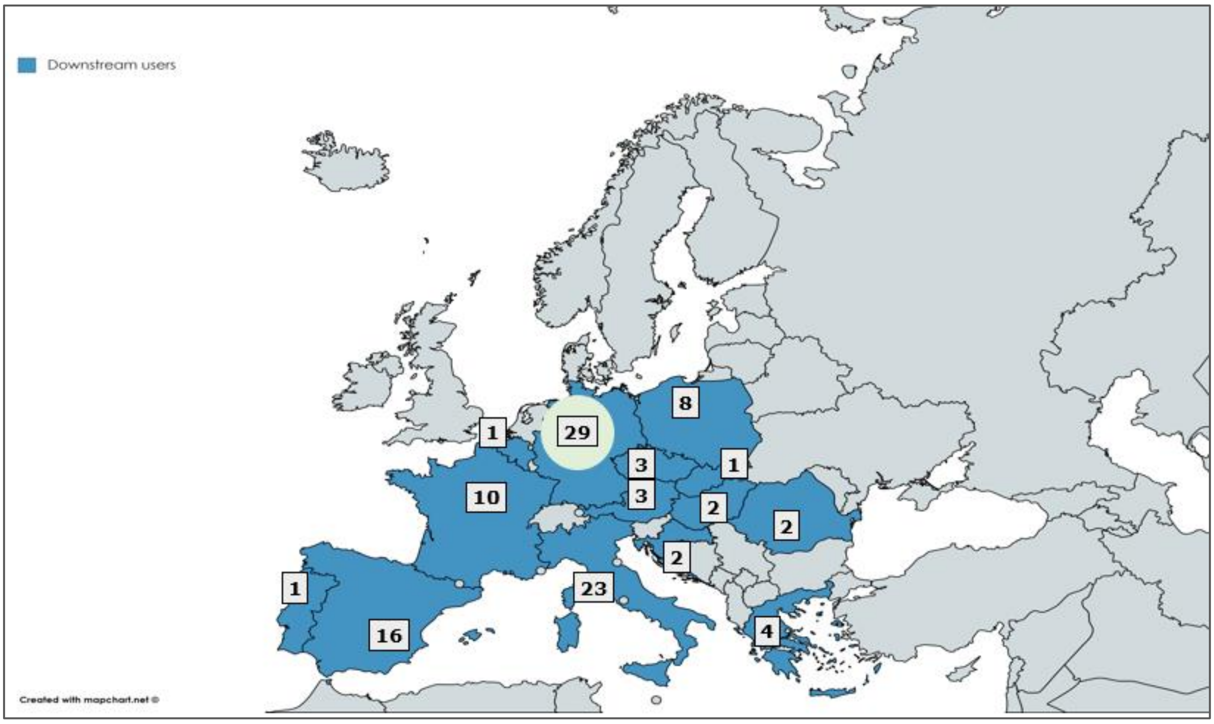

Figure 9: Demographics of the applicant's downstream users in the EEA

3.2.3.3 Downstream users by business model

As shown in section 3.1.1 (see Table 2), the DUs are segmented into Type I, Type II and Type III users depending on whether they are intermediate service providers or printing shops that coat gravure cylinders for self-use or both.

Table 8 shows the frequency of the type of downstream users that answered the survey by their business model.

Table 8: Number of DUs segmented by the type I, II, and III

Types of DUs	Number of DUs that answered the survey	% share in total DUs that answered the question (70)
Type I: Intermediate service provider	24	34%
Type II: Printing companies with gravure cylinder manufacturing for self-use	36	52%
Type III: Printing companies with gravure cylinder manufacturing for self-use and intermediate service providers of the self-coated cylinders	10	14%
TOTAL	**70**	

It can be observed from the 70 responses in Table 8 that, Type II (52%) constitutes the majority of DUs followed by Type I (34%) and Type III (14%) DUs in the decreasing order. These results are in line with K. Walter's knowledge that approximately 40% of DUs are intermediate service providers while approximately 60% coat their cylinders for own printing activities.

Since Type III DUs perform activities of both Type I and II DUs, their main business activity between the two was asked in the questionnaire where 80% (n=8) of respondents said that their main activity was related to the Type II rather than Type I (n=2). It can therefore be said that type III users are most similar to type II users i.e., printing shops with gravure coating for self-use form the majority in K. Walter's downstream users.

3.2.3.4 Number of cylinder production sites

Cylinder production sites can be defined as the sites where gravure cylinders are coated with chromium trioxide for use in numerous applications. Accordingly, K. Walter supplies its plating units and formulations to a total of 117 cylinder production sites in the EEA.

3.2.3.5 Downstream users by application in the printing industry

To specify the sectors of the main applications within the printing industry that their final consumer products or services belong to, DUs were asked to choose between publication, packaging, or decorative printing and embossing industrial segments (see section 3.5.1). The question was required to be answered in a rank based manner where assigning rank = 1 to an industrial segment would imply that this segment generates the highest sales revenue for the corresponding DU followed by subsequent ranks for other segments in decreasing order of share of sales revenue.

Table 9 describes the number of DUs, according to the most important sector supplied by them in terms of the highest share of revenues generated. 62 DUs attributed a single industrial segment to their highest revenue stream (rank = 1), while a few DUs attributed two industrial segments as their largest sources of revenue (rank = 1).

Table 9: Number of DUs segmented by types of application in the printing industry

Industrial segment	Number of DUs and its types that assigned rank = 1 to the industrial segment	
Publication	Type I	
	Type II	13
	Type III	
		13
Packaging	Type I	15
	Type II	16
	Type III	9
		40
Decorative	Type I	5
	Type II	4
	Type III	
		9

From Table 9, it can be concluded that packaging forms the mainstream of revenue (rank=1) for most of K. Walter's DUs followed by publication and decorative in a decreasing order. These results also coincide with K. Walter's segment specific revenue shares for consumables in the EEA printing market for these three printing segments – Packaging ([redacted]%)>Publication ([redacted]%) and Decorative ([redacted]%) (see Figure 13).

Additionally, 11 DUs attributed more than two industrial segments with other than rank 1 (rank = 2, 3, or 4) and a total of 18 DUs also identified other industrial segments/applications in the printing industry that they attribute their sales revenue to. Some of these responses fall into the categories of packaging, publication and decorative. Examples of other applications that did not fall into this category include printing and embossing of post stamps, functional surfaces and printing for tobacco products.

3.2.3.6 Downstream users by company size

This section describes the DUs by size of their firm in terms of their total annual revenue within the EEA. To describe the DUs' revenue share related to use 2, their revenue associated with K. Walter's plating units/machines in the EEA was asked. Further, to assess the impacts on the DUs for use 2, a profit margin for associated with the affected consumer product in the EEA was asked. Responses were asked in non-confidential ranges to receive the maximum input from DUs thereby, avoiding confidentiality issues. These non-confidential ranges were chosen on an arbitrary basis.

Towards the end of this section, a summary table comprising aggregated data collected for the variables described above has been included. Further use of this section has been made to extrapolate these answers to deduce results for DUs that did not answer the survey. These observations are used to characterise a model DU for each type to bridge the gap in the impact assessment.

3.2.3.6.1 Downstream users by annual revenue

To define their total annual revenue in the EEA, the respondents were asked to choose between the following non-confidential ranges:

- < EUR 1 million
- EUR 1-10 million
- EUR 10-100 million
- >EUR 100 million

Figure 10 shows the frequency of the observations segmented by the type of DU.

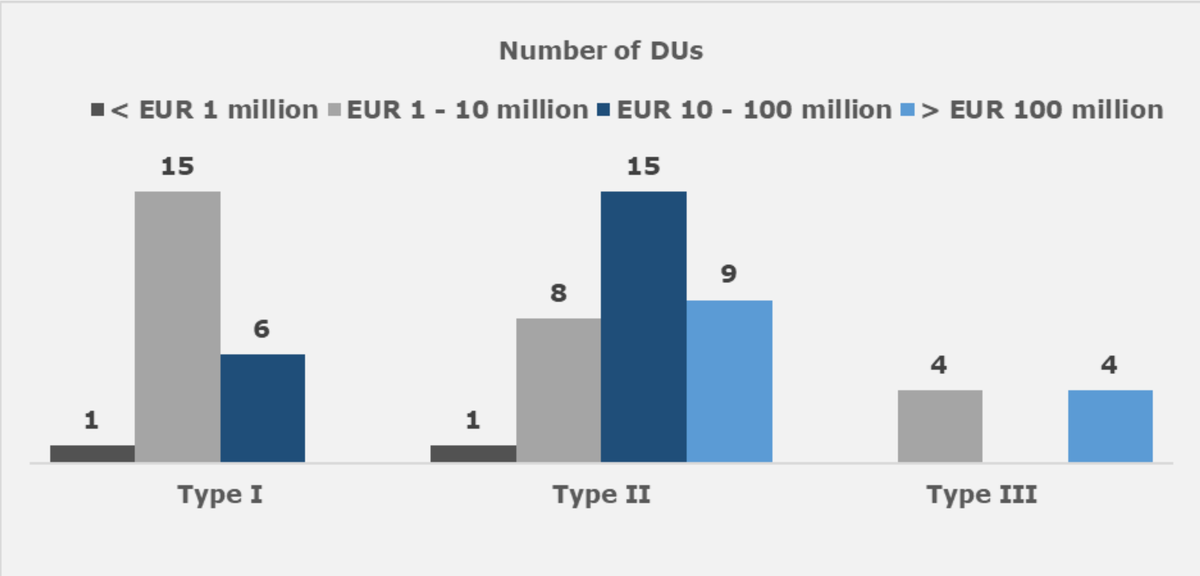

Figure 10: Number of DUs segmented by the total annual revenue within the EEA

From the figure above, it can be observed that for the entire data collected i.e., when observing the data without any categorization, most DUs (mode of the data), in general, have an annual revenue between EUR 1-10 million followed by EUR 10 – 100 million.

3.2.3.6.2 Downstream users by % of revenues related to Use 2

To define the % of revenues related to Use 2, each respondent was asked to provide the share of revenues associated with the use of K. Walter's machines within the EEA. For this purpose, the respondents were asked to choose between the following non-confidential ranges:

- 1-10%
- 10-20%
- 20-30%
- 30-40%
- 40-50%
- >50%

Figure 11 shows the frequency of the observations segmented by the type of DU.

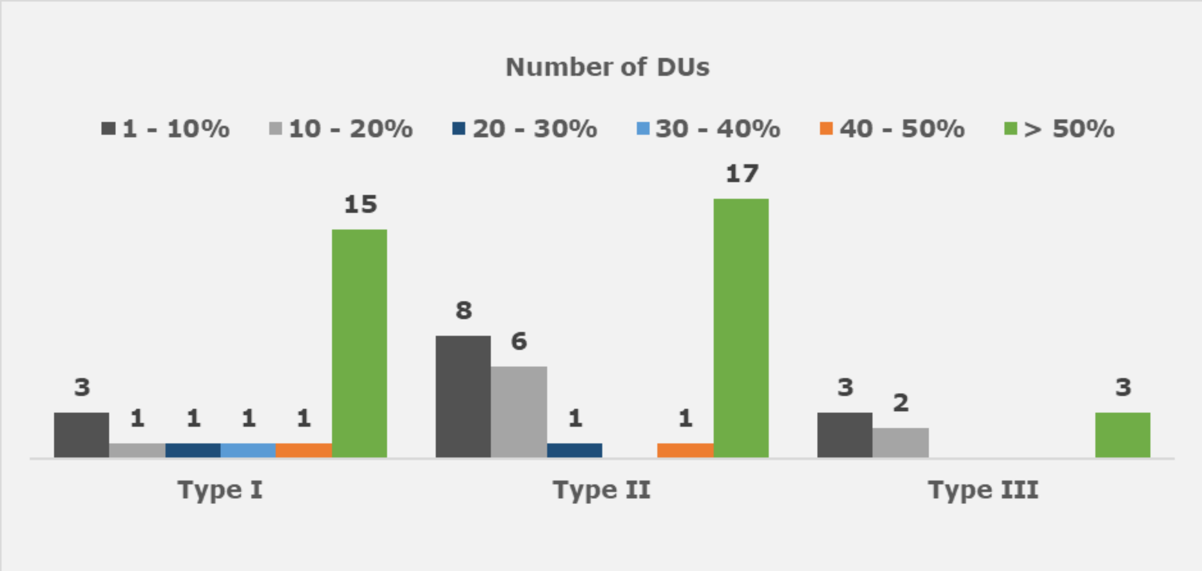

Figure 11: Number of DUs segmented by the share of revenues related to the use of K. Walter's machines for electro chrome plating within the EEA

From the figure above, it can be observed that most DUs, irrespective of their Type have an annual, use 2 related revenue shares of >50% in the EEA. This implies that most of K. Walter's DUs attribute more than 50% of their revenue towards sales of coated cylinders to printing firms (Type I), sales of the rotogravure printed product (Type II) or sales of both (Type III).

3.2.3.6.3 Downstream users by profit margin related to Use 2

To define the profit margin associated with use 2, each respondent was asked to provide the average annual profit margin (%) associated with the affected product within the EEA. For this purpose, the respondents were asked to choose between the following non-confidential ranges:

- <10%
- 10-20%
- 20-30%
- >30

Figure 12 shows the frequency of the observations segmented by the type of DU.

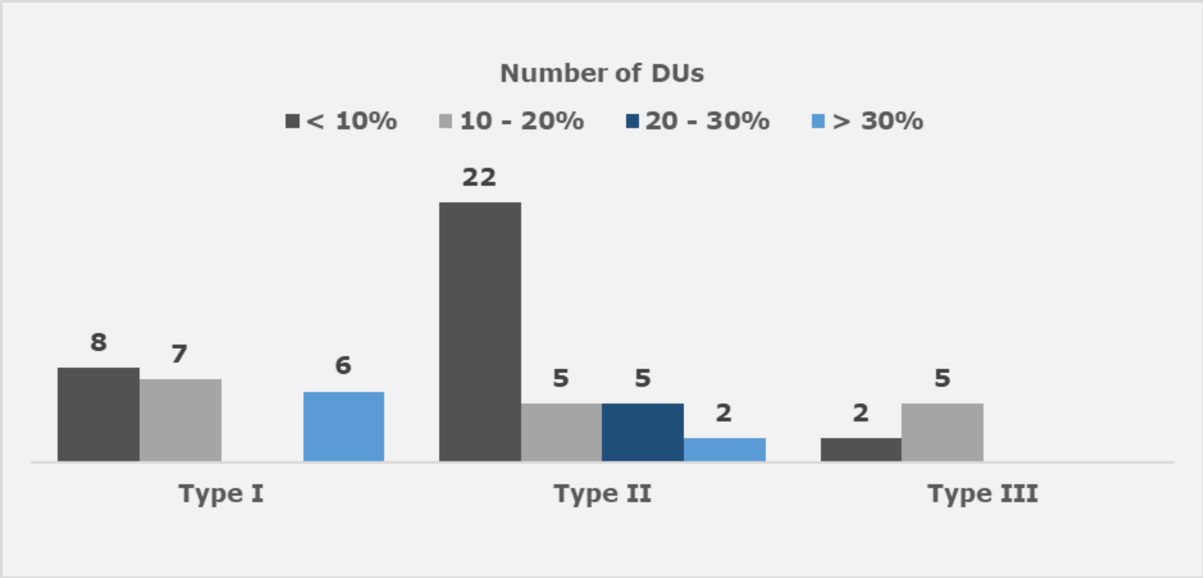

Figure 12: Number of DUs segmented by the average annual profit margin (%) associated with rotogravure printing within the EEA

For this application, it was assumed that the DUs may not answer a direct question regarding their profits due to the public nature of this application. Partly, this was also due to the fact that within the same industry, the DUs also compete amongst each other. Therefore, they were asked to choose non-confidential profit margins from the options provided in the survey. From the figure above, it can be observed that most DUs, in general, without categorization, have an annual, use 2 related profit margins of <10% in the EEA. Since <10% is still a broad range for a profit margin, for simplicity in this application, this range is broken down into 1-10%, assuming that each DU certainly has a positive profit margin of at least 1%. Thus, it can be said that most DUs have a use 2 related profit margin between 1-10% in the EEA. It should be noted here that 1% would be a highly conservative estimate and has been considered purely to avoid any overestimations in this application.

3.2.3.7 Number of exposed workers

To estimate the total number of exposed workers, the numbers obtained from the survey for the chemical safety report (CSR) were used. These numbers were extrapolated to estimate the total number of workers for all 117 sites.

Table 10 shows the estimates for number of exposed workers for a total of 117 sites. It should be noted here that these estimates have been derived based on a conservative approach leading to an overestimation of the number of workers that are exposed to the risks of chromium trioxide.

Table 10: Total number of exposed employees at downstream users' firms

Total number of sites	Corresponding total number of exposed employees
117	**657**

3.2.3.8 Summary

The sections above demonstrated the data collected from the DUs on their financial performance related to use 2. This section aggregates this data to provide a complete picture for all the DUs as well as split by their Type in Table 12 below. The table considers individual input by each DU to aggregate the total annual revenue and profits related to use 2.

As mentioned above, each quantified variable has been answered by the DUs in non-confidential ranges. To aggregate this data, these ranges were split into a lower and upper bound. The following steps were followed to achieve this:

1. Wherever a lower bound was not defined, the following adjustments were made:
   - If the company's total annual revenue within the EEA was <EUR 1 million a lower and upper bound of 0 and EUR 1 million was assumed respectively
   - If the company's profit margin related to use 2 was <10%, a lower and upper bound of 1% and 10% was assumed respectively

It should be noted here that the estimates taken above represent a highly conservative estimate and have been considered purely to avoid any overestimations in this application.

2. Wherever an upper bound was not defined, the following adjustments were made to avoid overestimation:
   - If the company's total revenue within the EEA was >EUR 100 million, a lower and upper bound of EUR 100 million each was taken, assuming that the company had an annual revenue of at least EUR 100 million
   - If the company's revenue share related to use 2 within the EEA was >30%, a lower and upper bound of 30% each was taken, assuming that the company had a use 2 related revenue share of at least 30%
   - If the company's profit margin related to use 2 within the EEA was >50%, a lower and upper bound of 50% each was taken, assuming that the company had a use 2 related profit margin of at least 50%

3. Table 11 shows the lower and upper bounds of all non-confidential ranges used for each variable described in Table 12 below. Please note that for the total number of employees at each DU no non-confidential range was provided in the survey. This question was answered by the DUs as actual estimates for the survey and therefore only an aggregate has been provided for the same in Table 12.

Table 11: Upper and lower bound of non-confidential ranges

	Lower bound	Upper bound
Company's total annual revenue within the EEA		
< EUR 1 million	0	1
EUR 1-10 million	1	10
EUR 10-100 million	10	100
>EUR 100 million	100	100
% of revenues related to use 2		
1-10%	1%	10%
10-20%	10%	20%
20-30%	20%	30%
30-40%	30%	40%
40-50%	40%	50%
>50%	50%	50%
Profit margin related to use 2		
<10%	1%	10%
10-20%	10%	20%
20-30%	20%	30%
>30	30%	30%

4. These simplified ranges were then used to calculate the individual revenues and profits related to use 2 for each DU. An aggregate of these variables is thus presented in Table 12 below, segmented by Type.

Table 12: Summary of data collected for DUs

Type	Total number of DUs per Type	Total number of cylinder production sites	Total annual revenue of all DUs by type (in EUR million)		Total annual revenues related to Use 2 for all DUs by type (in EUR million)		Total annual profit related to Use 2 for all DUs by type (in EUR million)		Number of total employees by type[6]
			Lower bound	Upper bound	Lower bound	Upper bound	Lower bound	Upper bound	
I	**24**		75	750	29.72	321	2.82	52.30	3,493
II	**36**		1058	2480	371.74	929	21.71	151.91	17,182
III	**10**		404	440	102.71	130	0.68	10.00	5,815
TOTAL	**70**	**117**	**1537**	**3670**	**504.17**	**1380**	**25.21**	**214.21**	**26,490**

[6] Please refer to section 8.2.1 to see the distribution of total number of employees at DUs by type

3.2.3.9 Discussion

The following points have been deduced from the above sections:

- From an overview of the observations made in the section above, it can be deduced that majority of DUs are Type II (51.43%) followed by Type I (34.29%) and Type III (14.29%) in a decreasing order respectively in terms of their business model.

- Only taking Type II DUs in consideration because of their majority, an average Type II DU has 1 site and a total annual revenue between EUR 10-100 million. The average revenue share related to Use 2 is >50% with an average profit margin of <10%. Packaging constitutes the highest revenue generating industrial segment followed by decorative and publication. The results show the heavy reliance of these DUs on K. Walter's plating machines that use chromium trioxide coated gravure cylinders for various printing applications. Amongst these, the DUs that have customers outside the EEA attribute less than 25% of their annual revenue to these customers. These figures justify that the business within the EEA is the mainstream of revenue generation for majority of K. Walter's DUs, implying that in case of a refused authorisation, if this revenue stream is closed, majority of the downstream users do not have the means in terms of another revenue stream to set up a new business model in or outside the EEA.

3.3 Model Downstream user

As the section above summarises the aggregated data for all the DUs related to use 2 of K. Walter, this section will focus of establishing a model DU to extrapolate the impacts for DUs that did not answer the survey.

These values have been derived using the mode of the total annual revenue of the 70% of DUs obtained from the survey, as shown in Table 12. Further, mode values of % of revenue share and profit margin related to use 2 from Table 12 were used to define representative figures for a model DU. The estimates of annual revenues and profits related to use 2 for a model DU were derived using these three figures. The values below have been derived to avoid overestimation as far as possible.

To derive the average number of exposed workers per DU by type, the total number of exposed workers was divided by the total number of DUs addressed in the survey for socio-economic assessment. As opposed to the approach of using underestimates for financial figures, the number of exposed employees as explained in section 3.2.3.7, has been calculated based on a conservative approach to include the maximum risk to these workers.

Table 13: Number of employees derived for a model DU by type

Total extrapolated number of exposed workers	657
Total number of legal entities as DUs	105
Average number of exposed workers per DU	**6**

For extrapolation of these variables, segmentation by Type is not taken into account.

Table 14: Characteristics of a model DU

Characteristics of a model DU		
Number of sites per DU	1	
Average total annual revenue	EUR 1 million	EUR 10 million
Representative % revenues related to Use 2	50%	
Average revenues related to Use 2	EUR 0.5 million	EUR 5 million
Representative average profit margin related to Use 2	1%	10%
Average profit related to Use 2	EUR 0.005 million	EUR 0.5 million
Average number of exposed employees	6	

These estimates will be used further in the impact assessment.

3.4 Affected production activity and resulting product segments

The rotogravure printing cylinder is an engineered product, designed to efficiently transfer ink to almost precise or exact levels at all times, implying that there is no variation between patterns in subsequent print runs due to the optimized ink applications and usage (8). This whole optimization process leads to decrease in ink consumption bringing consistency and robustness to the overall gravure process (8). These cylinders require chrome-plating to protect the cylinder surface by preventing wear and maintaining the efficiency over multiple runs by facilitating ink release and transfer (8). When compared with flexography, obtaining a high range of tones on a single flexo plate has been a challenge where it often becomes necessary to use two separate plates for the same color. Gravure printing, on the other hand, can effectively deliver a complete range of tones for a given color. Moreover, special tonal effects such as vignettes can be produced in higher quality via gravure printing (8) and gravure printing achieves higher printing resolutions as compared to flexography. While gravure printing offers high printing quality consistency over long printing runs, the printing forms in flexography have to be renewed multiple times due to an wear-induced decrease of printing quality.

Chromium trioxide is used each year to produce 1.25 million gravure cylinders which accounts for only 1.5% of the total chromium trioxide that is imported into the EU (9). The application of gravure cylinders by the DUs is used in large and diverse market segments of the printing industry as elaborated below. The applicant in cooperation with Heliograph Holding serves products mainly in three market segments in the printing and embossing industry covering the following:

- Packaging gravure
- Publication gravure and
- Decorative gravure

The widespread application of gravure printing in these sectors can be demonstrated by consumer products such as major magazines and catalogues in the EU and overseas, all types of packaging, especially the flexible packaging material required for consumer brand articles, decorative paper or film for furniture, flooring and wallpaper. Most of these articles necessitate the use of gravure printing (10). Some examples include the following -

- 50% of all packaging for all kinds of products available in supermarkets, discounters, drugstore, such as food products, cosmetics, or tobacco or labels for bottles,
- News and other magazines, catalogues, advertising inserts or flyers,
- Decorative laminates for floors and furniture,
- other products such as wallpaper, tissue, blister packs, security printing (bank notes) (11).
- Examples of embossing sector: embossing of flexible/plastic films, decorative or functional textiles or direct embossing of printing products

Extensive examples have been covered in section 3.5.1.

3.5 Market trends and competitive dynamics

3.5.1 Market position of K. Walter

Gravure contributes to 50%, 80% and 20% of the total printing processes in Europe, Asia and USA/Latin America respectively (8). Gravure stagnated in America, whilst gaining market in Europe over the last years (8). Contrary to both the regions, it has always dominated the market in Asia (8).

Products for the printers and intermediate service providers for plating and engraving represent one of the main service areas serviced by K. Walter, for which it undertakes intensive research and development activity. The company supplies products containing chromium trioxide and the substances and mixtures along with plating units for coating of gravure cylinders. The applicant has a worldwide market share of [redacted]% and an EEA specific market share of [redacted]% for chromium trioxide based liquid formulations facing strong competition from firms like Vopelius, Atotech and IPT.

However, the competition from these firms appears only in the sales of formulations. For instance, K. Walter's market share in the EEA for plating units or machines is [redacted]%, leaving a share of 20% from companies like the Chinese YUBO, the Italian competitor Acigraph and the Japanese Think Laboratory (see Table 15). K. Walter also expects a higher gradual shift of its share to approximately 90% over the next years. This is related to the fact that the current trend in the market is inclined towards automated production equipment. Currently, K. Walter is the only company in the European market with such products in its portfolio.

Table 15: K. Walter's market share and competitors in the EEA and worldwide for use 1 and use 2

Name of the brands	Market share in EEA	Market share worldwide	Competitors
Formulations (use 1)	[redacted]	[redacted]	Vopelius, Atotech and IPT
Plating units or machines (use 2)	[redacted]	[redacted]	YUBO, Acigraph, Think Laboratory

The companies of the Heliograph Holding also provide additional equipment (i.e. engraving and logistics) and hold a share in different market sectors in EEA and worldwide. In the EEA market, the firms face the following competitors (see Table 16).

Table 16: Heliograph Holdings' market share and competitors in the EEA and worldwide

Name of the brands	Market share in EEA	Market share worldwide	Competitors
Bauer	[redacted]	[redacted]	Horstmann, Think Laboratory, Acigraf
HELL Gravure Systems	[redacted]	[redacted]	Think Lab, , Hangzhou Cosun Equipment, DMA
Schepers Laser Technology	[redacted]	[redacted]	Think Lab, ALE UK, DV,

Figure 13 below depicts the total sales in the printing industry in the EEA and the market share of decorative, packaging and publication segments in total EEA sales respectively.

[redacted]

Figure 13: Share of different print segments in the printing industry

Figure 13 shows that sales in the packaging segment comprise [redacted]% of the total EEA print sales followed by publication and decorative segments with a market share of [redacted]% and [redacted]% respectively. It further depicts the market share of the applicant in the EEA for the specific segments mentioned above in terms of its sales of electroplating units supplied to its DUs in each sector. For instance, the applicant has the largest share of total electroplating unit sales to the publication segment, followed by packaging and decorative uses covering [redacted]%, [redacted]% and [redacted]% of the individual markets respectively in the EEA.

These contributions are representative of the high market shares that the applicant covers within the EEA based formulations along with its electroplating units to its downstream users. It further depicts the future market trend in each segment as forecasted by the applicant. For instance, the future forecast for sales in decorative and packaging segments are expected to remain stable whereas, it is expected to decline for the publication segment.

3.5.2 Market/industrial trends

As coating of rotogravure cylinders is an intermediate step towards the final printing product that brings the additional value to the entire process, much of this section focuses on the gravure printing process, its advantages over other available printing techniques and the varied market/industrial segments that these printed products belong to. Moreover, as discussed in section 3.2.3.3, since most of K. Walter's DUs (Type II) have an in-house plating and printing site, only trends related to gravure printing (final marketed product) are discussed here. These trends can, however, be directly correlated to trends in the cylinder coating process as it forms an integral intermediate process step and all printing firms using rotogravure are dependent on it. Further, it should be emphasized again that most gravure printing firms do not have their own plating line in the EEA and are dependent on intermediate service providers for engraved cylinders.

3.5.2.1.1 Advantages of gravure printing

Before elaborating on the market for gravure printing, it is important to understand the advantages offered by this technology in comparison to alternative printing technologies in the market. These advantages work as key drivers of the gravure market. Since gravure printing is a long-run, high-speed and high-quality printing method to produce fine, detailed images, it is mostly utilised for high volume printing or long printing runs of packaging, furniture and flooring surfaces wallpaper and gift wrap and less commonly for printing magazines and high-volume advertising pieces **(12)**. When compared with other printing technologies, gravure printing provides high quality of the product, durability of the image surface, seamless printing patterns and high-volume capability **(13)**. It is the only printing process in which the volume of ink applied to the paper at any one point can be varied.

A study by [redacted], [redacted], mentions that gravure printing guarantees the highest quality and is usually seen as the ideal print process for high volumes as compared to other available technologies such as flexography and digital printing (14). As per industry experts, the rotogravure process has always been acknowledged as superior to any other process given its advantages in print reproduction quality, consistency of print quality during a print run and its ability to reproduce the exact print as the first run in case repeated or subsequent print runs are needed (8). However, the process faces a drawback in terms of high initial set-up cost in terms of cylinder costs where an alternative technology such as flexography could only step in, if the print quality is compromised. Thus, when long print runs are needed, the preference goes to gravure printing (8).

Flexography is mostly used for medium and small volumes requiring medium but overall, acceptable quality and digital printing is only used mostly for very small volumes and personalized printing due to its higher printing ink costs and is not used for substrates such as films – which is the major substrate for printing flexible packaging material (14).

Some factors responsible for driving the growth of the gravure market include increasing flexible packaging fields expenditures, retrofitting and renovation of old technology and the demand for sophisticated technology (12).

A key driving factor is the global increase in applications in the end-use industries such as packaging and lamination in the gravure printing market. Further down the packaging segment, flexible wrappings are expected to dominate the market demand. Owing to its high and consistent graphic quality printing and higher ink coating weight, gravure printing is considered to be dominant and preferred over its counterparts. Mainstream applications include food packaging, magazines, furniture laminates, wallpaper and panelling. With regards to the mainstream applications, increasing processed food demand leading to rising food packaging demand is also anticipated to drive market growth (15).

The increasing use pattern of gravure printing is demonstrated below in terms of continuous investments in gravure plants and presses all over Europe where:

- Plants define the number of units using gravure technology for their product and
- Presses define the number of gravure printing machines installed in Europe. Further, in a press, there are 5 – 12 printing units for gravure cylinders.

The manufacturers of rotogravure printing machine recorded the highest number of sales in 2015. Figure 20 below shows that in 2015, 933 press machines were installed, and 365 plants were opened altogether in Europe and Turkey. In Europe, Germany recorded the highest number of new plants and presses in 2015 (16).

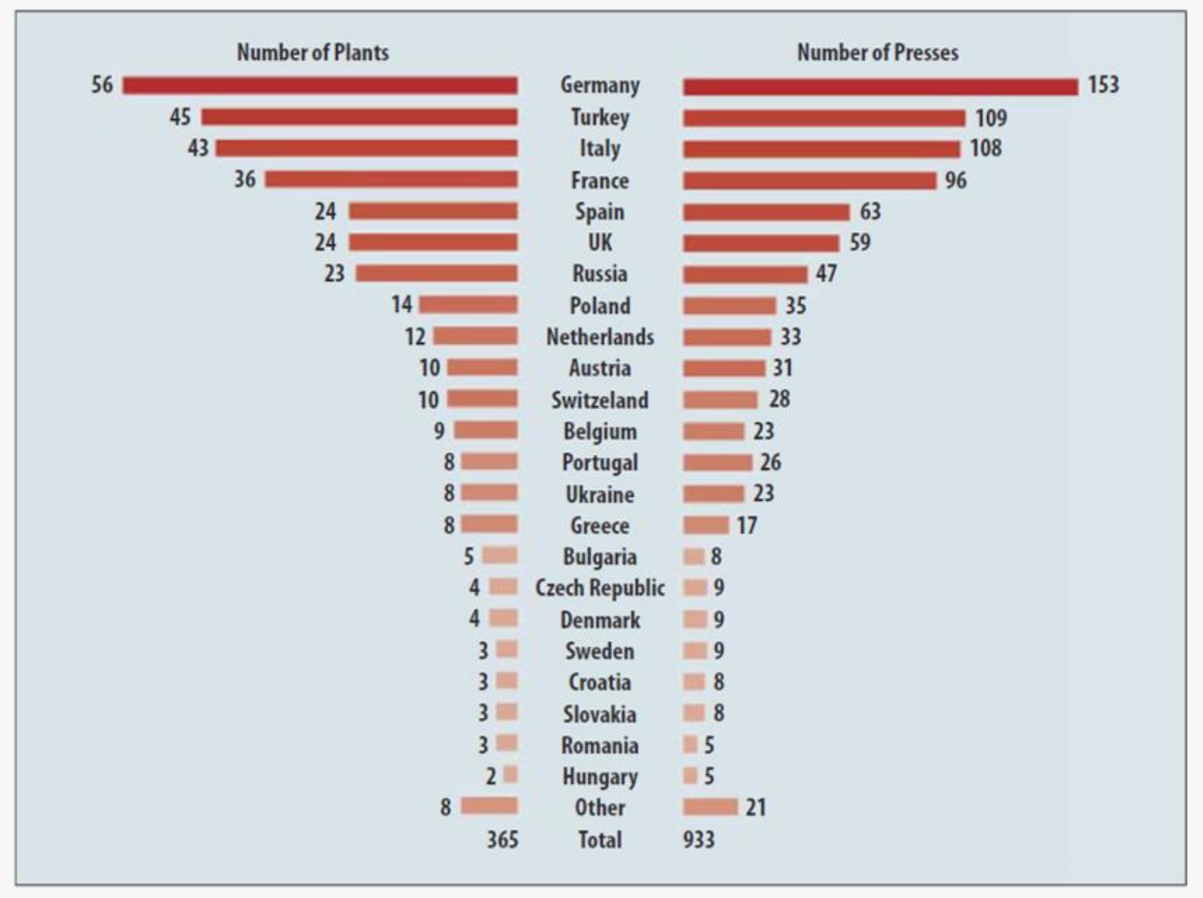

Figure 14: Number of plants and presses for packaging rotogravure in Europe and Turkey (16)

The overall commercial sales due to gravure printing presses in EU-28 between 2008 and 2015 are shown in Figure 15. The sales flattened after the fluctuation between 2008 and 2011 accounting for EUR 165 million in 2015. Lowest sales were accounted for EUR 40 million in 2009 (17).

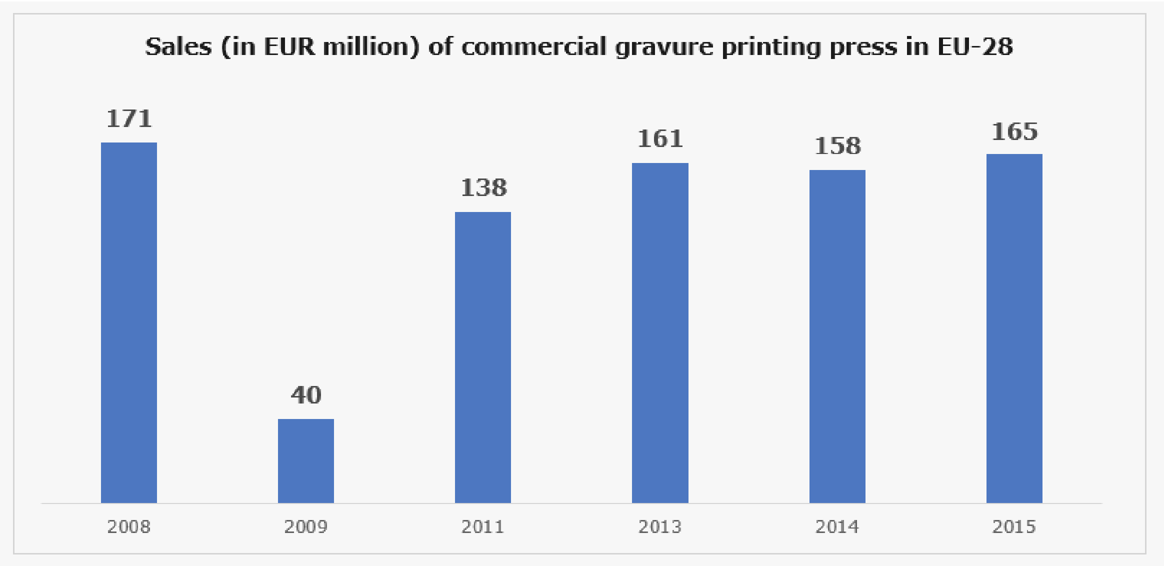

Figure 15: Commercial printing press sales by Gravure in EU-28 in EUR million (17)

In the following sections, the market is further explained by the different segments dependent on rotogravure printing. This section further aims to summarise these market segments to explain their applicability and context for the downstream user or intermediate and end consumer.

3.5.2.2 Publication

The printing process of publication rotogravure is applied to, for instance, catalogues, brochures, and magazines (finished products) (see Figure 16). In Europe, there are approximately 23 publication rotogravure plants in operation. Across these facilities, some 93 publication rotogravure presses provide an estimated printing capacity of 2,567 thousand tonnes paper per year (2). Gravure printing is more efficiently used and is a preferred choice for long print runs (8). However, structural market changes arising from the internet such as decline in print runs of magazines and the current replacement of the mail order companies with online shopping will lead to constant decline.

K. Walter respectively has a different market strategy and specification for these segments under the different market trends. Gravure cylinders are required to print products for publication segments. Thus, the applicant attempts to gain market share with solutions geared to the large cylinder as well as competent throughput times necessary for publication printing (18).

It currently assumes that the market for publication rotogravure will decline constantly over the next 10 years. Nevertheless, technologies evolved through the production for publication gravure are also utilized for packaging and decorative printing (18).

Figure 16: Print samples from packaging and publication (19)

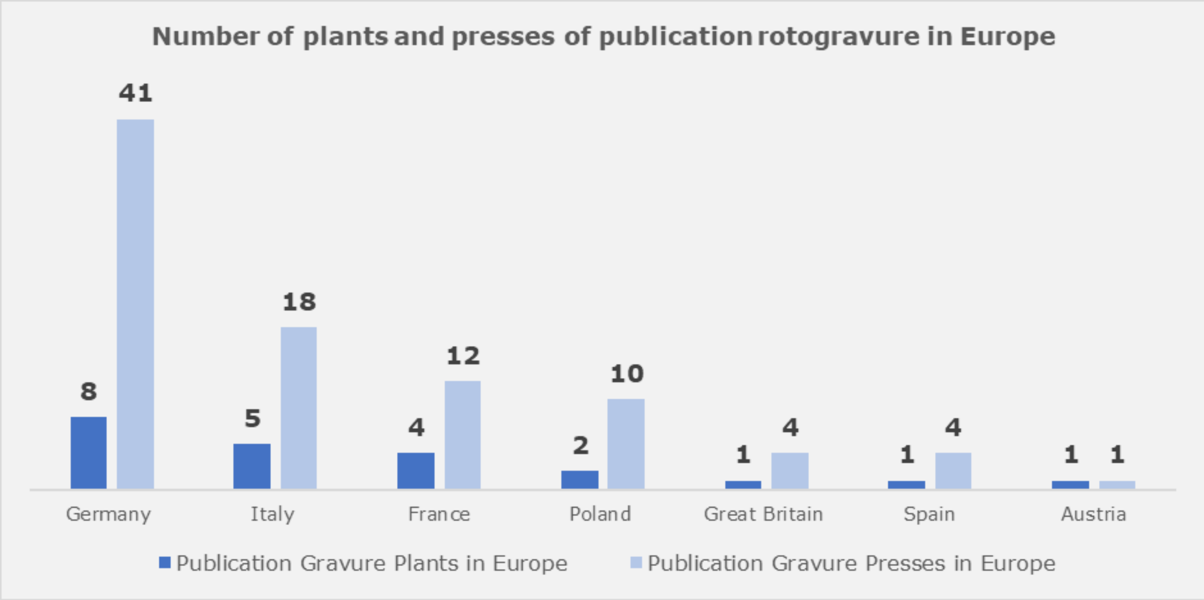

Figure 17: Publication rotogravure plants and presses in Europe[7]

3.5.2.3 Packaging

This segment is most sensitive to the use of chromium trioxide on the surface of the gravure cylinder, due to the required usage of different print substrates. These substrates for printing an image on a packaging material come in a wide variety. Additionally, a market trends towards more frequent changes in packaging designs results in often shorter print run lengths. This makes this segment very competitive. Such a dynamic market demands strict standards for conveying the brand value via these printed images. Gravure is used in packaging industry for flexible packaging, labels, etc. In packaging gravure, a wide variety of material is used for print substrate: paper, board, plastic and aluminium foil. The market in this segment is dominated by large brands operating in food packaging and confectionary products (20).

[7] The ERA website, from which this data was extracted did not mention the exact year of data accumulation. However, the website is shown to be updated in the year 2020.

Figure 18: Print samples from packaging and publication (19)

K. Walter and Heliograph Holding have developed key competencies in the research, development and manufacture of machines and equipment for the packaging market and maintain automated solutions providing high speeds of electromechanical engraving machines and coordinated processes with maximum utilization. Especially, their high-resolution linework and large volumes with directly lasered or etched rotogravure and embossing cylinders have been very advantageous in packaging printing for tobacco industry, because they expect packaging to convey a strong message and be instantly recognizable (18).

Furthermore, there are approx. 345 packaging rotogravure plants with over 874 packaging rotogravure printing presses in Europe (2). Figure 19 represents the distribution of packaging rotogravure plants and presses in Europe. The concentration of packaging plants and presses was shown to be the highest in Germany and lowest in Greece. [8]

[8] The ERA website, from which this data was extracted did not mention the exact year of data accumulation. However, the website is shown to be updated in the year 2020.

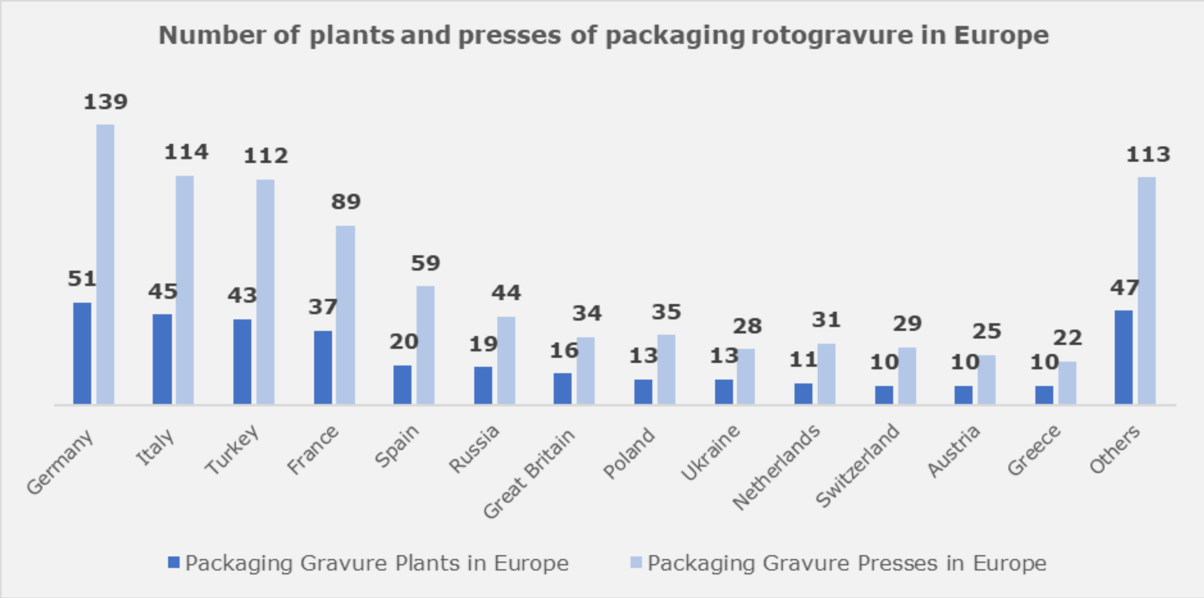

Figure 19: Packaging rotogravure plants and presses in Europe (2)

3.5.2.4 Decorative

Rotogravure process is well suited for decorative products such as base paper for laminate flooring, PVC flooring, furniture, kitchen units, and wallpaper (21). In Europe, there are approximately 81 decorative rotogravure plants with some 300 decorative rotogravure printing presses as shown in Figure 20.

Print quality is the utmost priority in decorative gravure. Given the advantages of gravure printing, elaborated above, it is mostly considered the only option for use in this market segment beside inkjet/digital printing for short runs. Concerning the quality for color reproduction, decorative printing was the first market segment to apply stringent requirements. This is in part because, it is important to operate large cylinder surface that is possible for long production runs. The equipment needs to be high wear resistant and applicable for color reproduction to incorporate the narrowest of tolerances if print runs of wood grain reproduction, wallpaper, and floor coverings are to be repeated, whenever required. With regards to tissue and gift wrap paper, both large and small cylinder must be able to deliver the high ink transfer volumes with large engraving depths and applicability to all kind of ink system. Concerning these market trends, K. Walter and Heliograph Holding focus on the service of full range of electromechanical engraving and laser process in high precision (18).

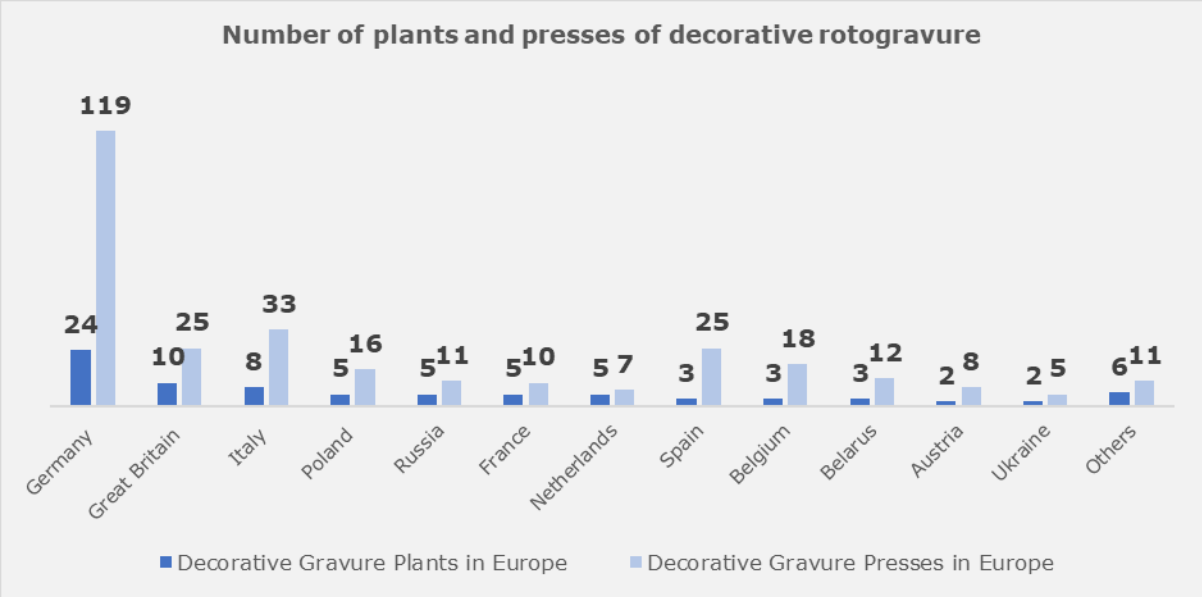

Figure 20: Decorative rotogravure plants and presses in Europe[9] (2)

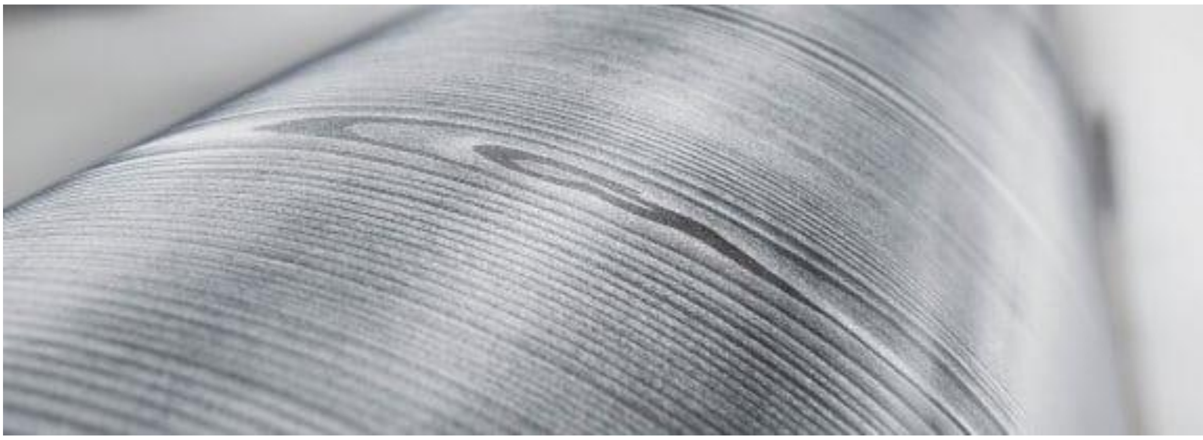

Figure 21: Sample of decorative printing related to wood-based furniture/flooring products (22)

Imports and International Trade

High quality gravure machine and printings are manufactured in a large variety for publication, packaging, and decorative uses in all European member states. In EUROSTAT and United Nations Commodity Trade Statistics Database (COMTRADE), two have been identified to be the most relevant in the context of this application. All the value will be expressed in EUR[10]:

- 28991450 - Gravure printing machinery
- Harmonized System Codes (HS Code) 844317 - Printing machinery; gravure

[9] The ERA website, from which this data was extracted did not mention the exact year of data accumulation. However, the website is shown to be updated in the year 2020.
[10] Exchange rate 1 USD = 0.9019 EUR on 22 of January 2020 (60)

- Among EU-28, Germany is the most important exporting country of gravure printing machinery of the EEA, resulting in approximately EUR 66.8 million, followed by Italy with EUR 48.2 million in 2018. Some of the most relevant contributors in the EU include Bobst, Cerutti, Windmöller&Hölscher and Moog.

Table 17: Balance of trade of gravure printing machinery for Germany in EUR (23)

Year	Import Value	Export Value	Export Surplus
2014	425,490	48,679,720	48,254,230
2015	508,150	49,833,820	49,325,670
2016	1,465,050	29,277,170	27,812,120
2017	1,228,680	51,201,070	49,972,390
2018	7,215,190	66,781,360	59,566,170

Germany is the strongest exporting country in EU-28, recording EUR 66.8 million. The total export value exceeded the volume of imports in terms of value by EUR 59.6 million in 2018 (see Table 18) (23). 16% of gravure printing machinery is exported to Russia (EUR 11.1 million), followed by Vietnam and Turkey. Germany has a strong trade partnership with Italy. 79% of imports of gravure printing machinery are derived from Italy (EUR 5.95 million). Amongst the non-EEA importers, USA accounts for the majority with a 6% share (EUR 0.45 million) (24).

Table 18: Balance of trade of gravure printing machinery for Italy (in EUR) (23)

Year	Import Value	Export Value	Export Surplus
2014	11,399,840	46,658,570	35,258,730
2015	3,612,840	48,633,150	45,020,310
2016	826,370	36,683,420	35,857,050
2017	580,560	43,665,390	43,084,830
2018	3,271,230	48,223,610	44,952,380

Italy also has a large export surplus. The export surplus reached approximately EUR 45 million in 2018 (see Table 18) (23). 83% of gravure printing machinery is imported from Germany to Italy. On the other hand, Italy mostly exports domestic build machinery to China accounting for 16% of total exports (EUR 8.48 million) (24).

These imports influence a fierce competition as well as several challenges for European producers of gravure printing machinery in general, due to lower labour cost and high capability of fulfilling European consumer standard by non-EU companies (25). This renders it even more important for European producers to maintain and further improve production, product price and quality, and strengthen their market position.

All these trends are closely related to specialization in gravure printing industry. Providers need to shorten print-run and reduce sizes, in order to cope with frequent change of design and package for specific owners of the brand. The tendency of smaller runs and shorter set-up times are also in demand for the manufacturers of printing equipment with high quality packaging efficiency and economic feasibility. By relying on these competitive advantages, European companies can compose their value proposition and resort to competing on a cost and price basis (26).

3.6 Analysis of the substance functions and technical requirements for the products

This section presents an overview of rotogravure printing and embossing. The functionalities provided by Cr(VI) in the Cr(VI)-based electroplating of gravure cylinders is also discussed. Even though these processes and their end products are different, the functionalities provided by the chrome coating applied via hard chrome plating are identical for both. Likewise, the Cr(VI)-based electroplating process is the same for rotogravure and embossing cylinders. The key functionalities used to assess the performance of potential alternatives are therefore the same for both applications. The assessment of alternatives is also valid for both processes, as is the substitution timeline described in section 4.5.1.

3.6.1 Rotogravure printing

Rotogravure printing is a printing technique based on the transfer of fluid ink from engravings on a gravure cylinder, or roll, to the surface of a substrate, or the material to be printed. An impression roller is used to apply pressure from the other side of the substrate against the printing cylinder. This causes ink to be transferred from the engravings on the printing cylinder's surface to the substrate due to the ink's surface tension (Figure 22 a)). Rotogravure is used primarily for long printing runs in applications such as packaging, magazines, catalogues, inserts, wallpapers and floorings, among many others, achieving fine and clear images and high printing consistency. An entire printing press for application of one print/image consists of the following components (Figure 22 b)):

- an engraved cylinder (printing roll) whose circumference can differ according to layout of product being made;
- an ink fountain;
- a doctor blade assembly, which removes excess ink picked up by cylinder;
- an impression roller; and
- a dryer (oven).

To start the printing process, the printing cylinder (also called printing roll) is covered with ink, which penetrates and fills the engravings on the surface. As observed in the setup shown in Figure 22, the printing cylinder is partially submerged in an ink fountain holding one colour. As the cylinder rotates, the ink fills the engraved cells on the cylinder's surface. Excess ink is removed by the doctor blade to ensure that the it stays only in the cells engraved in the cylinder's surface. To transfer the ink from the cylinder's surface to the substrate (the printing material), the latter is pressed between the printing cylinder and the impression roll. The printed substrate then goes to a dryer or oven, as it must be completely dry before going on to the next colour unit where a different colour is applied. Each colour unit, consisting of one printing cylinder, one impression roller and the doctor blade, applies only one colour. The final printed surface appears from the overlapping of various colour layers, typically, cyan, magenta, yellow and black.

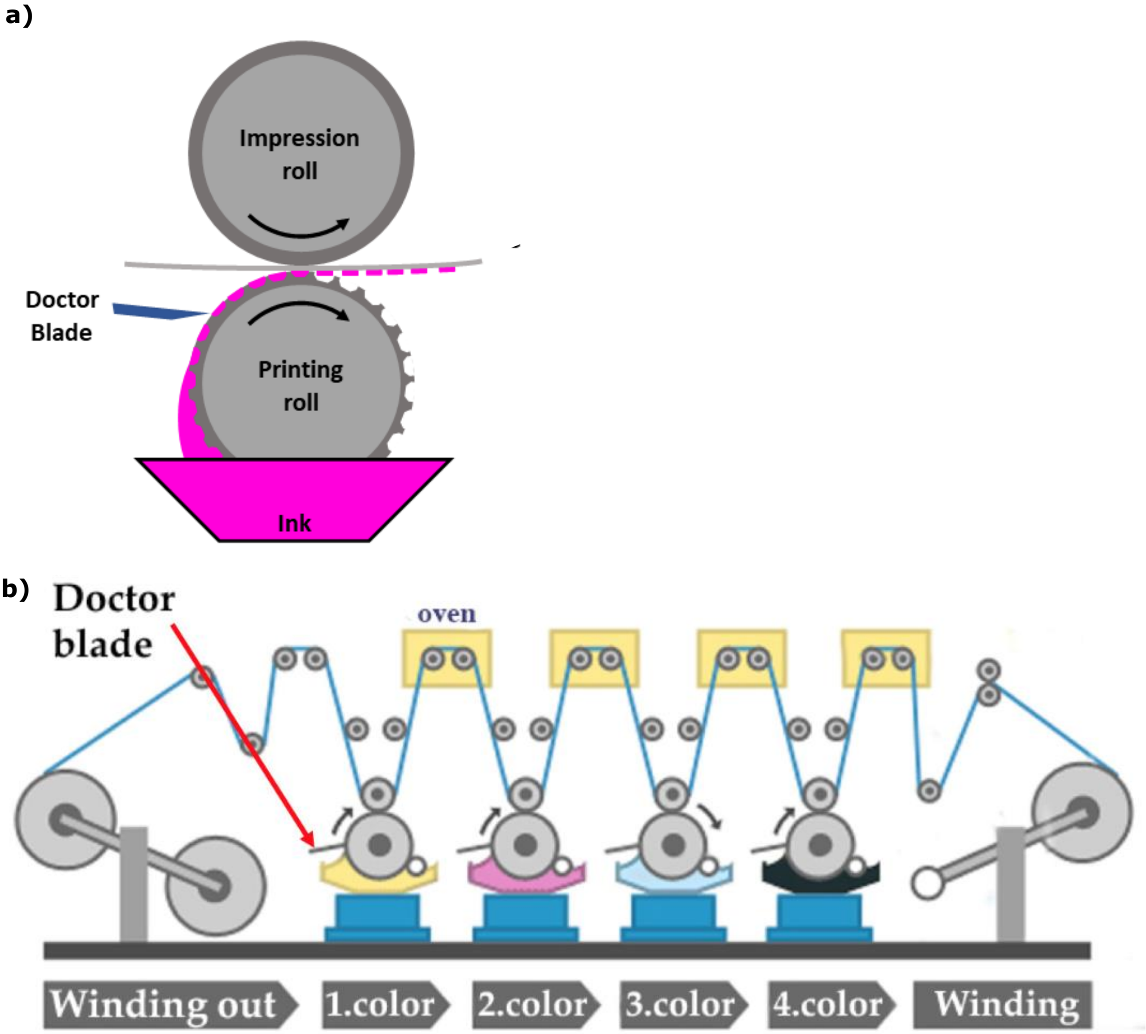

Figure 22: Overview of rotogravure printing: a) sketch of ink transfer process; b) sketch of printing unit

3.6.2 Embossing

Embossing is a process by which a relief is created on a substrate by means of a gravure cylinder (Figure 23). It is usually carried out on an industrial scale in roll-to-roll processes. This technique is used for giving a 3D-texture to the embossed surface for both decorative and functional purposes. An example of a decorative application is the embossing of a texture into a protective foil in which the embossing follows the printed image below. In this way, a printed wood look can be given the haptics corresponding to the pattern, for example, thus increasing the value of the embossed surface. Another typical example from the packaging industry is chocolate packaging, in which printed sections are raised to match letters or drawings on the package. For technical applications, an example is the embossing of a specific surface pattern that provides anti-slip properties to the surface.

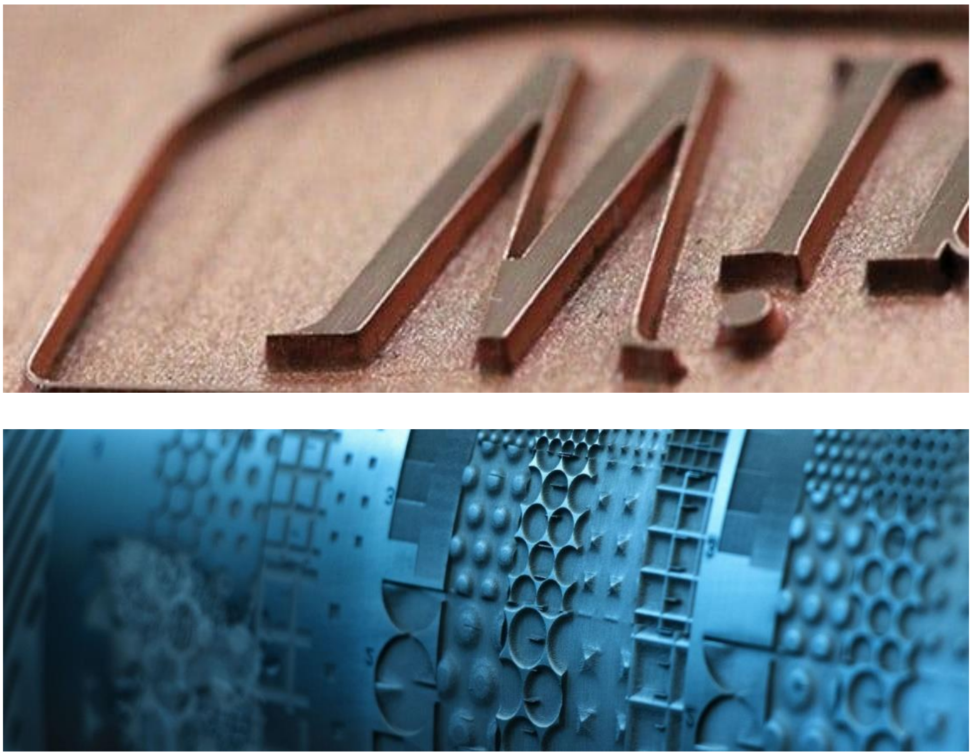

Figure 23: Examples of embossing patterns on gravure cylinders.

A variety of substrates are used for embossing, including paper, flexible foils, aluminium foils, ceramic glass, textiles, leather or PVC floor coverings. In applications where a printed image is to be texturally replicated by embossing, the embossing can be done in the same production process as printing. The size of the individual embossing features can be either several mm or a few µm in size. The following components are typically required for embossing:

- an embossing cylinder whose circumference can differ according to the layout of the product being embossed;
- a second embossing cylinder with the negative embossing relief to enhance embossing through the interlocking of the reliefs of the two cylinders; and
- or a cylinder of a soft material (rubber) which is used to impress the substrate.

Although the appearance is usually clearly defined for the final embossing structure, the production of the embossing form is less obvious. For complex embossing, several forms often must be produced and optimized iteratively before the actual embossing pattern of the cylinder matches the desired texture. Since this makes the production of individual embossing forms very complex and expensive, embossing cylinders are used over a long period of time. A functional chrome layer on these cylinders protects the embossing pattern and allows the cylinders to be resistant against wear and corrosion throughout their service life. In case the functional chrome layer is worn down, the cylinders can easily be refinished by removing the "old" chrome layer (de-chroming) and subsequent re-application of the functional chrome layer (functional chrome plating). The big advantage of the electrolytical de-chroming process is that the actual embossing pattern (in copper) is not removed. This is a crucial economic and sustainable aspect for K. Walter's customers.

3.6.3 Preparation of gravure cylinders

The production of gravure cylinders starts with the degreasing of base cylinders, either in steel or copper, followed by copper plating and finishing. The printing pattern is then embedded into the copper coating through either engraving or laser imaging, depending on the application in which the cylinders are to be used. Regardless of the method applied, the cylinders are then degreased and finally plated with chromium in a 20-minute step carried out in a closed galvanic unit (Figure 24 a) and b)). For the chrome-plating step, cylinders are first lifted into the empty upper tank into which the chromium electrolyte is pumped from the lower tank once the lid is closed. The concentration of chromium trioxide in the electroplating unit is between 260 and 310 g/L, and the temperature is 55 °C – 65 °C. Next, electrical current is applied for 10 to 20 minutes with a current density of 50 – 90 A/dm², causing Cr to deposit on the cylinder's surface. Once the chrome-plating step is completed, the electrolyte flows back into the lower tank of the plating machine and the cylinders are automatically sprayed/cleaned with deionized water to remove residual chromium trioxide. This cleaning water flows back to the lower tank containing the electrolyte. The lid is then opened, and the cleaned cylinder is lifted out of the machine. Following a finishing step in a polishing machine, the cylinder is ready for printing. The entire cylinder preparation process takes approximately 210 minutes if the cylinders are engraved and approximately 230 minutes if direct laser imaging is used instead. Figure 24 c) shows a finished chrome-plated printing cylinder.

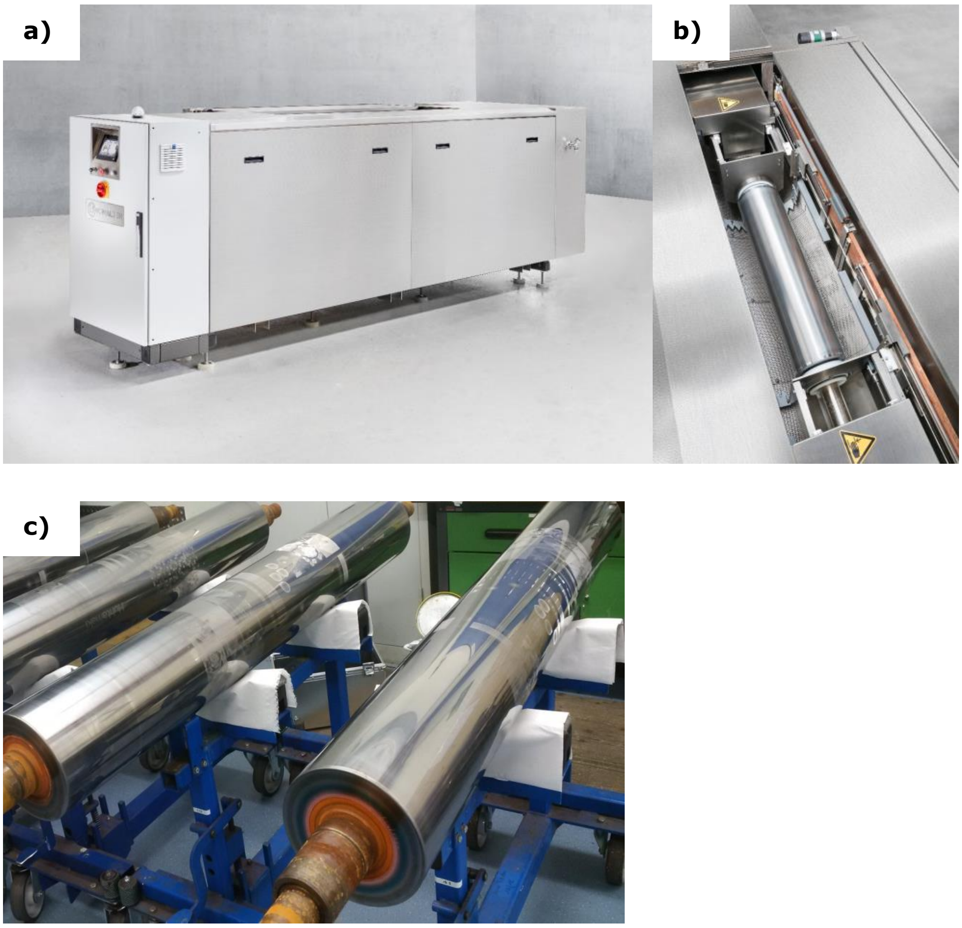

Figure 24: a) Outside and b) inside view of electroplating machine. c) Engraved printing cylinder.

After use, the worn cylinders can be de-chromed, which means that the remaining chromium coating is electrochemically removed. The image-carrying copper layer is subsequently removed by mechanical cutting and grinding This is beneficial for refurbishing worn cylinders and for establishment of new printing campaigns, where the cylinder is engraved with a new gravure and subsequently chrome coated (refinishing).

Figure 25 below shows an overview of the cylinder preparation process.

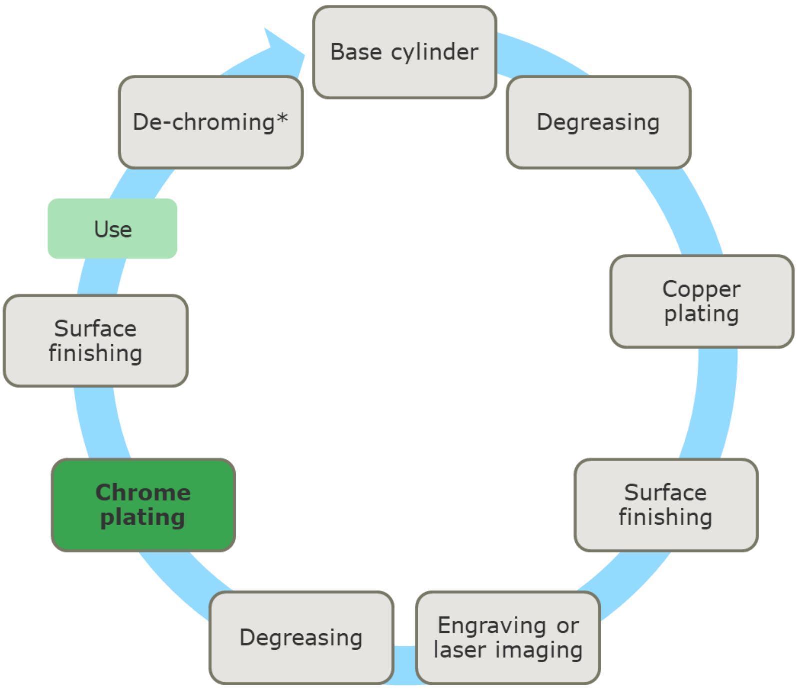

Figure 25: Flow diagram of cylinder preparation process. *De-chroming can refer to either refurbishing or refinishing.

3.6.4 Description of the technical function provided by the Annex XIV substance

Functional chrome plating is a surface treatment method whereby a surface is coated with a thin layer of metallic chrome through electrodeposition. Unlike decorative chrome plating, where the deposited chrome layer mainly serves an aesthetic purpose, in functional chrome plating the chrome layer provides properties such as wear resistance and hardness. In all rotogravure printing and embossing processes (publication rotogravure, packaging rotogravure and decorative rotogravure printing) the gravure cylinders must be covered with a functional hard chromium layer. It is important that the surface of the cylinders is homogeneous, scratchproof, highly wear resistant, corrosion resistant and hard (> 900 HV), as interaction with hard ink particles, with the doctor blade and the substrate causes wear to the cylinder's surface.

The plating process is suitable for mass production with short cycle times which is required in the printing cylinder production operating with time critical jobs and very short lead times: between 300 and 3.000 heavyweight cylinders are produced monthly in a production plant.

In functional chrome plating of printing cylinders, the use of chromium trioxide has the following advantages:

- it provides a hardness of more than 900 HV;
- it deposits in a homogeneous layer on the surface of the printing cylinders and forms a layer with an adequate thickness between 6 and 15 µm;
- the plating step is completed in less than 40 minutes due to a deposition rate of up to 1 µm/min;
- the resulting coating has an appropriate morphology with the right density of microcracks;
- the coated cylinders have a specific roughness that facilitates the interaction with the substrate, the ink and the doctor blade;
- the top layer offers a topographic reproduction of the underlying layer, what is important for the printing application;
- the coated cylinders are resistant to wear and can be used for long printing runs.
- the coating renders the cylinders resistant to oxidation, enabling the use of water as a printing ink solvent, and allows long term storage of the cylinders.

To date, no other technology can provide the printing cylinders with a coating which is able to withstand long printing runs (printing campaigns) in combination with a high level of colour schemes and highest printing resolutions.

Table 19 below summarizes the key functionalities fulfilled by chromium trioxide in the functional chrome plating of gravure cylinders. These are then described afterwards.

Table 19: Key performance functionalities

Key performance functionalities	Requirement
Hardness	900-1500 HV
Layer thickness	6 – 15 µm
Layer homogeneity	Application of homogenous layer
Adhesion to substrate	High adhesion to substrate
Deposition rate/plating time	20 to 40 minutes
Surface morphology/density of microcracks	200 – 700 cm^{-2} are required to ensure optimal ink/lubrication distribution
Coefficient of friction / surface roughness (Rz)	0,3- 0,5 µm
Wear resistance	Comparable to currently produced cylinders
Corrosion resistance	Resistance over entire service life of cylinders

Hardness: This is a measure of a material's resistance to localized deformation upon the application of a force. It is usually measured using the Vickers Hardness (HV). Printing cylinders must have a Vickers Hardness of at least 900 HV to withstand the high mechanical stress arising from the constant contact with hard ink particles, the doctor blade and the substrate itself. A low hardness would result in surface damages that would compromise the printing quality. This in turn, would mean a more frequent replacement of the cylinders and therefore shorter printing runs, which, given the demanding schedules for printers, would be unacceptable.

Layer thickness: The thickness of the deposited chromium layer has a significant impact on the surface properties of the coating. Thin layers decrease the risk of cracks forming, while a thick layer enhances the resistance to wear and other properties. Therefore, the deposited chrome layer must have a precisely defined thickness to ensure the optimal balance between interlinked properties such as coating adhesion and wear resistance. Depending on the application, this layer must be between 6 and 15 µm thick.

Layer homogeneity: The homogeneity of the deposited chromium layer is also an important factor affecting the performance of the gravure cylinders. The distribution of the chromium coating must be extremely homogeneous, as the tolerance levels for printing cylinders are very low (maximum 0.01 mm/m deviation in the conicity/roundness and maximum 0.02 mm in the concentricity to the lateral surface). This ensures the correct transfer of the ink to the substrate (rotogravure printing) and the accuracy of the embossing pattern (embossing) and, ultimately, the quality of the printed or embossed image.

Adhesion to substrate: The deposited chrome layer must adhere to the engraved metal layer on the cylinder and remained adhered over the whole lifespan of the cylinder. The quality of this adhesion influences the longevity of the printing cylinders and, therefore, the frequency with which these have to be renewed. Adhesion is not measured directly with a quantitative method but is rather assessed indirectly using the cylinder's lifespan and the print quality as a reference.

Deposition rate/plating time: The deposition rate is a measure of how fast the chromium ions deposit as metallic chrome on the cylinder's surface to form a uniform layer. This rate is important because it finally determines the overall length of the cylinder manufacturing process. If the rate is too slow, the plating step takes too long and leads to interruptions in printing runs or delays in normal operation. Given the highly demanding environment in which gravure cylinders are used, a plating time between 20 and 40 minutes is acceptable. This is comparable to the current time needed for plating gravure cylinders using Cr(VI)-based electroplating.

Surface morphology/density of microcracks: The deposited chromium layer features a series of micro cracks. Ink generates a non-printing lubrication layer on the surface of printing cylinders, which enhances tribological properties and prevents that the doctor blade comes into direct contact with the chromium surface. Microcracks facilitate the generation of this lubrication layer. Microcrack density should be in the range of 200 to 700 microcracks per square centimetre. This property is also closely related to the surface roughness.

Friction coefficient / surface roughness: Roughness is a measure of how much an even surface deviates from an ideal flat shape. This is an important property because it determines how the coated cylinder's surface will interact with other components of the printing setup such as the substrate material and the doctor blade. One way to determine the roughness of a surface is to measure the vertical distance between the highest peak and the deepest valley in various samples. The average of these measures, Rz, is the surface roughness. For gravure cylinders, this value should be between 0,3 and 0,5 µm.

Wear resistance: Wear resistance is a measure for the service life of gravure cylinders. For alternative coatings, it must be comparable to functional chrome coated cylinders. For K. Walter's customers, replacing the cylinders more often entails increased manufacturing costs, longer down time of presses and more material consumption. In other words, additional economic efforts which are not acceptable. Gravure cylinders are typically able to print up to 1 million meters of flexible packaging material. This time might be shorter if more abrasive inks and harder substrate materials are used.

Corrosion resistance: Corrosion is the process by which a metallic material oxidizes under the effect of humidity, oxygen, and other chemicals (e.g. inks, oils, etc.). In this case, the coated gravure cylinders must be able to withstand the chemical environment in which they are used without material degradation. Protection against corrosion is important for ensuring the cylinders' integrity when using water as an ink solvent, for example, and for allowing cylinders to be stored for long periods. Cylinders have to withstand 1 – 12 months in storage and must resist printing with water-based inks over their entire service lives.

3.6.1 Description of printing and embossing products

3.6.1.1 Packaging printing

In packaging printing, gravure cylinders are used for the printing of packaging on flexible (plastic) films, paper, or aluminium foil. The main competition to gravure printing in this sector is flexographic printing. However, gravure printing has a cost advantage for large production volumes (from approx. 50 thousand running meters). In gravure printing, printing forms (cylinders) can be reused for long printing runs with no loss of quality. This has the advantage that for a new print job the printing forms do not have to be produced again, lowering overall production costs. Moreover, gravure printing can print halftones (colours with low saturation), whereas with other printing processes these must be simulated by a full saturation – no saturation matrix. Therefore, gravure printing is the first choice for high-quality packaging with high production volumes. Some examples of high-quality packaging include chocolate or tobacco packaging.

3.6.1.2 Decorative printing

As for packaging printing, decorative printing uses films and paper as substrate materials. Often wood or stone optics are printed, e.g. wood optics for pressboard furniture, wood laminate or stone optics on tiles. The inks are usually highly pigmented and water-based (large colour pigment particles), which is why they have a highly abrasive and corrosive effect on the printing cylinders. A hard chrome-plated surface is therefore ideal as a protective layer. However, the durability is limited and significantly shorter than in package printing, for example. When using heavily pigmented inks, large ink volumes must be used. The flexible cell geometry in gravure printing makes this possible. A seamless printing form is needed for printing continuous patterns, which can only be achieved with gravure or digital (short runs) printing.

3.6.1.3 Publication printing

Examples of products in this category include catalogues or magazines that are printed in high volumes and contain many images. Due to the possibility of printing real halftones with rotogravure printing, the highest image quality can be achieved with this technique. Additionally, large volumes can be printed in a short time because of the speed of rotogravure printing. The direct competitor for this sector is offset printing.

3.6.1.4 Embossing

Embossing of substrates plays a role in all the sectors mentioned above. Embossing can increase the value of the print results by adding a 3D-structure and specific haptic to it. Since the same cylinder dimensions are used as in rotogravure printing, it is easy to provide the print with the appropriate structure directly after the printing process within the same process (printing + embossing). This can be done in an embossing unit in the printing press.

The production of embossing forms is very expensive. Therefore, a wear-resistant protective layer is important. Since this layer can be produced in the same equipment as the protective layer of the rotogravure cylinders, no additional coating equipment needs to be purchased.

3.7 Annual tonnage

The total tonnage of chromium trioxide that is used per year is estimated at a maximum of 160 – 220 ([redacted]) tonnes.

3.8 Remaining risk of the "applied for use" scenario

The analysis of risk to human health and the environment is a complex task that takes into account the exposure of humans and the environment to a particular SVHC and derives a characterization of excess risk for human health and environmental quality. These risks are defined via certain identified endpoints such as diseases or other damages that have a probability of resulting from exposure to the hazardous substance.

The concept of excess risk, hence, the change in risk attributable to the use of chromium trioxide considers that chromium trioxide based activities covered under use 1 and use 2 would cease within the EEA in case of a refused authorisation. The relevant exposure would thus, exit the (geographic) scope of assessment given the termination of these uses due to a refused authorisation. This implies that the endpoint risks related to the production activities with chromium trioxide is assumed zero in the non-use scenario and that the incremental change in risk is equal to the absolute value of risk under the applied for use scenario.

3.8.1 Identified endpoints

The risk assessment of chromium trioxide focuses on endpoints related to human health. This results from the classification of chromium trioxide as a carcinogenic and mutagenic toxicant with regard to the intrinsic properties of the substance specified in Annex XIV of REACH Regulation. Based on this classification, the evaluation of any potential hazards to the environment is unnecessary for this risk assessment.

The two identified human health endpoints of risk are lung cancer for the inhalation of the substance and intestinal cancer for oral uptake.

3.8.2 Human health impacts of the applied for use scenario

Chromium trioxide is classified under REACH as a Substance of Very High Concern (SVHC) according to Article 57(a) of Regulation (EC) No 1907/2006 (REACH) (27) and is categorised as a non-threshold substance and therefore the SEA route is foreseen under REACH (28). The dominating health effect resulting from the intrinsic hazardous properties of chromium trioxide is lung cancer due to inhalation of dust and/or aerosols.

The assessment of human exposure to chromium trioxide differentiates between workers potentially exposed at the production facilities and the people potentially exposed in the direct neighbourhood, hence, man via the environment (MVE_{local}).

For the human health impact of **directly exposed workers**, in accordance with the RAC document on the dose-response relationship (RAC/27/2013/06 Rev.1), it is assumed, that all particles are in the respirable size range. Hence, the oral route (mucociliary clearance and swallowing of the non-respirable fractions) is not considered, due to the absence of exposure. Following this, the risk assessment for workers exposed in this SEA is restricted to inhalation of airborne residues of chromium trioxide (lung cancer).

For the **general population**, in addition to inhalation of chromium trioxide, oral exposure to chromium trioxide via the food chain is taken into account. Oral exposure via the food chain leads to an additional risk of small intestine cancer.

Based on the exposure assessment and the existing reference dose-response function established for carcinogenicity of hexavalent chromium, the impact on the number of cancer cases for each identified endpoint is derived. Part B, chapter 9 and 10 of the CSR constitute the basis for this assessment. In a further step, a willingness-to-pay (WTP) study for the reduction of cancer risk, commissioned by the European Chemicals Agency (ECHA) in 2014, is utilized to value health impacts in monetary terms.

For simplicity, only aggregated health impacts have been described separately for use 1 and use 2. The methodology to assess the remaining risk of the "applied for use" scenario is described in detail in the Appendix.

3.8.2.1 USE 1 – Human exposure to hexavalent chromium

This section assesses the health impact of exposure to chromium trioxide on formulators covered under the applied for use scenario.

3.8.2.1.1 Endpoint 1: Lung cancer

A. Workers

In total the number of potentially directly exposed employees is 13 in Germany. Table 20 depicts the exposure values that are used for the assessment of health impacts to workers at the production site. The values reported in the table are already adapted to frequencies and possible personal protective equipment (PPE).

Table 20: Exposure estimates for workers – use 1

Worker Contribution Scenario (WCS)	Activity	Estimated exposure in µg Cr(VI) per m³ (cf. CSR)	Number of workers
WCS-1	Delivery and storage of solid CrO3	0.00E+00	6
WCS-2	Preparation of the CrO_3 containing formulation	1.84E-01	3
WCS-3	Sampling	1.56E-01	1
WCS-4	Maintenance	4.53E-04	2
WCS-5	Wastewater sampling and waste management (solid and liquid)	6.80E-04	1

A. General population

The health risk to man via environment in the neighbourhood of the facility where chromium trioxide is formulated is a sum of the PEC_{local} and $PEC_{regional}$ exposure. Using Chesar, regional exposure ($PEC_{regional}$) in this case is estimated to be 0 mg/m³ and henceforth not considered further. The maximum number of people exposed locally via the environment, i.e. people exposed in proximity of the production site, is assumed to be 10,000 based on a cautious standard estimate. Therefore, for use 1 only the following PEC_{local} exposure estimate applies (see Table 21).

Table 21: Exposure estimate for humans in the local environment (endpoint 1) – use 1

Exposure pathway	Site	Estimated exposure to Cr(VI) (cf. CSR)
Inhalation (µg/m³)		
PEC_{local}	Germany	1.54E-06
$PEC_{regional}$	Germany	0

As shown in Table 22 above, $PEC_{regional}$ for man via environment is estimated to be 0 µg/kg bw/day and thus not considered further in the calculations.

3.8.2.1.2 Endpoint 2: Intestinal cancer

A. General population

For the endpoint of intestinal cancer, only the number of people exposed locally via the environment is accounted. Similar to the case of endpoint 1, the number of people exposed in proximity of the production site is estimated at 10,000 based on a cautious approximation. Table 22 reports the corresponding PEC_{local} exposure estimate.

Table 22: Exposure estimate for man via environment (endpoint 2) – use 1

Exposure pathway	Site	Estimated exposure to Cr(VI) (cf. CSR)
Oral uptake (µg/kg bw/day)	Germany	6.52E-06

3.8.2.1.3 Excess lifetime risk of cancer

The excess lifetime risk (ELR) of developing cancer is derived specifically for each endpoint and group of potentially exposed people as shown in Table 23. These figures are defined by the reference dose-response relationships reported by ECHA's Risk Assessment Committee (RAC) (29).

Table 23: Excess lifetime risk of cancer

Endpoint	Exposed people	ELR
Endpoint 1: Lung cancer	Workers	ELR = 4.0E−03 per µg Cr(VI)/m³ for 40 years
	MVE	ELR = 2.9E−02 per µg Cr(VI)/m³ for 70 years
Endpoint 2: Intestinal cancer	MVE_{local}	ELR = 8.0E−04 per µg Cr(VI)/kg bw/d for 70 years

3.8.2.1.4 Number of estimated statistical cancer cases

Based on the ELR and the number of exposed people, the number of statistical cancer cases can be calculated to approximate the impact on human health of granting the requested authorization title for use 1.

Table 24: Estimated statistical cancer cases – use 1

Endpoint	Exposed people	Estimated statistical cancer cases	
		Non-fatal	Fatal
Endpoint 1: Lung cancer	Workers	2.31E-04	7.21E-04
	MVE_{local}	2.46E-05	7.66E-05
Endpoint 2: Intestinal cancer	MVE_{local}	4.63E-06	4.31E-06

3.8.2.2 USE 2 - Human exposure to hexavalent chromium

This section assesses the health impact of exposure to chromium trioxide on downstream users covered under the applied for use scenario. For this purpose, data was accumulated using the survey for all DUs within the EEA. Details on the data collected for exposure assessment and number of workers can be found in section 9.1 and 9.3 of the chemical safety report.

3.8.2.2.1 Endpoint 1: Lung cancer

A. Workers

In total the number of potentially directly exposed employees due to downstream activities in the EEA is 657. Table 20 depicts the exposure values that are used for the assessment of health impacts to workers at the production site. The values reported in the table are already adapted to frequencies and possible personal protective equipment (PPE).

Table 25: Exposure estimates for workers – use 2

Worker Contribution Scenario (WCS)	Activity	Estimated exposure in µg Cr(VI) per m³ (cf. CSR)	Number of exposed workers
WCS 1	Delivery and storage of raw material	0.00E+00	269
WCS 2	Chrome electroplating unit	5.00E-01	515
WCS 3	Sampling	1.55E-02	257
WCS 4 - 2	Concentration adjustment with liquid CrO3	4.55E-02	246
WCS 5 - 1	Maintenance - 1 (Cleaning of anodes, weekly)	2.20E-01	211
WCS 5 - 2	Maintenance - 2 (Complete maintenance, annually)	7.40E-02	304
WCS 5 - 3	Maintenance - 3 (Exchange of the electrolyte, infrequent)	1.82E-02	234
WCS 6	Waste management	0.00E+00	117

B. General population

The health risk to man via environment in the neighbourhood of the facility where chromium trioxide is used is a sum of the PEC_{local} and $PEC_{regional}$ exposure. Number of people potentially at risk of lung cancer locally and regionally have been estimated as follows:

- The maximum number of people exposed via the environment, i.e. people exposed in proximity of the production site, is assumed to be 10,000 for each facility based on a cautious standard estimate. Thus, for use 2, PEC_{local} has been estimated for locally exposed general population of 1,170,000, corresponding to 117 DU sites.
- $PEC_{regional}$ however, has been estimated for the entire population of EU due to the large presence of DUs. For this purpose, an estimate of EU-27 population at 447.7 million as of 1st January 2020 from Eurostat was taken[11].

[11] On 1 January 2020 the population of the EU-27 was estimated at 447.7 million inhabitants (62)

In addition to the exposure values estimated for directly exposed workers, for man via environment, regional exposure ($PEC_{regional}$) was calculated for an average tonnage of [redacted] t CrVI per annum[12], obtained from the DU survey. At this tonnage value, Chesar estimated a $PEC_{regional}$ of 0 mg/m^3. Therefore, an extrapolation based on the maximum tonnage value of [redacted] t CrVI per annum was performed. For the maximum tonnage value, Chesar estimated a $PEC_{regional}$ of 1.59E-15 mg/m^3. Based on this, a factor of [redacted] ([redacted]) was used to derive the $PEC_{regional}$ of 4.37E-16 mg/m^3 for an average tonnage of [redacted] t CrVI per annum that has been used in this assessment.

Table 26 reports the corresponding exposure estimates (local and regional) per site per person.

Table 26: Exposure estimate for man via environment (endpoint 1) – use 2

Exposure pathway	Site	Estimated exposure to Cr(VI) (cf. CSR)
Inhalation (µg/m³)		
PEC_{local}	Per DU site in the EU	5.88E-04
$PEC_{regional}$	Per DU site in the EU	4.37E-13

3.8.2.2.2 Endpoint 2: Intestinal cancer

A. General population

For the endpoint of intestinal cancer, only the number of people exposed via the environment is accounted. Similar to the case of endpoint 1, the number of people exposed in proximity of one production site is estimated at 10,000 based on a cautious approximation. Thus, for use 2, the estimate of general population exposed to the substance is 1,170,000, corresponding to 117 DU sites. Table 22 reports the corresponding exposure estimate.

Table 27: Exposure estimate for humans in the local environment (endpoint 2) – use 2

Exposure pathway	Site	Estimated exposure to Cr(VI) (cf. CSR)
Oral uptake (µg/kg bw/day)	Per DU site in the EU	2.02E-06

3.8.2.2.3 Excess lifetime risk of cancer

The excess lifetime risk (ELR) of developing cancer is derived specifically for each endpoint and group of potentially exposed people as shown in Table 23. These figures are defined by the reference dose-response relationships reported by ECHA's Risk Assessment Committee (RAC) (29).

[12] Please refer to the CSR for further justification.

Table 28: Excess lifetime risk of cancer

Endpoint	Exposed people	ELR
Endpoint 1: Lung cancer	Workers	ELR = 4.0E−03 per µg Cr(VI)/m³ for 40 years
	MVE	ELR = 2.9E−02 per µg Cr(VI)/m³ for 70 years
Endpoint 2: Intestinal cancer	MVE_{local}	ELR = 8.0E−04 per µg Cr(VI)/kg bw/d for 70 years

3.8.2.2.4 Number of estimated statistical cancer cases

Based on the ELR and the number of exposed people, the number of statistical cancer cases can be calculated to approximate the impact on human health of granting the requested authorisation for use 2. For further details, please refer to appendix section 8.1.

Impacts due to $MVE_{regional}$ follow the same dose-response curve as MVE_{local} and have been derived in a similar manner as explained in appendix section 8.1.

Table 29: Estimated statistical cancer cases – use 2

Endpoint	Exposed people	Estimated statistical cancer cases	
		Non-fatal	Fatal
Endpoint 1: Lung cancer	Workers	8.13E-02	3.51E-01
	MVE_{local}	7.92E-01	3.42E+00
	$MVE_{regional}$	2.25E-07	9.72E-07
Endpoint 2: Intestinal cancer	MVE_{local}	1.67E-04	1.56E-04

3.9 Monetised damage of human health

Based on data regarding the marginal trade-off between survival probability and income, generated by ECHA's WTP study, a Value of Statistical Life (VSL) of EUR 3.5 million in 2012-prices will be used for the monetization of human health impacts. Moreover, the WTP to avoid disutility caused by cancer morbidity, estimated by the same study at EUR 0.41 million in 2012-prices, is used for monetary valuation. Further taking into account data on the disease latency and fatality rates, as well as inflation adjustment and discount rates between 2% (upper bound) and 4% (lower bound), a cautious approach for the monetization of potential health impacts is followed. Details on the calculation of the values are given in the appendix section 8.1.

Before proceeding to the economic and social impact assessment, the following chapters will analyse in detail the non-use scenario that defines the consequences of a refused authorisation for use 1 and use 2 of chromium trioxide.

3.9.1 USE 1

Table 30 sets out the monetised health impacts for directly exposed workers as well as for indirectly exposed humans on site and in the general population of the direct neighbourhood. It is important to note that an overestimated number of people present in the impact radius is used for the purpose of assessment and that therefore, these values, too, must be understood as extremely cautious estimates.

These cautiously derived values are taken into consideration in the subsequent impact analysis, resulting in a likely overestimation of actual impacts. Therefore, it should be noted that the reported values are considered worst-case estimates that do not require the application of further sensitivity analysis.

Table 30: Summary of monetised potential health impacts over 12 years review period – use 1

Type of potentially exposed humans	Lower bound (EUR)	Upper bound (EUR)
Formulator		
Potentially exposed workers	2,112	3,516
Potentially indirectly exposed workers and humans in the direct neighbourhood (MVE_{local}, inhalation, MVE_{local}, oral)	232	390
Total for 12 years	2,344	3,906

Table 31: Summary table – monetised potential health impacts per year (annuity) – use 1

Type of potentially exposed population	Lower bound [EUR]	Upper bound [EUR]
Potentially exposed workers	225	374
Potentially indirectly exposed workers and direct neighbourhood (PEClocal, inhalation and PEClocal, oral)	25	42
Total	**250**	**416**

3.9.2 USE 2

For use 2, Table 32 sets out the monetised health impacts for directly exposed workers as well as for indirectly exposed humans on site and in the general population of the direct neighbourhood. It is important to note that an overestimated number of people present in the impact radius is used for the purpose of assessment and that therefore, these values, too, must be understood as extremely cautious estimates. For calculating the number of workers directly exposed to chromium trioxide due to the downstream use, data from the survey was utilised.

To avoid a massive overestimation related to the number of workers, a rather realistic approach was taken where the mean value of the exposed workers per exposure scenario was utilised. This further avoids any underestimation of such impacts excluding the need of a sensitivity analysis. Please refer to section 9.1 and section 9.3 of the chemical safety report for more details. A justification for potential massive overestimation by using the total number of workers answered in the DU survey is provided.

Table 32: Summary of monetised potential health impacts over 12 years review period – use 2

<table>
<tr><th colspan="2">Type of potentially exposed humans</th><th>Lower bound (EUR)</th><th>Upper bound (EUR)</th></tr>
<tr><td colspan="4">117 DUs in the EEA</td></tr>
<tr><td colspan="2">657 potentially exposed workers</td><td>1,020,053</td><td>1,702,595</td></tr>
<tr><td rowspan="3">Potentially indirectly exposed workers and humans in the direct neighbourhood</td><td>$MVE_{local, inhalation}$</td><td>9,934,648</td><td>16,582,161</td></tr>
<tr><td>$MVE_{regional, inhalation}$</td><td>3</td><td>5</td></tr>
<tr><td>$MVE_{local, oral}$</td><td>263</td><td>587</td></tr>
<tr><td colspan="2">Total for 12 years</td><td>10,954,967</td><td>18,285,348</td></tr>
</table>

Considering a review period of 12 years, the total monetised potential health impacts for use 2 amount to **EUR 10,954,967** for the lower bound and **EUR 18,285,348** for the upper bound, following the approach described in the methodology.

Table 33: Summary table – monetised potential health impacts per year (annuity) – use 2

Type of potentially exposed population		Lower bound [EUR]	Upper bound [EUR]
Potentially exposed workers		108,689	181,415
Potentially indirectly exposed workers and humans in the direct neighbourhood	$PEC_{local,\ inhalation}$	1,058,558	1,766,865
	$PEC_{regional,\ inhalation}$	0.32	0.53
	$PEC_{local,\ oral}$	28	62
Total		**1,167,275.32**	**1,948,342.53**

Before proceeding to the economic and social impact assessment, the following chapters will analyse in detail the non-use scenarios that defines the consequences of a refused authorisation for use 1 and use 2 of chromium trioxide in the applicant's production activity.

4 SELECTION OF THE "NON-USE" SCENARIO

4.1 Efforts made to identify alternatives

K. Walter already has experience with the substitution of hazardous substances. Some examples of activities carried out in the past to identify and substitute such substances in K. Walter's processes are:

- The development and implementation of a new PFOS-free wetting agent to reduce bubble size and therefore to reduce the use of Cr(VI)-containing mist formation during electroplating.
- The development of "QUICK Connect," a new system to connect tanks containing Cr(VI) to plating unit supply lines. This technology significantly reduced the risk of worker exposure during the exchange of the tanks containing the Cr(VI) electrolyte.
- The development of new Cr(VI)-plating chemicals to omit lead anodes in the electroplating equipment.
- The implementation of preformulated electrolytes in which Cr(VI) is already dissolved. These electrolytes come in barrels or Intermediate Bulk Containers (IBCs) and can be directly connected to the plating equipment via the "QUICK Connect" system. This eliminates the risks of handling solid CrO_3.

The feasibility of replacing chromium trioxide has been and continues to be extensively investigated in different R&D activities across industrial and public sectors. However, currently, no alternative to the functional chrome plating processes has been identified fulfilling all necessary requirements.

As soon as a suitable alternative becomes available, additional time is needed for transition from one substance to another and from one process to another to replace chromium trioxide. Internal R&D as well as approval and release time spans play a major role on the customer side. In the following sections, efforts of K. Walter in R&D on identifying alternatives are presented.

4.1.1 Current R&D projects for substitution of chromium trioxide

K. Walter has dedicated significant efforts to the identification of potential alternatives to chromium trioxide. As a result of the ongoing research, K. Walter has developed a triple parallel strategy for substituting chromium trioxide in the manufacture of rotogravure and embossing cylinders. This strategy is called HelioGreen. This strategy features the development and implementation of the alternative manufacturing techniques Helio® Pearl and HelioChrome® NEO, coupled with the submission of this AfA for the extended use of chromium trioxide until 2032 a project that K. Walter has named ChromeXtend. K. Walter's goal is to implement Helio® Pearl and HelioChrome® NEO to achieve a significant, lasting improvement in the competitiveness of gravure printing by making gravure form manufacture more cost-efficient, more environmentally friendly, and a more secure investment. HelioChrome® NEO focuses on the development of Cr(III)-based electroplating as an alternative to the current process and has been ongoing since 2013. Helio® Pearl was started in 2014 and targets the development of polymer-based coatings. Combined, these developments could potentially substitute current applications of K Walter's customers.

The ChromeXtend strategy consists of the application for authorisation for the continued use of chromium trioxide in the EU past the CTAC authorisation expiration date by means of this AfA. It is an initiative launched by K. Walter to secure an authorisation that is tailored to the specific requirements of the gravure industry. Its goal is "to enable the continued long-term use of Cr(VI) beyond 2024, in line with the highest possible safety standards." Until a field-tested and commercial alternative is available, Cr(VI)-based electroplating is the only feasible technique for applying a functional chrome coating on engraved gravure cylinders with high quality.

4.1.2 Past R&D activities

From 2012 to 2014 K. Walter collaborated with external institutions and other companies to assess different technologies for new coating techniques, such as various vacuum-dependent processes including chromium-based coating with chromium nitride (CrN, Cr_2N), nickel plating, diamond-like carbon (DLC) coatings, polymer coatings, cold spraying, and high-velocity thermal processes. The main findings and conclusions of these consultations are discussed in section 4.3.

K. Walter has further evaluated Cr(III)-based functional hard chrome coatings currently in development, namely Atotech BluCr and Coventya DURATRI 240. While it appears to be that these technologies might fulfil most performance parameters when becoming generally available, it was found that two parameters render the technologies unsuitable for rotogravure. First, these Cr(III) processes rely on a high amount of organic complexation agents to stabilize the metal cations in the electrolyte. This leads to a high carbon content in the resulting hard chrome layer (e.g. DURATRI 240 3 - 4%). K. Walter's tests with a self-developed process resulting in a similar carbon content showed that a carbon concentration of >2% can lead to sparking, due to the high mechanical stress when the doctor blade wipes over the chrome-plated cylinder during printing. This sparking lead to a fire in a printing unit, when the sparks ignited the organic solvents from the printing ink. Having identified the carbon content as the source of this problem, K. Walter decided to concentrate its R&D activities on a chemical composition of the electrolyte that results in carbon contents of < 0.8% in the final chromium layer.

Second, both Atotech BluCr and Coventya DURATRI 240 rely on an underlying nickel layer for corrosion protection and deposition of the Cr(III) layer due to macrocracks within the coating. Macrocracks can protrude the entire chromium layer and expose the underlying copper layer to air and water, and therefore corrosion. Since the hard chrome layer in gravure applications is rather thin (printing < 8 µm), no closed coating is expected and a nickel layer would be mandatory. So far, the chrome layer has been deposited directly on the engraved copper layer. Due to the nickel intermediate layer, an additional nickel electroplating would be necessary. Since nickel plating itself poses several health risks, K. Walter's position is that such a layer would be a step back for a Cr(III)-based process and therefore opted for developing its process in such a way that this layer is not needed. Further information on this alternative is also shown in section 4.3.

4.1.3 Data searches

The information on R&D projects, as well as the technical assessment of alternatives provided are based on K. Walter's own investigations and in-house experience or obtained from consultations with other companies and institutions, including the Fraunhofer

Institute for Surface Engineering and Thin Films IST, Helmut Schmidt University, [redacted] Interpane AG, MacDermid Enthone GmbH, Coventya GmbH and Atotech GmbH. Searches for publicly available documents and literature were also conducted to ensure that all potential alternatives and alternative processes to chromium trioxide-based functional chrome plating of gravure cylinders which are of actual relevance were considered in the data analysis.

4.2 Identification of known alternatives

Through its close relations with European-level rotogravure industry associations such as ERA, as well as local associations like ACIMGA in Italy or GAA in the US, and the collaboration with local distribution partners, K. Walter is well informed about other technologies offered to DUs. K. Walter's opinion is that no SAGA currently exists for this use.

The alternatives currently being developed by K. Walter constitute the most promising alternatives but are not yet mature enough to substitute Cr(VI). The status of their development and the remaining challenges are discussed in section 4.4. Other alternatives considered by K. Walter but rejected as feasible alternatives are presented and discussed in section 4.3.

4.2.1 Alternatives considered by K. Walter

Two general alternative categories can be distinguished for the substitution of chromium trioxide in gravure applications: alternative methods to the use of chromium trioxide in the coating of gravure cylinders but for which the same printing or embossing mechanism is applied (a cylinder is used to transfer ink to a substrate or to imprint a pattern); and alternative printing methods that spare the use of gravure cylinders in printing applications altogether. Since K. Walter's business is based on the manufacture of plating equipment applied to coat gravure cylinders, the second alternative category (alternative printing methods) is not relevant for its business and substitution activities. A transition to one of these alternative printing methods would constitute a complete change of the business sector, which is clearly out of the scope of this AfA. However, K. Walter realizes that transitioning to alternative printing methods constitutes a possibility for partial substitution of gravure printing for some downstream users. Therefore, alternative printing technologies are also considered in this assessment, albeit as alternatives that are not relevant for K. Walter's business.

Potential alternatives identified by K. Walter that are relevant for gravure cylinders as well as alternative printing methods considered in this assessment are summarized in Table 34 below. The short-listed alternatives are those currently under development as part of the HelioChrome® NEO and Helio® Pearl strategies, corresponding to Cr(III)-based electroplating and polymer-based coatings, respectively. The reasoning for the exclusion of the rejected alternatives is presented in section 4.2.2.1.

Table 34: Overview of alternatives considered by K. Walter

Category	Alternative	Type
Short-listed alternatives	Cr(III) electroplating with Cr(III)-based electrolyte	Alternative substance to CrO_3
	Polymer-coatings	Alternative coating technology
Rejected alternatives	Vacuum processes (Diamond-like carbon (DLC), Roto-hybrid technology, plasma vacuum, PVD processes, CVD processes (CrN))	Alternative coating technology
	Nickel, nickel alloys and nickel-phosphorus electroplating	Alternative substance to CrO_3
	Spray Coatings	Alternative coating technology
	Bronze	Alternative base material for cylinders
	Cobalt and cobalt phosphorous coatings	Alternative substance to CrO_3
	Anodized aluminium on aluminium embossing cylinders	Alternative base material for cylinders
	Steel or nitrided steel	Alternative base material for cylinders
	Offset Printing	Alternative printing technology
	Flexographic-printing	Alternative printing technology
	Digital printing	Alternative printing technology

4.2.2 DU survey

4.2.2.1 Results

K. Walter's clients (DUs) using Cr(VI)-based electrolytes for coating gravure cylinders were asked to participate in a survey aiming to collect relevant information for this AfA. From a total of 105 AoA and SEA-related DU surveys distributed, a total of 73 responses were collected, representing a response rate of 70%. DUs were asked in the survey whether they were aware of any chromium trioxide-free plating alternatives for printing cylinders or whether they could apply a different printing technology that would work without the chrome plating of gravure cylinders. Only those DUs who answered this question affirmatively were asked to continue to the next questions of the survey. These subsequent questions asked DUs to specify the alternative or technology referred to in the first question and to estimate the implementation costs and time of this alternative. Finally, DUs were asked whether a transition to this alternative would be economically feasible.

The distribution of the responses to the first DU survey question regarding the availability or awareness of a potential alternative are shown below in Figure 26. Approximately 72%

of the participants reported not being aware of an alternative, 17% are aware of a potential alternative, and 11% did not provide an answer.

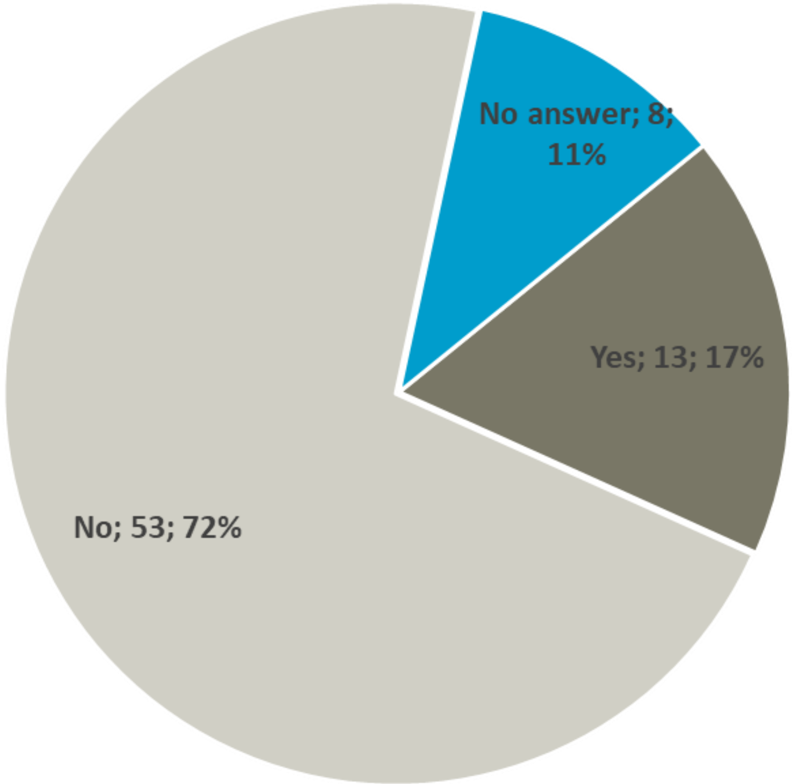

Figure 26: DU survey results, availability or awareness of potential alternatives

As shown in Figure 26, only 13 of the DU who participated in the survey expressed that they are aware of a potential alternative or could implement an alternative printing method. Seven of these DUs specified at least one of the alternatives being developed by K. Walter, with seven DUs listing Cr(III)-based plating and four of them listing polymer-based coatings. The remaining alternatives mentioned were flexographic printing (3 responses), digital printing (2), DLC coatings (3), Dynacyl (1), nickel coatings (1) and PVD (1). It is important to highlight that DUs also consider alternative printing technologies different to those facilitated by K. Walter's products (gravure printing). This means that DUs could potentially switch to a different supplier when transitioning to a printing technology that does not use gravure cylinders. Such alternative printing methods are not relevant for K. Walter because they constitute completely different technologies outside K. Walter's business area.

For eight of the companies that are aware of an alternative, the estimated implementation costs associated with a transition to this alternative lie over EUR 1 million. Six of these stated that these costs are economically feasible. For one DU implementation costs between EUR 10 K and EUR 100 K are not economically feasible. These results are shown in Figure 27.

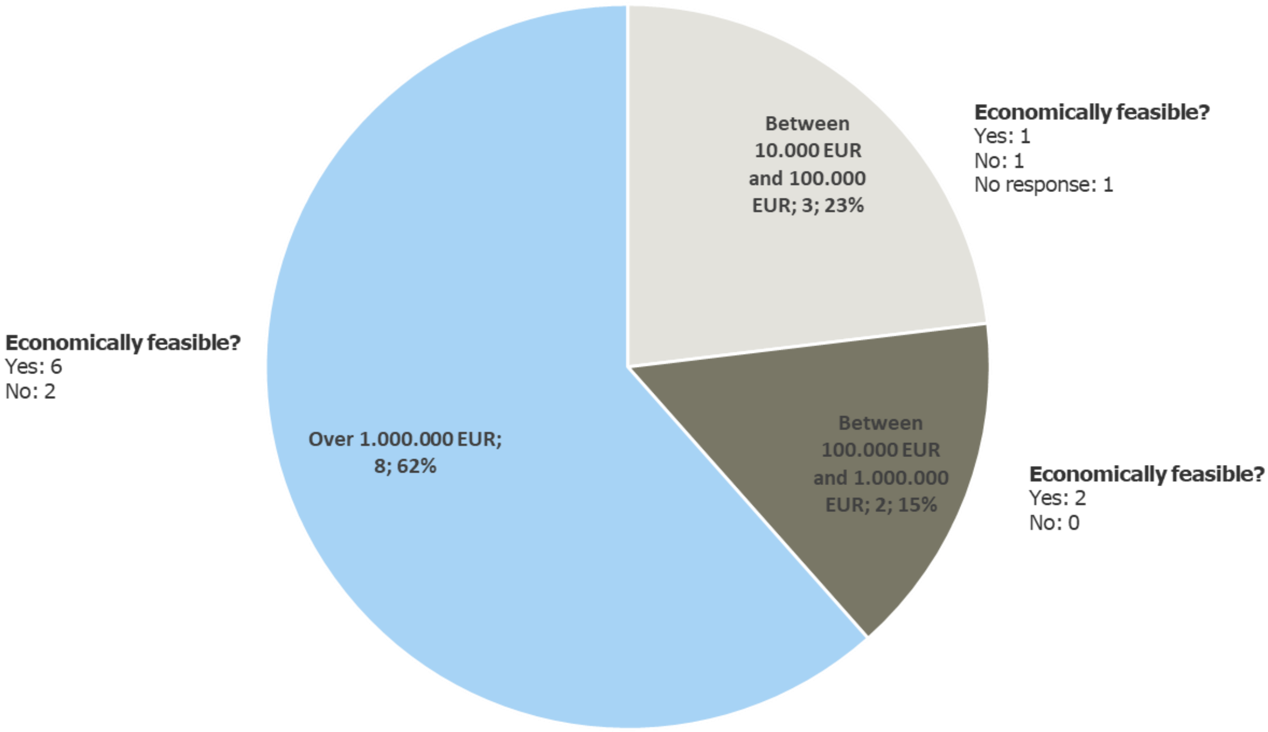

Figure 27: DU survey results, estimated implementation costs and economic feasibility

Finally, almost half of the companies (six) estimate the time needed for the implementation of such an alternative would be between one and four years, four estimate this time would be between four and seven years, two would need one year or less, and one would need more than 12 years. These results are summarized in Figure 28. Importantly, this time represents the time needed by DUs to conduct all necessary testing and substitution activities in their own processes and is therefore not comparable to the review period requested in this AfA. This time does not account for the time K. Walter needs to develop the two most promising alternatives nor the time needed for the manufacture of the new machines once these technologies are fully developed. The results from this section can be more accurately related to the "External R&D" phase described in the implementation plan presented in section 4.5.

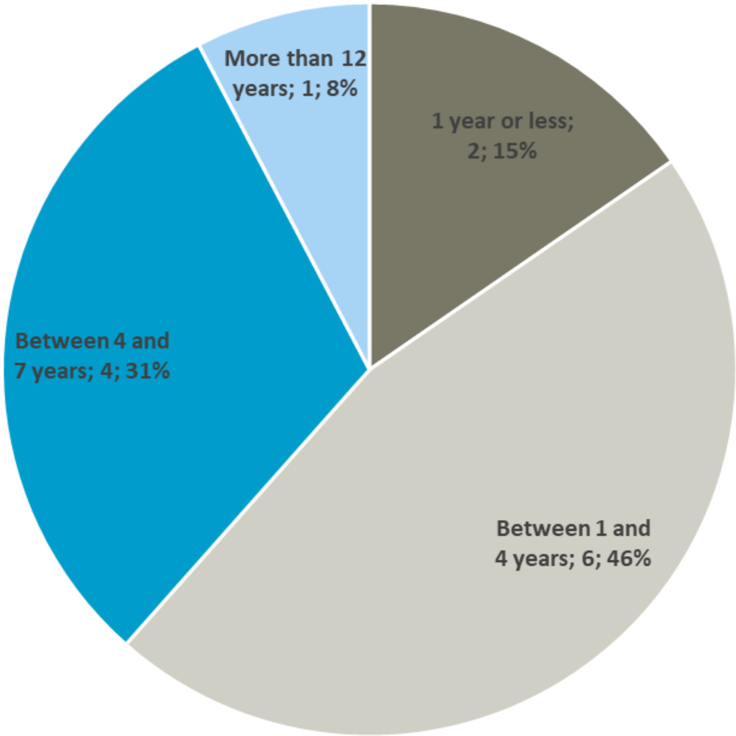

Figure 28: DU survey results, estimated time needed for implementation of an alternative

4.2.2.2 Conclusions

The majority (72%) of the DUs providing an answer to the AoA section of the questionnaire are not aware of a potential alternative to Cr(VI)-plated gravure cylinders in their application. Half of the alternatives mentioned correspond to at least one of the technologies that K. Walter is currently developing and that are described in this AfA (see section 4.4). The remaining half of the alternatives listed constitute either alternative printing technologies which are not relevant for K. Walter, or alternatives already considered by K. Walter but assessed as unsuitable for substituting Cr(VI) (see section 4.3). The decision to switch suppliers in favour of a completely different printing technique does not depend on K. Walter but only on the DUs and their own clients. Therefore, the results from the survey are only indicative of a different substitution approach that is not necessarily applicable to K. Walter's case.

For most of DUs providing an answer, the transition to an alternative would be economically feasible, even though 62% of the responses indicated costs over EUR 1 million. Finally, almost half (46%) of the DUs that participated in the survey estimate that they would need between one and four years to implement an alternative, while 31% estimated this transition to take between four and seven years. This period, however, is not comparable to the review period requested by K. Walter in this application, as it only reflects the individual time required by each DU to implement an already-available alternative and therefore does not include phases such as R&D development, testing at DU sites or equipment assembly. Further statements about the transition to an alternative cannot be made from the data collected.

4.3 Assessment of rejected alternatives

4.3.1 Vacuum processes (Diamond-like carbon (DLC), plasma vacuum, PVD processes, CVD processes)

These coating technologies rely on the direct evaporation and subsequent deposition of a coating material, or a chemical reaction which generates the coating material during deposition in a low-pressure environment. The processes require a high vacuum of about 10^{-3} pascal (10^{-5} mbar), so they must be carried out inside a vacuum chamber. The biggest cylinders in publication rotogravure or embossing can have a width of about 5 m. Therefore, a vacuum chamber of around 6−7 m length (considering cylinder axles) would be necessary. Pumping down such large vacuum chambers to low enough pressures is expected to take 2 hours. For smaller cylinders, such as those used in packaging applications (Type A), the time needed to generate the required vacuum is not expected to be shorter than 1.5 hours. To be practical for the DU, vacuum chambers cannot be built to just fit one small cylinder dimension but have to be able to accommodate the largest gravure cylinders from the respective DU, and therefore also smaller cylinder dimensions will have pumping times similar to the largest cylinders. Long cylinder manufacturing times are not acceptable for DUs, especially for applications where the time between editorial deadline to sellable printed product is very short.

In the scope of vacuum processes, K. Walter assessed between 2010 and 2013 the possibility to build a CVD magnetron-sputter-coating reactor for the deposition of CrN/Cr_2N on copper engraved cylinders. Despite specifically testing sputter-coatings, the study also assessed the feasibility of vacuum processes in general by considering the time and costs needed to generate the required vacuum. This project was carried out in collaboration with the Fraunhofer Institute for Surface Engineering and Thin Films IST in Braunschweig, Germany and Interpane AG, Lauenförde, Germany. During the conceptual design of the coating equipment, it was found that this technology is disproportionately expensive and time-consuming compared to the existing technology and will remain so even after completion of the development work. With the large cylinder dimensions used in rotogravure printing and embossing, the starting pressure required for these processes cannot be achieved in less than an hour, even if a large number of turbomolecular pumps (>10) are used (pump capacity ≈2000 L/s each).

A further problem became evident as coating experiments with small gravure cylinders were carried out at the Fraunhofer IST, where vacuum pumping times of >1.5 h were needed: a clean and degreased surface is highly important for depositing these surface coatings. Such a surface is typically achieved by cleaning the gravure cylinder in a wet degreasing process using surfactants and acids. Consequently, considerable amounts of water adhere to the surface of the gravure cylinder, which further prolong vacuum pumping times due to the slow desorption of surface adhered water. Additionally, processes like CVD and PVD have very high surface cleanliness requirements to achieve good surface adhesion. Therefore, surfaces need to be cleaned by an additional plasma cleaning step, which adds to process time and equipment complexity. As a result of these experiments and considerations, further R&D activities on vacuum processes were discontinued and the focus was shifted to Cr(III)-based plating and polymer coatings.

In general, the long pumping and therefore also cylinder production times could in theory only be compensated by a higher number of machines or further drying steps with additional equipment. However, a higher number of machines also translates into a considerable increase in system and energy costs. Considering a process time of only 20 min for the current Cr(VI) process and a pumping and coating time of at least 1.5 h for vacuum based technologies, production capacities could only be retained by purchasing 4 to 5 times the amount of current chromium plating units. Furthermore, considering the expected costs to be at least 3 times the current Cr(VI) plating unit costs, this would result in a 13.5-fold increase in investment costs, in addition to the higher running costs of this number of vacuum-based systems. This is not economically feasible for DUs.

While Roto-Hybrid has demonstrated that a DLC protection layer can be a suitable technology for rotogravure printing under specific conditions (30), K.Walter considers this technology to be not applicable in practice. K. Walter expects the technologies currently under development (HelioChrome® NEO and Helio® Pearl) to perform as well as or better than vacuum processes, but at significantly lower costs and faster production speeds. The enormously large power consumption of vacuum processes technologies is also problematic (about 5 times higher), and further contributes to making these alternatives economically unviable. Thus, vacuum-based technologies, including PVD/CVD processes, DLC-based technology, plasma vacuum and CrN sputtering are not regarded as suitable replacements.

4.3.2 Nickel and nickel alloys; Nickel-phosphorus (electroless or electrolytic); Nickel-phosphorus with hexagonal boron nitride

Nickel in general is too soft to be used as a surface in rotogravure printing and embossing and has many toxicologically problematic properties. Many printing and embossing products have direct contact with food or are touched by the end consumer. DUs have concerns about the future regulatory status of nickel and nickel-containing process chemicals. This renders these technologies not acceptable by DUs and customers.

With nickel-phosphorus it is possible to reach a hardness of up to 700 HV, lower than the 900 HV required for gravure applications. The developer of the system (IPT, Stuttgart) has the opinion that nickel-phosphorus could potentially be used if the printing process is optimized for lower hardness. The developer reports that tests with small rotogravure cylinders show a good printability. With additional thermal treatment a higher hardness could be reached. However, DUs are sceptical about thermal treatments because of the long time needed and the possible effects of thermal warping on the shape and balance of the cylinders. Thermal warping, in this case, refers to the deformation of the printing cylinders due to the uneven thermal expansion of different sections of the cylinder. The tolerance levels for printing cylinders are very low (maximum 0.01 mm/m deviation in the conicity/roundness and maximum 0.02 mm in the concentricity to the lateral surface), so effects arising from thermal warping would deem the cylinders unusable for printing.

4.3.3 Spray coatings: cold spray coatings (Helmut Schmidt University, Hamburg); ceramic produced through spraying; thermal spraying (TF) with High Velocity Oxygen Fuel (HVOF)

All processes based on spraying produce non-homogeneous and rough/porous surfaces. The resulting pores in the layer can be larger in diameter than a printing cell. Therefore, printing from these surfaces is not possible. Also, the thickness of the layer is not constant.

The coating applied via spraying methods does not follow the underlying engraving and therefore is not suitable for gravure applications.

K. Walter had consultations and exchanges with the Kirk group (Australia) and the Helmut-Schmidt University, Hamburg, as part of K. Walter's Expert Consulting Program. These institutions attempted to apply brass and zinc layers by cold spraying serving as protective layers. However, no layers suitable for gravure printing could be produced.

Additional tests were carried out together with the DU ICR Ioannou S.A. by imaging directly into a brass surface created by an HVOF process. Per nature of this process, the homogeneity of the surface was not suitable for homogeneous engraving, resulting in many imaging errors and surface defects.

4.3.4 Bronze (Cu > 60%, Sn 10-22% or Mg, Pb, Al, Zn)

Bronze is too "soft" to be used in gravure applications. The achieved hardness is only 200 - 600 HV, which is significantly too low compared to the hardness required for gravure printing (at least 900 HV).

4.3.5 Cobalt and cobalt alloy coatings

Cobalt layers do not meet the required levels of hardness and wear resistance. Cobalt-phosphor coatings achieve 600 – 700 HV and therefore also do not meet the hardness demands in gravure applications. Heat treatments at 300 – 400 °C that increase hardness to 1,000 – 1200 HV are not acceptable with rotogravure cylinders due to possible cylinder warping and long heating / cooling times (see section 4.3.2). Wear resistance assed by Taber testing of nanocrystalline Co-P alloys showed that surface wear is up to ten times higher as compared to chromium surfaces (see (31) and (32)).

Additionally, the listing of the cobalt compounds investigated on the REACH candidate list excludes serious consideration of these as an alternative to functional chrome plating. Several Co(II) compounds are also on the list of Substances of Very High Concern.

4.3.6 Anodized aluminium on aluminium embossing cylinders

This alternative is not considered technically feasible. New gravure cylinders would have to be bought for every printing form, what represents higher costs for DUs. Moreover, grinding away the protection layer for every new engraving would progressively decrease the cylinder's circumference, shortening their lifespan significantly. In gravure printing, cylinder circumference is determined by the product to be printed and cannot be chosen by the manufacturer. From a technical perspective, anodized cylinders do not have an adequate hardness (<600 HV) and wear resistance, so they are also not a suitable alternative for gravure printing.

4.3.7 Surface modification – Nitrided steel

Surface modification processes are primarily nitration (nitriding) processes which are only usable directly on steel. The preparation of gravure printing forms needs a soft material, usually copper, for engraving, which is then covered by a protective layer (functional chrome coating). The direct imaging of a steel cylinder is not possible within an acceptable time. Moreover, the reuse of the base cylinder would not be possible. The temperature of the process is also too high for gravure printing cylinders (see nickel processes). The removal of the modified cylinder surface would include grinding of the base material, so that the circumference of the cylinder would change significantly over time. This is not acceptable for gravure cylinders.

4.3.8 Offset printing

Offset printing is a commonly used printing technique whereby ink is transferred from a printing plate to a rubber blanket and then to the substrate material (e.g. paper). Quality and consistency, however, are not comparable to those achieved by Cr(VI)-based rotogravure. Especially for packaging printing, offset is not considered as a suitable replacement, mainly because it is not possible to print on films or foils. Furthermore, offset printing is not a seamless printing technology and therefore continuous patterns cannot be printed.

4.3.9 Flexographic printing

Flexographic printing uses a flexible printing plate wrapped around a cylinder to transfer ink onto a substrate. This technique also shows high flexibility in terms of the substrates that can be printed. Compared to rotogravure printing, clear disadvantages include the difficulty of making designs and the reproduction of colours in images due to the lower ability of flexographic printing to print colours with decreased saturation (half tones). Another disadvantage of flexographic printing is that quality decreases over long printing runs. Moreover, flexographic printing shows limitations when applying large quantities of ink and in the transfer of some heavily pigmented, large volume inks as these inks are not easily transferred by the stamp.

4.3.10 Digital printing

Digital printing uses electronic information to create the printed pattern on the substrate’s surface. It can be divided into two categories: inkjet printing, and electrophotographic printing. Neither technology uses a printing plate or cylinder to transfer ink onto a surface but rather convert information stored in an electronic form into instructions to direct the deposition of the ink. Currently, digital printing is not developed enough to substitute rotogravure printing in many applications. The high costs (mainly ink costs) of this technique are one of its main limitations.

4.3.11 Conclusion

In conclusion, although extensive and promising R&D activities have been carried out over the last years, no alternatives to chromium trioxide are currently available that meet all the requirements for rotogravure printing and embossing applications. At present, only Cr(VI)-based coatings can fulfil the key performance functionalities needed for this demanding industry sector.

For some methods like PVD/CVD, performance parameters are fulfilled, but the process and equipment costs, as well as the manufacturing time of the gravure protection layer are not economically feasible. The equipment cost for the protection layer is more than 10 times higher than the current cost, considering both equipment and production costs.

Alternative printing methods are available that could substitute Cr(VI)-coated gravure cylinders for some applications. However, these technologies are not relevant for K. Walter because they lie outside the company's area of expertise and business sector. They use a completely different mechanism to gravure printing and embossing. For a more detailed discussion on alternative printing technologies available for DUs please refer to section 4.2.2, where results from the DU survey conducted are provided.

Transitioning to a completely new printing technology is a costly process because investments in printing presses are vastly higher than investments in printing form production equipment. Substituting to a different coating method such as Cr(III)-based electroplating constitutes a more feasible option for DU, both from an economic and a technical perspective. This transition, however, must also be carried out slowly to ensure the quality of the final products (see section 4.1.1 for a description of the R&D plan).

4.4 Assessment of shortlisted alternatives

As a result of the consultations with experts and its own R&D activities, K. Walter decided to focus on the development of the HelioChrome® NEO and Helio® Pearl system, consisting of the replacement of Cr(VI) by Cr(III)-based plating and the development of polymer-based coatings, respectively. Further R&D is needed until these alternatives are mature enough to substitute chromium trioxide in the gravure industry. These technologies are assessed in the following sections.

To assess the technical feasibility of the short-listed alternatives, color-coded summary tables are included in the document. The colours are defined as shown below in Table 35.

Table 35: Definition of colour codes used for alternative assessment

Colour	Definition
(red)	Not sufficient - the parameters/assessment criteria do not fulfil the requirements
(yellow)	Experimental data only partly available– further R&D required
(green)	Sufficient - the parameters/assessment criteria do fulfil the requirements
	No data available/not relevant;

Potential alternatives must fulfil all key functionalities described in section 3.6.4 to be considered as technically feasible substitutes for chromium trioxide in the functional chrome plating of rotogravure cylinders.

4.4.1 Cr(III)-based electroplating (HelioChrome® NEO)

4.4.1.1 Description

HelioChrome® NEO is based on depositing a hard chrome layer from a Cr(III) electrolyte. Cr(III)-based electrolytes have been investigated and are currently phased in as a potential alternative to Cr(VI) for thin decorative coatings. Cr(III)-based electrolytes for decorative coatings are generally not suitable for functional hard chrome plating due to low hardness and low wear resistance. As described in 4.1.2, hard chrome Cr(III)-based processes currently in development by other developers, namely Atotech and Coventya, feature a carbon content that is not suitable for gravure cylinders as well as significant macrocracking, which facilitate corrosion of the underlaying copper layer. Since 2013, K. Walter has worked on the challenge of developing its own Cr(III) technology that can potentially meet the high tribological demands of gravure cylinders. The aim is to develop a safer technology that can produce a metallic chrome surface with comparable mechanical properties and quality as the Cr(VI) equivalent.

4.4.1.2 Technical feasibility

For the Cr(III)-based plating process, most of the individual steps already used in the production of gravure cylinders (e.g. cleaning, surface polishing and engraving) can be retained as only the Cr(VI)-based step would be substituted by the new Cr(III)-based step. However, current results show that substantial changes to the galvanic systems are needed for depositing a chrome coating from Cr(III) electrolytes. This implies that Cr(VI) cannot be substituted in a one-to-one manner by Cr(III), and that DUs must invest in new plating equipment if transitioning to this alternative. For Cr(III) deposition, the key process parameters are very sensitive and must be strictly monitored to a much higher extent than for Cr(VI). While Cr(III) is deposited as metallic chromium (Cr(0)) at the cathode (the gravure cylinder), oxidation of Cr(III) to Cr(VI) at the anode must be avoided. The formation and presence of Cr(VI) not only interferes with Cr(III) deposition but should also be avoided from a safety perspective. Preventing Cr(III) oxidation requires time-consuming development of new anodes, consisting of other materials such as metal-metal oxide alloys.

Since 2015, HelioChrome® NEO is being developed by K.Walter at Huhtamaki Flexible Packaging. The goal is to achieve stable and reproducible electroplating results, optimizing plating parameters, and assessing wear resistance. The preliminary results show that the achieved cylinder surface quality matches those obtained when using conventional chrome plating and are therefore promising for rotogravure applications. Moreover, tribological layer properties and electrolyte stability have been established. Depending on the wear and printing behaviour, further adjustments to the plating process must be made before the first Cr(III) plating equipment can be installed at beta-test sites where the technology will be evaluated under production conditions.

An assessment of each key functionality is shown below.

Hardness

The hardness of Cr(III)-based coatings is high enough for gravure applications (approx. 1050 HV). This key functionality is fulfilled at the current stage of development.

Layer thickness

The layer thickness achieved with this alternative is appropriate for gravure applications. This key functionality is fulfilled at the current stage of development.

Layer homogeneity

The layer homogeneity provided by this alternative is satisfactory. This key functionality is mostly fulfilled at the current stage of development with occasional surface defects. Further R&D is therefore needed.

Adhesion to substrate

The adhesion of Cr(III)-based coatings to the metal substrate is appropriate. This functionality is fulfilled at the current stage of development.

Deposition time/plating time

The deposition time achieved with this alternative is acceptable. This functionality is fulfilled at the current stage of development.

Surface morphology /density of microcracks

The surface morphology obtained with this alternative is adequate. This functionality is mostly fulfilled at the current stage of development with occasional surface defects. Further R&D is therefore needed.

Friction coefficient / surface roughness

Surface properties have been successfully established. This functionality is therefore fulfilled at the current stage of development.

Wear resistance

Wear resistance tests have started and are ongoing. Depending on the wear and printing behaviour, further adjustments to the plating process must be made before the first Cr(III) plating equipment can be installed at beta test sites where the technology will be evaluated under production conditions.

Corrosion resistance

Corrosion resistance has been established for this alternative. This key functionality is fulfilled.

Table 36 below shows an overview of the assessment of Cr(III)-based electroplating.

Table 36: Colour-coded assessment of Cr(III)-based plating

Hardness	Layer thickness	Layer homogeneity	Adhesion to substrate	Deposition time/plating time	Surface morphology/ density of microcracks	Friction coefficient/ roughness	Wear resistance	Corrosion resistance
(green)	(green)	(yellow)	(green)	(green)	(yellow)	(green)	(yellow)	(green)

4.4.1.3 Economic feasibility and economic impacts

The expected equipment investment for DUs lies between 400 - 500k EUR. Projects costs, such as chemicals and services are estimated to fall within 10 – 30k EUR. Potential additional costs for DUs include disposition of old equipment and plant modifications, among others.

The total development costs for K. Walter for HelioChrome® NEO lie between EUR 1,5 and 2 million.

4.4.1.4 Availability

Cr(III)-based electroplating technology is still under development and is not currently available for substituting chromium trioxide in the chrome-plating of rotogravure and embossing cylinders. More time is needed to develop Cr(III)-based plating into a mature alternative that can be implemented into the different processes applied by K. Walter's DUs.

4.4.1.5 Reduction of overall risk due to transition to HelioChrome® NEO

Cr(III) salts demonstrably pose fewer environmental and health concerns compared to chromium trioxide. The risk associated with the use of this alternative is expected to be lower than that posed by the current Cr(VI) process.

4.4.1.6 Conclusion

Many of the technical requirements have already been successfully established for this alternative. However, further testing is needed at DU sites to ensure the reliability of this technology. These tests are expected to start in 2021. Because Cr(III)-based electroplating uses different equipment and process parameters than the current Cr(VI)-based method, downstream users will need to implement new plating units while replacing the Cr(VI) ones. Given the large investment costs associated with this transition, it will occur slowly (see section 4.1.1 for a description of the R&D plan).

4.4.2 Polymer coatings (Helio® Pearl)

4.4.2.1 Description

One of K. Walter's ongoing R&D efforts focuses on the development of a polymer-composite coating. This approach is called Helio® Pearl. The polymer composite can be engraved directly on the surface of the cylinder. This allows the direct replacement of both the copper and chromium protective layers. This R&D is currently conducted in collaboration with the [redacted].

Helio® Pearl is based on polymeric, laser-engravable monolayer technology. Only three process steps are needed for coating gravure cylinders: a coating step, a surface finishing step and direct laser engraving. The coating step uses the polymeric Helio® Pearl layer instead of copper or chromium layers to coat each gravure cylinder. This layer is then ground to give the surface the desired finish. Finally, the coated cylinder is engraved using a high-resolution laser.

The use of thick polymer coatings for gravure applications is part of a new R&D project. This project is carried out within the Federal Ministry of Education and Research, funded by the *GravoMER* cluster, and in collaboration with the [redacted], the company Sächsische Walzengravur and the Leipzig University of Applied Sciences.

4.4.2.2 Technical feasibility

The use of polymer coatings will lead to an overall reduction in complexity in gravure cylinder production because, as mentioned in previous sections, only three manufacturing steps are needed: i) pre-polymer coating of the cylinder and subsequent UV-induced direct polymerization on the cylinder surface; ii) polishing of the cylinder surface; and iii) laser engraving. This will lead to lower investment costs for new gravure cylinder manufacturing lines. Furthermore, K. Walter estimates that cylinder production costs will be reduced. A drawback of this technology, however, is its lower wear resistance, which means that cylinders must be recoated more frequently. Additionally, it is assumed that the lowered wear resistance will hinder the use of polymer-coated cylinders for decorative rotogravure, where inks containing particles such as titanium dioxide (TiO_2) and more abrasive printing substrates might lead to unacceptable high cylinder wear.

One significant challenge of polymer-based coatings is the engraving of gravure cylinders. Traditional engraving via a diamond stylus is not suitable because the polymer coat is too brittle and cannot withstand the cutting process. One possible way around this problem is engraving through laser ablation, a technique that is slowly becoming more widespread in industry. While laser ablation is an established technology and is currently being adopted by the industry for engraving metal cylinders, the currently available laser systems are not suitable for polymer engraving. New laser systems are therefore being developed that are tailored to the special requirements of polymer coatings.

Helio® Pearl achieves high printing qualities due to the direct laser imaging. Developing this technology involves not only creating a composite material that can be laser engraved and has tribological properties suitable for gravure printing, but also inventing the now-patented end-to-end procedure, including coating, surface treatment, and imaging.

Initial printing tests are promising. The run stability of 100,000 meters in print and on the tribological test rig with doctor blade and ink with low abrasive inks is a good starting point for further improvements. The current performance standard is based on several tests carried out at K. Walter's dedicated testing centre in Munich, Germany. Over 400 cylinders have been coated using a specially developed machine and the best of more than 200 material combinations have been selected. The optimum laser power for engraving has also been identified and the polymer's resistance to the solvents typically used in gravure printing has been tested. Based on tests results, the printing performance of the Helio® Pearl technology has been continuously improved.

An assessment of each key functionality is shown below.

Layer thickness

Polymer coatings can be designed to have the desired layer thickness. Currently, layers of 240 µm thickness are used for printing applications. This functionality is not directly comparable to the layer thickness of chromium coatings because these are different materials with different properties. Since the polymer coating will be used as a substitute for both copper and chromium layer and the thickness is sufficient for laser engraving, this functionality is considered as being fulfilled at the current stage of development.

Layer homogeneity

Polymer coatings show a high level of surface homogeneity comparable to that achieved with Cr(VI). This functionality is therefore fulfilled at the current stage of development.

Adhesion to substrate

Polymer coatings show a very high adhesion to the underlying substrate. Peeling of the coating material is not expected to constitute a major concern. This functionality is fulfilled at the current stage of development.

Deposition time/plating time

The deposition time for polymer coatings lies around 30 minutes for each cylinder. This is comparable to the time currently needed for coating gravure cylinders using Cr(VI)-based functional chrome coating. This functionality is therefore fulfilled at the current stage of development.

Surface morphology /density of microcracks

Microcracks appear not to be needed with this technology. This functionality is considered fulfilled by polymer coatings at the current stage of development.

Friction coefficient / surface roughness

Polymer coatings can be designed to have the same surface roughness as chromium layers. This functionality is fulfilled at the current stage of development.

Wear resistance

Polymer coatings allow for printing runs of approximately 100.000 meters. This is a shorter lifetime than what can be achieved with chrome coatings. A drawback of this technology is its lower wear resistance, which means that cylinders must be recoated more frequently. It is assumed that the lowered wear resistance will hinder the use of polymer coated cylinders for decorative rotogravure, where inks containing particles such as titanium dioxide (TiO_2) and more abrasive printing substrates might lead to unacceptable high cylinder wear.

Corrosion resistance

Corrosion resistance has been established for this alternative. This key functionality is fulfilled.

Table 37 below provides an overview of the assessment for polymer-based coatings.

Table 37: Colour-coded assessment of polymer-based coatings. N/A = Not applicable

Hardness	Layer thickness	Layer homogeneity	Adhesion to substrate	Deposition time/plating time	Surface morphology/ density of microcracks	Friction coefficient/ roughness	Wear resistance	Corrosion resistance
N/A								

4.4.2.3 Economic feasibility and economic impacts

Polymer coating is linked with high initial investment costs because the main parts of the process must be redesigned, and new machines must be bought. For example, the traditional engraving of the printing plate with a diamond stylus cannot be used in combination with a plastic coating because the brittle polymer layer is unable to withstand the shape cutting without shattering. Consequently, K. Walter is developing new processes based on laser ablation for the direct engraving of the polymer coating. This represents higher development costs for K. Walter and higher investment costs for DUs.

A further advantage of the Helio® Pearl technology, in terms of cost-efficiency, is that all existing steel, aluminium, and copper gravure forms can be used, meaning that no additional investments in new cylinders is required.

The total development costs for K. Walter for the Helio® Pearl technology lie between EUR 1,6 and 2,0 million. The estimated total costs for DUs lie around EUR 1 million, aligned with estimates provided by DUs. According to results from the DU survey (see section 4.2.2), most of the DUs participating in the survey find the costs associated to a transition to one of the alternatives investigated by K. Walter economically feasible.

4.4.2.4 Availability

K. Walter is currently dedicating significant R&D efforts to develop its polymer-based coating alternative. At present, this technology is not suitable for substituting Cr(VI)-based plating of rotogravure and embossing cylinders, and more time is clearly needed until this can be achieved. A description of the tasks needed to achieve complication is given in section 4.5.

4.4.2.5 Reduction of overall risk due to transition to Helio® Pearl

The Helio® Pearl technology is environmentally friendly as it uses non-toxic materials and does not yield polluted water or exhaust streams. It will therefore lower the risk associated with the continued use of chromium trioxide.

4.4.2.6 Conclusions

Helio® Pearl constitutes a promising alternative. Positive test results have been achieved, even though further R&D efforts and testing are needed to develop this technology into a mature option. The main disadvantage of this technology is its lower wear resistance, which means that cylinders must be recoated more frequently. This will hinder the use of polymer-coated cylinders for applications with long printing runs as well as decorative rotogravure, where inks containing particles such as titanium dioxide and more abrasive printing substrates might lead to unacceptable high cylinder wear. This technology is currently not suitable for substituting Cr(VI)-based plating of gravure cylinders, and more time is needed until this can be achieved. Further tests at DU sites will also be required to ensure the reliability of this technology.

4.5 Information on the substitution process

4.5.1 Substitution timeline

K. Walter foresees that at least 12 years will be needed for a complete transition to a Cr(VI)-free alternative. This time includes the technical development of the short-listed alternatives and, most importantly, the time needed for DUs to evaluate and switch to the new alternative processes (transition period). The technical development of Cr(III)-based electroplating and polymer coatings is already ongoing and runs in parallel. Importantly, DUs will decide which of these two alternatives better fits their specific application, mainly considering economic and technical aspects (see results from DU survey in section 4.2.2).

The steps needed for completing the transition to Cr(VI)-free alternatives are discussed below.

Technical development (2 years)

This step comprises the development of stable process parameters to ensure the quality and reproducibility of the new technology. In the case of Cr(III)-based functional plating, this phase includes the design of new anodes and equipment. Development work in recent years has shown that the process control of Cr(III)-based electroplating is much more difficult than that of Cr (VI)-based functional plating. For this reason, a new type of chrome electroplating unit was developed including new software for process control. For polymer-based coatings, this phase includes the following tasks: chemical formulation of the polymer coating (evaluation of toxicity of the coating, formulation optimisation according to developments on laser technology, temperature and time stability testing); construction of first coating machines; optimization of laser engraving on polymer for controllable ink transfer; abrasion/wear testing; and assessing stability of polymer coating in printing machines.

For both alternatives, technical development must be completed before continuing to the next step in the implementation process, the external R&D phase.

External R&D phase (5 years)

New gravure cylinders (either Cr(III)-plated or with polymer coatings) must be tested under real operating conditions at several beta-testing sites, where parameters such as wear can be finally evaluated. Beta tests are tests carried out at customer locations under real operating conditions and without any intervention from K. Walter. First beta tests for both alternatives are scheduled to start in 2021.

For Cr(III)-based electroplating, a first pilot system will be integrated into the automatic line at K. Walter's existing development site at a packaging printer in Ronsberg Germany (Huhtamaki Flexible Packaging). A second one will be integrated into the automatic line at a second packaging printer that has not yet been finally determined. Subsequently, both pilot systems will have to prove in regular operation that they have the same quality and process stability as the previous Cr(VI) systems without the intervention of K. Walter's process engineers. In discussions with K. Walter's development partner, the qualification criteria were defined which are necessary to be able to consider the alternative as a full replacement for the Cr(VI)-based technology: it must be possible to run for three months without any major, unplanned changes to the plating unit or process that cannot be performed by the partner's own production staff. If the processes show that there are still major instabilities, K. Walter will consider redesigning the process and restart beta-testing at Huhtamaki Flexible Packaging in Ronsberg. As soon as the beta tests are positive, the electroplating unit design can also be released for sale and assembly by K. Walter.

For polymer coatings, potential development partners are companies that have their own printing plants. This is because beta tests must primarily evaluate the coated cylinders in terms of their suitability for printing. Unlike Cr(III)-based electroplating, however, the first test setup for polymer-based coatings will be located at K. Walter's site (first full-scale beta facility), as no electroplating lines need to be installed. Cylinders would then be sent directly to potential customers for testing. However, the closest development partner and first installation site for preparing engraved cylinders with polymer coatings outside the company would again be Huhtamaki Flexible Packaging in Ronsberg, Germany, favoured by its proximity to K. Walter. The second beta plant in this case will not be built before the end of 2022. Further development and implementation timelines will otherwise be very similar to those of Cr(III)-based electroplating. The focus will initially be on packaging printing because of its lower surface stress and the technology will then be optimized for other application areas in succession.

Cylinders coated with Cr(III)-based technologies and with polymer coatings must be tested with different substrates, inks and doctor blades to demonstrate that the printing quality is not compromised. The timetable described above is currently only for cylinders of type A and C (see section 1.2), which correspond to the packaging and publishing industries, respectively. Decorative rotogravure is more demanding in terms of cylinder wear. Here, particles such as TiO_2 are often added to the ink and more abrasive substrates are used, wearing down the cylinders more quickly. Polymer coatings might not be able to fulfil performance parameters for Type B (decorative) applications because wear might be too high. This application will take 1-2 more years compared to packaging printing, for a total of 4 to 5 years. Overall, the external R&D phase will take 5 years to be fully completed.

Transition period (at least 8 years):

The transition period is expected to start approximately two years before the end of the External R&D phase. Within this period, K. Walter will continuously substitute the Cr(VI)-based technology at DUs with either Cr(III)-based electroplating or polymer coatings. A progressive decrease in the volume of Cr(VI) used by DUs will take place, while use of an alternative will increase accordingly. As mentioned above, the development of both alternatives is carried out in parallel. In general, DUs will substitute their Cr(VI)-based units with the alternative that better suited for their specific application (see results from the DU survey in section 4.2.2). It needs to be highlighted that for both alternative processes DUs will need to purchase new equipment because the electroplating units currently produced and sold by K. Walter can only be used with the Cr(VI)-based electrolyte. Substituting the electrolyte only is therefore not possible. This means that the electroplating units will first need to be manufactured and distributed by K. Walter.

The length of the transition period is determined by how fast these Cr(VI)-based electroplating units can be substituted by an alternative process. This, in turn, is determined by how fast K. Walter can manufacture the new machines and how fast it can build the know-how required for their service. However, it is very difficult to estimate an average production rate of new machines because this rate is expected to increase gradually throughout the transition period. During the first 2 to 3 years, for example, technicians will have to be trained in the installation and service of the new machines, so fewer of them will be manufactured. Another limiting factor might be the low availability of qualified personnel on the labour market which could prevent the simultaneous installation and servicing of new plating units at several sites. As knowledge and experience increase, however, the number of machines produced every year will likely increase.

K. Walter estimates that the minimum average production rate will be of 20 machines per year, which is aligned with the current production rate of Cr(VI)-based electroplating machines at full capacity. At a minimum average production and installation rate of 20 electroplating machines per year and considering that at least 214[13] Cr(VI)-based units in the EEA need to be substituted, more than ten years would be needed for 100% substitution. These calculations do not include any new contracts, which would increase the number of units that need to be substituted and therefore the length of the transition period.

K. Walter expects that the first customers to transition to a Cr(VI)-free alternative are those with more than one chromium plating unit, for whom the additional unit might serve as a “fall-back” technology. Given the large investment required to substitute various plating lines, a transition to a completely Cr(VI)-free process is likely to proceed slowly. First customers of a potential alternative are also expected to be located closer to the city of Munich, where the applicant is based, because the first installations might need frequent visits from technicians. It should also be considered that the capacity to install the new technology as an additional line is often aggravated by regulations, space requirements or automation setup.

In a best-case estimated substitution scenario and under the premises of increasing the production capacity of the alternative equipment, K. Walter assumes that at least eight years are needed for substituting the largest portion of current Cr(VI)-based units by an alternative.

Companies who adopt a new process will not directly substitute 100% of their process but will use a Cr(III)-based unit or a polymer coating process in parallel to their current Cr(VI)-based process to minimise risks and gain experience with the new technology. A change is especially demanding for service houses which do not print and printers which do not have their own cylinder manufacturing line. If the new technology is not 100% reliable, downtimes of several days to weeks are to be expected for printers. This is quite important, since more than 50% of the produced gravure cylinders come from plating service providers.

An overview of the R&D plan discussed above is shown in Figure 29.

[13] Calculated based on results from DU survey and K. Walter’s internal knowledge.

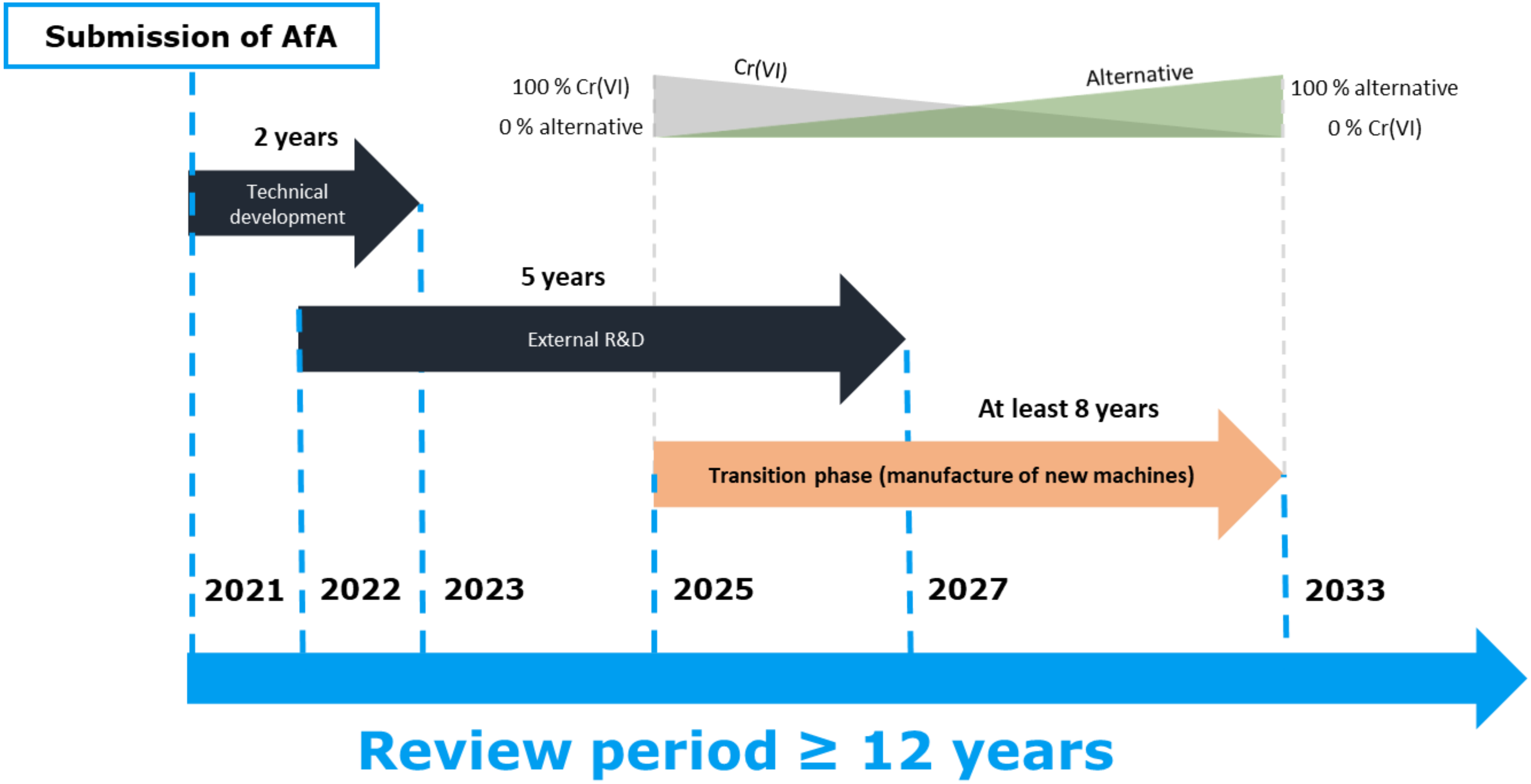

Figure 29: Overview of R&D plan for substitution of Cr(VI)

4.5.2 Monitoring of substitution timeline

The development of the most promising alternatives, Cr(III)-based electroplating and polymer coatings, is managed through separate project leaders. For both projects, internal timetables as well as milestones with due dates are defined to monitor development/substitution progress. Each project is split into three different teams: mechanical engineering, electrical engineering and software and process engineering. Updates of the team leaders are reported to the project leaders as well as the CEO in an internal weekly meeting. The manager responsible for the preparation of the AfA is a further member of this meeting.

Tests are continuously ongoing and are part of the development process. Tests for Cr(III)-based electroplating are carried out weekly together with the industry partner Huhtamaki Flexible Packaging on production printing presses. These tests are abrasion tests and aim to establish a reliable process and to assess wear resistance; no test printing jobs are yet carried out because these are expensive and time consuming. Polymer coated cylinders are evaluated on the printing press of the Hochschule der Medien, Stuttgart. Reports of the printing quality and surface wear are generated from the operators of the printing machines and sent to the project leaders of K. Walter.

Possible technologies not provided by K. Walter are discussed and monitored through the participation in biannual meetings of the industry associations (ACIMGA, ERA, GAA). Furthermore, national distribution partners, which are not part of Heliograph Holding, provide further insight in national markets and technologies offered to DUs.

4.6 The most likely non-use scenario

As the analysis of alternatives (AoA) above supports the absence of an economically and technically feasible alternative for functional chrome plating, the socio-economic analysis must provide a detailed evaluation based on the most likely non-use scenario. To conclude such a scenario, it is required by the applicant to consider every possible situation resulting from a potential refusal of authorisation in the absence of substitution. As derived in the analysis of alternatives, the timeline required for substitution of chromium trioxide in use 1 and use 2 is 12 years, starting from the compilation of the AfA submission dossier beginning of 2020. It should further be noted that, the discussion and elaboration of the non-use scenarios is independent of the fact that the applicant is covered under the CTAC authorisation until September 2024. Therefore, for the ease of assessment in this application, the impact triggering period begins from 2021 as soon as the application is submitted.

To achieve a meaningful conclusion, the most likely non-use scenarios have been derived separately for use 1 and use 2 explaining its consequences for each stakeholder in this upstream application.

4.6.1 USE 1

In case an authorization is refused, the following discussion to conclude on the most likely non-use scenario for Use 1 assumes that the authorization for Use 2 has been granted in anticipation. For use 1, non-use scenarios for only the formulator, K. Walter and the

Heliograph Holding's subsidiaries have been described. Heliograph Holding does not have any revenues associated with use 1 (see section 3.2.2, Figure 7).

4.6.1.1 Most likely NUS for K. Walter

Thus, in case the authorization for the use 1 of chromium trioxide is refused, the applicant/formulator must choose among the following response scenarios:

a) Outsourcing of chromium trioxide based liquid formulation from outside the EEA
b) Exclusive use of solid chromium trioxide salts

The subsequent sections describe the identified options and evaluate which of these is most likely to occur in the case of a refused authorization.

4.6.1.1.1 NUS A – Outsourcing of chromium trioxide based liquid formulation from outside the EEA

In case of a refused authorization, an option that has been considered by the applicant/formulator is to outsource chromium trioxide based liquid formulations to continue its business as usual. This scenario would entail that the applicant would have to find such a formulator/supplier outside the EEA and import this formulation back in the EEA to further supply its downstream users. After identification of a potential supplier and depending on the availability of production capacity at the supplier's end, for the DUs, this could potentially imply uninterrupted production of their affected article(s) in the EEA. However, for the formulator this scenario would imply a loss of business as the affected production activity is passed on to another formulator/supplier outside the EEA. As feasible as the scenario may sound, the applicant perceives a major bottleneck around identification of the formulator/supplier and maintenance of transportation and distribution networks of liquid formulations in and outside the EEA as explained below.

As per the baseline scenario, the applicant distributes large volumes of liquid formulation annually to its downstream users. Considering supply chain and logistics, careful packaging and transportation of such large-scale volumes of liquid solution present certain technical constraints directly impacting product quality. Whilst considering dry ice shipments to remove weight related hindrances associated with transportation of liquid products, tons of dry ice would be needed to keep the affected product under frozen conditions. Further, to be able to match lead times as in the baseline scenario, the applicant would have to maintain a stock of these formulations either in the EEA or outside which would require a prior calculation of stock to be maintained. This might lead to wastage in case the product is not used in time and passes its expiry date.

Besides the technical constraints that the scenario poses, the applicant also assumes that finding a supplier outside the EEA would require a timeframe of minimum one year leading to a subsequent supply disruption. Maintaining stocks of such a large amount of liquid formulation would require constructing extra storage capacities which is not a viable option for a short-term situation i.e., until a formulator/supplier is found outside the EEA. Given the highly competitive nature of the market, the applicant anticipates that its customers or DUs might shift to suppliers outside the EEA making it highly difficult for the applicant to remain competitive in the EEA after a supply disruption.

On the contrary, since the applicant holds majority of market in this business as of now, this scenario could also force the applicant and its DUs and subsequently the rotogravure process outside the EEA. The DUs could, consequently, partly stop the rotogravure process in the EU, move out of the EU or at least purchase the gravure cylinders from non-EU countries. Since the rotogravure business is completely dependent on the chrome plating process, the applicant as well as the associated firms under Heliograph Holding (see section 3.2.2) will be negatively affected in terms of economic welfare.

Considering the risk to business operations of not just the applicant but the firms associated as well, the applicant deems this scenario to be infeasible.

4.6.1.1.2 NUS B - Exclusive use of solid chromium trioxide salts

In case of a refused authorisation, another option that the applicant considers is to switch to supplying chromium trioxide for electroplating gravure cylinders in the form of solid salts instead of conventional liquid formulations. The applicant justifies that these salts can directly be incorporated in the electroplating process manually by the workers. Incorporation of such solid chromium trioxide salts would not hinder the electroplating process efficiency or quality but would however pose an increased risk to workers directly associated with handling these salts. Although the applicant would be supplying the salts, the burden of the risk would shift to the workers at the DUs directly handling such salts.

This would imply that the applicant loses its business in the liquid formulation sector but is still able to retain the raw material market for gravure printing in the EEA. However, as there are many suppliers of the salts in the market and K. Walter will not have a unique selling proposition, the applicant is expected to have none to significantly low sales of solid chromium trioxide salts to DUs. Business foregone in this scenario would be the difference between the profits accrued by sales of liquid formulations and solid salts of chromium trioxide.

As the applicant would still be able to retain its business in the EEA, the formulator, however, would lose its business in this scenario. Whether or not this could mean insolvency cannot be deduced from the above consequence as no information from the formulator regarding this scenario was obtained at the time of this application.

Following suit, the subsidiaries of Heliograph Holding located in the EEA will not remain competitive either. Two subsidiaries, Daetwyler-Hell France S.A.S. and Daetwyler-Hell Iberica S.L., selling chrome plating chemicals in France and Spain respectively, will lose their market share for liquid chromium trioxide mixtures or formulations. Subsequently, the subsidiaries will permanently shut down.

For the downstream users, this scenario would imply negative health consequences arising from the use of solid chromium trioxide salts, that pose a higher hazardous level as compared to the liquid formulation containing chromium trioxide. Whether or not this scenario would be acceptable by the downstream users is unknown. For simplicity however, it has been assumed that the downstream users would use solid chromium salts in the absence of other safer alternative(s).

Thus, in this scenario, depending on the stakeholders, following impacts could ensue -

Table 38: Impacts of the most-likely non-use scenario to a refused authorisation for Use 1

IMPACTS IN USE 1	Formulator	K. Walter	Heliograph Holdings	Heliograph Holding's subsidiaries	Downstream users
1. Foregone profits in 2021					
2. Job dismissals in 2021					
3. Health impacts for 12 years					

4.6.2 USE 2

Similar for Use 1, in case an authorisation is refused, the following discussion to conclude on the most likely non-use scenario for Use 2 assumes that the authorisation for Use 1 has been granted in anticipation i.e., the DUs continue to be supplied with the formulation from the applicant but remain dependent on an authorisation to use this formulation to produce chromium trioxide formulation coated cylinders for rotogravure printing and embossing applications.

To derive the most-likely NUS for use 2, DUs play a major role. Therefore, K. Walter's reaction to a refused authorisation for Use 2 depends highly on its DUs' reaction and has been assessed thereafter.

4.6.2.1 Most likely NUS for K. Walter's DUs

For the purpose of the evaluation, the results from the survey were used to derive the most-likely non-use scenario for each of the DUs. This section will describe the results in a meaningful way as follows.

4.6.2.1.1 Use of the downstream user survey

The DUs were asked to choose among the following response scenarios, in case K. Walter is refused an authorisation for use 2 of chromium trioxide:

- NUS A - Switching to an already available printing technology
- NUS B - Outsourcing of chromium trioxide coated gravure cylinders from outside the EEA
- NUS C - Relocation of chromium trioxide coated gravure cylinder production to a non-EEA country
- NUS D - Temporary shutdown of chromium trioxide coated gravure cylinder production in the EEA until an alternative is implemented
- NUS E - Permanent shutdown of chromium trioxide coated gravure cylinder production in the EEA
- NUS F - None of the scenarios above are applicable

DUs were asked to choose one or more possible responses in a rank based manner where assigning rank=1 will indicate the most-likely non-use scenario. Another possibility to choose a combination of non-use scenarios as their most-likely non-use scenario was also provided by to the DUs. For this purpose, they were asked to assign the same rank to all the non-use scenarios selected in this combination of the most-likely non-use scenario. To gain further clarity on the choice of the NUSs, a subset of questions spanning each NUS was further included in the survey. The respondent was asked to answer this subset associated with each NUS response selected and ranked 1, 2 or 3 in the survey. This subset has been used to elaborate the reasoning of the DU behind choosing the corresponding NUS. Towards the end of the subset of questions, the last question was always provided with a text box to add any justification or information for their choice of the non-use scenario. This further forms the basis for subsequent impact assessment for the DUs. After the first round of the survey, respondents that did not provide the most-likely NUS due to a refused authorisation, were contacted for further clarification.

The following adjustments were made to arrive at the most likely non-use scenario:

- NUS A was invalidated where, the respondent indicated that an already available alternative technology or process is not present.[14] NUS A was also invalidated wherever the DU mentioned that the alternatives are currently in development by K. Walter. It is assumed that the respondent may have misinterpreted it as an option that anticipates an alternative technology in the foreseeable future.

  In this case, the next-best non-use scenario (rank=2) selected by the respondent was assumed to be the most-likely non-use scenario (rank=1). In case the respondent did not select the next best non-use scenario, they were asked to provide the same in a follow-up round.

- Two responses were seen where the DUs provided a combination of non-use scenarios by assigning the same rank to each of the NUSs selected. However, these were not considered further as one response included NUS A alongside specifying no currently available alternate printing technology and the other included a combination of permanent shutdown (NUS E) and temporary shutdown (NUS D). In these two cases, the first option selected by the DU was listed as the most-likely NUS.

- Two respondents provided inconsistent responses to the question on the most-likely NUS after specifying NUS F. These responses were thus, not considered further.

- In case no rank was assigned and only one scenario was selected (other than NUS A), this was assumed to be the most-likely scenario for the respondent.

The next section discussed the number of DUs that opted for different most-likely non-use scenarios and elaborates on the reasoning behind the individual options from the responses to the corresponding sub-questions.

Response rate

As described in chapter 2, the overall response rate for the AOA/SEA survey is 70%. However, it differs for individual parts of the survey. For this section, a total of 64 responses were received constituting a response rate of approximately 61%.

[14] If the DU selected NUS A as an option, it was asked to specify/describe the alternative technology and to further mention if it is currently using this alternative technology

4.6.2.1.2 Number of DUs segmented by NUS

Figure 30 below depicts the number and share of DUs segmented by their most-likely NUS.

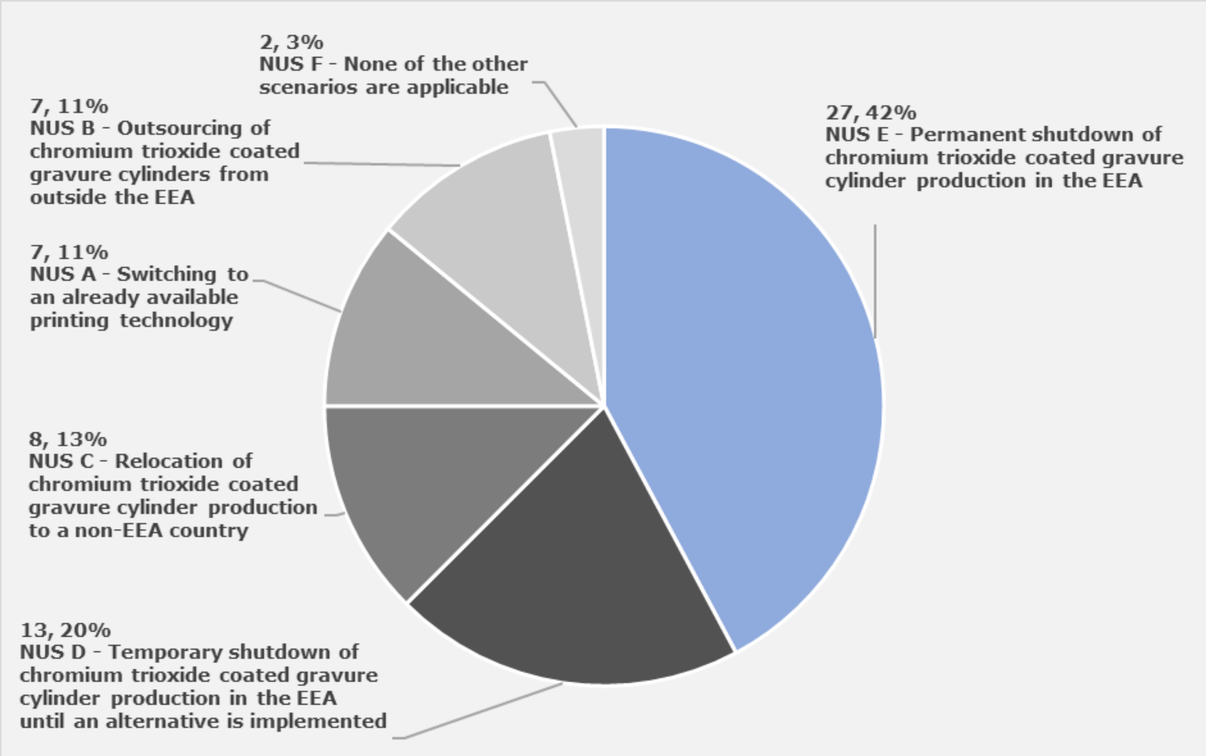

Figure 30: Number and % share of DUs segmented by type of NUS

Out of 64 DUs that provided a most-likely NUS, 11% DUs opted for NUS A and NUS B each, 13% of DUs opted for NUS C, 20% opted for NUS D and 27% opted for NUS E. 3% of DUs (n=2) that chose NUS F were not considered further in the analysis as explained in the adjustments above. Irrespective, NUS E was seen to be the most opted choice for the Downstream users followed by NUS D, C, A and B in the decreasing order.

When considered for each type of DUs (Type I, II or III), most types of DUs specified NUS E followed by NUS D as their most-likely non-use scenarios. The subsequent sections elaborate these scenarios based on the following criteria:

- Response rate of the most likely NUS based on rank=1
- Type of DUs that opted for the NUS
- Responses to subset of questions corresponding to the most likely NUS
- Comments/justifications provided

4.6.2.1.3 NUS A - Switching to an already available printing technology

This NUS describes the responses from the DUs that considered switching to an existing alternative printing technology currently being used at their site as a replacement for rotogravure printing if an authorisation to use 2 is refused.

Discussion of results

7 DUs, i.e., 11% of the respondents mentioned this NUS as their most-likely NUS (rank=1). It was observed that most Type II DUs (n=6) as compared to Type III (n=1) chose NUS A. This only covers approximately 17% and 10% of all Type II and Type III DUs respectively. The Type III DU, that chose NUS A also mentioned Type II as its main business activity. This option was not chosen by any Type I DU. This can be justified as sales from coated cylinders is a source of revenue for Type I and Type III DUs only. Therefore, where a printing firm that only relies on the sales of the final printed product for revenue generation (Type II) may be able to switch to an alternative printing technology, this option is infeasible for firms that rely on the sales of the intermediate product (chromium trioxide coated cylinders).

A sub-question related to specifying the currently available alternative printing technology highlighted the following points:

- For some DUs digital printing was an option either to compensate rotogravure printing fully or to a limited extent. The reason for the limitation was partly a lack of customer acceptance due to necessary changes required in the customer process chain and partly due to the added inflexibility in production of all products with this technology. Further, there would be restrictions on the quantity that can be produced resulting in considerable bottlenecks.

- Other alternative printing technologies such as flexography, polymer cylinders, printing of stamps using offset technology, roto offset printing, were also mentioned by the DUs. However, no justifications to their current use was provided.

No further specific sub-questions related to NUS A were placed in the SEA questionnaire as the AOA part of the questionnaire already covered further questions on the time required by the DUs to switch to an already existing, CrO3-free printing technology. Please refer to chapter 4.3 to see the assessment of rejected alternatives for use 2.

In summary, from the data above, it can be concluded that NUS A was considered as the most-likely NUS mainly by some Type II DUs with concerns of economic feasibility. This includes a higher implementation cost when comparing digital printing, the most mentioned option, with rotogravure printing. For other DUs, where Type II activity was not dominant, it was not seen to be an option.

Thus, based on the discussion above, the following impacts will be considered for the most-likely NUS A:

- Additional investment costs (one-off cost)
- Additional operating costs
- Foregone profits for one year
- Job dismissals
- Changes in product quality
- Changes in the market price for end consumers
- Changes in customer retention and market position

To see the number of responses obtained per sub-question, please check section 8.2.3.1 in the Appendix.

4.6.2.1.4 NUS B - Outsourcing of chromium trioxide coated gravure cylinders from outside the EEA

This NUS describes the responses from the DUs that considered outsourcing the affected production activity to an external supplier outside the EEA in case an authorisation for use 2 is refused. This implies that the affected products can still be sold in the regional market by them – where a temporary supply disruption may or may not hinder production depending on the time required by them to adapt to this scenario. This supply disruption could occur as a result of, for example, the time to find a subcontractor for the service DUs would like to outsource and the lead time required by the subcontractor. This would not only influence any supply disruption but also the subsequent profit losses that might occur in this scenario.

Discussion of results

A total of 7 DUs i.e., 11% of respondents mentioned this NUS as their most-likely NUS (rank=1). It was observed that most Type II DUs (n=5) as compared to Type I (n=2) chose NUS B. This covers approximately 14% and 8% of all Type II and Type I DUs respectively. This option was not chosen by any Type III DU.

Most Type II and all Type I DUs chose that they would outsource the production of coated cylinders from outside the EEA. Majority of DUs, irrespective of type, chose that less than one year would be required to find a suitable supplier but 2 Type II DUs mentioned a duration of 1 – 5 years. It was further indicated by 6 DUs that this scenario can entail supply disruption till the external supplier has additional capacities for production. However, an anticipated duration for such an extension was not asked in the survey. Further, most DUs could not anticipate based on current practices if they would maintain a positive profit margin based on NUS B as their most-likely NUS.

In summary, it can be concluded that Type I and Type III DUs are service providers of rotogravure cylinders applied in diverse printing industrial segments. Each industrial segment mandates process requirements different from each other. These requirements are governed by the characteristics that the final product must have. Where for Type II DUs it may be easier to define the end-use of their product, all Type I and III DUs may not be able to define the characteristics of the final product due to lack of contact with the end customer. To define a one-stop alternative solution without production interruption that covers all the requirements for all industrial segments is a dilemma that K. Walter's DUs will still face, despite outsourcing the affected production.

Thus, based on the discussion above, the following impacts will be considered for the most-likely NUS B:

- Additional investment costs (one-off cost)
- Additional operating costs
- Foregone profits for one year
- Job dismissals
- Changes in product quality

- Changes in the market price for end consumers
- Changes in customer retention and market position

To see the number of responses obtained per sub-question, please check section 8.2.3.2 in the Appendix.

4.6.2.1.5 NUS C - Relocation of chromium trioxide coated gravure cylinder production to a non-EEA country

This NUS describes the responses from the DUs that considered relocation of the affected production activity outside the EEA if an authorisation for use 2 is refused. This situation would require the DUs to define the level of their process – intermediate (coating of gravure cylinders) or final (printed consumer product), the production of which they would like to relocate - meaning that they would either relocate only part of their production where gravure cylinders are coated outside the EEA and imported back or their complete production process where the coated cylinder as well as the final printed product is produced outside the EEA or only the final printed product or the marketed/consumer product is imported back into the EEA. This could depend on their already existing business activities associated with the use of chromium trioxide. Additionally, the feasibility of this scenario would depend on the timeframe that they would require to relocate their production outside the European economic area.

Discussion of results

8 DUs, i.e., 13% of respondents mentioned this NUS as their most-likely NUS (rank=1). It was observed that most Type I DUs (n=4) followed by Type II (n=3) and Type III (n=1, Type II as main activity) chose NUS C as their most-likely NUS. This covers approximately 17%, 8% and 10% of all Type I, Type II and Type III DUs respectively.

Equal number of DUs chose between relocating the coating process and relocating all processes outside the EEA. While the majority of Type II DUs chose the former, equal number of Type I DUs chose both the options. Given their service line, all processes could be assumed either equivalent to only coating of cylinders or other service lines on which their remaining revenue stream relies on. A Type III DU opted to relocate all processes outside the EEA and import the final product only. From the answers obtained, the arithmetic mean of the estimated time required for such a relocation was 3.5 years in a range of 1 to 10 years[15]. Some DUs opted to relocate to Asia implying additional transportation costs related to this scenario while others indicated that such a forecast could not be decided based on current business practice. Only one Type II DU indicated relocation of business activities in Europe whilst mentioning additional costs.

In summary, most of the DUs that selected this option seem to have a total annual revenue between EUR 10 – 100 million including Type I and II DUs. The Type III DU has a total annual revenue of >EUR 100 million. Conclusively, while these DUs seem to have the financial resources to pursue such a scenario, for others this option was not amongst the most favored. However still, based on the discussion above, the following impacts have been indicated for the most-likely NUS C:

[15] Please refer to Table 105 for answers obtained to this question

- Additional investment costs (one-off cost)
- Additional operating costs
- Foregone profits for one year
- Job dismissals
- Changes in product quality
- Changes in the market price for end consumers
- Changes in customer retention and market position

To see the number of responses obtained per sub-question, please check section 8.2.3.3 in the Appendix.

4.6.2.1.6 NUS D - Temporary shutdown of chromium trioxide coated gravure cylinder production in the EEA until an alternative is implemented

This NUS describes the responses from the DUs that considered a temporary shutdown of affected production activity in the EEA until an alternative is implemented, if an authorisation to use 2 is refused. This implies that the affected products will temporarily not be sold in the regional market by them. The feasibility of this scenario will depend on the probable timeframe of the supply disruption that could be caused by the temporary shutdown of the DU activities in the European economic area. Additionally, efforts in terms of implementation of an alternative, consequently accounting for the duration of this supply disruption, will influence the feasibility of this scenario.

<u>Discussion of results</u>

13 DUs i.e., approximately 20% of respondents mentioned this NUS as their most-likely NUS (rank=1). It was observed that most Type I DUs (n=6) as compared to Type II (n=4) and Type III (n=3) chose NUS D. This covers 25%, 11% and 30% of all Type I, Type II and Type III DUs respectively. It is to be noted here that approximately 62% of DUs who chose NUS D as their most-likely NUS have a >50% share of revenues related to use 2 attributing packaging as the industrial segment for their highest source of revenue.
DUs that opted for this NUS were asked to define the period of supply interruption under this scenario. 8 DUs indicated a supply disruption of <1 year and 4 DUs indicated an interruption of 1 – 5 years. One Type I DU indicated a supply interruption of >10 years. Some DUs that opted for <1 year mentioned that, since an alternative is currently in the development stage, it is currently unclear if it can be accepted as a widely used alternative. Generally, this would depend on the capacity from K. Walter and time needed to finalise development and provide enough machines to the market given its capacity constraints. The DU further added that due to this uncertainty still, if an alternative were to be missing for several months and the use of chromium trioxide is not authorized, printing plate production would not be possible in the EEA and engravers (all DUs) would lose their businesses.

When asked if these DUs would be able to retain the lost market share or remain competitive in the EEA after such a supply disruption, 9 DUs answered that they cannot decide based on current practices and 4 DUs chose 'No' as an option. No DU selected 'Yes'.

In summary, it can be interpreted that these DUs, that do not have the resources to invest in other options and prefer to temporarily shut down their affected production consider this scenario as a risk to business continuity. Based on the discussion above, following impacts will be considered for the most-likely NUS D:

- Additional investment costs (one-off cost)
- Additional operating costs
- Foregone profits for one year
- Job dismissals
- Changes in product quality
- Changes in the market price for end consumers
- Changes in customer retention and market position

To see the number of responses obtained per sub-question, please check section 8.2.3.4 in the Appendix.

4.6.2.1.7 NUS E - Permanent shutdown of chromium trioxide coated gravure cylinder production in the EEA

This NUS describes the responses from the DUs that considered permanent shutdown of affected production activity in the EEA if an authorisation to use 2 is refused. This implies that the affected products will no longer be sold in the regional market by them. This could mean one of the following options – if dependent entirely on rotogravure printing, either all their business would be lost, and the firm would close, or the DUs would switch to another existing or new business activity.

Discussion of results

27 DUs i.e., 42% of respondents mentioned this NUS as their most-likely NUS (rank=1). It was observed that most Type II DUs (n=16) as compared to Type I (n=7) and Type III (n=4) chose NUS E. This covers approximately 44%, 29% and 40% of all Type II, Type I and Type III DUs respectively. Some DUs further justified their choice of NUS by commenting that in case no alternatives are available, and an authorisation is refused, this NUS would be their only available option.

DUs that opted for this NUS were asked if they would consider this scenario as insolvency. 24 DUs responded that their entire business will be lost, majority being Type II. It can be interpreted that these DUs, that do not have the resources to invest in other options and thus prefer to permanently shut down their affected production. Only 3 DUs responded that they cannot decide based on current practices.

Thus, based on the discussion above, the following impacts will be considered for the most-likely NUS E:

- Additional investment costs (one-off cost)
- Foregone profits for one year
- Job dismissals

To see the number of responses obtained per sub-question, please check section 8.2.3.5 in the Appendix.

4.6.2.2 Most likely NUS for K. Walter for Use 2

In case the authorization for use 2 of chromium trioxide is refused, K. Walter's DUs will no longer require the use of machines for coating of rotogravure cylinders provided by K. Walter. As most DUs either shut down or seek outsourced products or relocate their production outside the EU, rotogravure printing process will not be competitive any more in the EU due to increasing prepress (cylinder) costs.

As K. Walter loses the demand for its use 2 related services in the EEA due to a refused authorisation, it considers relocating its production to outside the EEA where the demand for galvanic machines for coating gravure cylinders with chromium trioxide exists. K. Walter as a system supplier for the rotogravure galvanic process will consequently lose its profits from the sales of electroplating units in the EEA (see Figure 5). The production of gravure printing products will either move out of the EU or will be replaced by other printing technologies and employees will have to be dismissed. Based on the non-EU turnover which will still be a business, the applicant assumes that around 40% of the employees will have to be dismissed. Consequently, the production site of K. Walter could move towards the customers main location (for example Asia). Additional investments involved for K. Walter for relocation amount to approximately EUR [redacted] million in 2021, i.e., a net present value of EUR [redacted] million in 2020 using a social discount rate of 4%.

For Heliograph Holdings, as their rotogravure business is strongly dependent on the sales of the plating units, the brands of the Holding located in the EEA will be negatively affected in case of a refused authorisation for use 2 and will also relocate outside the EEA leading to approximately [redacted] dismissals within the EEA.

Heliograph Holding's subsidiaries will however shutdown in case an authorisation for Use 2 is refused leading to [redacted] dismissals within the EEA.

In summary, in this scenario, depending on the stakeholders, following impacts could ensue:

Table 39: Impacts of the most-likely non-use scenario to a refused authorisation for Use 2

IMPACTS IN USE 2	Formulator	K. Walter	Heliograph Holding	Heliograph Holding's subsidiaries	Downstream users
1. Foregone profits in 2021					
2. Additional investment & operating costs					
3. Job dismissals in 2021					

5 HEALTH IMPACTS OF GRANTING AUTHORISATION

This section monetises the negative health impacts or costs of a granted authorisation where the stakeholders can use chromium trioxide for their production activities within the EEA. These costs of a granted authorisation will be further compared with the benefits of a granted authorisation assessed in chapter 6 below, in order to conclude on the net-benefit of a granted authorisation.

The evaluation of impacts will be carried out for a 12 year review period using 2020 as a base year for all calculations.

The assessment of impacts in this AfA is independent of the CTAC coverage implying that impacts are foreseen to occur immediately following a refused authorisation without considering if the applicant is covered under CTAC or not.

For further reference to these health impacts of continued use of chromium trioxide, please refer to section 3.8 and section 3.9.

5.1 USE 1

5.1.1 Human health impacts of continued use of chromium trioxide

Table 40 shows the number of fatal lung cancer cases that could accrue in case an authorisation is granted for use 1. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 40: Fatal Lung cancer cases in use 1

	Excess fatal lung cancer risk[2]	**Number of exposed people**	**Estimated statistical fatal lung cancer cases**	**Statistical fatal lung cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR**[1] (lower bound – upper bound)
Workers and general population					
Directly exposed workers[3]	1.15E-03	13	7.21E-04	2,835,896 - 4,764,776	218 - 366
Indirectly exposed workers[4] and local population	4.47E-08	10,000	7.66E-05	2,835,896 - 4,764,776	23 - 39
Total	**1.15E-03**	**-**	**7.97E-04**		**241 – 405**
Latency (years)	10 years				

Notes (valid for all the following tables in this chapter):

1. Annualised to a typical year based on the time horizon used in the SEA;

2. Excess risk is estimated over a lifetime working exposure (typically 40 years) and via the environment over a typical lifetime exposure (typically 70 years);
3. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8 hour Time Weighted Average (TWA) of a representative worker;
4. Indirectly exposed workers (bystanders) do not use the substance;

Table 41 shows the number of non-fatal lung cancer cases that could accrue in case an authorisation is granted for use 1. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 41: Non-fatal lung cancer cases in use 1

	Excess non-fatal lung cancer risk	**Number of exposed people**	**Estimated statistical non-fatal lung cancer cases**	**Statistical non-fatal lung cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR[1]** (lower bound – upper bound)
Workers and general population					
Directly exposed workers[3]	3.71E-04	13	2.31E-04	297,370 - 361,101	7 - 9
Indirectly exposed workers[4] and local population	1.43E-08	10,000	2.46E-05	297,370 - 361,101	1
Total	**3.71E-04**	**-**	**2.56E-04**		**8 - 10**
Latency (years)	10 years				

Table 42 shows the number of fatal intestinal cancer cases that could accrue in case an authorisation is granted for use 1. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 42: Fatal intestinal cancer cases in use 1

	Excess fatal intestinal cancer risk	**Number of exposed people**	**Estimated statistical fatal intestinal cancer cases**	**Statistical fatal intestinal cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR[1]** (lower bound – upper bound)
General population					
Local population	2.51E-09	10,000	4.31E-06	1,514,108 € - 3,470,881 €	1 - 2
Total	**2.51E-09**	**-**	**4.31E-06**		**1 - 2**
Latency (years)	26 years				

Table 43 shows the number of non-fatal lung cancer cases that could accrue in case an authorisation is granted for use 1. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 43: Non-fatal intestinal cancer cases in use 1

	Excess non-fatal intestinal cancer risk[2]	**Number of exposed people**	**Estimated statistical non-fatal intestinal cancer cases**	**Statistical non-fatal intestinal cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR[1]** (lower bound – upper bound)
General population					
Local population	2.70E-09	10,000	4.63E-06	158,768 - 263,043	0.08 - 0.13
Total	**2.70E-09**	**-**	**4.63E-06**		**0.08 - 0.13**
Latency (years)	26 years				

5.2 USE 2

This section shows the details of the summarised health impact assessment tabularised in section 3.9.2, Table 32.

5.2.1 Human health impacts of continued use of chromium trioxide

Table 44 shows the number of fatal lung cancer cases that could accrue in case an authorisation is granted for use 2. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 44: Fatal Lung cancer cases in use 2

	Excess fatal lung cancer risk[2]	**Number of exposed people**	**Estimated statistical fatal lung cancer cases**	**Statistical fatal lung cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR**[1] (lower bound – upper bound)
Workers and general population					
Directly exposed workers[3]	2.96E-03	657	3.51E-01	2,835,896 - 4,764,776	106,113 – 178,287
Indirectly exposed workers[4] and local population	1.71E-05	1,170,000	3.42E+00	2,835,896 - 4,764,776	1,033,468 - 1,736,398
Regional population	1.27E-14	447,700,000	9.72E-07	2,835,896 - 4,764,776	0.29 - 0.49
Total	**2.97E-03**	**-**	**3.77E+00**		**1,139,581 - 1,914,685**
Latency (years)			10 years		

Notes (valid for all the following tables in this chapter):

1. Annualised to a typical year based on the time horizon used in the SEA;
2. Excess risk is estimated over a lifetime working exposure (typically 40 years) and via the environment over a typical lifetime exposure (typically 70 years);
3. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8 hour Time Weighted Average (TWA) of a representative worker;
4. Indirectly exposed workers (bystanders) do not use the substance;

Table 45 shows the number of non - fatal lung cancer cases that could accrue in case an authorisation is granted for use 2. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 45: Non-fatal lung cancer cases in use 2

	Excess non-fatal lung cancer risk	**Number of exposed people**	**Estimated statistical non-fatal lung cancer cases**	**Statistical non-fatal lung cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR[1]** (lower bound – upper bound)
Workers and general population					
Directly exposed workers[3]	6.85E-04	657	8.13E-02	297,370 - 361,101	2,576 - 3,128
Indirectly exposed workers[4] and local population	3.95E-06	1,170,000	7.92E-01	297,370 - 361,101	25,090 - 30,468
Regional population	2.93E-15	447,700,000	2.25E-07	297,370 - 361,101	0.007 - 0.009
Total	**6.88E-04**	**-**	**8.73E-01**		**27,666 – 33,596**
Latency (years)			10 years		

Table 46 shows the number of fatal intestinal cancer cases that could accrue in case an authorisation is granted for use 2. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 46: Fatal intestinal cancer cases in use 2

	Excess fatal intestinal cancer risk	**Number of exposed people**	**Estimated statistical fatal intestinal cancer cases**	**Statistical fatal intestinal cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR[1]** (lower bound – upper bound)
General population					
Local population	7.79E-10	1,170,000	1.56E-04	1,514,108 - 3,470,881	25 - 58
Total	**7.79E-10**	**-**	**1.56E-04**		**25 - 58**
Latency (years)			26 years		

Table 47 shows the number of non - fatal intestinal cancer cases that could accrue in case an authorisation is granted for use 2. It further summarises this risk as a monetised value to be used in the final benefit – risk evaluation of granting this authorisation.

Table 47: Non-fatal intestinal cancer cases in use 2

	Excess non-fatal intestinal cancer risk[2]	**Number of exposed people**	**Estimated statistical non-fatal intestinal cancer cases**	**Statistical non-fatal intestinal cancer case in EUR** (lower bound – upper bound)	**Monetised excess risk per year in EUR**[1] (lower bound – upper bound)
General population					
Local population	8.34E-10	1,170,000	1.67E-04	158,768 - 263,043	2.83 - 4.69
Total	**8.34E-10**	**-**	**1.67E-04**		**2.83 - 4.69**
Latency (years)			26 years		

6 AVOIDED IMPACTS OF GRANTING AUTHORISATION[16]

The following impact assessment of a granted authorisation describes avoided negative impacts on human health as well as avoided socio-economic impacts of a continued use of chromium trioxide over the requested review period based on the most-likely non-use scenarios for each stakeholder involved. Thus, an analysis of the i) monetised health impacts and ii) socio-economic impacts avoided is presented here to allow an easier evaluation of the benefits of a granted authorisation. The combined assessment of all impacts will compare these avoided impacts or benefits of a granted authorisation with the negative human health of using chromium trioxide or costs of a granted authorisation, assessed in chapter 5, in order to conclude on the net-benefit of a granted authorisation.

The aim of this analysis is to support the findings of the qualitative description, where it has been concluded that the benefits of continued use of chromium trioxide would be substantial, while the remaining risks are well managed and limited, following the authorisation.

The evaluation of impacts will be carried out for a 12 year review period using 2020 as a base year for all calculations.

The assessment of impacts in this AfA is independent of the CTAC coverage implying that impacts are foreseen to occur immediately following a refused authorisation without considering if the applicant is covered under CTAC or not.

6.1 Use 1

6.1.1 Avoided additional health impacts to DUs due to a refused authorisation for formulation use

It is clear that in case an authorisation for use 1 is granted, potential health impacts can be derived from the exposure during the formulation activities. However, if an authorisation for use 1 (formulation) is NOT granted, there is potential of increased health impacts to the DUs due to the use of solid chromium trioxide (salts) instead of liquid formulations currently used in the applied for use scenario.

The additional impacts due to use of solid chromium trioxide in case an authorisation for the use of pre-formulated liquid chromium trioxide for use by DUs is refused, is perceived as the difference between health impacts due to adding solid CrO3 to the machines and health impacts due to usual use of pre-formulated liquid CrO3. The reason for an increased health risk due to the use of solid CrO3 is explained below.

The use of solid CrO3 is generally combined with a range of additional process steps in which exposure might occur or exposure is at least not as strictly controlled compared to the use of liquid CrO3. These include transport of drums to the laboratory/scale, aliquoting of material, opening of drums at the respective side, weighing of solid CrO3, potential cleaning of contaminated and emptied drums, cleaning of PPE and disposal of solid waste. Additionally, work with solid CrO3 would lead to potential for dust formation. Compared

[16] The following sections address the impacts of granting an authorisation in terms of impacts that will be incurred by the stakeholders due to a refused authorisation. These impacts can be perceived as impacts that will be avoided in case of a granted authorisation.

with the use of liquid CrO3, no dust formation or high temperatures for gas formation is expected due to a more contained work environment involving only change to intermediate bulk containers (IBCs)and other short tasks. For further justifications, please refer to section 9.1.3 in the CSR.

The explanation above justifies an additional health risk due to a refused authorisation to the use of formulating liquid chromium trioxide. Monetisation of such an impact however remained difficult due to lack of data on the above mentioned process steps.

The table below shows the stakeholders for which this impact is anticipated.

Table 48: Avoided health impacts of a granted authorisation to use 1

IMPACTS IN USE 1	Formulator	K. Walter	Heliograph Holdings	Heliograph Holdings' subsidiaries	Downstream users
Health impacts for 12 years					

6.1.2 Economic Impacts

In the following, benefits of a granted authorisation for use 1 are quantified in terms of economic impacts incurred due to a refused authorisation, according to the most realistic non-use scenario. In order to minimise any possible uncertainties related to this assessment, the quantified impacts have been mostly observed from the perspective of K. Walter.

For the calculation of impacts in both uses, the annual EBIT value forecasted in the applied for use scenario in 2021 is considered to represent the foregone profits and discounted to the base year 2020 at a 4% discount rate. In order to take into account all positive and negative effects of a non-granted authorisation, the applied for use scenario is compared with the assumptions made for the most likely NUS for use 1.

Economic impacts discussed in this section will include the following:

Table 49: Economic impacts avoided due to a granted authorisation for use 1

IMPACTS IN USE 1	Formulator	K. Walter	Heliograph Holdings	Heliograph Holdings' subsidiaries	Downstream users
Foregone profits in 2021					

A. Formulator

Under the most-likely non-use scenario for USE 1, for the formulator, all profits pertaining to liquid formulations supplied to the applicant will be foregone. The impact has not been monetised due to a lack of information from the formulator.

B. Applicant

Foregone profits

In the most realistic non-use scenario for use 1 (NUS B: Exclusive use of solid chromium trioxide salts), almost 100% of the forecasted annual EBIT value in 2021 is considered to represent foregone profits related to the loss in sale of the liquid chromium trioxide mixtures or formulations. This is based on the assumption that in case of a non-granted authorisation, the applicant's sales of solid chromium trioxide salts to DUs will be significantly low as there are many suppliers of the salts in the market and K. Walter will not have a unique selling proposition.

All calculations were made according to the following assumptions:

- Profit loss for only one year is taken into consideration based on standard practice.
- The impact realisation period begins in 2021
- 2018 has been considered as a representative year for K. Walter's business. Therefore, assuming constant future profits, profits accrued in 2018 are projected to 2021 for this assessment.

In case of a refused authorisation for use 1, K. Walter assumes that approximately EUR [redacted] million will be lost in profits in 2021[17]. The value has been discounted to the base year 2020 at a 4% social discount rate.

Table 50: Foregone profits for K. Walter in case of a refused authorisation for use 1

	Foregone profits for K. Walter [in EUR million]
Foregone profits related to Use 1 in 2021	[redacted]
NPV in 2020	[redacted]

C. Heliograph Holding and its subsidiaries

Foregone profits for Heliograph Holding

In case of a refused authorisation for use 1, Heliograph Holding will not have any economic impacts, as the brands of the holdings in the EEA are not involved in business of mixtures or formulations containing chromium trioxide.

Foregone profits for Heliograph Holding's subsidiaries

The subsidiaries located in the EEA, on the other hand, will incur foregone profits related to business of the mixtures or formulations. These losses, however, were seen as insignificant compared to losses for other stakeholders and thus, were not included in the assessment.

[17] This value is the forecasted value for 2021. The forecast is higher as compared to 2019 (EUR 0.2 million) due to expected higher market share.

D. DUs

Under USE 1, no major economic impacts are foreseen on the DUs as the supply of chromium trioxide for production of gravure cylinders will be maintained in the form of solid CrO3 salts. However, health impacts due to exposure of workers to solid chromium trioxide is foreseen and elaborated in section 5.1. Price differences between solid and liquid chromium trioxide have been considered to cancel the effect of any cost savings in the non-use scenario due to additional operational efforts required with the use of solid chromium trioxide salts.

Total economic impacts in USE 1

Summing up the impacts of a non-granted authorisation for use 1 in terms of foregone profits, the total economic impacts under the use 1 amount to EUR [redacted] million, as shown in Table 51.

Table 51: Total economic impacts under use 1

Economic impact factors	NPV 2020 [EUR million]
Foregone profits for K. Walter	[redacted]
Foregone profits for the Heliograph Holding	[redacted]
Foregone profits for Heliograph Holding's subsidiaries	[redacted]
Foregone profits for DUs	[redacted]
TOTAL	[redacted]

Thus, the total economic impacts due to a refused authorisation for Use 1 will amount to a net present value of EUR 0 – 1 [redacted] million in 2020, discounted at a standard social discount rate of 4%.

6.1.3 Social Impacts

Following the methodology presented in a report commissioned by ECHA (33), the social costs related to expected job losses in the most realistic NUS are valued under consideration of the following components:

- The value of lost output/wages during the period of unemployment
- The cost of acquiring a new job
- Recruitment costs
- The "scarring costs" (i.e. the impact of being made unemployed on future earnings and employment possibilities)
- The value of leisure time during the period of unemployment

The latter component is defined as a negative cost (i.e. a benefit) of unemployment. As such it is subtracted from the total cost resulting from the first four components.

The figures from the aforementioned paper have been updated with most recent data for 2019, using information on wages presented by Rogers and Philippe in 2019 (34) and using most recent data on the duration of unemployment in 2019 as reported by Eurostat (35). Moreover, the figures for average wages were projected to 2020 using the 5 years average of inflation rates provided by Eurostat.

The calculated social costs of non-authorisation, discounted to the base year of 2020 (end of year) using a social discount rate of 4%, is summarised in Table 53.

According to the most likely non-use scenario for use 1 in case an authorisation is refused, K. Walter will switch to supply solid CrO3 salts to its DUs. The social impacts of this most-likely NUS discussed in this section will include the following:

Table 52: Social impacts due to a refused authorisation to use 1

IMPACTS IN USE 1	Formulator	K. Walter	Heliograph Holding	Heliograph Holding's subsidiaries	Downstream users
Job dismissals in 2021					

The applicant estimates that approximately [redacted][18] employees in Germany will have to be dismissed in 2021 if no authorisation title can be granted for use 1.

Table 53: Social impact of employee dismissals at K. Walter in use 1

	Costs [EUR]	**Number of jobs affected**	**Total cost** [EUR]
Unemployment social cost of one job position in **Germany** adjusted to **2020** values (in EUR)	123,317[19]	[redacted]	[redacted]

As described above, social costs of unemployment incurred at the applicant's site can be valued at approximately EUR 1 – 5 [redacted] million.

As a result of refused authorisation to use 1, no job dismissals at Heliograph Holdings and its subsidiaries are foreseen. Job dismissals at the formulator are unknown since no information was available at the time of this AfA.

[18] The number of employees dismissed is based on the reduced total annual turnover, which needs to be compensated. If other effects can compensate the losses from use 1 it would affect less employees down to a minimum of 5. 5 Jobs are directly involved with use 1 and would have to be dismissed.

[19] The value of 1 lost job in Germany was extrapolated from 2016 to 2020 using the average of the inflation rates of last 5 years (2016-2020) in Germany. The data was obtained from Eurostat. Thus, average inflation rate of 1.18% was derived using last 5 years' inflation rates of 0.38%, 1.71%, 1.95%, 1.35% and 0.50%.

Total impacts for use 1

Table 54 shows the total impacts in case an authorisation is for use 1 is refused.

Table 54: Total avoided impacts for use 1 in case of a granted authorisation

Cost item	NPV 2020 [in EUR million]
Avoided Health impacts	Not quantified
Avoided economic impacts	[redacted]
Avoided social impacts	[redacted]
TOTAL	[redacted]

As shown above, the total impacts in the EEA in case an authorisation is not granted for use 1 are estimated to be EUR 1 – 5 [redacted] million.

6.2 Use 2

This section monetises the impacts of the individual most-likely non-use scenarios in the EEA for each stakeholder in case an authorisation to use 2 is refused.

6.2.1 Health Impacts

As a result of a refused authorisation, no health impacts are foreseen on the workers at the DUs in the EEA as the affected production either shuts down or is moved outside the EEA (see section 4.6.2.1). Hence, it can be said that in the EEA, the health impacts to workers and the neighbouring population due to the most-likely NUS for the DUs is seen to be zero in case an authorisation to use 2 is refused.

6.2.2 Avoided Economic Impacts

In the following, benefits of a granted authorisation for use 2 are quantified in terms of economic impacts incurred due to a refused authorisation, according to the most realistic non-use scenario for each stakeholder involved.

For the calculation of impacts in both uses, the annual EBIT value forecasted in the applied for use scenario in 2021 is considered to represent the foregone profits and discounted to the base year 2020 at a 4% discount rate. In order to take into account all positive and negative effects of a non-granted authorisation, the applied for use scenario is compared with the assumptions made for the most likely NUS for use 2.

The economic impacts discussed in this section will include the following:

Table 55: Economic impacts avoided due to a granted authorisation for use 2

IMPACTS IN USE 2	Formulator	K. Walter	Heliograph Holding	Heliograph Holding's subsidiaries	Downstream users
Foregone profits in 2021					
Additional investment & operating costs					

A. Formulator

In case an authorisation for use 2 is refused, K. Walter's DUs can no longer perform chromium trioxide related plating activities in the EEA. For the formulator this would imply that all profits pertaining to liquid formulations supplied to the applicant will be foregone. The impact has not been monetised due to a lack of information from the formulator.

B. Applicant

<u>Foregone profits for K. Walter due to relocation of production activities outside the EEA</u>

In case an authorisation for use 2 is refused, K. Walter's DUs can no longer perform chromium trioxide related plating activities in the EEA. Data from the DU survey shows that different DUs prefer different most-likely NUSs. As discussed in section 4.6.2.1.7, in this case, K. Walter would relocate its production activities outside the EEA and incur a profit loss of at least one year until the relocation is completed.

To calculate the profits foregone in 2020, the following assumptions were made:

- Profit loss for only one year is taken into consideration based on standard practice.
- The impact realisation period begins in 2021
- This evaluation of K. Walter's loss in profits is deduced from the profit values of all supplies of mixtures or formulations as well as galvanic machines to the DUs.

K. Walter, however, anticipates that approximately EUR [redacted] million[20] will be lost in profits in the EEA (EBIT value) in 2021 due to a refused authorisation for Use 2. The value has been discounted to the base year 2020 at a 4% discount rate in Table 56.

Table 56: Foregone profits for K. Walter in case of a non-granted authorisation for use 2

Cost item	[in EUR million]
Foregone profits in 2021	[redacted]
NPV in 2020	**0 – 1 [redacted]**

C. Heliograph Holding and its subsidiaries

In case an authorisation for Use 2 is refused, profit losses for Heliograph Holding and its subsidiaries are foreseen as it closely connected in K. Walter's supply chain. Please refer to Figure 3 to see the flow of activities between the Heliograph Holding, its subsidiaries and K. Walter. A final product cannot be produced without any of these firms/supply chain actors. As discussed in section 4.6.2.1.7, in this case, the Heliograph Holding would also relocate its production activities outside the EEA and the subsidiaries would permanently shut down their business activities. The associated entities are thus foreseen to incur profit losses of at least one year.

To calculate the profits foregone in 2020, the following assumptions were made:

- Profit loss for only one year is taken into consideration based on standard practice.
- The impact realisation period begins in 2021

Foregone profits for Heliograph Holding due to relocation of production activities outside the EEA

This evaluation of Heliograph Holding's loss in profits applies to the losses incurred by Hell, Schepers and Bauer only. It should be noted that this value does not include EBIT estimates for K. Walter.

The Heliograph Holding anticipates that approximately EUR [redacted] million will be lost in profits (EBIT value) within EEA in 2021 due to a refused authorisation for Use 2. The value has been discounted to the base year 2020 at a 4% discount rate in Table 57.

[20] EUR 0.9 million only depicts the profit losses in the EEA as compared with EUR 2.2 million of global annual profits shown in Figure 5.

Table 57: Foregone profits for the brands of Heliograph Holding located in the EEA (excluding K. Walter) in case of a refused authorisation for use 2

Cost item	[in EUR million]
Foregone profits in 2021	[redacted]
NPV in 2020	**1 – 5 [redacted]**

Foregone profits for the subsidiaries due to a permanent shutdown of the affected activities

This evaluation of Heliograph Holding's subsidiaries' loss in profits is deduced from the profit values of all supplies of mixtures or formulations as well as galvanic machines for chrome plating to the DUs.

Heliograph Holding anticipates that approximately EUR [redacted] million will be lost in profits (EBIT value) within the EEA in 2021 due to a refused authorisation for Use 2. The value has been discounted to the base year 2020 at a 4% discount rate in Table 58.

Table 58: foregone profits for the subsidiaries located in the EEA in case of a non-granted authorisation for use 2

Cost item	[in EUR million]
Foregone profits in 2021	[redacted]
NPV in 2020	**0 – 1 [redacted]**

D. Downstream users

This section evaluates the avoided economic impacts of a granted authorisation. These impacts have been listed as economic impacts that would incur if an authorisation is refused. To assess these impacts for the DUs, corresponding results from the survey were aggregated for each most-likely NUS in case an authorisation for use 2 is refused.

Two variables were included to enquire about economic impacts of the most-likely NUS for each DU. Options were provided to state the impacts qualitatively and quantitatively in the form of non-confidential ranges. It was specified in the questionnaire that impacts should be strictly provided for their business in the EEA only. After the first round of questions, respondents that did not provide the figures for changes in investment and operation cost due to a refused authorisation, were contacted for further clarification.

Each DU was then asked to choose among the following options corresponding to their most-likely NUS only.

1. Impact on investment cost (one-off cost)

Qualitative impact		Quantitative impact
Increase	by	< EUR 10,000
Decrease		EUR 10,000 – 100,000
No change		EUR 100,000 – 1,000,000

		>EUR 1,000,000

2. Increase, decrease or no change in operating cost per year

Qualitative impact		Quantitative impact
Increase		< EUR 10,000
Decrease	by	EUR 10,000 – 100,000
No change		EUR 100,000 – 1,000,000
		>EUR 1,000,000

3. Qualitative impact on the quality of product was asked by providing an option to choose between the following:
    - Enhanced product quality
    - Poor product quality that is acceptable in the market
    - Poor product quality unacceptable in the market
    - No change
    - Other (to specify)

4. Qualitative impact on the market price of the product for each DU's final customer was asked by providing an option to choose between the following:
    - Increase, decrease or no change

5. Qualitative impact on customer/consumer retention was asked by providing an option to choose between the following:
    - Yes, No or no change

The subsequent sub-sections will show an analysis of the results obtained for the above-mentioned variables and summarise them, clustered for each most-likely NUS chosen by the DUs. For this purpose, the following adjustments were made. As each quantified variable answered by the DU was in non-confidential ranges, as a first step, these ranges were split into a lower and upper bound.

- If the chosen quantitative impact within the EEA was <EUR 10,000 a lower and upper bound of 0 and EUR 10,000 was assumed respectively
- If the chosen quantitative impact within the EEA was >EUR 100 million, a lower and upper bound of EUR 100 million each was taken, assuming that the DU will have an impact of at least at least EUR 100 million

This separation has been shown in the calculation for impacts due to each most-likely NUS in the subsequent sections. These ranges were aggregated for the total number of respondents who chose a particular range for the corresponding question. The approach has been applied consistently for all variables mentioned above.

It should be noted that DUs that provided qualitative answers did not necessarily provide a quantitative answer. Therefore, the number of respondents for qualitative answers might differ from the number of respondents for a quantitative answer.

It should be noted here that the approach described above is cautiously derived to avoid any overestimation by including a lower and upper bound wherever possible. The provision of such a range reduces the uncertainty associated with a single aggregated estimate, excluding a sensitivity analysis.

D.1 Economic impact due to most-likely NUS A[21]

11% of DUs (7 out of 64) chose NUS A as their most-likely NUS. Table 59 shows additional investment costs of at least EUR 3 million and additional operating costs between EUR 2.1 – 3 million aggregated for these DUs in 2021 due to a refused authorisation. Please note that not all 7 DUs who chose NUS A as their most-likely NUS, provided input on the corresponding impacts. The costs in Table 59 are, however considered to be representative of all 7 DUs who chose NUS A as their most likely NUS. Please refer to section 8.2.3.1 and section 8.2.4.1 for aggregation of these costs.

Table 59: Aggregated economic impact for DUs to most-likely NUS A

Cost item	Cost incurred in 2021 [in EUR million]	
	Lower bound	Upper bound
Aggregated additional investment costs (one-off costs) (for instance, additional costs of implementing a new process, performance testing)	**3**	
Aggregated additional operating costs per year (for instance, additional costs of procurement)	**2.1**	**3**
Total	**5.1**	**6**

Most DUs selected increase in investment and operating costs as a result of this scenario. Only one DU selected decrease in investment and operating cost respectively. Further impacts will be seen as an increase in market price for the product and increase in customers moving to non-EEA suppliers if the DUs switch to a more expensive technology as compared to rotogravure. It should however be noted that the DU that opted for decrease in investment and operating costs chose flexography as an alternative printing technology but mentioned that the scenario will, however, lead to a poor product quality unacceptable in the market increasing the market price for the product. A decrease in costs albeit unacceptable product quality does not seem to be a feasible option for business continuity. Still, this decrease in investment and operating costs has been included in the final evaluation of economic impacts for NUS A.

D.2 Economic impact due to most-likely NUS B[22]

11% of DUs (7 out of 64) chose NUS B as their most-likely NUS. Table 60 shows additional investment costs between EUR 2.3 - 5 million and additional operating costs between EUR 1.1 – 2.3 million for these DUs in 2021 due to a refused authorisation. Please note that not all 7 DUs who chose NUS B as their most-likely NUS, provided input on the corresponding impacts. The costs in Table 60 are, however considered to be representative

[21] NUS A - Switching to an already available printing technology (see section 4.6.2.1.3). A total of 7 DUs i.e., 11% of respondents chose this NUS.

[22] NUS B – Outsourcing of chromium trioxide coated gravure cylinders outside the EEA (see section 4.6.2.1.4). A total of 7 DUs i.e., 11% of respondents chose this NUS.

of all 7 DUs who chose NUS B as their most-likely NUS. Please refer to section 8.2.3.2 and section 8.2.4.2 for aggregation of these costs.

Table 60: Aggregated economic impact for DUs to most-likely NUS B

Cost item	Cost incurred in 2021 [in EUR million]	
	Lower bound	Upper bound
Aggregated additional investment costs (one-off costs) (for instance, additional costs of finding a new supplier, quality assurance)	**2.3**	**5**
Aggregated additional operating costs per year (for instance, additional costs of transportation, storage, higher costs of supply procured)	**1.1**	**2.3**
Total	**3.4**	**7.3**

Most DUs selected increase in investment and operating costs as a result of this scenario. Only one Type II DU selected decrease in operating cost. Only this DU selected that it would outsource the final rotogravure based printed product into the EEA and not the coated cylinders. However, in the next sub-question, the DU specified that the former is not cheaper than the latter. The decrease in operating costs mentioned by this DU has been taken into account while aggregating the total costs for this scenario.

When asked about the impact on product quality, some DUs stated that the scenario would result in a poor product quality that is acceptable in the market whereas the majority stated that there will be no change. Most of them stated that further impacts will be seen as an increase in market price for the product. DUs further added that there will be an increase in customers moving to non-EEA suppliers as the DUs in the EEA increase their price as a result of increased costs of outsourcing either coated cylinders or rotogravure based printed products from outside the EEA.

D.3 Economic impact due to most-likely NUS C[23]

13% of DUs (8 out of 64) chose NUS C as their most-likely NUS. Table 61 shows additional investment costs between EUR 3.3 – 6 million and additional operating costs between EUR 3.2 – 5.1 million for these DUs in 2021 due to a refused authorisation. Please note that not all 8 DUs who chose NUS C as their most-likely NUS, provided input on the corresponding impacts. The costs in Table 61 are, however considered to be representative of all 8 DUs who chose NUS C as their most-likely NUS. Please refer to section 8.2.3.3 and section 8.2.4.3 for aggregation of these costs.

[23] NUS C – Relocation of chromium trioxide coated gravure cylinder production to a non-EEA country (see section 4.6.2.1.5). A total of 8 DUs, i.e., 13% of respondents chose this NUS.

Table 61: Aggregated economic impact for DUs to most-likely NUS C

Cost item	Cost incurred in 2021 [in EUR million]	
	Lower bound	Upper bound
Aggregated additional investment costs (one-off costs) (for instance, additional costs of relocation – expansion of own or building a new production facility, decommissioning of EEA facility, quality assurance, training of new staff)	**3.3**	**6**
Aggregated additional operating costs per year (for instance, additional costs of transportation, storage and distribution)	**3.2**	**5.1**
Total	**6.5**	**11.1**

Majority of DUs reported an increase in the investment and annual operating costs as a result of this NUS. A Type I DU justified that it is an engraving company that does not currently have a location outside the EEA. For this NUS, the DU would have to construct an additional site, most likely in Asia leading to additional investment costs of >EUR 1 million. DUs that specified a decrease in investment cost operating cost, were mainly Type I, intermediate service providers. The reasoning behind a decrease was however not mentioned by any of these DUs. Irrespective, this has been included while aggregating the total impact.

Further impacts of this scenario were reported as an increase in market price for the product and increase in customers moving to non-EEA suppliers. Some DUs estimate that relocation of coated cylinder production or the entire printing process outside the EEA may reduce the product quality. However, a DU mentioned that there hardly might be any change due to relocating the process, but strong deviation can be expected if the substance is changed. Another DU quoted that it cannot be assessed at the moment as it will strongly depend on the alternative technology.

D.4 Economic impact due to most-likely NUS D[24]

20% of DUs (13 out of 64) chose NUS D as their most-likely NUS. Table 62 shows additional investment costs between EUR 1.7 – 8.1 million and additional operating costs between EUR 1.2 – 3.4 million for these DUs in 2021 due to a refused authorisation. Please note that not all 13 DUs who chose NUS D as their most-likely NUS, provided input on the corresponding impacts. The costs in Table 62 are, however considered to be representative of all 13 DUs who chose NUS D as their most likely NUS. Please refer to section 8.2.3.4 and section 8.2.4.4 for aggregation of these costs.

[24] NUS D – Temporary shutdown of chromium trioxide coated gravure cylinder production in the EEA until an alternative is implemented (see section 4.6.2.1.6). A total of 13 DUs, i.e., 20% of respondents chose this NUS.

Table 62: Aggregated economic impact for DUs to most-likely NUS D

Cost item	Cost incurred in 2021 [in EUR million]	
	Lower bound	Upper bound
Aggregated additional investment costs (one-off costs) (for instance, additional costs of implementation of alternative)	**1.7**	**8.1**
Aggregated additional operating costs per year (for instance, increased costs of procurement, additional costs of marketing after a temporary shutdown)	**1.2**	**3.4**
Total	**2.9**	**11.5**

Most DUs selected increase in investment and operating costs as a result of this scenario. Further impacts of this scenario were reported as an increase in market price for the product and increase in customers moving to non-EEA suppliers as a result of temporary shutdown of chromium trioxide related use 2 production activities in the EEA until an alternative is implemented. 'Others' who responded to change in product quality as an impact mentioned that the quality cannot be assessed at the moment and depends on the behaviour of other materials.

D.5 Economic impact due to most-likely NUS E[25]

42% of DUs (27 out of 64) chose NUS E as their most-likely NUS. Table 63 shows additional investment costs between EUR 8.3-10.8 million for these DUs in 2021 due to a refused authorisation. Please note that not all 27 DUs who chose NUS E as their most-likely NUS, provided input on the corresponding impacts. The costs in Table 63 are, however considered to be representative of all 27 DUs who chose NUS E as their most likely NUS. Some DUs implied additional operating costs as an impact of this scenario. However, these costs have not been included in the assessment as no justification was provided. Please refer to section 8.2.3.5 and section 8.2.4.5 for aggregation of these costs.

[25] NUS E – Permanent shutdown of chromium trioxide coated gravure production in the EEA (see section 4.6.2.1.7). A total of 27 DUs, i.e., 42% of respondents chose this NUS.

Table 63: Aggregated economic impact for DUs to most-likely NUS E

Cost item	Cost incurred in 2021 [in EUR million]	
	Lower bound	Upper bound
Aggregated additional investment costs (one-off costs) (for instance, additional costs of decommissioning of EEA facility)	**8.3**	**10.8**
Aggregated additional operating costs per year	**-**	**-**
Total	**8.3**	**10.8**

Most DUs selected increase in investment costs as a result of this scenario. Further impacts of this scenario were reported as an increase in market price for the product and increase in customers moving to non-EEA suppliers. An increase in the market price of the product could be a result of higher costs of procurement (in terms of logistics) passed down to the EEA based customers as they shift to non-EEA based suppliers to meet their demand. Majority of the DUs also responded that a permanent shutdown may lead to push towards alternatives resulting in lower product quality in the market. For others, the product would just not be available/manufactured and thus product quality was not seen as an issue. One DU mentioned that there is currently no alternative to making the cylinder surface sufficiently resistant or even printable for the gravure process. In such a case, only cylinders manufactured outside the EU could be used. This DU further implied that gravure printing would have to be discontinued in most central European plants. It was also mentioned that it is not feasible to convert the existing gravure equipment to an alternative printing system for a DU, which would result in the closure of most gravure printing plants. Another DU mentioned that this scenario would lead to a disappearance of rotogravure prints in the EEA.

D.6 Total economic impacts for downstream users

As shown in Table 55, the total economic impacts for DUs in case an authorisation for use 2 is not granted comprise additional investment and operating costs and foregone profits. In the sections above, additional investment and operating costs for all the most-likely NUSs have been shown individually. Accordingly, these costs have been aggregated below to depict the estimates of additional costs incurred by the DUs that responded to the survey. As an additional step to extrapolate these impacts on all the remaining DUs that did not respond to the survey, an average value of the costs derived using the available information was used. However, to extrapolate profits that could be foregone for the remaining DUs, the values of use 2 related profits derived for a model DU in section 3.3 were used to avoid any overestimation of such an impact.

As the impact of a refused authorisation for a DU depends on its selection of the most-likely NUS, for the extrapolation of additional costs for the remaining DUs due to a refused authorisation, the following assumptions were made:

1. As the data obtained is considered representative for all DUs within the EEA (see section 3.2.3.2), it is assumed that the remaining DUs would also answer the

survey in a similar fashion as the respondents. This implies that the shares of most-likely NUSs will be the same for the respondents as well as the remaining DUs.

2. Based on the above, the proportion of the impacts per most-likely NUS aggregated from the respondents reflect the impacts for the remaining DUs. Thus, the mean value of the former would indicate the average estimate of aggregated impacts incurred by a DU irrespective of the most-likely NUS chosen.

3. The impact of a refused authorisation for use 2 in terms of additional operating costs has only been considered for one year. Ideally, this impact is foreseen to be incurred for the entire review period. Since the DUs were not specifically asked to list when a certain cost would be incurred, it is difficult to estimate the number of years for which each impact under each most-likely NUS should be monetised. For some sub-questions, DUs have listed when a certain impact will be realised, however, the responses differ for each DU. To maintain simplicity in the assessment and to avoid any inconsistency, additional operating costs have only been monetised for one year i.e., 2021.

A. Additional costs

Table 64 shows the aggregated additional investment and operating costs that will be incurred by DUs corresponding to their chosen most-likely NUS as a result of a refused authorisation. It should be noted that the costs in the table below have been calculated only for the respondents that answered the survey.

Table 64: Total additional costs for 64 DUs

NUS	**Additional investment and operating cost [in EUR million]**	
	Lower bound	**Upper bound**
NUS A	5.1	6
NUS B	3.4	7.3
NUS C	6.5	11.1
NUS D	2.9	11.5
NUS E	8.3	10.8
Total cost incurred in 2021	26.3	46.7
NPV 2020	**25.3**	**44.9**

To extrapolate the additional costs that will be incurred, the average of the values shown in Table 64[26] were used as follows:

Table 65: Total additional costs for the remaining 41 DUs

	Additional investment and operating cost [in EUR million]	
	Lower bound	**Upper bound**
Average of total additional investment and operating cost per DU (NPV 2020)	0.4	0.70
Total additional costs for remaining 41 DUs (NPV 2020)	**16.4**	**28.70**

Table 66 shows the additional costs incurred by all the DUs due to a refused authorisation.

Table 66: Total additional costs for all DUs

	Additional investment and operating cost NPV 2020 [in EUR million]	
Total additional costs for 64 DUs	25.3	44.9
Total additional costs for 41 DUs	16.4	28.70
TOTAL	**41.7**	**73.60**

The total additional investment and operating costs incurred by all the DUs in 2020 due to a refused authorisation can be estimated between EUR 42 million and EUR 74 million.

B. Foregone profits

To calculate forgone profits for each respondent the following assumptions were made:

- Calculation of foregone profits included all DUs who provided information on profits related to use 2. This was based on the assumption that irrespective of the most-likely NUS chosen, one year of profit losses would be a common impact as a result of adapting to a new scenario for business continuity or discontinuity. This can be depicted as follows:
    - For NUS A: No further specific sub-questions related to NUS A were placed in the SEA questionnaire as the AOA part of the questionnaire already covered further questions on the time required by the DUs to switch to an already existing, CrO3-free printing technology. When asked about the time each DU would require to switch to such an available printing technology, a minimum of 1 year was chosen by the respondents (see section 4.2.2).

[26] The average was obtained by dividing the total present value by the total number of DUs (64) that responded to this part of the survey.

- For NUS B: Majority of DUs, irrespective of type, chose that less than one year would be required to find a suitable supplier but 2 Type II DUs mentioned a duration of 1 – 5 years.

- For NUS C: The arithmetic mean of the estimated time required for such a relocation was 3.5 years in a range of 1 to 10 years.

- For NUS D: 8 DUs indicated a supply disruption of <1 year and 4 DUs indicated an interruption of 1 – 5 years. One Type I DU indicated a supply interruption of >10 years. However, this duration depends on K. Walter's ability to supply its DUs with an alternative.

- For NUS E: In a permanent shutdown of affected production activity, ideally all profits for the consequent years are lost but a minimum of one year is considered in this assessment.

This implies that Table 67 shows the foregone profits for 70% of the DUs in case of a refused authorisation.

- To derive profits based on non-confidential ranges of revenue shares and profit margins obtained, the assumptions used for deriving estimates in Table 12 were used. Please refer to section 3.2.3.8 on page 41 for the detailed assumptions

- The impact realisation period begins in 2021

Table 67 shows the foregone profits aggregated for 70% of the DU responses.

Table 67: Foregone profits for 73 DUs

Cost item	**[in EUR million]**	
Foregone profits	**Lower bound**	**Upper bound**
Total annual profits related to use 2 that will be foregone in 2021	25.21	214.21
NPV 2020	**24**	**206**

For the remaining 30% of the DUs that did not provide this information, lower and upper bound of profits has been extrapolated based on the values derived for a model DU in Table 14.

Table 68: Foregone profits for the remaining 32 DUs

Cost item	[in EUR million]	
Foregone profits	**Lower bound**	**Upper bound**
Total annual profits related to use 2 that will be foregone in 2021 per model DU	0.005	0.5
Total annual profits related to use 2 that will be foregone in 2021 for the remaining DUs	0.16	16
NPV 2020	**0.15**	**15.38**

Table 69 shows the total profits foregone, extrapolated to all DUs in case an authorisation to use to is refused.

Table 69: Total foregone profits due to a refused authorisation to use 2

Cost item	NPV 2020 [in EUR million]	
Foregone profits	**Lower bound**	**Upper bound**
Foregone profits for 73 respondents	**24**	**206**
Extrapolated foregone profits for remaining 32 DUs	**0.15**	**15**
Total foregone profits for DUs due to a refused authorisation	**24.15**	**221**

The total profits that will be foregone collectively by all the DUs can be estimated between EUR 24 – 221 million.

Table 70 shows the total economic impact for DUs in case an authorisation is not granted for use 2 within the EEA.

Table 70: Total aggregated economic impacts for DUs (in EUR million)

Cost item	NPV 2020 [in EUR million]	
	Lower bound	**Upper bound**
Total additional costs	42	74
Total foregone profits	24	221
Total economic impacts on DUs	**66**	**295**

6.2.2.1 Total economic impacts in USE 2

Table 71 shows the total economic impacts for K. Walter, Heliograph Holdings, its subsidiaries and the DUs in case an authorisation is not granted for use 2 within the EEA.

Table 71: Total economic impacts under use 2

Economic impact factors	**Lower bound - NPV 2020** [EUR million]	**Upper bound - NPV 2020** [EUR million]
Foregone profits for K. Walter	[redacted]	[redacted]
Foregone profits for the Heliograph Holdings	[redacted]	[redacted]
Foregone profits for the Heliograph Holdings' subsidiaries	[redacted]	[redacted]
Additional economic impacts on DUs	66	295
Total	[redacted]	[redacted]

Thus, the total economic impacts due to a refused authorisation for use 2 is estimated at a net present value between EUR 50 – 500 [redacted] million in 2020 when discounted at a standard social discount rate of 4%.

6.2.3 Avoided Social Impacts

The calculated social costs of non-authorisation, discounted to the base year of 2020 (end of year) using a social discount rate of 4%, is summarised in Table 73.

For the methodology for evaluating these impacts, please refer to the introductory paragraph in section 6.1.3.

The social impacts discussed in this section will include the following:

Table 72: Social impacts due to a refused authorisation to use 2

IMPACTS IN USE 2	Formulator	K. Walter	Heliograph Holding	Heliograph Holding's subsidiaries	Downstream users
Job dismissals in 2021					

A. Formulator

Job dismissals at the formulator are unknown since no information was available at the time of this AfA.

B. K. Walter

In case an authorisation to use 2 is refused, K. Walter will relocate its affected production activity outside the EEA. As a result, the applicant estimates that approximately [redacted] employees in Germany will have to be dismissed in 2021. It must be emphasised that only the production site will be relocated. Other units of K. Walter such as controlling, construction and R&D will continue their business from the current location.

Table 73: Social impact of employee dismissals at K. Walter in use 1

	Costs [EUR]	**Number of jobs affected**	**Total cost** [EUR]
Unemployment social cost of one job position in **Germany** adjusted to **2020** values (in EUR)	123,317[27]	[redacted]	[redacted]

As described above, social costs of unemployment incurred at the applicant's site can be valued at approximately EUR 1 – 5 [redacted] million.

C. Heliograph Holding and its subsidiaries

In case an authorisation to use 2 is refused, the Heliograph Holding will relocate its affected production activity outside the EEA. As a result of a refused authorisation to use 2, [redacted], [redacted] and [redacted] job losses are foreseen in Hell, Schepers and Bauer respectively.

In case an authorisation to use 2 is refused, Heliograph Holding's subsidiaries will permanently shut down its affected production activity in the EEA. As a result, [redacted], [redacted], and [redacted] job losses at Daetwyler-Hell France S.A.S., Daetwyler-Hell Iberica S.L., and MDC Max Daetwyler GmbH respectively are foreseen. This represents 100% of the workers for these subsidiaries, that engage in business activities associated with the use of chromium trioxide.

Table 74 shows the total social impact of the [redacted] job losses stated above in the EEA due to a refused authorisation to use 2.

[27] The value of 1 lost job in Germany was extrapolated from 2016 to 2020 using the average of the inflation rates of last 5 years (2016-2020) in Germany. The data was obtained from Eurostat. Thus, average inflation rate of 1.18% was derived using last 5 years' inflation rates of 0.38%, 1.71%, 1.95%, 1.35% and 0.50%.

Table 74: Social cost of unemployment at Heliograph Holding and its subsidiaries due to a refused authorisation to use 2

	Costs [EUR]	**Number of jobs affected**	**Total cost** [EUR]
Unemployment social cost of one job position in **Germany** adjusted to **2020** values (in EUR)	123,317	[redacted]	[redacted]
Unemployment social cost of one job position in **Spain** adjusted to **2020** values (in EUR)	68,683[28]	[redacted]	[redacted]
Unemployment social cost of one job position in **France** adjusted to **2020** values (in EUR)	113,314[29]	[redacted]	[redacted]
Total unemployment cost at Heliograph holding and its subsidiaries in 2020			[redacted]

As described in Table 74, social cost of unemployment incurred at the Heliograph Holding and the subsidiaries can be valued at approximately EUR 1 – 10 [redacted] million in 2020.

D. Downstream users

This section evaluates the social impacts that will be incurred at K. Walter's DUs as a result of a refused authorisation to use 2. Depending on applicability of the process, options were provided to state the impact of a refused authorisation on number of employees involved in cylinder production or printing process or both in qualitative and quantitative measures.

Collectively, for all the most likely NUSs for the DUs, a total of 5,239 employees will be dismissed as a result of a refused authorisation to use 2.

To estimate the present value of social costs of EU-28, corresponding EU-28 values for the year 2016 were obtained from the methodology commissioned by ECHA based on values from 2014 (33). These values were then extrapolated to the year 2020 using an inflation rate of 0.8918 obtained from Eurostat.

Table 75: Social cost of unemployment at 67 DUs due to a refused authorisation to use 2

	Costs [EUR]	**Number of jobs affected**	**Total cost** [EUR]
Unemployment social cost of one job position in **EU-28** adjusted to **2020** values (in EUR)	91,704	5239	**480,437,256**

As described in Table 75, social cost of unemployment incurred at the DUs that responded to the survey can be valued at approximately EUR 480 million in 2020. This value only

[28] The value of 1 lost job in Spain was extrapolated from 2016 to 2020 using the average of the inflation rates of last 5 years (2016-2020) in Spain. The data was obtained from Eurostat. Thus, average inflation rate of 0.78% was derived using last 5 years' inflation rates of -0.20%, 1.96%, 1.68%, 0.70% and -0.23%.

[29] The value of 1 lost job in France was extrapolated from 2016 to 2020 using the average of the inflation rates of last 5 years (2016-2020) in France. The data was obtained from Eurostat. Thus, average inflation rate of 1.07% was derived using last 5 years' inflation rates of 0.31%, 1.16%, 2.10%, 1.30% and 0.46%.

includes the monetised value of unemployment for 67 DUs for whom such an answer was available or deduced.

Please refer to section 8.2.5 for aggregation of these costs.

For the remaining 38 DUs, social impacts of unemployment were calculated using the model DU approach described in section 3.3, Table 13. This approach of extrapolation is taken to avoid any overestimation and fill gaps where DUs did not provide an input. For this purpose, it has been further assumed that directly exposed workers are more likely to be dismissed in case of a refused authorisation. According to this model, 6 directly exposed workers per DU are assumed to be dismissed at the remaining 38 DUs, who did not answer the social impacts of a refused authorisation in the survey. Accordingly, Table 76 shows the extrapolated social cost of 228 (38*6) directly exposed workers at 38 DUs that would be dismissed.

Table 76: Social cost of unemployment at 38 DUs due to a refused authorisation to use 2

Mean of directly exposed workers likely to be dismissed at a model DU	**6**		
Total number of directly exposed workers likely to be dismissed at 38 DUs	**228**		
	Costs [EUR]	**Number of jobs affected**	**Total cost** [EUR]
Unemployment social cost of one job position in **EU-28** adjusted to **2020** values (in EUR)	91,704	228	**20,908,512**

Table 77 shows the total social impact at DUs as a result of a refused authorisation.

Table 77: Total social cost of use 2 incurred by all DUs due to a refused authorisation

	NPV 2020 [in EUR million]
Social costs of unemployment for 67 DUs	480
Social costs of unemployment for 38 DUs	21
Total social impacts at all DUs	**501**

The total social cost of unemployment incurred at all the DUs collectively can be valued at approximately EUR 501 million in 2020.

It should be noted that the approach in Table 75 above only includes the estimates provided by 67 DUs. To extrapolate these dismissals to 38 DUs, the concept of a model DU was used in Table 76 to avoid any overestimation. However, 6 dismissals per DU can be clearly seen as a severe underestimation.

Clearly 38 DUs account for more than 50% (~57%) of 67 DUs. Assuming that the remaining 38 DUs would respond in a similar manner as the 67 DUs, the social cost of unemployment should be directly proportional and account for at least 50% of the unemployment costs obtained for 67 DUs i.e., at least 240 million. When compared with an impact of EUR 480 million for 67 DUs, an unemployment cost of EUR 20 million for 38

DUs only accounts for only 4% of the costs obtained for 67 DUs ((20/480)*100). This difference of EUR 220 million clearly justifies EUR 20 million as an underestimate.

Despite including the answers from the DUs above, the sensitivity analysis will check the effect of applying the approach of a model DU to all 117 DUs i.e., 6 dismissals at each DU site.

6.2.3.1 Total social cost of unemployment

Table 78 shows the total social cost of unemployment due to a refused authorisation for use 2.

Table 78: Total social cost of unemployment due to a refused authorisation to use 2

Stakeholder	Social cost of unemployment (in EUR million)
K. Walter	[redacted]
Heliograph Holding and its subsidiaries	[redacted]
DUs	501
Total	[redacted]

As shown above, the total social cost of unemployment for the stakeholders due to a refused authorisation to use 2 can be valued at EUR 500 - 1,000 [redacted] million in 2020.

6.2.4 Total impacts for use 2

Table 79 shows the total impacts in case an authorisation is for use 2 is refused.

Table 79: Total avoided impacts for use 2 in case of a granted authorisation

Cost item	NPV 2020 [in EUR million]
Avoided Health impacts	NA
Avoided economic impacts	[redacted]
Avoided social impacts	[redacted]
TOTAL	[redacted]

As shown above, the total impacts in the EEA in case an authorisation is not granted for use 2 are estimated to be between EUR 500 – 1,000 [redacted] million.

6.3 Wider Economic Impacts

6.3.1 Macroeconomic effects of a refused authorisation

For this AfA, only potential effects of the NUS on competition and economic development have been considered. The assessment of such impacts can be complex to evaluate given that these represent macroeconomic effects. Therefore, the assessment must be guided by considerations of the significance of 'shock' introduced to the system by a refused authorisation.

Considering that no chromium trioxide related DU pertaining this application receives an authorisation for functional chrome plating, it would create a ripple effect within the printing industry directly related to K. Walter's business. With the relocation of gravure technology outside the EEA, competitive forces may pave the way for inclusion of other technologies eventually phasing out use of gravure printing in the EEA. As described in the AfA, the demand associated with this technology and irreplaceable by other technologies may create gaps which will have to be fulfilled from non-EEA countries.

While the relocation of services to outside the EEA already lowers employment in the EEA, an economic downturn may exacerbate the loss of employment and reduce the demand for other industrial and consumer goods.

Another aspect that should not be neglected is the role and implied value of SMEs in the economic infrastructure of the EU. As mentioned before, SMEs have the potential to connect industrial centres with more rural regions, channelling a share of financial resources into these areas and facilitating employment and consumption in less industrialised regions. Thus, any impacts on such enterprises is likely to affect the growth in these regions along with the impact on EU's general economic performance.

6.3.2 Summary of benefits of continued use

The benefits of continued substance use describe the avoidance of the economic and social impacts due to the consequent non-use scenario and thus comprise avoided profit losses as well as the avoided social cost of unemployment for both the uses.

Table 80: Socio-economic benefits of continued use

Description of major impacts	**Quantification of impacts for use 1 [annualised to € million per year]**	**Quantification of impacts for use 2 [annualised to € million per year]**
1. Benefits to the applicant(s) and/or their supply chain		
1.1 Avoided profit loss due to ceasing the use applied for[30]	[redacted]	[redacted]
Sum of benefits to the applicant(s) and / or their supply chain	[redacted]	[redacted]
2. Quantified impacts of the continuation of the SVHC use applied for on other actors		
2.1 Avoided net job loss in the affected industry[31]	[redacted]	[redacted]
2.2 Avoided health impacts in the affected industry due to use of solid CrO_3	[redacted]	[redacted]
Sum of impacts of continuation of the use applied for	[redacted]	[redacted]
3. Aggregated socio-economic benefits (1+2)	[redacted]	[redacted]

6.4 Combined assessment of impacts

6.4.1 Comparison of impacts

The comparison of impacts draws from the previous impact assessment and compares socio-economic benefits of a granted authorisation with the monetised risk to human health. All values are annualised and expressed in EUR million.

[30] Profit losses to be counted in only for the first [x] years, see SEAC note on economic surplus changes (not yet available).

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

6.4.1.1 USE 1

Table 81: Comparison of socio-economic benefits and risks of continued use 1

Socio-economic benefits of continued use		**Monetised excess risks associated with continued use**	
Benefits to the applicant(s) and/or their supply chain [annualised to € million per year]	[redacted]	Monetised excess risks to workers directly exposed in the use applied for [annualised to € million per year]	0.000225 - 0.000375
Quantified impacts of the continuation of the SVHC use applied for on other actors	[redacted]	Monetised excess risks to the general population and indirectly exposed workers [annualised to € million per year]	0.000025 - 0.000045
Additional qualitatively assessed impacts	NA	Additional qualitatively assessed risks	NA
Aggregated socio-economic benefits [annualised to € million per year]	[redacted]	Aggregated monetised excess risk [annualised to € million per year]	0.00025 - 0.00042

Table 82: Benefit / risk summary – use 1

Net benefits [annualised to € million per year]	0 - 1 [redacted]
Benefit/monetised risk ratio	500 – 1,000 [redacted]

As illustrated by Table 81 and Table 82, the annualised net benefit of continued substance use per year can be valued at EUR [redacted] million per year and the ratio of annual benefits to risk (using the lower bound of calculated benefits and the upper bound of monetised risk and the upper bound of calculated benefits and the lower bound of monetised risk), lies between [redacted] per year for the entire review period of 12 years.

6.4.1.2 USE 2

Table 83: Comparison of socio-economic benefits and risks of continued use 2

Socio-economic benefits of continued use		**Monetised excess risks associated with continued use**	
Benefits to the applicant(s) and/or their supply chain [annualised to € million per year]	[redacted]	Monetised excess risks to workers directly exposed in the use applied for [annualised to € million per year]	0.11 - 0.18
Quantified impacts of the continuation of the SVHC use applied for on other actors	[redacted]	Monetised excess risks to the general population and indirectly exposed workers [annualised to € million per year]	1.06 - 1.77
Additional qualitatively assessed impacts	[redacted]	Additional qualitatively assessed risks	NA
Aggregated socio-economic benefits [annualised to € million per year]	[redacted]	Aggregated monetised excess risk [annualised to € million per year]	1.17 – 1.95

Table 84: Benefit / risk summary – use 2

Net benefits [annualised to € million per year]	50 – 100 [redacted]
Benefit/monetised risk ratio	10 – 100 [redacted]

As illustrated by Table 83 and Table 84, the annualised net benefit of continued substance use per year can be valued between EUR [redacted] million per year and the ratio of annual benefits to risk (using the lower bound of calculated benefits and the upper bound of monetised risk and the upper bound of calculated benefits and the lower bound of monetised risk), lies between [redacted] per year for the entire review period of 12 years.

6.4.2 Distributional impacts

The following distribution analysis aims to show, which groups inside and outside the applying legal entities are impacted more than others if K. Walter receives the requested authorisation in contrast to the most likely non-use scenario. Severity of impacts in the following table have been depicted by high (+++ or ---), medium (++ or --), low (+ or -), no or marginal impact (o), not applicable (n/a).

Table 85: Distributional impacts – use 1 and use 2

Affected group[1]	**Economic impact**		**Health and environmental impact**	
	Use 1	**Use 2**	**Use 1**	**Use 2**
Economic operator				
Applicant and Heliograph Holdings	+	+	-	-
Suppliers of alternatives in the EU	NA	NA	NA	NA
Suppliers of alternatives outside the EU	+	+	0	0
Competitors in the EU	0/-	0/-	0	0
Competitors outside the EU	--	--	0	0
Customer group 1 (DUs in the EEA)	0/-	+++	--	0
Public at large in the EU	++/+++	++/+++	0/-	0/-
Geographical scope				
EU	+++	+++	-	-
Within the applicant's business				
Employers/Owners	+++	+++	0/-	0/-
Exposed workers	++/+++	++/+++	-	-

6.5 Uncertainty analysis

The ECHA Guidance on SEA (36) proposes an approach for conducting the uncertainty analysis. This approach provides three levels of assessment that should be applied if it corresponds:

1. qualitative assessment of uncertainties;
2. deterministic assessment of uncertainties;

3. probabilistic assessment of uncertainties.

The ECHA Guidance further states: "*the level of detail and dedicated resources to the assessment of uncertainties should be in fair proportion to the scope of the SEA. Further assessment of uncertainties is only needed if the assessment of uncertainties is of importance to the overall outcome of the SEA*".

In this case the socio-economic impacts for use 1 outweigh the expected worst-case health impacts by a factor between [redacted]**:1** and [redacted]**:1.** For use 2, this ratio is between [redacted]**:1** and [redacted]**:1**.

However, a qualitative as well as deterministic analysis of uncertainties has been conducted.

6.5.1 Qualitative assessment of uncertainties

The aim of the qualitative assessment of uncertainties was to determine the general direction and the magnitude of uncertainties, whereas the direction refers to the question if uncertainties represent an under- or over-estimation. The magnitude (low, medium, high) refers to the extent that the uncertainty might potentially change the quantitative results of the SEA.

Consequently, the direction and magnitude of uncertainties was determined qualitatively based on the quality of input data used as parameters for the calculations and the underlying assumptions of the analysis. Depending on the variability of the used data and the room for bias in the assessment, those parameters were qualitatively assessed as having a low, medium, or high impact on the quantitative results of the SEA.

The following table illustrates the systematic identification of uncertainties related to human health impacts and addresses uncertainties to socio-economic impacts.

Table 86: Uncertainty analysis

Identification of uncertainty (assumption)	**Classification**	**Evaluation**	**Criteria and scaling (contribution to total uncertainty)**
Impact of temporary bottlenecks on market position	Parameter uncertainty	Temporary supply bottlenecks will occur in case of a non-granted authorisation. This will negatively affect the market position of the applicant because customers will switch to competitors.	Medium
Impact of assumptions taken for the most likely NUS for DUs (section 4.6.2.1)			
NUS A was invalidated where, the respondent indicated that an already available alternative technology or process is not present.[32] NUS A was also invalidated wherever the DU mentioned that the alternatives are currently in development by K. Walter. It is assumed that the respondent may have misinterpreted it as an option that anticipates an alternative technology in the foreseeable future. In this case, the next-best non-use scenario (rank=2) selected by the respondent was assumed to be the most-likely non-use scenario (rank=1). In case the respondent did not select the next best non-use scenario, they were asked to provide the same in a follow-up round.	Parameter uncertainty	Inclusion of inputs on potential but not currently functional alternatives would interfere with the robustness of the application leading to a false conclusion on the availability of feasible alternatives	Low

[32] If the DU selected NUS A as an option, it was asked to specify/describe the alternative technology and to further mention if it is currently using this alternative technology.

Identification of uncertainty (assumption)	Classification	Evaluation	Criteria and scaling (contribution to total uncertainty)
Two responses were seen where the DUs provided a combination of non-use scenarios by assigning the same rank to each of the NUSs selected. However, these were not considered further as one response included NUS A alongside specifying no currently available alternate printing technology and the other included a combination of permanent shutdown (NUS E) and temporary shutdown (NUS D). In these two cases, the first option selected by the DU was listed as the most-likely NUS.		Inclusion of incoherent responses could lead to a bias in the interpretation of the NUS.	Low
In case no rank was assigned and only one scenario was selected (other than NUS A), this was assumed to be the most-likely scenario for the respondent		Assuming that even if a response was provided with a rank assigned, the consequence of including these responses would be the same	Low
Parameters and assumptions used for health impact assessment			
Shape of exposure-response function (linear versus non-linear)	Model uncertainty	If non-linear, particularly at low exposure levels: overestimation	High
Working days (260 days) given by the dose-response curve	Parameter uncertainty	Not taking into account holidays, bank holidays, illness: overestimation	Medium
Use of PEClocal (distance only 100 m from the point source) for total local exposure calculation	Parameter uncertainty	PEClocal reduces according with the distance from the point source overestimation	High

Identification of uncertainty (assumption)	**Classification**	**Evaluation**	**Criteria and scaling (contribution to total uncertainty)**
Quantification of health impact assessment due to exposure of solid chromium trioxide salts. As a result of the non-use scenario for use 1, where the DUs will be supplied with solid chromium trioxide salts, it is recognized that the use of solid salt instead of the liquid formulation will lead to a higher exposure due to reasons mentioned in section 6.1.1. However, it remained difficult to quantify such an impact due to lack of data	Parameter uncertainty	Based on the assumption that exposure to solid chromium trioxide salts will lead to a larger health impact compared with the use of liquid formulation; inclusion of its quantification would increase the socio-economic benefits of granting an authorisation for use 1. This assumption, qualitatively explained as a consequence of the NUS does not have any impact on the benefit/risk ratio.	High
Parameters and assumptions used for socio-economic impact assessment			
Foregone profit calculation for K. Walter and Heliograph Holding assumes constant profits, linearity between profits and production volume.	Parameter uncertainty	Profits are expected to increase in the future. Lower / higher production volume might affect the costs per unit	Low
Assumptions used for aggregating profit losses at DUs due to a refused authorisation for use 2 (section 3.2.3.8)	Parameter uncertainty	Lower bound of the estimates are considered throughout. Actual estimates could be higher	Low
Assumptions used for aggregating socio-economic impacts for DUs (Section 6.2.2, DUs, Point 5)	Parameter uncertainty	Lower bound of the estimates are considered throughout. Actual estimates could be higher	Low

Identification of uncertainty (assumption)	Classification	Evaluation	Criteria and scaling (contribution to total uncertainty)
Reliability of data collected by DUs for assessment of economic and social impacts	Parameter uncertainty	Data for estimation of economic impacts due to a refused authorisation was collected in ranges to ensure a provision of lower and upper bound. The uncertainty has been minimised by always using the lower bounds wherever possible and by excluding responses which did not match the non-use scenario selected by the DU. Data on unemployment as a result of a refused authorisation was however collected in absolute numbers dependent on the DU. Based on experience, it was assumed that the DU would be able to provide a reasonable estimate of its employees. An uncertainty analysis is however included in section 6.5 to provide a lower bound of such an impact	Medium

6.5.2 Deterministic assessment of uncertainties

As seen from the table above, low to medium uncertainties are associated with the impact assessment due to a refused authorisation on downstream users. Despite obtaining answers from DUs, uncertainties arise based due to the unpredictable understanding of the survey questions on an individual level of the respondents. Uncertainties regarding estimation of economic impacts due to a refused authorisation to use 2 (section 6.2.2) have been minimised by taking a lower and upper bound.

However, for the estimation of social costs of unemployment at the DUs due to a refused authorisation for use 2, results rely on the input from DUs only. For this purpose, the sensitivity analysis below seeks to check the influence of a decrease in social cost on the cost-benefit ratio for granting an authorisation for use 2. Although being considered an underestimation, this sensitivity analysis will involve the use of the model DU approach used for extrapolating social costs of unemployment on 38 DUs (Table 76) who did not answer the survey.

Table 87: Social costs incurred by DUs due to a refused authorisation for use 2 – model DU approach

Mean of directly exposed workers likely to be dismissed at a model DU	**6**		
Total number of directly exposed workers likely to be dismissed at 105 DUs	**630**		
	Costs [EUR]	**Number of jobs affected**	**Total cost** [EUR]
Unemployment social cost of one job position in **EU-28** adjusted to **2020** values (in EUR)	91,704	630	**57,773,520**

<u>Sensitivity analysis</u>

Table 88 provides a sensitivity check for the social costs calculated above for DU in use 2.

Table 88: Sensitivity analysis for social costs incurred by DUs due to a refused authorisation for use 2

	NPV 2020	**Annualised value**
Total social cost of unemployment for use 2	EUR 71[33] million	EUR 7.57 million
Total benefits of a granted authorisation for use 2	EUR [redacted] million	EUR [redacted] million
Monetised risks due to a granted authorisation for use 2	EUR 11 – 18 million	EUR 1.17 – 1.95 million

[33] This includes social costs of EUR 58 million incurred by DUs and EUR [redacted] million incurred by K. Walter and the Heliograph holding

Table 89: Benefit / risk summary – use 2

Net benefit [annualised to € million per year]	EUR [redacted] million
Benefit/monetised risk ratio	[redacted]

Table 93 considers different scenarios varying the lower bound (obtained in Table 88) and upper bound (obtained in Table 77) of social impacts, with lower and upper bounds each of economic and health impacts of a refused authorisation for use 2, used in this AfA. Please note that the analysis is based on annualised values of multiple scenarios presented in Table 90.

Table 90: Lower and upper bounds of social, economic and health impacts considered for uncertainty analysis

Scenario	Social impact [in EUR million]	Economic impact [in EUR million]	Health impact [in EUR million]
Low	71	[redacted]	11
High	[redacted]	[redacted]	18

Table 91: Annualised value of lower and upper bounds of social, economic and health impacts considered for uncertainty analysis

Scenario	Social impact [in EUR million]	Economic impact [in EUR million]	Health impact [in EUR million]
Low	7.57	[redacted]	1.17
High	[redacted]	[redacted]	1.95

Table 92 summarises and combines the different scenarios analysed, showing the variations on the balance.

Table 92: Scenarios considered for uncertainty analysis for use 2

	Social impact [in EUR million]	Economic impact [in EUR million]	Health impact [in EUR million]
Scenario 1	Low	Low	Low
Scenario 2	Low	Low	High
Scenario 3	Low	High	Low
Scenario 4	Low	High	High
Scenario 5	High	Low	Low
Scenario 6	High	Low	High
Scenario 7	High	High	Low
Scenario 8	High	High	High

Table 93: Findings of the uncertainty analysis – use 2

	Social impact [in EUR million]	Economic impact [in EUR million]	Total socio-economic impact	Health impact [in EUR million]	Net benefit of granting an authorisation	Benefit/monetised risk ratio
Scenario 1	7.57	[redacted]	[redacted]	1.17	[redacted]	[redacted]
Scenario 2	7.57	[redacted]	[redacted]	1.95	[redacted]	[redacted]
Scenario 3	7.57	[redacted]	[redacted]	1.17	[redacted]	[redacted]
Scenario 4	7.57	[redacted]	[redacted]	1.95	[redacted]	[redacted]
Scenario 5	[redacted]	[redacted]	[redacted]	1.17	[redacted]	[redacted]
Scenario 6	[redacted]	[redacted]	[redacted]	1.95	[redacted]	[redacted]
Scenario 7	[redacted]	[redacted]	[redacted]	1.17	[redacted]	[redacted]
Scenario 8	[redacted]	[redacted]	[redacted]	1.95	[redacted]	[redacted]

Table **93** above, two scenarios with the highest and the lowest net benefit of a granted authorisation have been identified. Figures below show this positive difference in both scenarios graphically.

[redacted]

Figure 31: Scenario with the highest balance between the socio-economic and monetised health risk of use 2

[redacted]

Figure 32: Scenario with the lowest balance between the socio-economic and monetised health risk of use 2

From the analysis above, it can be seen that the benefits of granting an authorisation for use 2 outweigh the monetised risks even when the dismissals due to a refused authorisation are severely minimised and can be deemed unrealistic. Despite that,

Table 93 presents the monetised socio-economic and human health impacts in the respective scenario illustrating the ranges obtained for different parameters across the scenarios analysed. It shows that the outcome of the SEA is invariable, such that socio-economic impacts always outweigh human health impacts. This is the case for all the 8 scenarios in which key parameters or assumptions relating to socioeconomic and health impacts were varied. The ratio of socio-economic benefits of granting an authorisation to the monetised risks ranged from [redacted]:1 (Scenario 2) to [redacted]:1 (Scenario 7) across these 8 scenarios. Considering these results, including the lowest ratio of [redacted]:1, the overall outcome of this SEA must be considered robust. Hence, no further quantitative assessment of uncertainty is foreseen for this impact assessment due to low influence on the current assessment.

6.6 Substitution efforts taken by the applicant if an authorisation is granted

As described in detail in section 4.1, K. Walter and its partners have conducted extensive R&D on several alternatives over the last years. None of these alternatives were found to be suitable, meaning that currently no alternative (technology) is commercially available that ensures the essential combination of the technical key requirements as described in section 3.6.4. However, as a result of this extensive R&D work, K. Walter identified two potential alternatives that are considered the most promising for the future substitution of Cr(VI)-based plating of gravure cylinders: Cr(III)-based electroplating and polymer coatings. K. Walter has made significant progress in the development of these alternatives, but these are not yet ready to be implemented. K. Walter will further develop these alternatives according to the substitution timeline shown in section 4.5.1.

New equipment/machines that can operate using the alternative technologies must be designed, manufactured and implemented at each DU site. Two more years will be needed for the technical development of the most promising alternatives. Testing at DU sites under real operating conditions (beta tests) will start before the end of the technical development phase. The goal of these tests is to obtain information about parameters such as wear under real operating conditions, which is needed to optimize the performance of the new technologies according the specific application in which they are implemented. Once fully developed, K. Walter will start manufacturing and distributing the new machines. This transition phase is expected to take at least eight years given the large number of Cr(VI)-based units that must be substituted in the EEA.

K. Walter wants to emphasize that the R&D success of these alternatives is not guaranteed, and that technology failure and/or customer refusal can occur any time during development, resulting in completely different and prolonged R&D timelines.

7 CONCLUSIONS

Chromium trioxide-based functional chrome plating is applied on rotogravure printing and embossing cylinders to ensure that the surface of the cylinders is homogeneous, scratchproof, highly wear and corrosion resistant, and hard. These properties are especially important for gravure cylinders because interaction with hard ink particles, with the doctor blade and the substrate causes damage to the surface of gravure cylinders, reducing their service time.

Cr(III)-based electroplating and polymer coatings are considered the most promising alternatives for substituting Cr(VI) in the functional plating of gravure cylinders. In this AfA, these alternatives were assessed based on defined process- and performance-related key functionalities. Most of these functionalities are already fulfilled in in-house tests. However, more time is needed to finalize the technical development and to test these new technologies under real operating conditions. This last step is important to evaluate parameters such as wear and to adjust the operation of the new machines for optimal performance. As discussed in section 4.5.1, most of the review period requested is needed for the transition phase, in which new machines will be manufactured and distributed to DUs to replace the existing Cr(VI)-based units. The implementation of alternatives will require a close work of DUs with K. Walter to solve any unforeseen difficulties and to gain experience with the new technology. Due to the limited capacities to manufacture new machines and the large number of Cr(VI)-based units that must be substituted (more than 200 in the EEA), a transition period of at least eight years will be necessary to accomplish this transition.

As described in section 4.5.1, a review period of at least 12 years is needed for a complete substitution of Cr(VI) in the functional chrome plating of gravure cylinders.

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8 APPENDICES

8.1 Methodology for health impact assessment

Assessment of health impacts

In accordance with the CSR the risk assessment for workers exposed in this SEA is restricted to inhalation of airborne residues of chromium trioxide (lung cancer). For the general population, inhalation exposure to Cr(VI) and oral exposure to Cr(VI) via the food chain is also taken into account. Oral exposure via the food chain leads to an additional risk of small intestine cancer.

Toxicity to reproduction is not addressed in this SEA as the risk is adequately controlled (RCR < 0.01). For details please refer to the CSR.

A 1.1 Quantitative health impact assessment of workers

The assessment of health risks within this SEA utilises the results of a study endorsed by ECHA identifying the reference dose-response relationship for carcinogenicity of Cr(VI) (37)[34]. This paper has been agreed on at the RAC-27 meeting on 04 December 2013. These results on the carcinogenicity dose-response analysis of Cr(VI) containing substances are acknowledged to be the preferred approach of the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) and therefore have been used as a methodology for the assessment of health risks in this SEA.

Accepting this, the following steps are necessary to complete the health impact assessment according to the ECHA methodology:

- Evaluation of potential work exposure (CSR)
- Estimation of additional cancer cases relative to the baseline lifetime risk of developing the disease (ELR)
- Assessment of fatality rates (%) with reference to available empirical data
- Monetary valuation of fatal and non-fatal cancer risks based on the Willingness to Pay (WTP) study published by ECHA in 2016 (38).

These 4 consecutive steps are explained in detail in the following.

Data gathering on potential work exposure

For the assessment of potential worker exposure, the maximum number of potentially exposed workers as well as the worst-case exposure values and combined exposure values from the CSR are taken into account. For further information regarding exposure values, please consider the CSR.

[34] By reference to this, the applicant neither agrees nor disagrees with this dose-response relationship. However, the applicants acknowledge that the dose-response relationship is likely to be conservative and protective of human health, particularly considering the extrapolated linear relationship at low dose exposure concentrations.

Estimation of additional cancer cases in relation to baseline

The dose-response relationship for Cr(VI) with regard to lung cancer has been discussed in recent research published by ECHA (37). These dose-response functions of an excess risk for carcinogenic effects have been used as the basis for this assessment.

For the calculation of health impacts related to lung cancer, **excess lifetime risk** (ELR) is defined as the additional or extra risk of developing cancer due to exposure to a toxic substance incurred over the lifetime of an individual. Note that developing cancer may occur during working life or after retirement.

Linear exposure-risk relationship for lung cancer as estimated by ECHA (37):

$$Unit\ occupational\ excess\ lifetime\ risk = 4\text{E-03}\ per\ \mu g\ Cr(VI)/m^3$$

The dose-response relationship agreed upon by RAC refers to a working lifetime exposure with continuous working-daily exposure. As an average over different countries and economic sectors, full-time employee contracts (8 hours per day) and a working lifetime of 40 years are taken as a basis (37). Note that 8 working hours per day or 40 working hours per week, as well as 40 years per working life are explicit parameters used for the full-time working equivalent (FTE) underlying the exposure-response functions (37), p. 5, whereas 260 working days per year are implicitly given through the dose-response curve.

Adaptation factors for time frame of exposure

In order to apply this exposure-risk relationship to the case of authorisation, it has to be adapted according to the time frames used in this AfA.

Therefore, the following factors are used to adapt the exposure-risk relationship to the respective situation of this AfA:

- Factor for adaptation to the respective review period (years of authorisation granted up to the next revision envisaged)

$$\frac{envisaged\ review\ period\ [years]}{40\ years}$$

- Factor for adaptation to the actual working days per year[35]

$$\frac{working\ days\ per\ year}{260\ days}$$

Due to the fact that exposure values derived in the CSR are 8-hour time weighted average (TWA) concentrations, a correction for the actual exposure time per day is not needed. For activities not performed on a daily basis, the frequency of activities has been taken into account in the CSR and the presented exposure estimates are already corrected respectively (e.g. in case an activity is performed only once a week, the exposure estimate presented in the CSR already is an average long-term exposure corrected for frequency).

[35] 260 days per year are not explicitly stated in the RAC paper (RAC/27/2013/06 Rev.1), but are implicitly assumed by RAC. This can be shown by comparing the dose-response relationships for workers and the general population. According to the CSR, employees at the DU sites are working in three shifts Monday to Friday on 220 production days per year. Therefore, the correction factor for adaptation to the actual working days per year amounts to 220/260 = 0.846.

This means that the factor for adaptation of the actual working days has only been applied for daily activities.

Methodology for the estimation of additional lung cancer cases

For an individual person, the excess lifetime lung cancer **mortality** risk derived in the ECHA paper (37) indicates the differential in probability to die of lung cancer during the future life, i.e. the increase in probability compared to the baseline risk for an individual to die from this disease.

As described above and in line with ECHA, ELR of mortality associated with lung cancer = 4E-03 per µg Cr(VI) /m^3 times the concentration [µg Cr(VI) /m^3] (due to an exposure over the whole working lifetime of 40 years).

Excess risk used in this equation is defined as:

$$P_{excess} = P(x) - P(0)$$

with

$$P_{excess}(x) = Excess\ risk\ at\ exposure\ x$$

$$P(x) = lifetime\ risk\ of\ persons\ exposed\ for\ dying\ from\ lung\ cancer$$

$$P(0) = Background\ risk\ (lifetime\ risk\ of\ a\ non-exposed\ comparison\ group)$$

It has to be emphasised that $P_{excess}(x)$ is an additional risk, the unit is the expected number of additional **lung cancer deaths** of a population exposed by a concentration x in the sum (37).

In the source of ECHA (37), based on the research of the ETeSS consortium (39), and in underlying studies, excess risk is used in absolute terms, not percentage points. The excess risk $P_{excess}(x)$ is linear, i.e. proportional both to individual exposure and to persons exposed. Therefore, exposures of different persons can be added.

Consequently, the aggregated excess risk is the expected value of additional lung cancer deaths due to an exposure.

The calculation of the excess risk (i.e. additional lung cancer deaths) over all employees exposed is calculated per WCS by multiplying the individual excess risk times the respective number of workers exposed. Then, the excess risk of all WCS are summed up. Thus, the estimated amount of additional lung cancer deaths is the expected value due to a continued use of Cr(VI) for the respective time frame allowed by an authorisation up to the next revision.

According to the ECHA document (37), the term used is '*excess lifetime lung cancer mortality risk*'. This is also consistent with the results of ETeSS (2013) (39) where the respective table of a preliminary report is titled '*[u]nit occupational excess lifetime risks of lung cancer death determined by different authorities or publications*'. This signifies that the dose-response function developed refers only to additional lung cancers ending fatal. In this study, only data on deaths caused by lung cancer have been taken into account for the estimation of the dose-response relationship. This will be included in Step 4 of this methodology (the monetary valuation of fatal and non-fatal cancer risks).

Estimation of average fatality rates in %, based on EU wide empirical data

The individual development of cancer diseases may be fatal or non-fatal. Non-fatal cancer is defined as cancer not causing a premature death, i.e. life expectancy is not reduced due to the cancer disease, whereas fatal cancer is defined as cancer leading to premature death. This distinction is important when applying the ECHA guidance on socio-economic analysis in order to use consistent categories of monetary values.

For the determination of fatality rates for lung cancer, demographic data on age-specific cancer incidences and mortality rates have been taken into account; these are mainly:

- age profile of a population
- gender profile of a population
- relationship of risk of developing the disease and risk of dying from the disease

For lung cancer, during previous applications for authorisation, data of the International Agency for Research on Cancer (IARC) for the EU-27, as well as data for the EU Member States, showing the age and gender profile of cancer risks in more detail have been analysed and compared to selected other EU Member States with similar data collection sets (40).

Although the incidence risk and the mortality risk themselves are higher for men than for women, the relationship between incidence and mortality risk (i.e. the fatality rate) shows, apart from random fluctuations, there exist no major differences between males and females.

It has to be emphasised that any structural differences in the baseline risks (e.g. between men and women, between different EU Member States or between different age groups) do not influence the estimation of incremental cancer risks due to exposure to Cr(VI). Therefore, neither the share of male and female workers exposed at work nor the exact age of workers influence the outcome of the estimations.

The fatality rate is an important parameter for a monetary-based valuation of cancer risks. The reference dose-response relationship estimates additional fatal cancer risks only. A full health impact assessment will also consider lung cancer cases that do not result in fatality.

Latest data on cancer incidence and mortality available for the year 2018 stem from the European Cancer Information System (ECIS) as a specific collaboration between IARC and JRC. (41) For this SEA, it was decided to use the EU average for mortality rates. Although fluctuations in the relationship of incidence and mortality rates of a specific type of cancer from one Member State to another might be primarily random due to the small numbers of cases within one country and one specific year, rather than caused by structural differences in the populations and their vulnerability, medical treatment or health systems of the respective countries, the RAC/SEAC opinion on a previous SEA recommends using country-specific mortality rates if the health effects are calculated for each site separately, and not mortality rates of EU-28. Whereas average mortality rates for lung cancer in the EU-28 are 81.2% for both sexes. This value of 81.2% will be used for further analyses in this SEA.

Monetary valuation of additional cancer cases

In order to evaluate the additional cancer cases in monetary terms, monetary values for cancer cases as suggested by the latest study published by ECHA (2016) (38) are used.

In this study, the values of a statistical life (VSL) and the values for morbidity due to cancer (VCM) have been found to be the following (see Table 94).

Table 94: Relevant values for the valuation of health impacts taken from ECHA review from 2016 (ECHA, 2016)

Value	Lower bound [in EUR 2012]	Upper bound [in EUR 2012]
Value of statistical life (VSL)	3,500,000	5,000,000
Value of cancer morbidity (VCM)	410,000	410,000

Since values are based on the year 2012, they are adjusted to the respective base year for the calculation of the net present values (NPV) of costs and benefits by using gross domestic product (GDP) deflator indexes. This will be explained in the following.

Implementation of a price adjuster

In this SEA, costs and benefits are made comparable by basing them to the base year (the base year is used as reference for all cost estimations of the SEA). Therefore, health risks as well as additional costs relating to the continued use of Cr-VI in case of the authorisation are based to this year.

To adjust the values to the base year, these values are multiplied by a price adjuster, which is the appropriate price index of the reference year divided by the appropriate price index of the year 2010. When using as appropriate price index the GDP deflator of the EU-27 (i.e. without UK since the review period relates to the time after the Brexit) issued by the statistical office of the European Union (EUROSTAT), complete data was gathered up to the year 2019. The quarterly deflator is calculated from seasonally adjusted GDP values and rescaled so that 2010 equals 100. For 2019, the deflators of the 4 quarters range from 110.41 (first quarter) to 111.88 (fourth quarter), with an arithmetic mean of 111.09 for the 4 quarters.[1][36] A price index development from 104.4 (in 2012 based on 2010=100) up to 111.88 in 2019 is equivalent to an average annual growth factor of 1.008918 (geometric mean over 7 years from 2012 to 2019). We assume that in the average the calculated rate of price increase will continue in future from 2019 up to the reference year; therefore, the factor of 1.008918 per year is applied to extrapolate the price index development into the future.

[36] Source: http://ec.europa.eu/eurostat/tgm/table.do?tab=table&plugin=1&language=en&pcode=teina110 [Cited: 24 April 2020].

Table 95: Monetary values for VSL and VCM - ECHA review (2016)

	Lower bound	Upper bound
Value of statistical life for cancer (2012)	EUR 3,500,000	EUR 5,000,000
Value of cancer morbidity (2012)	EUR 410,000	EUR 410,000
Adjusting the 2012 values to the reference year (2020)	$1.008918^{\text{reference year – 2012}}$	$1.008918^{\text{reference year – 2012}}$
Value of statistical life for cancer (2020)	EUR 3,757,639	EUR 5,368,055
Value of cancer morbidity (2020)	EUR 440,181	EUR 440,181

Calculation of an additional cancer case based on adjusted VSL and VCM values

The value for one additional lung cancer case (fatal and non-fatal) is calculated by the following equation:

Value of a fatal lung cancer case = $(\mathbf{1}+\boldsymbol{i})^{-\boldsymbol{l}} \times (\boldsymbol{VSL}+\boldsymbol{VCM})$

Value of a non-fatal lung cancer case = $(\mathbf{1}+\boldsymbol{i})^{-\boldsymbol{l}} \times \boldsymbol{VCM}$

with

$\boldsymbol{i}$ being the discount rate (considered to be **4% a year** for the lower bound and **2% a year** for the upper bound, since ECHA recommends in the SEA guidance using a lower rate or a decreasing rate over time for environmental and health impacts because they are different than economic impacts (36), p. 176). Alternatively, it can be argued that discounting due to the latency period between exposure and the potential incidence of a disease reflects the individual time preference rate of the interviewed persons in the contingent valuation survey, which in general differs from the social time preference rate.

Note that a lower discount rate in the case of latency between exposure and disease leads to a higher monetary value and vice versa. Therefore, the final upper bound stems from the combination of the parameters 2% for the discount rate and EUR 5,000,000 for the VSL (2012), the lower bound results from the combination of the parameters 4% for the discount rate and ÉUR 3,500,000 for the VSL (2012),

$\boldsymbol{l}$ being the latency period (assumed to be **10 years for lung cancer** as done in the ECHA review from 2016 (38))

For each fatal cancer case, an additional share of $\frac{(\mathbf{1}-\boldsymbol{f})}{\boldsymbol{f}}$ non-fatal cancer cases will occur, with

$\boldsymbol{f}$ being the fatality rate of the cancer type (assumed to be 81.2% for lung cancer in the EU) (41). Therefore, the additional share of non-fatal cancer cases per one fatal cancer case amounts to 18.8%.

Taking into account the VSL (lower and upper bounds) and VCM values as adjusted for 2020 and following the formula and assumptions described above, the values of one additional fatal lung cancer case (lower and upper bounds) amount to **EUR 2,835,896 and EUR 4,764,776.** The values of one additional non-fatal lung cancer case (lower and upper bounds) amount to **EUR 297,370 and EUR 361,101.**

Individual ELR per WCS

In order to monetise the excess risk (i.e. additional fatal lung cancers) relating to the authorisation of the continued use of chromium trioxide, first the excess risk is calculated according to the following equation:

$$ELR = \frac{review\ period\ [years]}{40\ years} \times \frac{working\ days\ per\ year}{260\ days} \times \text{4E-03 per } \frac{\mu g\ Cr(VI)}{m^3} \times \text{concentration} \left[\frac{\mu g\ Cr(VI)}{m^3}\right]$$

where

$$\text{concentration} \left[\frac{\mu g\ Cr(VI)}{m^3}\right]$$

represents the Cr(VI) concentration taken from the ES in the CSR.

As already mentioned before, the correction factor for working days is only applied where necessary.

Total ELR over all WCSs and workers

The calculation of the excess risk (i.e. additional fatal lung cancers) over all employees potentially exposed is calculated per WCS by multiplying the individual excess risk with the respective number of workers potentially exposed. Then, the excess risk of all WCS are summed up. Thus, the estimated amount of additional fatal lung cancers is the expected value due to a continued use of Cr(VI) for the respective time frame allowed by an authorisation up to the next revision.

$$\sum_{i=1}^{n} (\boldsymbol{ELR_i} \times \boldsymbol{number\ of\ workers_i})$$

i = WCS

Monetisation of the total ELR

In the next step, the monetisation of the total ELR is done by multiplying the total ELR value by the value of one additional lung cancer case (this was done separately for fatal and non-fatal cases).

Note: The monetisation approach suggested in the ECHA review from 2016 (38) was not fully adopted in the present assessment because it does not match with the available dose-response relationship for inhalation exposure to hexavalent chromium (37). The dose-response relationship for lung cancer made available by ECHA refers to an excess lifetime lung cancer **mortality risk** while the monetisation approach suggested in the review from 2016 (38) deals with a dose-response relationship referring to **cancer (incidence) risk.** In the case where the dose-response relationship refers to a mortality risk, the monetisation approach must additionally account for the cancer cases which did not end up in death of the patient, as it is done in the present assessment.

Quantitative health impact assessment of the general population

According to ECHA Guidance on information requirements and chemical safety assessment section R.16: Environmental exposure estimation, version 2.1, October 2012 (ECHA Guidance R.16) (42), potential exposure via the environment should be assessed on 2 spatial scales: locally in the vicinity of point sources of release to the environment, and regionally for a larger area which includes the point source or all point sources in that area. Releases at the continental scale are not used as endpoints for exposure. The end results of the exposure estimation are predicted environmental concentrations (PECs) in the environmental compartments for both local and regional scale which have been calculated in the ES.

As noted in the EU risk assessment report (RAR) for Cr(VI) substances (43), "*releases of Cr(VI) from any sources are expected to be reduced to Cr (III) in most situations in the environment (…)*" and "*the impact of Cr(VI) as such is therefore likely to be limited to the area around the source*." (p. 26). For this reason, the aforementioned EU RAR for Cr(VI) substances set the focus of its assessment on the local impacts of the emissions.

Such understanding about the impacts of Cr(VI) being limited to the area around the source has been shared by RAC in previous opinions such as in the opinion on the AFA-O-0000006480-78-01/D (44), where it is stated: "*Cr(VI) is effectively reduced to Cr(III) in the environment, which is why EU RAR concluded that the regional exposure may not be relevant. RAC agrees with EU RAR that regional exposure is likely not to be very relevant*." (p. 35).

Given this background, the present SEA considers the regional exposure of MVE as not relevant and focuses its assessment on the local exposure of MVE.

The local Predicted Environmental Concentration (= MVE local), based on modelled data, is used to calculate potential risks for on-site workers not directly exposed as well as the direct neighbourhood. The respective value for MVE oral provided in the CSR has been taken as a basis for calculation of impacts resulting from oral uptake via the food chain.

MVE local

The local exposure assessment considers workers that do not work with Cr(VI), but work in the vicinity (potentially indirectly exposed workers) as well as people living in the direct neighbourhood of the sites. As a default number recommended as the basis of the local exposure assessment in the ECHA Guidance R.16 (42), the total number of people potentially exposed on a local scale is estimated in 10, 000 per site using Cr(VI).

As a worst-case scenario, the exposure concentration used for the risk assessment of the whole group of people is the PEC_{local} independent from the distance from the emitting source.

Since there is no basis for a reliable distinction between the number of potentially indirectly exposed workers and people living in the neighborhood, the dose-response curve for the general population is taken as a basis following the worst-case approach, i.e. workers would be exposed for less time, e.g. 8 hours per day for 220 days, than the general population (24 hours per day for 365 days of exposure).

Table 96 summarises the most important input parameters.

Table 96: Overview of the most important input parameters for calculation of health impacts for MVE

Exposure concentration	Group of potentially exposed people	Number of potentially exposed people	Dose-response curve for
PEC_{local}	Potentially indirectly exposed workers and direct neighbourhood per site	10,000	General population

Estimation of additional cancer cases in relation to baseline

In addition to inhalation exposure to Cr(VI) via the environment, for the general population oral exposure to Cr(VI) via the food chain is also taken into respect, which leads to an additional risk of small intestine cancer. Dose-response relationships, but also fatality rates and latency times and therefore monetary valuation of cancer cases are different for small intestine cancer than for lung cancer.

The dose-response relationship for Cr(VI) with regard to lung and small intestine cancer for the general population has been discussed in recent research published by ECHA (37).

Linear exposure-risk relationship for lung cancer as estimated by ECHA (37):

$$Unit\ excess\ lifetime\ risk = 2.9\ \text{E-02}\ per\ \mu g\ Cr(VI)/m^3$$

Linear exposure-risk relationship for small intestine cancer as estimated by ECHA (37):

$$Unit\ excess\ lifetime\ risk = 8\ \text{E-04}\ per\ \mu g\ Cr(VI)/kg\ bw/day$$

It has to be emphasised that for small intestine cancer the dose-response relationship refers to the incidence and not to fatality of cancer, unlike for lung cancer. According to the ECHA document (37), the term used is '*excess lifetime intestinal cancer risk*'. This signifies that the dose-response function developed refers to additional intestinal cancers ending either fatal or non-fatal. In this study, data on cancer incidence, not cancer mortality have been taken into account for the estimation of the dose-response relationship. This will be included in step 4 of this methodology (the monetary valuation of fatal and non-fatal cancer risks).

Adaption factor

The dose-response curve for the general population considers 365 days of exposure and 70 years of life-time. Accordingly, it is necessary to adjust the exposure duration to the foreseen review period of 12 years by the factor 12/70.

Estimation of average fatality rates in %, based on empirical data for EU

As explained, the individual development of cancer diseases may be fatal or non-fatal. The fatality rate is an important parameter for a monetary-based valuation of cancer risks.

As stated above the reference dose-response relationship for lung cancer estimates the fatal cancer risks, whereas the reference dose-response relationship for small intestine cancer estimates both fatal and non-fatal cancer risks.

According to IARC the average mortality rates for lung and intestinal cancer in the EU are 81.2% and 48.3%, respectively, for both sexes, i.e. intestinal cancer has a more favourable survival prognosis than lung cancer. This value will be used for further analyses in this SEA.

Monetary valuation of additional cancer cases

Analogous to the previous approach the additional cancer cases are evaluated in monetary terms. As stated before, the average mortality rate for lung cancer and intestinal in EU are 81.2% and 48.3%, respectively.

MVE local

Individual ELR lung cancer (local):

$$ELR = \frac{review\ period\ [years]}{70\ years} \times 2.9\text{E-}02 \text{ per } \frac{\text{µg Cr(VI)}}{\text{m}^3} \times \text{ MVE local inhalation}$$

Individual ELR intestinal cancer (local):

$$ELR = \frac{review\ period\ [years]}{70\ years} \times 8.0\text{E-}04 \text{ per } \frac{\text{µg Cr(VI)}}{\text{kg bw/day}} \times \text{ MVE local oral}$$

where MVE local represents the predicted local environmental Cr(VI) concentration taken from the ES in the CSR.

Total ELR

For the calculation of the total ELR related to MVE local, the total number of potentially indirectly exposed people is assessed taking into account the foreseen population potentially exposed around each site as described above.

The calculation of the total excess risk follows the methodology previously described according to the following equations:

ELR lung cancer (local)

$$ELR = \frac{review\ period\ [years]}{70\ years} \times 2.9\text{ E-}02 \text{ per } \frac{\text{µg Cr(VI)}}{\text{m}^3} \times \text{ MVE local inhalation} \times \text{number of people potentially exposed}$$

ELR intestinal cancer (local)

$$ELR = \frac{review\ period\ [years]}{70\ years} \times 8.0\text{ E-}04 \text{ per } \frac{\text{µg Cr(VI)}}{\text{kg bw/day}} \times \text{ MVE local oral} \times \text{number of people potentially exposed}$$

Monetisation of an additional cancer case based on adjusted VSL and VCM values

Due to differences in the dose-response relationships of lung cancer and small intestine cancer (the first relationship measures mortality risk while the second calculates cancer risk), the monetisation of total ELR for each of the cancer types is done using different equations.

The monetised values for one additional lung cancer case (fatal and non-fatal) is calculated in the same way as described above for worker exposure and therefore ranges between

EUR 2,835,896 and EUR 4,764,776 (fatal) and **EUR 297,370 and EUR 361,101 (non-fatal).**

In regard to small intestine cancer, the monetised value for one additional small intestine cancer case (ending fatal or non-fatal) is calculated following the same approach described in the ECHA review from 2016 (38):

Value of cancer case = Discount factor x (fatality probability x VSL + VCM)

or

$$(\mathbf{1}+\boldsymbol{i})^{-\boldsymbol{l}} \times (\boldsymbol{f} \times \boldsymbol{VSL} + \boldsymbol{VCM})$$

with

i being the discount rate (considered to be **4% a year** for the lower bound and **2% a year** for the upper bound), as described in the approach for calculating the value of fatal and non-fatal lung cancer cases for directly exposed workers.

l being the latency period (assumed to be **26 years for small intestine cancer** (45))

f being the fatality rate of the cancer type

Considering the VSL (lower and upper bounds) and VCM values as adjusted for 2020, the values of one additional small intestine cancer case (lower and upper bounds) amount to **EUR 1,514,108 and EUR 3,470,881 (fatal intestinal cancer case)** and to **EUR 158,768 and EUR 263,043 (non-fatal intestinal cancer case)**. Note that due to the longer latency assumed the ratios between upper and lower bounds are higher than for lung cancer, caused by the effect of different discount rates.

Monetisation of total ELR

In the next step, the monetisation of the ELR regarding general population exposure is done by multiplying the ELR value by the value of one additional cancer case (separately for the four combinations of lung or small intestine cancer ending fatal or non-fatal, according to the ELR calculated).

Following this methodology, the actual assessment of health impacts related to the authorisation of the continued use of chromium trioxide is conducted in Appendix 2.

Overestimation of the quantitative assessment

The overall calculation approach entails an overestimation of health impacts for the following reasons:

- The exposure estimates presented in the CSR are already worst-case assumptions regarding frequency of activities (see CSR for more details).
- Applicants have been asked to provide worst case estimations for number of exposed workers. This means that for example workers not involved in relevant activities have nevertheless been counted in case there is a theoretical possibility that these workers enter respective areas.
- Taking into account that the MVE local air represents the concentration 100 m from

the point source (considered to represent the average distance between the release source and the border of the industrial site), it is clear that in reality it is impossible that 10,000 people are exposed to concentrations calculated for MVE local air at the boundary of each site at which Cr(VI) is used. It can reasonably be inferred that the majority of the population is located much more than 100 m from the point source. Therefore, the majority of the local population is exposed to concentrations much lower than the estimated concentration 100m from the point source. This is because the concentration of Cr(VI) is decreasing with increasing distance from the emission source. However, for the calculations in the SEA all of these people have been assumed to be exposed at exposure rates as predicted 100 m from the stack (MVE local). Differently spoken, all the potentially exposed local population have been assumed to be located only 100m from the emission source, which results in a clear overestimation of impacts.

- Calculating the excess of risk evolving cancer for the general population on basis of the dose-response curve published by ECHA (37) assumes a linear relationship between dose and response, even at low doses (below 0.1 µg/m^3). The ETeSS study (39) which was the basis for the dose-response curve published by ECHA (37) itself recognizes that a linear dose response relationship for carcinogenicity of Cr(VI) is not established below 1µg/m^3. The study conducted by ETeSS on behalf of ECHA clearly states that: '[…] the lower the exposure (certainly below 1µg/m3), the more likely it is that the linear [dose-response] relationship overestimates the cancer risk.' The study further states that 'the risk estimates for […] exposures lower than 1 µg Cr(VI)/m^3 might well greatly overestimate the real cancer risks. It is also considered that at progressively lower Cr(VI) air concentrations (from about 0.1 µg/m^3 downwards), cancer risks may be negligible.' The MVE_{local} 100 m from the point source considered in the CSR is 1.03E-03 µg/m^3 and therefore approximately 100 times lower than the concentration from where the ETeSS study states that cancer risks may be negligible.
- For the calculation of health impacts for the local population, the respective dose response relationship provided by RAC has been used. This dose response curve is based on the estimation that exposure occurs 365 days a year and 24 h a day. In reality, the local population is not present in the relevant area every day a year for full 24 h. For example, people leave the area for 8 h a day in case their work places are located somewhere else or go on holidays for several days a year. The dose response function has not been corrected and therefore over-estimates risk based on inflated assumptions about exposure frequency and duration.

8.2 Additional results from the DU survey

8.2.1 Downstream users by export shares

Figure 33 shows the number of DUs in terms of customers outside the EEA. Among the respondents to the question, 30%, 28%, and 44% of Type I, II, and III do not have customers outside the EEA respectively.

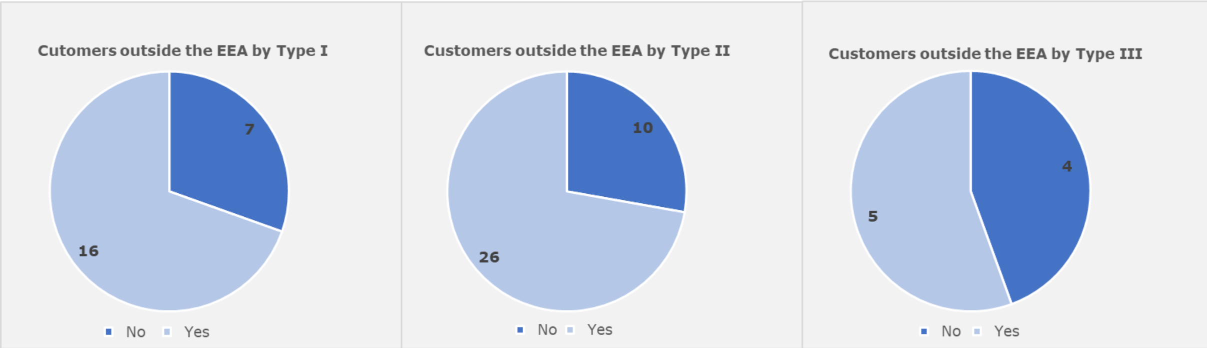

Figure 33: Number of DUs segmented by the customers outside the EEA

Among the respondents who have customers outside the EEA, a total of 39 DUs have less than 25% of the share in their total sales (see Figure 34).

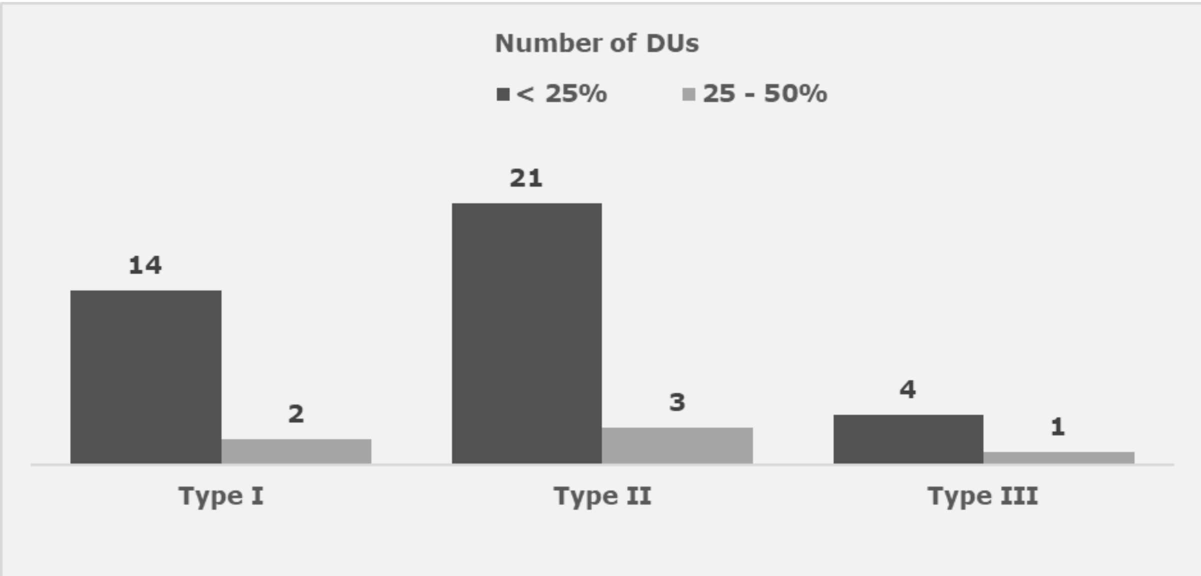

Figure 34: Number of DUs segmented by the share of sales from customers outside the EEA in the total sales

8.2.2 Number of employees at the downstream users' firms

To obtain the number of employees at each DU, a numerical blank field was requested to be filled by the respondents. In this case, no non-confidential ranges were provided in the survey. The confidential numbers received in this case were aggregated to present the total non-confidential number of employees per type.

Table 97 shows the total number of employees aggregated for Type I, II and III DUs in the EEA respectively.

Table 97: Total number of employees at the downstream users' firms by type

Type of DU	Aggregated number of employees
Type I	3,493
Type II	17,182
Type III	5,815
TOTAL	**26,490**

Collectively, downstream user that answered the survey employ a total of 26,490 employees for all their activities.

8.2.3 Responses to sub-questions for DUs for each NUS

Out of the DUs that ranked a scenario as their most-likely NUS, the following responses were obtained based on the subset of questions for each non-use scenario:

8.2.3.1 NUS A

Table 98: Frequency of different options selected by DUs by type to change in investment and operating cost due to most likely NUS A

	Investment cost									**Operating cost**								
	Increase				Decrease				No change	Increase				Decrease				No change
	<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000		<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000	
Type I																		
Type II			1	3			1				1		2			1		
Type III									1									
Total			**1**	**3**			**1**		**1**		**1**		**2**			**1**		

Table 99: Frequency of options selected by DUs by type to change in product quality, market prince and consumer retention due to most likely NUS A

	Product quality					**Market price**			**Consumer retention**	
	Enhanced product quality	Poor product quality that is acceptable in the market	Poor product quality unacceptable in the market	No change	Other (to specify)	Increase	Decrease	No change	Yes	No
Type I										
Type II	1	2	1	2		4	1		5	
Type III				1				1		
Total	**1**	**2**	**1**	**3**		**4**	**1**	**1**	**5**	

Table 100: Frequency of options selected by DUs by type to change in employment due to most likely NUS A

	Workforce in cylinder production			**Workforce in printing process**		
	Increase	Decrease	No change	Increase	Decrease	No change
Type I						
Type II		4	1		4	
Type III		1			1	
Total		**5**	**1**		**5**	

8.2.3.2 NUS B

	Please select a suitable option			If you selected option B in the previous question, is this option cheaper than choosing option A?			What would be the time required to find a suitable subcontractor outside the EEA?				Will there be a supply disruption after a suitable subcontractor has been identified?		Will you maintain a positive profit margin as a result of this scenario?		
	A. We would outsource the production of coated cylinders	B. We would outsource the final printed product	C. Both	Yes	No	Cannot decide based on current practice	<1 year	1 – 5 years	5-10 years	>10 years	A. Production will begin right after the subcontractor is identified	B. There can be a supply disruption if the subcontractor has no spare capacity	Yes	No	Cannot decide based on current practice
Type I	2						2				1	1			2
Type II	3	1	1		1	1	3	2				5		1	4
Type III															
Total	**5**	**1**	**1**		**1**		**5**	**2**			**1**	**6**		**1**	**6**

Table 101: Schedule of sub questions for NUS B

Table 102: Frequency of different options selected by DUs by type to change in investment and operating cost due to most likely NUS B

	Investment cost									**Operating cost**								
	Increase				Decrease				No change	Increase				Decrease				No change
	<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000		<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000	
Type I			2								1	1						
Type II			1	2					2		2	1	1			1		
Type III																		
Total			**3**	**2**					**2**		**3**	**2**	**1**			**1**		

Table 103: Frequency of options selected by DUs by type to change in product quality, market prince and consumer retention due to most likely NUS B

	Product quality					**Market price**			**Consumer retention**	
	Enhanced product quality	Poor product quality that is acceptable in the market	Poor product quality unacceptable in the market	No change	Other (to specify)	Increase	Decrease	No change	Yes	No
Type I		1		1		1		1	2	
Type II		2		3		5			5	
Type III										
Total		**3**		**4**		**6**		**1**	**7**	

Table 104: Frequency of options selected by DUs by type to change in employment due to most likely NUS B

	Workforce in cylinder production			**Workforce in printing process**		
	Increase	Decrease	No change	Increase	Decrease	No change
Type I		2				
Type II		4	1			
Type III						
Total		**6**	**1**			

8.2.3.3 NUS C

Table 105: Schedule of sub questions for NUS C

	Please select a suitable option		What is your estimated timeline (in years) for relocation?	Can you identify a country outside the EEA where relocation would seem feasible with respect to regional market entry, competition and transportation costs for imports to the EEA? [For instance, relocating to China may give rise to prohibitive transportation costs which might be comparatively bearable in Turkey]			
	A. We would relocate the coating process and import the coated cylinders into the EEA for printing	B. We would relocate all processes outside the EEA and import the end product into the EEA	Number of years required (Number of respondents *[Min – 1, max – 10, mode – 1, median – 2.5, average – 3.5]*	Most likely in America	Most likely in Asia	Most likely in Europe	Cannot decide based on current practice
Type I	2	2	1(2), 1(4), 1(10)		2		2
Type II	2	1	2 (1)			1	1
Type III		1	1(3)		1		
Total	**4**	**4**	**6**		**3**	**1**	**3**

Table 106: Frequency of different options selected by DUs by type to change in investment and operating cost due to most likely NUS C

	Investment cost									**Operating cost**								
	Increase				Decrease				No change	Increase				Decrease				No change
	<10, 000	10,000 - 100,000	100,000- 1,000, 000	>1,000,000	<10,000	10,000 - 100,000	100,000- 1,000, 000	>1,000,000		<10, 000	10,000 - 100, 000	100,000- 1,000, 000	>1,000 ,000	<10, 000	10,000 - 100, 000	100,000- 1,000, 000	>1,000,000	
Type I				2			1					2	1					
Type II			1	1								1	1					
Type III							1						1					
Total			**1**	**3**			**2**					**3**	**3**					

Table 107: Frequency of options selected by DUs by type to change in product quality, market prince and consumer retention due to most likely NUS C

	Product quality					**Market price**			**Consumer retention**	
	Enhanced product quality	Poor product quality that is acceptable in the market	Poor product quality unacceptable in the market	No change	Other (to specify)	Increase	Decrease	No change	Yes	No
Type I			1	1	2	4			4	
Type II		1		1		2			1	1
Type III		1				1			1	
Total		**2**	**1**	**2**	**2**	**7**			**6**	**1**

Table 108: Frequency of options selected by DUs by type to change in employment due to most likely NUS C

	Workforce in cylinder production			**Workforce in printing process**		
	Increase	Decrease	No change	Increase	Decrease	No change
Type I		4			1	
Type II		2				2
Type III		1			1	
Total		**7**			**2**	**2**

8.2.3.4 NUS D

Table 109: Schedule of sub questions for NUS D

	In case of a temporary shutdown of activities, how long will the supply be interrupted for?				Would you be able to regain the lost market share or remain competitive in the EEA market after the supply disruption?		
	<1 year	1-5 years	5-10 years	>10 years	Yes	No	Cannot decide based on current practice
Type I	4	1		1		2	4
Type II	2	2				2	2
Type III	2	1					3
Total	**8**	**4**	**0**	**1**	**0**	**4**	**9**

Table 110: Frequency of different options selected by DUs by type to change in investment and operating cost due to most likely NUS D

	Investment cost									**Operating cost**								
	Increase				Decrease				No change	Increase				Decrease				No change
	<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000		<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000-1,000,000	>1,000,000	
Type I			3	2					1	1	3		1		1			
Type II			3					1			1	2			1			
Type III	1	1	1							1	2							
Total	**1**	**1**	**7**	**2**				**1**	**1**	**2**	**6**	**2**	**1**		**2**			

Table 111: Frequency of options selected by DUs by type to change in product quality, market prince and consumer retention due to most likely NUS D

	Product quality					**Market price**			**Consumer retention**	
	Enhanced product quality	Poor product quality that is acceptable in the market	Poor product quality unacceptable in the market	No change	Other (to specify)	Increase	Decrease	No change	Yes	No
Type I		2	1	2	1	4	1	1	6	
Type II	1		2		1	4			4	
Type III	1			2		2		1	2	1
Total	**2**	**2**	**3**	**4**	**2**		**10**	**1**	**2**	**12**

Table 112: Frequency of options selected by DUs by type to change in employment due to most likely NUS D

	Workforce in cylinder production			Workforce in printing process		
	Increase	Decrease	No change	Increase	Decrease	No change
Type I	1	3	2			1
Type II		2	2		1	2
Type III		1	2			3
Total	**1**	**6**	**6**		**1**	**6**

8.2.3.5 NUS E

Table 113: Schedule of sub questions for NUS E

	Would you consider this as insolvency?		
	A. Yes, the entire business will be lost	B. No, we will switch to another business activity	C. Cannot decide based on current practices
Type I	7		
Type II	14		2
Type III	3		1
Total	**24**		**3**

Table 114: Frequency of different options selected by DUs by type to change in investment and operating cost due to most likely NUS E

	Investment cost									**Operating cost**								
	Increase				Decrease				No change	Increase				Decrease				No change
	<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000		<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000	<10,000	10,000 - 100,000	100,000- 1,000,000	>1,000,000	
Type I			1			1	1	2			2	1			1			
Type II			3	9		1		1			1	5	4				2	
Type III			1	2			1					1	2				1	
Total			**4**	**11**		**2**	**2**	**3**			**3**	**7**	**6**		**1**		**3**	

Table 115: Frequency of options selected by DUs by type to change in product quality, market prince and consumer retention due to most likely NUS D

	Product quality					**Market price**			**Consumer retention**	
	Enhanced product quality	Poor product quality that is acceptable in the market	Poor product quality unacceptable in the market	No change	Other (to specify)	Increase	Decrease	No change	Yes	No
Type I			3		1	2		2	5	1
Type II		8	3		2	8	2	3	12	2
Type III		1		1	2	2		2	2	2
Total		**9**	**6**	**1**	**5**	**12**	**2**	**7**	**19**	**5**

Table 116: Frequency of options selected by DUs by type to change in employment due to most likely NUS E

	Workforce in cylinder production			**Workforce in printing process**		
	Increase	Decrease	No change	Increase	Decrease	No change
Type I		6				
Type II		13	1		10	2
Type III		3	1		2	2
Total		**22**	**2**		**12**	**4**

8.2.4 Aggregation of economic impacts

8.2.4.1 NUS A

Table 117: Quantitative impact for DUs due to most-likely NUS A

Additional investment costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	4	by	< EUR 10,000		-
			10,000	100,000	
			100,000	1,000,000	1
			1,000,000	1,000,000	3
Decrease	1		-100,000	-1,000,000	1
No change	1		-	-	-
TOTAL	**6**		**3,000,000**		**5**
Additional operating costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	5	by	< EUR 10,000		-
			10,000	100,000	-
			100,000	1,000,000	2
			1,000,000	1,000,000	2
Decrease	1		-100,000	-1,000,000	1
No change	0		-	-	-
TOTAL	**6**		**2,100,000**	**3,000,000**	**5**

8.2.4.2 NUS B

Table 118: Quantitative impact for DUs due to most-likely NUS B

Additional investment costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	5	by	< EUR 10,000		-
			10,000	100,000	
			100,000	1,000,000	3
			1,000,000	1,000,000	2
Decrease	-		-	-	
No change	2		-	-	-
TOTAL	**7**		**2,300,000**	**5,000,000**	**5**

Additional operating costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	6		< EUR 10,000		-
			10,000	100,000	3
			100,000	1,000,000	2
			1,000,000	1,000,000	1
Decrease	1		-100,000	-1,000,000	1
No change	0		-	-	-
TOTAL	**7**		**1,130,000**	**2,300,000**	**7**

8.2.4.3 NUS C

Table 119: Quantitative impact for DUs due to most-likely NUS C

Additional investment costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	4	by	< EUR 10,000		-
			10,000	100,000	
			100,000	1,000,000	3
			1,000,000	1,000,000	3
Decrease	3		-	-	
No change	0		-	-	
TOTAL	**7**		**3,300,000**	**6,000,000**	**6**
Additional operating costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	6		< EUR 10,000		-
			10,000	100,000	1
			100,000	1,000,000	2
			1,000,000	1,000,000	3
Decrease	1		-	-	
No change	0		-	-	
TOTAL	**7**		**3,210,000**	**5,100,000**	**6**

8.2.4.4 NUS D

Table 120: Quantitative impact for DUs due to most-likely NUS D

Additional investment costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	11	by	< EUR 10,000		1
			10,000	100,000	1
			100,000	1,000,000	7
			1,000,000	1,000,000	2
Decrease	1		-1,000,000	-1,000,000	1
No change	1		-	-	-
TOTAL	**13**		**1,720,000**	**8,100,000**	**12**
Additional operating costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	11		< EUR 10,000		2
			10,000	100,000	6
			100,000	1,000,000	2
			1,000,000	1,000,000	1
Decrease	2		-10,000	-1,00,000	2
No change	0		-	-	-
TOTAL	**13**		**1,240,000**	**3,400,000**	**13**

8.2.4.5 NUS E

The below mentioned additional operating costs have, however, been disregarded for the impact assessment in this AfA.

Table 121. Quantitative impact for DUs due to most-likely NUS E

Additional investment costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	16	by	< EUR 10,000		-
			10,000	100,000	0
			100,000	1,000,000	5
			1,000,000	1,000,000	11
Decrease	7		-10,000	-100,000	2
			-100,000	-1,000,000	2
			-1,000,000	-1,000,000	3
No change	0		-	-	-
TOTAL	**23**		**8,280,000**	**10,800,000**	**23**
Additional operating costs					
Qualitative impact	**Number of respondents**		**Quantitative impact (in EUR)**		**Number of respondents**
Increase	16	by	< EUR 10,000		-
			10,000	100,000	3
			100,000	1,000,000	7
			1,000,000	1,000,000	6
Decrease	4		-10,000	-100,000	1

			-1,000,000	-1,000,000	3
No change	1		-	-	-
TOTAL	**21**		**3,730,000**	**10,300,000**	**20**

8.2.5 Aggregation of social impacts of unemployment

Table 122: Quantitative social impact of employee dismissals at the applicant's DUs located in the EEA in use 2

	Number of employees	**Number of respondents**	**Total cost** [EUR] (=**x*number of employees**)
NUS A			
Total number of employee dismissals in cylinder production	66	5	4,563,588
Total number of employee dismissals in the printing process	530	5	36,646,994
Total Social Costs adjusted to 2020	**596**	**10**	**41,210,582**
NUS B			
Total number of employee dismissals in cylinder production	130	6	8,988,885
Total number of employee dismissals in the printing process	0	1	0
Total Social Costs adjusted to 2020	**130**	**7**	**8,988,885**
NUS C			
Total number of employee dismissals in cylinder production	295	7	20,397,855
Total number of employee dismissals in the printing process	340	2	23,509,392
Total Social Costs adjusted to 2020	**635**	**9**	**43,907,247**
NUS D			
Total number of employee dismissals in cylinder production	450	6	31,115,372
Total number of employee dismissals in the printing process	80	1	5,531,622
Total Social Costs adjusted to 2020	**530**	**7**	**36,646,994**
NUS E			
Total number of employee dismissals in cylinder production	642	22	44,391,264
Total number of employee dismissals in the printing process	2706	12	187,107,104
Total Social Costs adjusted to 2020	**3348**	**34**	**231,498,368**
Total	**5239**	**67**	**362,252,076**