AfA ZF Friedrichshafen AG

Submission number: RU968687-80

Communication number: AFA-C-2114376513-47-01/F

Substance: Chromium trioxide, EC number: 215-607-8

The questions from the RAC/SEAC are provided in **bold** font. The response from the applicant, ZF Friedrichshafen AG, is provided in normal font under each respective comment or question.

RAC QUESTIONS TO THE APPLICANT

1. Man via environment: Air monitoring data

In order for RAC to verify the calculations that resulted in the exposure estimate from air emissions of 4.68E-6, please provide the values of the input calculations used in the estimation.

In 2013 and 2015 not all chimneys have been sampled as ZF is only required to conduct these measurements every 3 years. Therefore, the measurement value for 2015 was added to the values for 2013 to provide cover all three chimneys. In the next step, the average value was calculated for 2012 and 2013/15 respectively. These were converted first into g/year using the total hours of operation and afterwards to kg/d. The average over the years was built in the following and using the respective factor from the ECHA guidance document (2.78E-04) the emission at 100m distance from point source was calculated.

Table 1: Emission calculation at 100m distance from point source

Year	**Max. Value per chimney**					
	Ch1	**Ch2**	**Ch3**	**Total**	**Total in g/year (Total x 8760h)**	**kg/d**
2012	<0.016	0.135	0.2	**0.343**	3004.68	0.008232
2013	0.034		0.233			
2015		0.793		**1.06**	9285.6	0.02544
Mean 2012-2013/15 (kg/d)						**0.016836**
in 100m from point source				(Mean x 2.78E-04)		**4.6804E-06**

Please take into account that we applied a worst-case approach for our calculations. For all measurements, we used the maximum level from the emission measurements and not the mean value as you can see, for example, from the following table showing the 2015 measurement. All values are provided in mg/m³.

Table 2: 2015 CrVI emission measurements for chimney 3

Sample 1	Sample 2	Sample 3	Mean Value	Maximum Value	Limit value according to TA-Luft*
0,013	0,004	0,028	0,015	0,028	0,05

*TA-Luft: Technical Instructions for Air Quality

The value from Sample 3 correlates to the mass flow of 0.793 g/h which was used for the calculations. All concentrations are below the limit value.

2. Biomonitoring

Please provide more descriptive information on biomonitoring? For instance, what type of workers were monitored in each of the years and what was the distribution regarding the guidance value presented?

Operators which are part of the occupational preventive medical examination (including biomonitoring) are those with potential exposure to CrO3, either as an initial examination (before first time starting work with potential for CrO3 exposure) or as examination in regular intervals (once per year). As workers who operate the lines conduct most of the regular maintenance (Total Productive Maintenance, covered by WCS 6), they are automatically included in the biomonitoring. Results are provided to the workers in writing (confidential) and if the measurement exceeded the guidance value, re-measurements are conducted. If these re-measurements again exceed the guidance value, the line manager will be informed to discuss necessary provisions.

Data from occupational medical examinations are sensible with regard to data privacy protection and the data provided so far already required the agreement of the employee organization of the site. According to the medical service and the worker's council, we cannot provide more employee-specific data.

3. Data used in the worker exposure assessment (WCS 2 and 3)

Please provide a justification as to why a 2 hours sampling period was considered representative of the full shift?

The sampling is conducted by a certified institute selecting the time period for which a representativeness of the sample for all full shift reasonably can be assumed.

As the plating processes are continuous processes, 2 hours are adequate to cover the full shift (measuring "other" two hours would not result in different values). This is standard for continuous processes in Germany. However, as we asked the certified institute for a lower LOD in the second measurement campaign, they had to increase the air volume, which was achieved by increasing the sampling time.

Can the applicant confirm that the sampling period included the period of time when plant operators undertook control walks and sampling along the plating baths?

We assume that this question relates to the semi-closed plating process (WCS 3). Because the measurements were static measurements conducted near to the CrO3 plating baths, the

measurements provide worst-case results regarding individual exposure potential independent of if a control walk has been conducted during measurement time or not.

Please provide a breakdown /further elaboration as to how the mean values were obtained.

The mean values were calculated as following for WCS 2:

Table 2: mean values for WCS 2

Site	**Date**	**in mg/m³**	**in µg/m³**	**accounting for LOD (50% of LOD values)**	
[redacted]	9/2/2017	< 0.0006	< 0.6	0.3	automatic / encapsulated
[redacted]	8/2/2017	< 0.0008	< 0.8	0.4	automatic / encapsulated
[redacted]	8/2/2017	< 0.0009	< 0.9	0.45	automatic / encapsulated
[redacted]	9/2/2017	< 0.0009	< 0.9	0.45	automatic / encapsulated
[redacted]	9/2/2017	< 0.0009	< 0.9	0.45	automatic / encapsulated
[redacted]	8/2/2017	< 0.0008	< 0.8	0.4	automatic / encapsulated
[redacted]	12/4/2016	< 0.000625	< 0.625	0.3125	automatic / encapsulated
[redacted]	12/4/2016	< 0.000625	< 0.625	0.3125	automatic / encapsulated
Mean value				0.38	

And for WCS 3:

Table 3: mean values for WCS 3

Site	Date	in mg/m³	in µg/m³	accounting for LOD (50% of LOD values)	
[redacted]	9/2/2017	< 0.0006	< 0.6	0.3	automatic / semi-closed
[redacted]	8/2/2017	< 0.0007	< 0.7	0.35	automatic / semi-closed
Mean value				0.325	

During the Trialogue the rapporteurs asked for clarification regarding the frequency adjustments used for the ELR calculations which have been provided by the applicant as a separate Excel Sheet (Annex 1) to the responses to the RAC questions.

For infrequent activities, frequency of exposure was considered the following way:

- If an activity is conducted maximal one time per week (WCS 5, WCS 6, second sub-scenario), a factor of 0.2 was used for exposure assessment (one fifth of the week).
- If an activity is conducted less than 1 time per month (WCS 7, first sub-scenario), a conservative frequency factor of 0.05 was applied (12 times per year would be around 0.033).
- If an activity is conducted less than 2 times per year (WCS 7, second sub-scenario), a conservative frequency factor of 0.008 was applied (2 times per year would be around 0.0055).

4. Maintenance WCSs

RAC takes note of the English version of the manufacturers website indicating that the RPE used has an APF of 20. This will be noted as an uncertainty within the RAC opinion, except the applicant can provide a letter of confirmation from the manufacturer to remove this uncertainty.

Moldex Europe with headquarter in Germany provides on its German website an APF 30 for this type of mask/filter. On their English language website, the APF provided for this type of mask/filter is 20, on the French language website 50. Obviously, the manufacturer assigned protection factors according to national recommendations.

The APF of 30 provided on the German language website is in accordance with the German BG rule "BGR/GUV-R190". The APF assigned in this rule for a half-face mask with P3 filter is also 30. Therefore, we do not see any reason not applying this APF for the exposure and risk assessment for two German sites.

Furthermore, we do not understand why RAC is seeing this as an uncertainty because the consequences for using an APF value of 30 instead of 20 are minimal in this scenario; the exposure estimate for this maintenance task would increase from 6E-04 µg/m^3 to 9E-04 µg/m^3, both indicating a very low level of risk.

Furthermore, what information was used to support the decision that no RPE is required for all tasks (except of course some maintenance tasks)?

According to the German Hazardous Substances Ordinance (GefStoffV), companies have to conduct a work place/task specific risk assessment and based on the results of this risk assessment, have to define adequate operational conditions and risk management measures for the work places to minimize risk for their employees. The results of the workplace air monitoring show no measurable CrO3 exposure (i.e. all results below the LOD of the measurement) and therefore RPE was not seen as a necessary risk reduction measure in most of the possible situations.

A risk analysis for machines and equipment is also a mandatory and standard process in the declaration of CE conformity for the manufacturer of machines. All Atotech plating equipment is compliant to this European law.

5. **Request for applicants feedback on Public consultation comments related to worker exposure**

The Rapporteurs have taken note of the comments from the public consultation in particular the comment with respect to the potential for exposure from the encapsulation plant design versus the public consultation comment with respect to a "zero- discharge" plating system. The Rappourteurs also take note of the public consultation comments with respect to potential exposure from rig unloading and maintenance activities. So the Rapporteurs are aware of the deadline (27.10.2017) given to the applicant for a response on the outcome of the Public Consultation, they cordially invite him to explain his point of view.

RAC related comments

First of all, the comment assumes that outside the encapsulated plating line CrO3 could be detected at the two ZF sites ["Although, we are surprised that outside the encapsulation, Cr(VI) could be detected (we expected not detectable),"…(p. 2); "Therefore we expected zero exposure, which surprisingly could not be demonstrated, if we understand the CSR correctly" p.2-3)]

As it is stated and shown in the CSR (pg. 32) that all "sampling results were below the respective detection limit of the measurement", therefore CrO3 could not be detected. All values used for exposure estimation and risk assessment already consider this fact. The concrete values used were derived by using 50% of the respective detection limit of the measurement. We assume that the comment from Maysan Mando is based on a misunderstanding of the nature of the provided exposure estimates.

Maysan Mando further assumes that "missing respiratory protection inside the box during maintenance puts an increased unacceptable risk to workers". They especially refer to WCS 4, WCS 6 and 7. Sampling (WCS 4) is conducted for a very limited time period (less than 5 minutes) while the plating line is switched off but the local exhaust ventilation is still in operation. This activity is carried out in Eitorf one time per week, and in Schweinfurt on a daily basis. While a residual inhalation exposure to CrO3 cannot be completely excluded, any relevant increase in risk due to inhalation exposure cannot be expected from this task (as it was demonstrated in the exposure model). The same is true for WCS 6, regular maintenance work according to detailed maintenance plans, while the plating line is switched off but the local exhaust ventilation is still in operation. Usually this type of maintenance is conducted when the electrolyte is at room temperature. WCS 7 describes more rare maintenance activities, for example for checking the anodes and cathodes twice a year with emptied baths. In case LEV is off, RPE has to be worn. Any relevant inhalation exposure cannot be expected from these tasks. For each type of task a detailed maintenance plan including necessary PPE is available.

The loading of the racks for the automatic/encapsulated lines is conducted either by robots or by automated linear handling. In both cases, there is no handling by the workers and therefor no exposure occurs from this task. For the semi-closed line loading/unloading is conducted by the workers. The exposure for inhalation is not different from for the workers operating the line. However, in case the rinsing was insufficient, which would be a deviation from the

standard process, dermal contact with CrVI might occur. Therefore, respective PPE is required for the unloading of the racks (gloves.)

Maysan Mando describes the Gramm GST Technology as "Zero Emission Hard Chrome Plating Technology". As valuation of the "zero emission", a summary from a German measurement report is part of the document (p. 8-10). This report shows that all air monitoring results were below the Limit of Detection (LOD), and so not different from the results of the air monitoring at the encapsulated lines of ZF. "Zero emission" cannot be measured – all air monitoring can provide at best results below the detection limit of the measurement.

SEAC related comments

ZF as a global leader for shock absorbers and chassis systems knows the described GST Technology from company Gramm-Technik, Germany. First contacts and discussions with Gramm-Technik started in 2006, followed up by several visits and meetings including sample production in 2007 and 2010. Based on our evaluation the Gramm-Technik used by Maysan Mando does not meet the ZF quality specifications.

ZF History

Before ZF decided the implementation of Atotech Dynachrome machinery, we already made experience with different hard chrome processes. In the past, ZF was operating two high speed chrome plating lines from Yamaha next to a few semi-closed plating lines.

The Yamaha Rapid Plating System (YRPS) was launched in the 90's at Schweinfurt. At this time those machines were the most recent chrome plating system available on the market and very much comparable with the Gramm technology described by Maysan Mando.

We used to operate [redacted] lines with a maximum of [redacted] closed plating cells with pure platinum anode tubes. The chemistry was pumped into the cells. The plating speed was faster than the equipment from Gramm-Technik nowadays (current density approx. [redacted] A/dm²).

We replaced the Yamaha lines in [redacted].

Main reasons for replacing those machines by the Atotech Dynachrome lines were the downtimes by unscheduled maintenance. Major critical parts affected by these high maintenance requirements were sealing, piping, pumps and the exhausting system.

Comparison

If we have to compare the Technology of Atotech Dynachrome with the GST technology of Gramm-Technik, we see following disadvantages for the equipment of Gramm-Technik:

- Each change of the diameter needs a setup scenario of the machines (change of plating cells to adapt new diameter). This leads to unacceptable downtimes with our diameter range from 11 to 28 mm.
- The geometry is limited and the equipment is not able to plate all our products.
- Etching process: Etching with chrome acid is a mandatory process to get best adhesion quality for the chrome layers without chrome pearls. The Gramm option for etching with chrome acid is not clear yet.

- Waste disposal: Increased residual material (such as Cr, Cr3+, copper, iron, sulfuric acid) is one consequence of the Gramm-Technik plating process to be handled and disposed of with high effort.
- Based on our knowhow we expect high maintenance with all negative effects on the worker contribution scenarios during maintenance and unscheduled breakdowns.

Conclusion

Based on the risk to run into a non-use scenario with the usage of hexavalent chromium, ZF is not going to invest into new hexavalent chromium plating equipment in the EU. We are more seeking for a future alternative plating solution without using hexavalent chrome.

Compared to the Atotech plating system the Gramm technology does not show sufficient improvements and advantages to ZF.

SEAC QUESTIONS TO THE APPLICANT

1. **Please provide further explanation of the costs of requalification - what steps are required in the requalification process and how does this feed through into the cost per test figure used in the analysis? How are the number of tests that are required determined, both internally and by customers?**

From the point of view that 'time equals money' question 1 (costs) and question 2 (timing) could be addressed to be the same.

ZF is an automotive TIER 1 supplier and therefore not only providing the top-coating of a piston rod. ZF is a system supplier for shock absorbers and/ or complete modules of chassis components.

We act to meet the high demands of our customers. Critical issues are friction, corrosion and hardness of the surface.

ZF has standardized the design verification process (DVP, details see below and Table 4) of their shock absorber modules. This design verification can be broken down to each single part in the system.

Regarding the calculation of requalification costs in the non-use scenarios, it is important to note that it is mandatory to verify and qualify all changes. In this regard, it does not make a difference if ZF switches to an alternative coating process or if the production location is changed (transfer of the complete piston rod production to a non-EU country). All changes might have an effect on the quality of the parts and therefore thorough requalification becomes necessary, both internally and at the customer side.

A design verification process consists of a range of different performance (e.g. friction, oil tightness) and durability tests (e.g. corrosion, temperature), see also table below. These tests have

The basic cost for one single DVP for piston rod re-qualification is EUR [redacted] (see Table 4). The excel sheet provided to SEAC in the course of the previous round of questions provided details on the calculation of the total requalification costs. Details on the costs and duration of one DVP and the number of repetitions needed shall be given in the following.

In general, the costs for one DVP (approx. EUR [redacted]) are comprised of the following items.

- **Personnel costs:** Staff of the following departments is involved in the requalification of a new system Administration, Controlling, Purchasing (of services from external service providers), Product development, Design etc. The main costs however occur in Laboratory for test preparation and analysis of test results (laboratory staff, test engineers etc.)
- **Test bench costs:** The different steps in the DVP require different test benches which are then occupied for a certain time. This of course entails costs, which can be treated as costs for machine hours
- **Material and energy costs:** costs for materials to be tested and energy

An example for one test ([redacted]) is provided below:

- Preparation of a Standard test: [redacted] h (lab/test engineers);
  - Prepare and assemble sensors for tests
  - Cover shock absorber with cooling devices
- Test duration approx. [redacted] h on test bench ([redacted])
- [redacted] h of analysing and documentation (lab/ test engineers)
- Definition and determination of improvements for repeating the test

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Approx. EUR [redacted] to run a [redacted] (1 set = [redacted] shock absorbers)

1 DVP takes into account:

- [redacted] piston rods for 1 DVP + additional parts to build up complete shock absorbers
- [redacted] weeks

[redacted] repetitions takes into account

- [redacted] piston rods for [redacted] repetitions + additional parts to build up complete shock absorbers
- [redacted] weeks
  - Incl. procurement process (e.g. parts supply from overseas)
  - Incl. waiting times for test rigs

Repetitions are necessary if a single DVP does not meet the specifications.

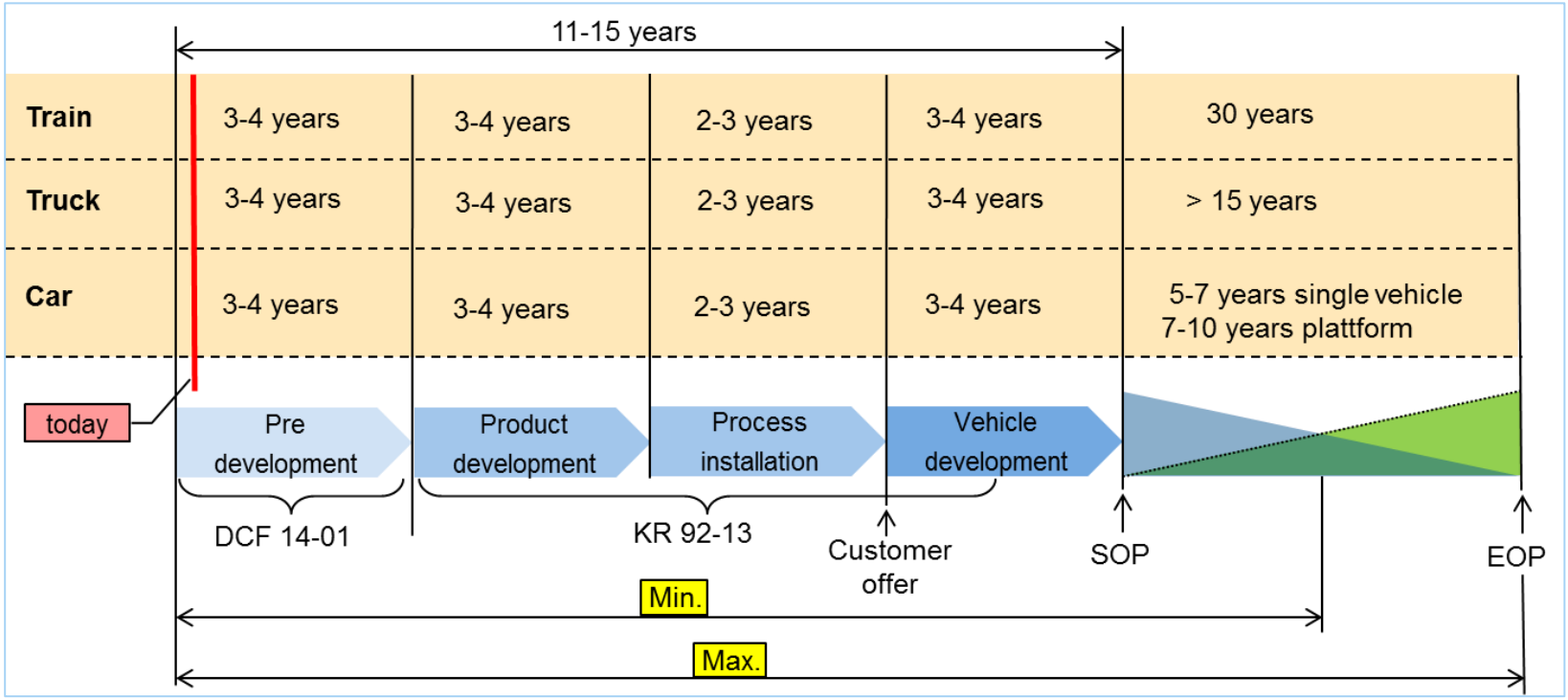
After internal qualification is finished, the customer approval can start. The ZF internal DVP covers approx. 85% of all customer requirements. However, all customers define different/additional requirements that are different from the ZF internal approval. Therefore, additional tests under different conditions (temperatures/dust/mud/water) and/or forces are needed to get customer approval.

Further, it is important to note that the damper system is safety critical (e.g. McPherson struts are connected to the wheel guiding of a car), therefore it is especially important to thoroughly test the system performance, internally at ZF and at the customer side.

Table 4: Design Verification Plan and Report

2. Please clarify further the different tasks and the total length of time required for requalification

Table 5: timeframes for requalification and development



The duration of the requalification is scheduled to be 11-15 years. As soon as we are talking of a new surface we need to follow up with group directive requirements for internal development activities (see Table 5)

Pre-Development 3-4 years (internal)

- Create ideas and release fundamentals and principle study, evaluate the ideas roughly in terms of technical and economic criteria.
- Concept and system study is developed which can be used best to implement the product idea from technical and economic points of view.
- Product design for experimental models is produced in house or with external suppliers acc. ZF and customer specification.
- Proof of function for experimental models on test benches or in the vehicle, check evidence to fulfill all functions with the selected solution approach.
- Check and evaluate first results, create risk assessment.

Product Development 3-4 years (internal)

Product development requirements regarding function, safety, reliability, accuracy, etc. acc. customer requirements/product and process features.

- Technical objectives (e.g. reliability requirements, weight, maintenance, customer service, spare parts supply, new materials, new technologies, supplier development)
- Target costs (e.g. parts/material costs according to current parts list status, project costs, investments)
- Deadlines (e.g. for market launch, project reviews, important milestones, maturity periods, design freeze)
- Warranty, Capacities, Quality, Technology, Environmental, Safety, Scheduling

Process Installation (Machines and equipment) 2-3 years (internal)

Investment plan and release, create equipment specification, evaluation and select supplier, place order, monitor design and manufacturing of equipment, test and release at supplier site, ship and install to ZF, test and release at ZF site, validate new process acc. ZF and customer specification.

Vehicle Development (Project with customer) 3-4 years

Design new product for new vehicle acc. customer specification, build prototypes, test and validate new product at ZF site. Installation test at customer prototype vehicle. Test rides at customer proving ground. Adjust and build preproduction parts. Test rides on public roads. Requalification if needed.

SOP – Run Off Activities with customers

Production process and product release (PPF process) (initial production sample release) Performance test/process validation (run at rate) to confirm SOP and production readiness. Launch new process / product.

3. **Further to the information provided on a normal (7 year) or long (12 year) review period, what would be the consequences of not obtaining the longer review period requested? (21 years). Can you compare the impacts of a <u>long</u> (12y) review period to the impacts of <u>applied</u> (21y) review period considering a normal re-application possibility.**

The demand for the review period is driven by the customers who want to be covered during complete life time of their product with parts of the same quality.

As it can be seen from the figure above, already the timeframe from pre-development of a new damper system until start of production (SOP) at the customer covers 11-15 years. Another 5-10 years of production of the respective car model at the OEM need to be added. During this time, parts need to be delivered continuously to the OEM until EOP (end of production) is reached. Therefore, 12 years review period (with the necessity to re-apply for authorization 18 months in advance) is considered too short to confirm supply security to the customer. In addition, of the car model, ZF is obliged to deliver the same parts as spare parts for usually 10 years for cars up to 30 years for train application after EOP.

Looking at the timelines described above, a re-application for authorisation becomes necessary even if a review period of 12 years is granted.

4. **Please provide some ranges or orders of magnitude for the monetized confidential information, in order to be able to describe the overall balance between the monetized risks and the benefits.**

The non-confidential ranges in the baseline scenario are as follows (ref. p. 80-85 SEA):

Decommissioning expenses:	EUR 5 000 000 – 10 000 000 ([redacted])
Requalification expenses:	EUR 20 000 000 – 30 000 000 ([redacted])
Social impacts:	EUR 55 000 000 – 65 000 000 ([redacted])
TOTAL:	**EUR 80 000 000 – 105 000 000**

Below you can find the updated Table 25 (page 86 of the SEA) including the range for requalification costs.

Table 6: Deterministic uncertainty analysis – summary (ref. p. 86 SEA)

Uncertainty Scenario (US)	Health impacts	Requalification costs (economic impacts)	Decommissioning expenses	Social costs	Total socio-economic impacts	Ratio health impacts : socio-economic impacts
US1	119 027	20 000 000 – 30 000 000 ([redacted])	5 000 000 – 10 000 000 ([redacted])	35 000 000 – 60 000 000 ([redacted])	60 000 000 - 90 000 000 ([redacted])	At least 1:504 ([redacted])
US2	119 027	20 000 000 – 30 000 000 ([redacted])	5 000 000 - 10 000 000 ([redacted])	35 000 000 – 60 000 000 ([redacted])	60 000 000 - 90 000 000 ([redacted])	At least 1:504 ([redacted])
US3	2 510 133	20 000 000 – 30 000 000 ([redacted])	5 000 000 - 10 000 000 ([redacted])	35 000 000 – 60 000 000 ([redacted])	60 000 000 - 90 000 000 ([redacted])	At least 1:23 ([redacted])
US4	2 510 133	20 000 000 – 30 000 000 ([redacted])	5 000 000 - 10 000 000 ([redacted])	35 000 000 – 60 000 000 ([redacted])	60 000 000 - 90 000 000 ([redacted])	At least 1:23 ([redacted])

An updated version of Table 27 (page 87 of the SEA) including the summarised non-confidential ranges can be found below.

Table 7: Quantitative comparison of impacts (p. 87 SEA)

Type of impact	Uncertainty Scenario 3 [EUR]	Uncertainty Scenario 2 [EUR]
Potential health benefits associated with a non-authorisation of the continued use of chromium trioxide	198 804	119 027
Potential health benefits 'man via the environment' associated with a non-authorisation of the continued use	2 311 330	0
Negative economic impacts associated with a non-granted authorisation	25 000 000 – 40 000 000 [redacted]	25 000 000 – 40 000 000 [redacted]
Negative social impacts associated with a non-granted authorisation	35 000 000 – 60 000 000 [redacted]	35 000 000 – 60 000 000 [redacted]
Net benefits of a granted authorisation	**57 489 865 – 97 489 865** [redacted]	**59 880 973 – 99 880 973** [redacted]

Summing up, the ratio of health benefits of a non-granted authorisation to the negative socioeconomic impacts of a non-granted authorisation is between 1:23 and 1:840 ([redacted] and [redacted]).