Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Lead chromate sulfochromate yellow (C.I. Pigment Yellow 34)

use: Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)

ECHA/RAC/SEAC: AFA-O-0000004723-74-17/D

Consolidated version

Date: 11 December 2014

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Consolidated version of the

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to an application for authorisation for:

Chemical name(s):	**Lead chromate sulfochromate yellow (C.I. Pigment Yellow 34)**
EC No.:	**215-693-7**
CAS No.:	**1344-37-2**

for the following use:

Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)

Intrinsic property referred to in Annex XIV:

Carcinogenic (Article 57(a) of the REACH Regulation)

Toxic to reproduction (Article 57(c) of the REACH Regulation)

Applicant

DCC Maastricht B.V. OR

Reference number

11-0000000341-88-0001

Rapporteur, appointed by the RAC: **Lina Dunauskienė**

Co-rapporteur, appointed by the RAC: **Normunds Kadiķis**

Rapporteur, appointed by the SEAC: **Karine Fiore**

Co-rapporteur, appointed by the SEAC: **Simone Fankhauser**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On **19 November 2013 DCC Maastricht B.V. OR** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **28 January 2014** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **12 February 2014**. Interested parties were invited to submit comments and contributions by 9 April 2014.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

The draft opinions of RAC and SEAC take into account the responses of the applicant to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **28 November 2014**.

On **9 December 2014** the applicant informed that it did not wish to comment on the opinions and the draft opinions of RAC and SEAC were therefore considered as the final on **11 December 2014.**

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **27 November 2014**.

The draft opinion of RAC was adopted by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **11 December 2014**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **12 September 2014**.

The draft opinion of SEAC was adopted by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of SEAC was adopted as final on **11 December 2014**.

THE OPINION OF RAC

RAC confirmed that it is not possible to determine a DNEL for the carcinogenic (category 1B) properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that it is not possible to determine a DNEL for the reproductive toxic (category 1A) properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that the exposure assessment in the application is demonstrated to be appropriate and effective in limiting the risk, provided that the risk management measures and operational conditions are as described in the application.

The duration for the review period has been suggested below.

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC took note of RAC's confirmation that it is not possible to determine a DNEL for the carcinogenic (category 1B) nor for the reproductive toxic (category 1A) properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant

SEAC considered that the applicant's assessment of (a) the potential socioeconomic benefits of the use, (b) the potential adverse effects to human health or the environment of use and (c) the assessment used to compare the two is based on acceptable socio-economic analysis. Therefore, SEAC does not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health or the environment, whilst taking account of any uncertainties in the assessment.

The duration for the review period has been suggested below.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Conditions

The following conditions are recommended in case the authorisation is granted:

In order to allow ECHA's committees to evaluate the possible review report with appropriate scrutiny, the applicant shall provide the following information:

1. The data from the current biomonitoring programme according to Occupational Health and Safety Legislation (OSH) requirements for lead, gathered by the applicant from his own plants and from the downstream users.
2. The data from regular air monitoring according to OSH requirements for chromium gathered by the applicant from his own plants and from the downstream users. Measurements of the workplace air concentration (personal sampling) should be performed representing each of the tasks for which pigments are used.

Information so gathered should be documented, evaluated and used to improve the overall effectiveness of the risk management measures. It should also be used to support any review report.

RAC sets the condition that for the Applicant and the Downstream Users a programme for the selection, appropriate use and maintenance of, and training with, RPE/PPE should be in place and documented. This applies for the applicant' own plants and for downstream users.

These recommendations provided by RAC are intended to complement the obligations of the applicant under the Occupational Health and Safety Legislation.

Monitoring arrangements

The following monitoring arrangements are recommended in case the authorisation is granted:

- No additional monitoring arrangements to those described in the application are proposed.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant and the comments received on the broad information on use the duration of the review period for the use is recommended to be twelve (12) years.

JUSTIFICATIONS

Substance name:	Lead sulfochromate yellow (C.I. Pigment Yellow 34)
Name of applicant(s):	DCC Maastricht B.V. OR
Use name:	Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)
Reference number:	11-0000000341-88-0001

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property / properties:

- ☒ Carcinogenic (Article 57(a))
- ☐ Mutagenic (Article 57(b))
- ☒ Toxic to reproduction (Article 57(c))
- ☐ Persistent, bioaccumulative and toxic (Article 57(d))
- ☐ Very persistent and very bioaccumulative (Article 57(e))
- ☐ Other properties in accordance with Article 57(f) [please specify]:

2. Is the substance a threshold substance?

- ☐ YES
- ☒ NO

Justification:

Chromium(VI) causes lung tumours in humans and animals by the inhalation route and tumours of the gastrointestinal tract in animals by the oral route. These are both local, site-of-contact tumours – there is no evidence that Cr(VI) causes tumours elsewhere in the body, or via the dermal route. A clear mode of action for Cr(VI)-induced tumors has not been established. The overall body of evidence indicates that Cr(VI) is genotoxic in vivo, resulting in the formation of DNA adducts and oxidative DNA damage. However, clear evidence of mutagenicity in vivo in the target tissues (lung and intestine) by relevant routes of exposure is lacking. This supports the contention that Cr(VI) is only weakly mutagenic in vivo and that its mutagenicity is most likely to be only one contributory factor in the carcinogenic process, together with tissue injury/irritation/inflammation and cell proliferation. However, there is insufficient evidence to exclude a genotoxic mode of action and therefore a threshold cannot be set both for inhalation route (lung cancer) and oral route (intestinal cancer). These considerations were outlined in the ECHA report ”Application for authorisation: establishing a reference dose response relationship for carcinogenicity of hexavalent chromium“ published on 4 of December 2013.

Lead is a reproductive toxicant in animals and humans. It impairs male fertility and neurodevelopment of children. The latter is the most sensitive effect, and results from pre- and post-natal lead exposure. No threshold for this adverse effect has been identified in humans.

3. Hazard assessment. Are the DNEL(s) appropriate?

Justification:

The substance has been included in Annex XIV on the basis of two endpoints (carcinogen category 1B and reproductive toxicant category 1A).

Cr(VI)

RAC has established a non-legally binding reference dose response relationship for carcinogenicity of hexavalent chromates for both inhalation and intestinal exposure by linear extrapolation (RAC/27/2013/07 Rev. 1). Extrapolating outside the range of observation inevitably introduces uncertainties. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be an overestimate.

The applicant used this dose response relationship, but adjusted it to compensate for the low bioavailability of Cr(VI) as a result of the low solubility of the pigments. RAC acknowledges that the bioavailability and toxicokinetics of chromates depends largely on its water solubility and subsequent availability for local and systemic absorption. In the ECHAs report "Application for authorisation: establishing a reference dose response relationship for carcinogenicity of hexavalent chromium" published on 4th of December 2013 is noted that information from epidemiological and mechanistic studies indicates that the carcinogenic potency of Cr(VI) compounds to the lung is greater for substances of high and moderate solubility in comparison to the insoluble chromates. However, quantifying any differences in lung carcinogenic potency for Cr(VI) compounds of different solubility is not possible with the currently available data. Thus, inhalation exposures to aerosols of highly soluble, slightly soluble and insoluble Cr(VI) compounds should be treated in the same way, accepting that obtained excess cancer risks will perhaps overestimate risks in the case of exposure to insoluble chromates.

For the respirable fraction, the excess lifetime lung cancer mortality risk based on a 40 year working life (8h/day, 5 days/week) equals $4*10^{-3}$ per µg Cr(VI)/m^3.

For the non-respirable fraction, which follows the oral route due to swallowing, the excess lifetime intestinal cancer risk for a worker, based on a 40 year working life (8h/day, 5 days/week) equals $2.0*10^{-4}$ per µg Cr(VI)/kg bw/day.

Lead

EFSA (2010) derived a lower benchmark dose level (BMDL(01)) of 0.5 µg/kg bw/d for the potential adverse effects of lead on children. This corresponded to a change in blood level of 12 µg Pb/L and an IQ loss of 1 point.

The applicant used the EFSA BMDL(01) as DMEL in the risk assessment for the inhalatory and dermal exposure to lead. As to dermal exposure, RAC noted that the dermal absorption of lead is less than 0.1% and is therefore of less significance than absorption via the respiratory or gastro-intestinal routes. Therefore, RAC did not further take account of dermal exposure to the pigment as it will not contribute greatly to the systemic exposure to lead.

As to inhalation exposure, RAC compared the EFSA reference value (corresponding to 12 µg Pb/L) to other available limit values for lead (SCOEL, MAK, Council Directive 98/24). These vary from 100 to 700 µg Pb/L. SCOEL emphasises that the BLV of 300 µg Pb/L is not seen as being entirely protective for the offspring of working women because no threshold for potential central nervous system effects in newborns and infants could be identified. The MAK value has been revised from 100 to 70 µg Pb/L. It is important to note that this MAK value is not a hazard-

related value but is simply an indicator for the 95th percentile of actual blood lead levels in women of childbearing age in Germany. The value of 700 µg Pb/L in the Directive 98/24 is a binding value with no relevant information on risks to pregnant women.

RAC is of the opinion that in the context of this application, the EFSA reference value is more relevant and appropriate than the other values discussed above, in light of the effect of concern and the population to be protected. The EFSA value of 0.5 µg/kg bw/d converts to 3.5 µg/m3 (assuming 70 kg bw and an inhalation volume of 10 m3 per workday).

4. Exposure assessment. Is the exposure from the use adequately described?

☒ YES

☐ NO

Justification:

- **Modelled Data**

In total, exposure assessment for 14 contributing scenarios for workers within the use "***Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)***" is modelled. For 7 contributing scenarios out of 14 no RPE is prescribed. In 7 contributing scenarios RPE with APF of 10 or higher is prescribed.

- Inhalation exposure

For almost all of identified uses the worker inhalatory exposure was estimated using The Advanced REACH Tool v1.5 (ART). MEASE tool was used in those cases when ART model did not allow to make valid assessment.

Initial parameters for the ART model were based on the information gathered during site visits to downstream users (from more than 10 facilities in 5 different member states). Additional information was retrieved from OECD emission scenario documents for both the paint and plastic industry. In order for the assessment to be a realistic worst case scenario, the 90th percentile of the long term inhalable exposure estimate for each contributing scenario was calculated. These were based on the actual durations of use during the workday, and normalized to 8 hrs for actual durations less than 8 hrs. For contributing scenarios with higher exposures, where no further technical risk management measures (RMM) are feasible, an assigned protection factor for respiratory protection was applied. The calculated values were adjusted to a maximum chromium and lead level of 15% and 60% respectively in PY. 34 and PR. 104, and for percentage of respirable fraction (0.0% for the paste, 2.2% weight percent of total pigment for the powders, for mixing, rollering, brushing of the paint and 12% for the spraying of the paint or for abrasion).

Relevant combinations of tasks for a realistic working day of certain worker groups were composed by combining the contributing scenarios. Six worker groups were considered in this evaluation:

- Spray painter manual,
- Spray painter automated booth,
- Lab worker / Quality control,
- Heat curing paint applicator,

- Mixer,
- Filler.

The exposure estimates (in µg total pigment/m^3) are presented in the following summary table.

	Spray painter manual	**Spray painter automated booth**	**Lab worker / Quality control**	**Heat curing paint applicator**	**Mixer**	**Filler**
Without RPE/PPE	µg/m³	µg/m³	µg/m³	µg/m³	µg/m³	µg/m³
Total Pigment	214,2	3,1	1,5	2,8	0,5	8,2
Cr (VI)	32,13	0,47	0,22	0,42	0,07	1,23
Pb	128,5	1,9	0,9	1,7	0,3	4,9
With RPE/PPE	µg/m³	µg/m³	µg/m³	µg/m³	µg/m³	µg/m³
Total Pigment	0,6	0,3	1,5	2,5	0,5	0,6
Cr (VI)	0,09	0,04	0,22	0,37	0,07	0,09
Pb	0,4	0,2	0,9	1,5	0,3	0,4

See section 6 for general description of the available RMM other than PPE.

- Dermal exposure

The ECETOC TRA tool (version 3) as incorporated into CHESAR was used to assess the dermal exposure to lead. Given however that the dermal absorption of lead is less than 0.1%, and thus of much less significance for the systemic exposure to lead than the respiratory or gastro-intestinal routes, RAC will not take further into account the dermal exposure to lead from the two pigments.

Lead

- Biomonitoring data

The applicant has presented a whole range of blood measurements for lead (total number of measurements = 376). The table below gives distribution of Blood Lead Levels (376 samples) provided by the applicant:

< 60 µg/L	>60 µg/L	>100 µg/L	>120 µg/L	>300 µg/L	>700 µg/L
95.7%	4.3%	2,7%	2,7%	0,27%	0%

It should be noted that the background Pb blood levels have decreased during the last 20-30 years from ~200 µg/l to ~50 µg /l (SCOEL, SUM 83, p13). The biomonitoring data provided by the applicant from the plants investigated give no evidence for differences to the background

blood lead levels as 95.7% of the samples showed blood lead levels below 60 µg/l. This gives some reassurance about the order of magnitude of exposure of the general worker population in the industry sector under consideration.

- Conclusion

RAC concludes that the exposure assessment of the applicant is comprehensive and that the exposure for workers is adequately described.

As to the modelled data, RAC considers that the combination of tasks in reference worker groups describes well the relevant combinations of contributing scenarios.

RAC considers that the approach used to estimate exposures is adequate to estimate worst case impacts for consideration by SEAC. For lead biomonitoring is present and the data gives some reassurance about the order of magnitude of exposure of the general worker population in the industry sector under consideration.

Assessment of the risk of indirect exposure of man through the environment is not performed as it is considered to be not applicable due to very low predicted environmental exposure levels which are much lower than the background environmental concentration in different compartments. Therefore, exposure assessment for general public is not applicable.

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

Justification:

Not applicable

6. If adequate control is not demonstrated, is the remaining risk reduced to as low a level as is technically and practically possible?

Justification and concluding on the remaining risk:

Exposure by inhalation was assessed for 6 worker groups (Spray painter manual, Spray painter automated booth, Lab worker / Quality control, Heat curing paint applicator, Mixer, Filler).

Cr (VI)

The highest Cr(VI) exposure level without RPE is 32.13 µg/m³ for spray painter manual. The highest Cr(VI) exposure level with RPE is 0.37 µg/m³ for heat curing paint applicator.

The corresponding combined (lung and gastrointestinal tract) excess cancer risks (worker/lifetime) related to the chromium part in these highest pigment exposures are $1.6*10^{-2}$ without RPE and $4.3*10^{-5}$ with RPE.

The actual chromium exposure is likely to be lower than calculated for the following reasons:

a) The dose-response-relationships for chromates suggests non-linearity in the lower exposure range.
b) The actual exposure to lead chromates is likely to be lower because of the low solubility.

Therefore, overall, the exposure and risk estimations are not reasonable worst case, but rather worst-case risk estimations. Therefore, for chromium the risks are considered to be lower than calculated. Quantification of these uncertainties is not possible because of lack of corresponding scientific data.

Lead

RAC assumes that the toxicological evaluation has to be based on women in the workplace that did not report their pregnancy. In line with current EU legislation (Directive 92/85/EEC) on occupational health, pregnant women have to be actively excluded from contact with lead once they have reported their pregnancy, hence eliminating their occupational exposure.
The highest Pb exposure level without RPE is 128.5 µg/m³ for spray painter manual. The highest Pb exposure level with RPE is 1.5 µg/m³ for heat curing paint applicator.

The corresponding ratios between these exposures and the reference level of 3.5 µg/m³ are 36.7 without RPE and 0.43 with RPE.

The actual Pb exposure is likely to be lower than calculated due to the low solubility of the chromate pigments.

Therefore, overall, the exposure and risk estimations are not reasonable worst case, but rather worst-case risk estimations. Therefore, for Pb the risks are considered to be lower than calculated. Quantification of these uncertainties is not possible because of lack of corresponding scientific data.

Some further reassurance can be found in the biomonitoring data from the plants investigated, where no evidence of differences from the background lead levels were observed.

Risk Management Measures in place:

The following RMM are in place: local exhaust ventilation, work time scheduling, training, local ventilation and etc. Technical installations have a high level of containment in order to prevent emissions of volatile organic compounds (VOC) and components used. Manhole and other dosing points are generally fitted with local exhaust ventilation. General ventilation is present. In order to control the explosion risk (both dust and vapour) the effectiveness of both general and local ventilation is well managed. Emissions of pigments are minimalized and spills are cleaned as pigments have a large and permanent staining capacity.

Conclusion

RAC considers that the exposure levels without RPE/PPE are high. With proper use, of the RPE/PPE seem to be appropriate in reducing the risk from exposure to chromium and lead. It seems that the requirements as to the necessary hierarchy of risk management measures have been followed and that technical and organizational risk reduction measures have been taken into account before picking up the last resort of RPE.

RAC considers that some of the factors for the effectiveness of RPE/PPE might not be achieved in practice and has reservations about the intensity of use and overreliance on RPE/PPE reported in the workplace. Therefore RAC requires that in the event of a review, the report shall contain a more extensive description and valid documentation of the effectiveness of RPE/PPE over the intervening period.

RAC further sets the condition to continue the biomonitoring for lead exposures of the employees involved and further continue their efforts to minimise possible exposures.It is emphasized that, according to art. 36 of the REACH regulation the authorisation holder and downstream users are required to assemble and keep available all the information he requires to carry out his duties. The authorisation holder and the downstream users shall make this information available without delay upon request to any competent authority.

7. Justification of the suitability and availability of alternatives

7.1 Would the alternatives lead to overall reduction of risk?

☐ YES

☐ NO

☒ NOT APPLICABLE

7.1.1 Are the risks of alternatives adequately described and compared with the Annex XIV substance?

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

This report summarises the key major concerns with respect to each major alternative family. The major potential alternatives to PY.34 and PR.104 in commerce today can be broken down into the following simplified families:

1. Inorganic Pigments:
   a. Bismuth Vanadate – PY.184
   b. Mixed metal oxides/complex inorganic pigments – e.g. PY.53 and PBr.24
   c. Iron oxides – e.g. PY.42 and PR.101
2. Organic Pigments:
   a. Azo diarylides – e.g. PY.12, PY.13, PY.17, PY.83, PO.13, PO.34
   b. Azo dianisidine – e.g. PO.16
   c. Azo benzimidazolones – e.g. PO.36, PY.151, PY.154, PY.194
   d. Monoazo – PY.65, PY.73, PY.74, PY.75, PY.97
   e. Metal azo yellows – PY.61, PY.62, PY.168, PY.183, PY.191
   f. Specialty azo – e.g. PO.64, PO.67, PY.155
   g. Specialty other – e.g. PY.110, PY.138, PY.139
   h. DPP – PO.73, PR.254
   i. Swedish listing (not included above) – PR.2, PR.4, PR.53:1, PR.57:1, PR.122
3. Hybrid Pigments, for example Paliotans

Classification and labelling information for most alternatives collected from Classification &

Labelling Inventory is provided in Annex 5. It can be noted that few alternatives are themselves classified as CMR's in the EU. Some of the alternatives notably in the organic pigments contain classified or at the very least possibly dangerous precursor molecules. Not infrequently these precursor molecules will leach over time or be emitted into the environment at some stage in life or during recycling. Some alternatives are substances already known to be of equivalent concern to CMRs and therefore unsuitable as viable alternatives. Some alternatives require ATEX ("ATmosphere EXplosible") factories or similar specific production standards as the molecules are highly explosive, volatile or polluting. Issues related to various alternatives are provided in Annex 6.

7.2 Are the alternatives technically and economically feasible for the applicant?

☐ YES

☒ NO

7.2.1 Are the technical and economic feasibility of alternatives adequately described and compared with the Annex XIV substance?

☒ YES

☐ NO

Justification:

The applicant provides an extensive AoA for this use of PY34 (an identical AoA has been provided for use 3 also applied for in the same application which is also identical for PR104). The applicant explains that substitution with a one-by-one (direct) alternative is not possible, which was also confirmed by all STOs who provided comments during the public consultation. Furthermore, the applicant claims that, in general, there does not exist any suitable alternative to PY34 for this use.

Alternatives assessed

The applicant assessed in total 36 alternatives: 5 inorganic pigments (bismuth vanadate-PY184, mixed metal oxides- PY53 and PBr24, iron oxides-PY42 and PR101), 20 organic pigments (6 azo diarylides, 1 azo dianisidine, 4 azo benzimidazolones, 3 monoazo, 2 specialty azo and 4 specialty other), DPP (Diketopyrrolopyrol-PR254) as well as 10 pigments suggested by Sweden as alternatives in their restriction proposal. The applicant assessed these alternatives regarding their technical feasibility, sustainability, availability and economic feasibility and concluded that none of them is suitable for the use 2 applied for.

Technical feasibility

None of the alternatives identified by the applicant meets the same technical requirements as PY34. The alternatives are assessed against the technical functions provided by PY34 which are: chroma, opacity, heat stability, weather fastness, shade, dispersibility. These functions allow the paints and coatings to demonstrate a high level of durability, reliability, signal and contrast functions as well as quick drying, which are highly demanded for applications such as e.g. agricultural machinery, petrochemical piping, steel bridges, construction arches, etc. These properties make also PY34 particularly desirable for safety applications (cognitive effect/communication capacity for warnings and information of colour) such as safety road signs or signs at work.

PY34 shows high technical performance and "unique functionalities" compared to the alternatives identified and assessed. All the alternatives present technical drawbacks (such as lack of chroma, inferior brightness, lower level of gloss retention, limited spectrum, insufficient durability for outdoor applications, etc.). Even PY184 (Bismuth vanadate), which is presented by the applicant as the closest possible alternative (the "least bad alternative") to PY34, shows lacks in shade functionality and, to some extent, opacity. It is a green shade yellow and has thus to be mixed with other colour pigments to make other colours and this also results in decreasing opacity and weather fastness. According to the applicant, the use of other pigments or combinations of pigments is possible but the performance and the quality of the products would be much lower and the safety of some applications would be compromised. A specific (and generic) analysis is devoted to the colour matching and mixing sector[1] which is a high technology, global-oriented and very specialized sector for which none of the alternatives are suitable as the use of PY34 is essential to the technologies in question as regards the world market.

Some further information provided by STOs[2] tends to confirm that lead-chromates pigments can possibly not be substituted, at least not for all applications. EC's recent conclusion related to a merger between two big manufacturers of chemicals, coatings and plastics[3] indicates that organic and inorganic pigments should be further segmented by class, since – according to their characteristics (different chemistry, features, colour, shade and performance), they are not interchangeable from either the supply-side or the demand-side point of view (based on markets investigation). Furthermore, EC concludes in its document that certain pigments cannot be used in all applications as there are different relevant product markets e.g. for Bismuth Vanadate and for lead chromates, which would further confirm the applicant's view that currently, substitution is not possible.

However, also contradictory comments have been received from STOs during public consultation. Some stakeholders claim that some of the alternatives identified by the applicant (and others such as water-based lead-free paints) could be used as alternatives and some of them are indeed already in place for the same uses and applications as the ones applied for. Although it is agreed that no exact one-by-one alternative is available, the same STOs still consider that it is not necessary to have one single substance for direct replacement and that alternatives and smart combinations of organic and inorganic pigments are technically possible and can be used for the same purposes within the paints and coatings industry and the reduction of the range of options is not deemed as insurmountable. Some STOs have already completely phased out the use of all lead chromates such as PY34 and stated that the alternative pigments (especially inorganic ones) allow obtaining the desired coating product characteristics and performance. One STO provided an extensive list of 30 alternative pigments (for both, PY34 and PR104, some of them are included in the applicant's AoA) and listed a ten chemical groups which are claimed to be already most commonly used in the coating industry.

In response to the negative comments, the applicant emphasized that these alternatives cannot meet exactly the same technical requirements as lead chromates and are therefore not suitable. The applicant considers that if they are still used by some customers and downstream users, this may be either for other uses than the ones applied for (what is contradicted by the

[1] This sector offers both software and machine tools that are able to create any colour based on a palette and the use of a starting set of basic colours
[2] Information provided during the trialogue
[3] REGULATION (EC) No 139/2004 MERGER PROCEDURE

abovementioned STOs) or because the DUs have necessarily accepted some technical compromise. According to the applicant, these alternatives (e.g. such as BASF's Paliotan®) do not resolve the complex and very difficult nature of replacing PY34. The purchase of these products are likely to be driven by considerations other than technical performance such as marketing, image or costs-related arguments since any of the alternatives identified would necessarily lead to products of inferior quality.

Economic feasibility

The assessment of economic feasibility of alternatives submitted by the applicant is based on the direct cost of alternatives (i.e. the purchasing price as a raw material) and associated costs (costs of additional coatings needed/ additional solvents required in order to achieve the same performance as provided by PY34, cost of transition, loss of business due to narrowing spectrum/loss of demand due to no longer available specific colours) and provides an estimate of the expected resulting increase in price on the coatings market (see section 8 below for more details) as well as unquantifiable impact due to some loss of spectrum.

PY34 has a relatively low price compared to the alternatives. Some are much more costly (e.g. some alternatives are six times more costly than PY34) and others are more, but not prohibitively, expensive. However, even for the latter, according to the applicant, the total substitution costs might in the end be significant since much more of the pigments have to be used in order to come close to the same colour spectrum, opacity or protection from the coating and more solvent would be needed to maintain the viscosity of the coating. Moreover, materials would have to be painted more often since they durability would be strongly reduced, which would imply extra costs. Substitution costs are estimated in the SEA (see section 8 below).

The comments received during public consultation tend to confirm that the alternatives are, in most cases, more expensive. However, one big manufacturer of pigments and paints explains that the cost of alternative pigments and formulations actually depends on the level of desired performance: in the most demanding performance level, the cost for lead-chromate-free formulations are 2-3 times higher, in the mid-performance area already comparable and in the "good-enough" area already cheaper. This statement is supported by illustrative (but rough) estimates. This STO even concludes that, depending on shade and performance, lead-chromate free formulations could be more cost efficient than lead-chromate containing paints and coatings. However, this statement is not supported and substantiated by any further data. Additionally, the STOs who have already replaced lead-chromates in their products, stated that the alternatives can be used at an acceptable cost. According to another STO, higher formulation costs associated with the replacement of lead chromates such as PY34 in paints and coatings must often be accepted; the final cost depends on the colour shade and the required performance. However, with regard to the final coated article, the increase in pigment cost is often deemed as negligible (based on the examples of cars or agricultural equipment and machinery). Nevertheless, these statements are not supported and substantiated by any quantitative data.

Research & Development

Finally, regarding R&D and the possibility of developing new pigments, the applicant explains that the actual users of the pigments invest a large percentage of their turnover in R&D (from 2% to 10%). Still, the applicant does not have nor is aware of any major developments leading towards new pigments that might be suitable as replacements for PY34. The history of the

development of pigments since the 19th century indeed shows that the innovation cycle is very long (more than 20 years). The latest innovation took place in the early 1980s with the DPP reds and oranges and nothing significant since. The applicant states that on the basis of purely statistical analysis one should not expect another pigment in the yellow (or red) spectrum to be discovered within 20 years. This statement seems to be corroborated by the highly R&D intensive colour matching and mixing sector (consulted by the applicant himself) according to whom, at this time, there is no technically feasible manner to match colour and other characteristics to arrive at the specific qualities and spectrum of PY34. Additionally to the unsuitability of alternatives, the long duration of the innovation cycle is a justification from the applicants' view to request a 12 years review period (see item 10 below).

7.3 If alternatives are suitable, are they available to the applicant?

☐ YES

☐ NO

☒ NO SUITABLE ALTERNATIVES EXIST

Justification:

An extensive analysis of alternatives has been performed within the application. According to the applicant, some potential alternatives are not and are not expected to be produced in sufficient volumes to substitute PY34 (due to shortages in raw materials or monopolistic production, etc.). Some others seem to be available in sufficient quantities (such as inorganic pigments). Anyhow, the alternatives identified and analysed by the applicant are not suitable for the use applied for.

8. For non-threshold substances, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT

Justification:

The applicant provided a SEA for this use of PY34, in which the costs and the benefits associated with the non-use scenario are assessed, based on the following:

- Assessment of compliance/substitution costs:
    - No relevant changes in investment or administrative costs are expected under the NUS by the applicant.
    - The compliance costs of the NUS mainly consist of substitution costs. As explained above, no alternative is considered suitable but, based on information received by the applicant from the paint industry, it is indicated that Bismuth Vanadate (PY184) is regarded to be the most suitable choice among alternatives (with a technical negative compromise though). The applicant assumes that paint formulators will not bear any additional costs. Those will be passed on to the endusers. The substitution costs are thus calculated based on the direct replacement costs of PY34 and indirect associated costs (such as described above) considering the prices of PY34 and the alternative, the cost of additional

coatings (based on the need for at least one additional layer), the need for repainting and the need for a higher quantity of the alternative pigment. These costs range between € 522 million (discounted over 7 years) and € 1,700 million (discounted over 30 years) and may, amongst others, be particularly explained by the need for a higher amount of the alternative pigment, by the need for more layers in order to achieve the same characteristics and by the need for repainting.

- Additionally, other costs are described but not quantified: a welfare loss borne by the DUs due to a lower quality of the paint as well as some loss of jobs are expected; costs of relocation for the most affected downstream manufacturing and a fall in demand up to 10-15% in the EU coatings markets are expected, depending on the alternatives adopted. Markets for very specific applications (e.g. those with high safety requirements) might face a loss of competitiveness (additional costs) in case the pigment is no longer available.
- Collateral cost impacts are also expected for the export-oriented high-technology machine tool and colour matching industries which could lose up to 100% of their non-EU markets according to the applicant, with a cost estimated between €15 million and €21 million.

- Assessment of the benefits to human health: the HHIA provided in the AfA initially included an assessment of the excess risk of lung cancer in workers only and was performed jointly for both, PR104 and PY34. During the opinion-making process this was extended by an assessment of the excess small intestinal cancer risk in workers. Subsequently, the corresponding valuation of the respective health benefits was performed also for both pigments. In order to give a clear overview of the human health impacts for PY34 specifically, SEAC has split up the benefits, based on the applicant's calculations.
  - The assessment of the health benefits of the NUS associated with **lung cancer** cases avoided includes the medical cost of treatment (based on economic values for health care cost available in the economic literature), the productivity loss (based on the retirement age and the average gross salary in the EU) and the welfare loss (based on the VSL[4] and the WTP[5] accounting for respectively the mortality and the morbidity cases). For PY34, the NUS is expected to avoid less than 1 lung cancer case per year (8.13E-04)[6] with corresponding benefits estimated to be € 1,456.42 per year. A worst-case calculation has been carried out (based on upper bounds for all input parameters) by the applicant indicating a benefit of € 2,587 per year[7] associated with the non-use of PY34.
  - The assessment of the health benefits of the NUS associated with the **small intestinal cancer** cases avoided also includes the medical cost of treatment (based on economic values for health care cost available in the economic literature), the productivity loss (based on the retirement age and the average gross salary in the EU) and the welfare loss (based on the VSL and the WTP[8]

[4] Value of statistical life

[5] Willingness to Pay

[6] 8.13E-04 (= 7.32E-04/90%) includes fatal and non fatal cases; This figure is not provided as such by the applicant but has been calculated and split up by SEAC, based on the number of 7.32E-04 of fatal lung cancer cases associated to PY34 and the ratio of 90% of patients who die within 5 years from diagnosis, both provided by the applicant.

[7] This figure is not provided as such by the applicant but has been split up by SEAC, based on the aggregated figure provided.

[8] Willingness to pay to avoid cancer

accounting for respectively the mortality and the morbidity cases). For PY34, the non-use scenario is expected to avoid less than 1 small intestinal cancer case per year (1.28E-07)[9] with corresponding (negligible) benefits estimated to be € 0.16 per year or € 1.34 discounted at 4% over 7 years. No worst-case calculation has been performed by the applicant for this health impact.

- As a whole, for PY34, the health benefits associated with the non-use scenario for use 2 amount to € 1,456.58 per year (not including worst-case assumptions).

- SEAC agrees with the methodology used for the assessment of costs and benefits.

Regarding the costs/benefits ratio presented by the applicant, the costs of the NUS largely outweigh the risks arising from the continued use of the substance.

Furthermore, the applicant concludes that not granting the authorisation for use 2 of PY34 would lead to a relocation of the respective industries outside of Europe and to the acceptance of products with consistently poorer quality and therefore reduced safety standards. While SEAC has no data at hand to conclude on a possible relocation of industries outside Europe it seems obvious that not granting an authorisation would lead to a lower quality of products which is assumed to lead to reduced safety standards in several applications.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Detailed description for additional conditions and monitoring arrangements:

In order to allow ECHA's committees to evaluate the possible review report with appropriate scrutiny the applicant shall provide the following information:

1. The data from the current biomonitoring programme according to Occupational Health and Safety Legislation (OSH) requirements for lead, gathered by the applicant from his own plants and from the downstream users.
2. The data from regular air monitoring according to OSH requirements for chromium gathered by the applicant from his own plants and from the downstream users. Measurements of the workplace air concentration (personal sampling) should be performed representing each of the tasks for which pigments are used.

Information so gathered should be documented, evaluated and used to improve the overall effectiveness of the risk management measures. It should also be used to support any review report.

RAC sets the condition that for the Applicant and the Downstream Users a programme for the selection, appropriate use and maintenance of, and training with, RPE/PPE should be in place and documented. This applies for the applicant' own plants and for downstream users.

These recommendations provided by RAC are intended to complement the obligations of the

[9] 1.28E-07 includes fatal and non fatal cases and is provided by the applicant as being the number of small intestinal cancer cases associated to PY34

applicant under the Occupational Health and Safety Legislation.

10. Proposed review period:

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification for the suggested review period:
In identifying the review period SEAC took note of the of the following considerations

- RAC considers that some of the factors for the effectiveness of RPE/PPE might not be achieved in practice.
- RAC has reservations about the intensity of use and overreliance on RPE/PPE reported in the workplace.
- On the basis of the above RAC recommended a short review period
- The applicant requests a 12 years review period on the grounds that there are no suitable alternatives available to replace PR104 for this use.
- Moreover, the innovation cycle in the pigments sector is considered to be very long.
- The technical suitability of alternatives is particularly important when safety is required for some specific applications such as plastic safety helmets or industrial warning signs.

Given these elements as well as the very low risks and associated health benefits of the non-use scenario for a long review period of 12 years is recommended by SEAC.