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NOTE

From: General Secretariat of the Council

To: Delegations

Subject: ClientEarth Request for internal review under Title IV of the Aarhus Regulation in relation to Council Regulation (EU) 2022/109 of 27 January 2022 fixing for 2022 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in Union waters and for Union fishing vessels in certain non-Union waters

Delegations will find attached additional annexes to the note on the above-mentioned subject, as received from ClientEarth.

Schedule of Annexes

to

ClientEarth Request for Internal Review of Regulation (EU) 2022/109 of 27 January 2022 fixing for 2022 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in Union waters and for Union fishing vessels in certain non-Union waters

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List of all TACs and stocks included in ClientEarth’s analysis comparing the agreed 2022 TACs with the underlying ICES headline advice. This analysis covers both EU-only stocks for which the TACs are included in the Contested Act, and EU/UK shared stocks for which the Contested Act contains provisional TACs, whereas the final figures agreed between the EU and the UK are specified in the Agreed Written Record and the Commission’s proposal for the first amendment of the Contested Act.¹ It excludes stocks for which the TAC and advice figures are not directly comparable due to a mismatch between the TAC and stock areas, as well as stocks falling under other processes such as negotiations with third countries other than the UK.

Common species name	TAC code(s) ²	Advice code(s) ³	ICES Process ⁴	ICES advice basis ⁵	ICES advice in t	Agreed TAC in t	Covered by	Relevant Tables
							this Request for Internal Review?	with further detail ⁶
Cod	COD/03 AS.	cod.27.21	EU only	PA	0	97	Yes	1; 3; 5
Norway lobster	NEP/8C U25	nep.fu.25	EU only	MSY	0	1.7	Yes	2; 3
Common sole	SOL/7B C.	sol.27.7bc	EU only	PA	19	34	Yes	2; 3; 5
Hake	HKE/8C3 411	hke.27.8c9a	EU only	PA	6947	7836	Yes	2; 3; 5

¹ The analysis summarised in this Annex includes 60 TACs overall, including 20 which exceed the ICES headline advice and 40 that were set at or below this advice. Out of the 20 TACs exceeding the ICES headline advice, 8 refer to EU-only stocks, another 8 to EU/UK shared stocks where both the final and the provisional TACs exceed the advice, and 4 to EU/UK shared stocks where the final TACs as specified in the Agreed Written Record exceed the advice, but the provisional TACs as included in the Contested Act do not. The Request for Internal Review covers all 8 EU-only TACs exceeding the ICES headline advice, as well as the 8 EU/UK shared stocks where both the final and the provisional TACs exceed the advice, i.e. 16 stocks. It also covers 6 further TACs which do not exceed the single-stock advice for those stocks themselves, but which – if fully exhausted – are projected (in mixed fisheries considerations and additional catch scenarios provided by ICES) to result in overshooting the single-stock advice and/or the TAC of one or more of the other 16 stocks covered by this Request for Internal Review. In total, this Request therefore covers 22 of the 60 TACs included in ClientEarth’s analysis. The methodology and scope used in this analysis is further described in ClientEarth’s report “Taking stock 2021 – are TACs set to achieve MSY?”, November 2021. <https://www.clientearth.org/latest/documents/taking-stock-2021-are-tacs-set-to-achieve-msy/>.

² The TAC codes are taken from the Contested Act.

³ These are the ICES stock codes identifying the different stocks. The references to the relevant ICES single-stock advice documents that the information in columns 4 and 5 of this table is taken from are provided in Annex 10 for all stocks covered by this Request for Internal Review, and can otherwise be found on the ICES website: <https://www.ices.dk/advice/Pages/Latest-Advice.aspx>.

⁴ This column identifies which process the respective TACs fall under, i.e. whether they are set by the Council of EU ministers directly (“EU only”) or negotiated between the EU and the UK (“EU/UK”).

⁵ PA means the advice is based on the ICES precautionary approach; MSY means it is based on the ICES MSY approach; MAP means that the advice is based on F_{MSY} ranges provided for in a multiannual plan; the figures specified in this table refer to the respective F_{MSY} point value scenario from the respective ICES advice.

⁶ This column specifies which of the 6 main tables listing the TACs covered by the different pleas in this Request for Internal Review present further detail on the respective TACs.

Common species name	TAC code(s) ²	Advice code(s) ³	ICES Process ⁴	ICES advice basis ⁵	ICES advice in t	Agreed TAC in t	Covered by	Relevant
							this Request for Internal Review?	Tables with further detail ⁶
Norway lobster	NEP/9/3 411	nep.fu.2627 nep.fu.2829 nep.fu.30	EU only	PA ⁷	316 (0 + 266 + 50)	355	Yes	2; 3; 5
Pollack	POL/8AB DE. POL/08C . POL/9/3 411	pol.27.89a	EU only	PA	905	1851 (1482 + 166 + 203)	Yes	2; 3; 5
Anglerfish	ANF/8C3 411	mon.27.8c9 a ank.27.8c9a	EU only	MAP (F _{MSY} ranges)	3868 (1969 + 1899)	3868	Yes	6
Common sole	SOL/8AB .	sol.27.8ab	EU only	MAP (F _{MSY} ranges)	2233	2233	Yes	6
Four-spot megrim, megrim	LEZ/8C3 411	ldb.27.8c9a meg.27.8c9 a	EU only	MAP (F _{MSY} ranges)	2445 (1892 + 553)	2445	Yes	6
Norway lobster	NEP/03A .	nep.fu.3-4	EU only	MAP (F _{MSY} ranges)	14449	8501	Yes	6
Norway lobster	NEP/8A BDE.	nep.fu.2324	EU only	MSY	3880	3880	Yes	6
Whiting	WHG/08.	whg.27.89a	EU only	PA	2276	2276	Yes	6
Cod	COD/5B E6A	cod.27.6a	EU/U K	MSY	0	Provisional: 320	Yes	1; 4

⁷ The NEP/9/3411 TAC covers several stocks with separate ICES advice, and the advice for FUs 28-29 and FU 30 is based on the precautionary approach, whereas the advice for FUs 26-27 is based on the MSY approach and precautionary considerations.

Common species name	TAC code(s) ²	Advice code(s) ³	ICES Process ⁴	ICES advice basis ⁵	ICES advice in t	Agreed TAC in t	Covered by this Request for Internal Review?	Relevant Tables with further detail ⁶
						Final: 1279		
Cod	COD/7X AD34	cod.27.7e-k	EU/U K	MSY	0	Provisional: 202 Final: 644	Yes	1; 4
Whiting	WHG/07 A.	whg.27.7a	EU/U K	MSY	0	Provisional: 289 Final: 721	Yes	1; 4
Northern prawn	PRA/2A C4-C	pra.27.4a	EU/U K	PA	0	Provisional: 165 Final: 990	Yes	1; 4; 5
Herring	HER/7G- K.	her.27.irls	EU/U K	MSY	0	Provisional: 217 Final: 869	Yes	2; 4
Cod	COD/5W 6-14	cod.27.6b	EU/U K	PA	14	Provisional: 19 Final: 74	Yes	2; 4; 5
Herring	HER/5B6 ANB HER/6A S7BC	her.27.6a7b c	EU/U K	PA	0	Provisional: 1210 (870 + 340) Final: 4840 (3480 + 1360)	Yes	2; 4; 5
Cod	COD/07 A.	cod.27.7a	EU/U K	PA	74	Provisional: 52 Final: 206	No (provisional TAC not above advice)	NA

Common species name	TAC code(s) ²	Advice code(s) ³	ICES Process ⁴	ICES advice basis ⁵	ICES advice in t	Agreed TAC in t	Covered by this Request for Internal Review?	Relevant Tables with further detail ⁶
							No	NA
Pollack	POL/56-14 POL/07.	pol.27.67	EU/U K	PA	3360	Provisional: 2403 (46 + 2357) Final: 8168 (156+8012)	No (provisional TAC not above advice)	NA
Undulate ray	RJU/9-C.	rju.27.9a	EU/U K	PA	31	Provisional: 12.5 Final: 50	No (provisional TAC not above advice)	NA
Anchovy	ANE/9/3411	ane.27.9a	EU only	PA	15005	15005	No (not above advice)	NA
Common sole	SOL/3A/BCD	sol.27.20-24	EU only	MAP (F _{MSY} ranges)	723	723	No (not above advice)	NA
Horse mackerel	JAX/09.	hom.27.9a	EU only	MSY	143505	143505	No (not above advice)	NA
Norway lobster	NEP/8C U31	nep.fu.31	EU only	MSY	20	20	No (not above advice)	NA
Plaice	PLE/7BC	ple.27.7bc	EU only	PA	19	19	No (not above advice)	NA
Plaice	PLE/8/3411	ple.27.89a	EU only	PA	155	155	No (not above advice)	NA
Sole	SOO/8C DE34	sol.27.8c9a	EU only	MSY	320	320	No (not above advice)	NA
Anglerfish combined (white and	ANF/07. ANF/8AB	mon.27.78a bd	EU/U K	MSY/PA	52936 (34275+1866)	Provisional: 12085 (9531+2554)	No (not above advice)	NA

Common species name	TAC code(s) ²	Advice code(s) ³	ICES			Agreed TAC in t	TAC for Internal Review?	Relevant
			Proce ss ⁴	advice basis ⁵	ICES advice in t			Covered by this Request with further detail ⁶
black-bellied)	DE.	ank.27.78ab			1)	Final: 52205 (41173+11032)		
Boarfish	BOR/678 -	boc.27.6-8	EU/U K	PA	22791	Provisional: 5745 Final: 22791	No (not above NA advice)	
Common sole	SOL/07A .	sol.27.7a	EU/U K	MSY	787	Provisional: 188 Final: 787	No (not above NA advice)	
Common sole	SOL/07D .	sol.27.7d	EU/U K	MSY	2380	Provisional: 1252 Final: 2380	No (not above NA advice)	
Common sole	SOL/07E .	sol.27.7e	EU/U K	MSY	1810	Provisional: 477 Final: 1810	No (not above NA advice)	
Common sole	SOL/7F G.	sol.27.7fg	EU/U K	MSY	1337	Provisional: 347 Final: 1337	No (not above NA advice)	
Common sole	SOL/7HJ K.	sol.27.7h-k	EU/U K	PA	213	Provisional: 70 Final: 213	No (not above NA advice)	
Haddock	HAD/07A .	had.27.7a	EU/U K	MSY	3038	Provisional: 843 Final: 3038	No (not above NA advice)	
Haddock	HAD/6B1 214	had.27.6b	EU/U K	MSY	5825	Provisional: 2094 Final: 5825	No (not above NA advice)	

Common species name	TAC code(s) ²	Advice code(s) ³	ICES Proc ess ⁴	ICES advice basis ⁵	ICES advice in t	Agreed TAC in t	Covered by	Relevant
							for Internal Review?	Tables with further detail ⁶
Haddock	HAD/7X7 A34	had.27.7b-k	EU/U K	MSY	15946	Provisional: 3597 Final: 15000	No (not above NA advice)	
Herring	HER/07A /MM	her.27.nirs	EU/U K	MSY	8455	Provisional: 1835 Final: 8455	No (not above NA advice)	
Megrim	LEZ/07. LEZ/8AB DE.	meg.27.7b-k8abd ldb.27.7b-k8abd	EU/U K	PA / MSY ⁸	23831 (867+22964)	Provisional: 4990 (4536 +454) Final: 20786 (18916+1870)	No (not above NA advice)	
Norway lobster	NEP/07.	nep.fu.19 nep.fu.22 nep.fu.2021 nep.27.7out FU nep.fu.14 nep.fu.15 nep.fu.16 nep.fu.17	EU/U K	MAP (F _{MSY} ranges) / MSY / PA ⁹	19576 (407+1257+ 1978+150+8 35+11785+2 804+360)	Provisional: 4507 Final: 17038	No (not above NA advice)	
Norway lobster	NEP/2A C4-C	nep.27.4out FU nep.fu.7 nep.fu.8	EU/U K	PA / MSY ¹⁰	25460 (301+14803 +3216+2062 +1940+1570)	Provisional: 7631 Final: 24268	No (not above NA advice)	

⁸ The LEZ/07. and LEZ/8ABDE. TACs cover two stocks with different advice basis.

⁹ The NEP/07. TAC covers several functional units with different advice basis.

¹⁰ The NEP/2AC4-C TAC covers several functional units with different advice basis.

Common species name	TAC code(s) ²	Advice code(s) ³	ICES		ICES advice in t	Agreed TAC in t	Covered by this Request for Internal Review?	Relevant Tables with further detail ⁶
			Proce ss ⁴	basis ⁵				
		nep.fu.9 nep.fu.6 nep.fu.5 nep.fu.34 nep.fu.10 nep.fu.33			+566+46+95 6)			
Norway lobster	NEP/5B C6.	nep.fu.11 nep.fu.12 nep.fu.13 nep.27.6aoutFU	EU/U K	MSY / PA ¹¹	12274 (3853+3977 +(3607+628) +209)	Provisional: 3736 Final: 11862	No (not above NA advice)	
Plaice	PLE/07A	ple.27.7a	EU/U K	MSY	2747	Provisional: 658 Final: 2747	No (not above NA advice)	
Plaice	PLE/7DE	ple.27.7d ple.27.7e	EU/U K	MSY / PA ¹²	9138	Provisional: 4588 Final: 9138	No (not above NA advice)	
Plaice	PLE/7FG	ple.27.7f-g	EU/U K	PA	1735	Provisional: 432 Final: 1735	No (not above NA advice)	
Plaice	PLE/7HJ K.	ple.27.7h-k	EU/U K	MSY	114	Provisional: 34 Final: 114	No (not above NA advice)	

¹¹ The NEP/5BC6. TAC covers several functional units with different advice basis.

¹² The PLE/7DE. TAC covers two stocks with different advice basis.

Common species name	TAC code(s) ²	Advice code(s) ³	ICES Process ⁴	ICES advice basis ⁵	ICES advice in t	Agreed TAC in t	Covered by	Relevant
							for Internal Review?	Tables with further detail ⁶
Small-eyed ray	RJE/7FG	rje.27.7fg	EU/U K	PA	123	Provisional: 31 Final: 123	No (not above NA advice)	
Sprat	SPR/7D E.	spr.27.7de	EU/U K	MSY	2897	Provisional: 362 Final: 550	No (not above NA advice)	
Undulate ray	RJU/7DE	rju.27.7de	EU/U K	PA	2552	Provisional: 140 Final: 234	No (not above NA advice)	
Undulate ray	RJU/8-C.	rju.27.8ab rju.27.8c	EU/U K	PA	202	Provisional: 8.25 Final: 33	No (not above NA advice)	
Whiting	WHG/56-14	whg.27.6b whg.27.6a	EU/U K	MSY / PA ¹³	4121	Provisional: 234 Final: 1800	No (not above NA advice)	
Whiting	WHG/7X7A-C	whg.27.7b- ce-k whg.27.47d (7d part)	EU/U K	MSY	21244 ¹⁴	Provisional: 8352 Final: 10696	No (not above NA advice)	

¹³ The WHG/56-14 TAC covers two stocks with different advice basis.

¹⁴ The calculation for this stock, Celtic Sea whiting, is complicated by the fact that in addition to the Celtic Sea stock “whg.27.7b-ce-k” (catch advice: 4452 t), the TAC (WHG/7X7A-C) also includes a part of the North Sea stock assessed by ICES as a separate stock (stock code whg.47d, ICES (2021): Whiting (Merlangius merlangus) in Subarea 4 and Division 7.d (North Sea and eastern English Channel). ICES Advice: Recurrent Advice. Report. <https://doi.org/10.17895/ices.advice.7885>). The ICES advice corresponding to WHG/7X7A-C is therefore the sum of the advice for whg.27.7b-ce-k and the Eastern English Channel (area 7.d) part of the North Sea stock, whg.47d. This portion of the 7.d part within the overall North Sea advice was calculated as the proportion of the 7.d part of the human consumption fishery (HCF) of the total North Sea HCF, multiplied by the total North Sea catch, i.e. ((HCF in 7.d)/(HCF in 4&7.d))*(Total catch NS) = (16229 t/85460 t)*88426 t = 16792 t. The 16229 t come from Table 6b (row for 2022), the 85460 t come from Table 2 (row “MSY approach: $F = F_{MSY}$ ”) and the 88426 t is the total catch headline advice for the North Sea stock. This results in a total advice corresponding to WHG/7X7A-C of 4452 t + 16792 t = 21244 t.

1.7 Acronyms and terminology

Term / acronym	Description
Bayesian method	Assessment method that quantifies uncertainties and formulates advice on the basis of probabilities of reaching a limit or target point.
B_{lim}	Limit reference point for spawning stock biomass (SSB)
B_{pa}	Precautionary reference point for spawning stock biomass (SSB)
B_{MSY}	Spawning stock biomass (SSB) that results from fishing at F_{MSY} for a long time.
$B_{trigger}$	Value of spawning stock biomass (SSB) that triggers a specific management action
Catchability	The fraction of a fish stock which is caught by a defined unit of the fishing effort
Cpue	Catch per unit effort: The quantity of fish caught (in number or in weight) with one standard unit of fishing effort; e.g. number of fish taken per 1000 hooks per day or weight of fish taken per hour of trawling. Cpue is often considered an index of fish biomass (or abundance). Sometimes referred to as catch rate.
Discards	Are those components of a fish stock thrown back after capture e.g. because they are below the minimum landing size or because quota have been exhausted for that species. Most of the discarded fish will not survive.
Ecosystem approach	Ecosystem approach to fisheries management. Management that takes into account the effects of fisheries on the ecosystem and the effects of the ecosystem on the fish stocks.
Exploitation boundary	Threshold on exploitation (catch, mortality, effort) that is consistent with a management strategy or international agreement (e.g. exploitation boundary consistent with precautionary approach)
Exploitation pattern	Distribution of fishing mortality over the age composition of the fish population, determined by the type of fishing gear, area and seasonal distribution of fishing, and the growth and migration of the fish.
F Fishing mortality	Instantaneous Rate of Fishing Mortality. When fishing and natural mortality act concurrently, F is equal to the instantaneous total mortality rate (Z), multiplied by the ratio of fishing deaths to all deaths. Expressed on an exponential scale: $F=0.5$ means that $1-EXP(-0.5)=39\%$ are removed.
F_{pa}	Precautionary reference point for fishing mortality (mean over defined age range)
F_{lim}	Limit reference point for fishing mortality (mean over defined age range)
F_{MSY}	Fishing mortality consistent with achieving Maximum Sustainable Yield (MSY), (see ICES Advice, Section 1.2)
F_{MP}	Fishing mortality reference point as defined in management plans.
$F_{0.1}$	The fishing mortality rate at which the marginal yield-per-recruit (i.e. the increase in yield-per-recruit in weight for an increase in one unit of fishing mortality) is only 10 percent of the marginal yield-per-recruit on the unexploited stock. The fishing mortality rate at which the slope of the yield-per-recruit curve is only one-tenth the slope of the curve at its origin.

ICES Advice 2012, Book 1

Term / acronym	Description
F_{med}	Fishing mortality rate F corresponding to a SSB/ R equal to the inverse of the 50th percentile of the observed R /SSB.
F_{max}	Fishing mortality rate that maximizes equilibrium yield per recruit. F_{max} is the F level often used to define growth overfishing.
F_{sq}	F status quo
Fecundity	In general, the potential reproductive capacity of an organism or population expressed in the number of eggs (or offspring) produced during each reproductive cycle. Fecundity in fish usually increases with age.
Fishery	Group of vessel voyages targeting the same (assemblage of) species and/or stocks, using similar gear, during the same period of the year and within the same area (e.g. the Dutch flatfish-directed beam trawl fishery in the North Sea). See also: fleet, metier.
Fleet	A physical group of vessels sharing similar characteristics in terms of technical features and/or major activity (e.g. the Dutch beam trawler fleet < 300 hp). See also: fishery, metier.
FLR	Fisheries Library in R. The FLR library is a collection of tools in the R statistical language that facilitates the construction of bio-economic simulation models of fisheries and ecological systems. It is a generic toolbox, but is specifically suited for the construction of simulation models for evaluations of fisheries management strategies. The FLR library is under development by researchers across a number of laboratories and universities.
HCR Harvest Control Rule	An algorithm for pre-agreed management actions as a function of variables related to the status of the stock. For example, a control rule can specify how F or yield should vary as a function of spawning biomass. Also known as 'decision rules' or 'harvest control laws'.
Harvest rate	(= harvest ratio) Ratio between landings and total stock abundance (e.g. as estimated from TV surveys for <i>Nephrops</i>).
High-grading	The discarding of a portion of a vessel's legal catch that could have been sold in order to retain a higher or larger grade of fish that will bring higher prices. It may occur in quota and non-quota fisheries.
ICA	Integrated Catch Analysis; Stock assessment method
Lpue	Landings per unit effort, similar to cpue, but based on that part of the catches that are landed and reported.
Management plan	A management plan includes the decision-making processes (harvest control rules, tactical decision making) and the sanctions on implementation and the requirements for monitoring and reporting. Management plans may also exist in the form of rebuilding plans or recovery plans.
Management strategy	Management strategies consist of objectives with associated performance criteria, the implementation measures (e.g. input or output control) and what is considered a relevant knowledge base for decisions.

ICES Advice 2012, Book 1

Term / acronym	Description
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Metier Homogeneous sub-division of a fishery by fleet (e.g. the Dutch flatfish-directed beam trawl fishery by vessels < 300 hp in the North Sea). See also: fishery, fleet.

		TRIP ID (gear, area, mesh size (target species))	
		Fishery 1	Fishery 2
VESSEL ID (homeport, size, type)	Fleet A	Métier p	Métier q
	Fleet B	Métier r	Métier s

MSY Maximum Sustainable Yield. The largest average catch or yield that can continuously be taken from a stock under existing environmental conditions.

MSY $B_{\text{escapement}}$ A biomass reference point for short-lived species within the ICES MSY framework (see ICES Advice, Section 1.2) where the target is to leave the reference spawning stock biomass to spawn the next year.

MSY B_{trigger} A biomass reference point that triggers a cautious response within the ICES MSY framework (see ICES Advice, Section 1.2).

Population A group of fish of one species which shares common ecological and genetic features. The stocks defined for the purposes of stock assessment and management do not necessarily coincide with self-contained populations.

R Recruitment The amount of fish added to the exploitable stock each year due to growth and/or migration into the fishing area. For example, the number of fish that grow to become vulnerable to the fishing gear in one year would be the recruitment to the fishable stock that year. This term mostly used in referring to the number of fish from a year class reaching a certain age. For example, all fish reaching their first year are age 1 recruits.

Reduced reproductive capacity When SSB is at a level where the stock reproduction is impaired as evident from historical observations.

SSB Spawning stock biomass. Total weight of all sexually mature fish in the stock.

SSB_{MP} Spawning stock biomass reference point as defined in management plans.

SSB/R Spawning Stock Biomass per Recruit: expected lifetime contribution to the spawning stock biomass for a recruit of a specific age (e.g., per age 2 individual). For a given exploitation pattern, rate of growth, and natural mortality, an expected equilibrium value of SSB/R can be calculated for each level of fishing mortality.

SMS Stochastic Multispecies Model; Stock assessment method.

Term / acronym	Description
Stock	A part of a fish population usually with a particular migration pattern, specific spawning grounds, and subject to a distinct fishery. In theory, a Unit Stock comprises all the individuals of fish in an area, which are part of the same reproductive process. It is self-contained, with no emigration or immigration of individuals from or to the stock. On practical grounds, a fraction of the unit stock is considered a 'stock' for management purposes (or a management unit), as long as the results of the assessments and management remain close enough to what they would be on the unit stock.
SURBA	SURvey Based Assessment. Uses only relative abundance indicator(s)
Surplus production model	Mathematical representation of the way a stock of fish responds to the removal of its individuals. Usually a relationship between yield and/or cpue, and fishing effort or mortality. Expressed in biomass.
Sustainable	Can be sustained. In the light of the ICES interpretation of precautionary approach: fisheries management that keeps stock(s) above B_{pa} and fishing mortality below F_{pa} .
VPA	Virtual Population Analysis. An algorithm for computing historical fishing mortality rates and stock sizes by age, based on data on catches, natural mortality, and certain assumptions about mortality for the last year and last age group. A VPA essentially reconstructs the history of each cohort, assuming that the observed catches are known without error (Powers & Restrepo, 1992). VPA is often used as a generic description of an age-based stock assessment but this is not necessarily true because many stock assessments are based on different (statistical) assumptions.
XSA	Extended Survivors Analysis; Stock assessment method.
Year class	All the fish of a stock spawned or hatched in a given year.
Yield per recruit	The expected lifetime yield per fish recruited in the stock at a specific age. Depends on the exploitation pattern (fishing mortality at age) or fishing regime (effort, size at first capture) and natural mortality.

The terms in this glossary are taken and adapted from a number of sources:

Cochrane, K. L., Ed. (2002). A fishery manager's guidebook. Management measures and their application. FAO Fisheries Technical Paper. No. 424. Rome, FAO.

FAO Fisheries glossary (<http://www.fao.org/fi/glossary/default.asp>)

NOAA Definition of Fisheries Technical Terms (http://www.nefsc.noaa.gov/techniques/tech_terms.html)

Powers J.E., and V.R. Restrepo. 1992. Additional options for age-sequenced analysis. ICCAT SCRS/91/040.

ICES Advice 2012, Book 1



EUROPEAN COMMISSION

Brussels, 2.5.2017
C(2017) 2914 final

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Client Earth
████████████████████

██████████
European Environmental Bureau
(EEB)
████████████████████

██████████
The International Chemical
Secretariat (ChemSec)
████████████████████

██████████
International POPs Elimination
Network (IPEN)
████████████████████

Subject: Request for internal review under Article 10 of Regulation 1367/2006 of Commission Decision C(2016) 5644 granting an authorisation for uses of lead sulfochromate yellow and lead chromate molybdate sulfate red

Dear ██████████,

Dear ██████████,

Dear ██████████,

Dear ██████████,

I am responding to your request of 26 October 2016 to the European Commission for an internal review in accordance with Article 10 of Regulation (EC) 1367/2006 of Commission Decision C(2016) 5644 granting an authorisation for uses of lead sulfochromate yellow (C.I. Pigment Yellow 34) and lead chromate and lead chromate molybdate sulfate red (C.I. Pigment Red 104).

The request meets the requirements set out in Article 10(1) of Regulation (EC) 1367/2006 and therefore it is admissible.

Your organisations request the internal review of that Decision on grounds that: (1) it breaches Article 60(7) of Regulation (EC) No 1907/2006 (REACH) because the application is not in conformity with the requirements in Article 62(4) of REACH; (2) it is vitiated by a manifest error of assessment of the risks to human health and the

environment and therefore is in breach of Article 60(4) of REACH; (3) it breaches Article 60(4) and (5) and Article 64(2) of REACH; (4) it breaches the obligation to state the reasons under Article 296 TFEU; (5) it breaches the precautionary principle under Article 191 TFEU, and (6) is incompatible with the Dubai Declaration on International Chemicals Management.

After careful consideration of the grounds put forward in your request, I have come to the conclusion that the Commission has neither infringed any of the provisions of the REACH Regulation referred to in your request for internal review, nor any obligations under the Treaty on the Functioning of the European Union or under international law. Accordingly, the grounds put in your request for internal review have to be dismissed as unfounded. The Commission's assessment of each of those grounds is provided in Annex to this letter.

Should you not agree with the present reply, you may make a complaint to the Ombudsman in accordance with Article 228 TFEU or institute proceedings before the General Court under the conditions laid down in Article 263 TFEU.

For the Commission

Elzbieta Bieńkowska
Member of the Commission



ANNEX

Assessment of grounds for review of Commission Decision C(2016) 5644 granting an authorisation for uses of lead sulfochromate yellow and lead chromate molybdate sulfate red

1. Alleged lack of conformity and breach of Article 60(7) of REACH¹

In your request you contend that Decision C(2016) 5644 granting an authorisation for uses of lead sulfochromate yellow and lead chromate molybdate sulfate red (hereinafter referred to as “authorisation Decision”) is in breach of Article 60(7) of REACH because the application for authorisation to which it refers (hereinafter referred to as “application”) was not in conformity with the requirements of Article 62 of that Regulation. Your conclusion on the lack of conformity is based on the grounds that the application failed to define the uses of the substances in accordance with Article 62(4)(c) of REACH and did not meet the requirement to submit an analysis of alternatives in accordance with Article 62(4)(e) of REACH.

1.1. Alleged infringement of Article 62(4)(c) of REACH²

In the request you allege that the application failed to define the uses of the substance, contrary to the requirement in Article 62(4)(c) of REACH. That allegation is based on two arguments: firstly, that the application did not define the functions and performance characteristics of the substances, and secondly, that the uses covered by the application are too broad.

With regard to the first point, you state that the application failed to detail the function of the substances, and you refer in support of that statement to the explanation provided by the applicant in his analysis of alternatives for one of the uses of lead sulfochromate yellow³, which in your view does not explain the value added of that substance compared to other yellow pigments and does not specify which shade of yellow and why only yellow are necessary to achieve the claimed safety needs. You claim the authorisation Decision acknowledged the failure of the application to define the technically required performance characteristics.

The statement from the application which is referred to as evidence does not reflect such failure in any way. The statement is taken from the introduction of an extensive analysis of alternatives for that use, and is presented as if that were the sole reference to the alternatives made in the analysis. Contrary to your claim, the document in question provides an assessment of the properties of over thirty pigments grouped in families of inorganic, organic and hybrid pigments, depending on their chemical composition. The technical properties assessed are chroma, opacity, heat stability, weather fastness, shade and dispersibility. The analysis includes a matrix (in its Appendix I) of all the identified potential alternatives and their respective technical performance characteristics as compared to lead sulfochromate yellow. Contrary to your claim, this comparison shows that the combination of these desired properties cannot be achieved with other pigments, which explains the added value and specificity of lead sulfochromate yellow (as well as of the second lead chromate pigment). Furthermore, whereas Article 62(4)(c) requires that the application for authorisation specifies the use of the substance for which an

¹ Par. 80-107

² Par. 82-98

³ Par. 86

authorisation is sought, and covering the use of the substance in mixtures and/or the incorporation in articles where relevant, it does not require a justification for the necessity of such mixtures or articles, which is rather defined by societal preferences and the market. The ground for review in this regard is therefore manifestly unfounded.

Your claim that the authorisation Decision did “acknowledge the failure to define” the technically required performance characteristics of the substances⁴ is not supported by the facts, either and is based on an incorrect reading of an excerpt of Recital 12 of the Decision. That Recital points towards the difficulties of fully ascertaining the lack of technically feasible alternatives for the entire scope of the uses covered by the application, and on that basis requires the holder of the authorisation to submit a report on the status of the suitability and availability of the alternatives and to use that information to refine the description of the uses. Furthermore, the Decision requires the authorisation holder to submit a report, further refining the description of the uses and linking them to individual technical performance characteristics required for each refined use on the basis of the technical performance characteristics which have already been identified in the analysis that supported the application and, in turn, also in the conditions for granting the authorisation⁵.

Secondly, in the request you contend that the application failed to specify in sufficient detail the scope of the uses applied for making the assessment of the analysis of alternatives meaningless, and that constitutes an infringement of Article 62(4)(c) of REACH, and you provide as evidence the wording of one of the six uses applied for as well as a reference to Recital 12 of the authorisation Decision.

Firstly, it should be noted that the REACH Regulation does not specify at which level of detail the use applied for has to be described in an application for authorisation. The ECHA *Guidance on How to develop the description of uses in the context of Authorisation*⁶ states that the level of detail of the use description will depend on the circumstances of each case, and thus, whereas in some circumstances the description may benefit from a very detailed and narrow scope, in others a lower level of detail and a larger scope may be more suitable. Therefore the fact that in a particular case the description of a use covers for example different types of paint or different types of articles to be painted by different painting techniques (as in the example referred to in your request) is not in itself an indication that the use has not been described appropriately, as this has to be assessed in each case.

In the case at hand, the Commission Decision acknowledges that the description of the uses needed further refinement, since as described in the application, it was difficult to fully ascertain whether technically feasible alternatives were available for the entire scope of the use applied for. However, the Commission did not consider this to amount to a lack of conformity of the application or a reason to refuse an authorisation. The Commission Decision addressed this point, on the one hand, by specifying the condition under which the uses were authorised (“*under the condition that the performance of the pigment premixes, paints and pre-compounds containing that substance, or of finished articles containing them, in terms of shade functionality and chroma, opacity (hiding power), dispersibility, durability (light and weather fastness), heat stability or non-leaching behaviour, or a combination thereof, is technically achievable only by using*

⁴ Par. 87

⁵ The introductory text of Article 1(1) and (2)

⁶ *How to develop the description of uses in the context of Authorisation*, https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf/14b5f647-1778-47de-8178-2e2dad170424

that substance and that such performance is necessary for the intended use"⁷ (emphasis added) and, on the other, by requiring the authorisation holder to report to the Commission by 31 December 2017 on the status of the suitability and availability of alternatives for his downstream users and to refine the description of the uses on the basis of that information. By imposing conditions on the authorisation to demonstrate that the above mentioned technical performance characteristics are needed, the Commission ensured that only the uses concerned are covered by the authorisation (that is, the specific "niche application" to which the applicant for authorisation referred to in the public consultation). It should also be noted that those conditions apply to the downstream users in the supply chain of the authorisation holder if they wish to be covered by the authorisation pursuant to Article 56(2) of REACH. These conditions give grounds to the Member State enforcement authorities to verify whether the downstream users are using the substance within the remits of the authorisation, as set out by these conditions, and act accordingly if this is not the case.

In your request you argue that the REACH Regulation does not provide for the possibility to make the authorisation conditional upon reporting obligations aimed at further refining the use⁸. This claim is not founded on the text of the Regulation, which does not specify in any way the concrete conditions that may be imposed in an authorisation decision. In fact, Article 60(9)(d) of REACH provides for the possibility to impose conditions in a very broad way ("*any conditions under which the authorisation is granted*"), which in itself constitutes an acknowledgement that applications may potentially contain shortcomings that can be addressed in the decision granting an authorisation.

In view of the above, the Commission considers these grounds for review as unfounded.

1.2. Alleged infringement of Article 62(4)(e) of REACH⁹

In your request you claim that the Commission should have considered the application not to be in conformity and therefore refuse the authorisation on the basis that the analysis of alternatives was not in conformity. You argue that, by acknowledging the uncertainties regarding the lack of technically feasible alternatives for the entire scope of the uses covered by the application, the authorisation Decision is recognising the lack of conformity of the application with Article 62(4)(e) of REACH, and therefore, the Commission should have refused the authorisation on the basis of Article 60(7) of the Regulation. You also argue that the authorisation Decision interprets Articles 60(8) and 60(9) of REACH as allowing the Commission to grant an authorisation despite the lack of conformity of an application, if it sets a review period that is shorter than the one recommended by SEAC.

As stated under point 1.1, the Commission acknowledged the uncertainties regarding the lack of technically feasible alternatives due to the broad scope of the uses in the application and addressed those by imposing certain conditions on the authorisation holder, which in effect limit the scope of the authorised uses and thus more appropriately reflect the conclusions of the analysis of alternatives. The Commission did not consider those uncertainties in the analysis of alternatives to amount to lack of conformity of the application, but considered that they could be addressed by imposing particular conditions through the authorisation.

⁷ Article 1(1) and (2)

⁸ Par. 94

⁹ Par. 108-117

According to Article 60(8) of REACH the duration of the review period shall be determined on a case by case basis taking into account all relevant information. The review period set in the authorisation Decision is based on the merits of the present case, among them the difficulties in fully ascertaining lack of technically feasible alternatives for the entire scope of the uses. The fact that the adopted review period is shorter than the one recommended by SEAC does not mean that setting a shorter a review period is a tool to compensate lack of conformity of an application. As already stated, the Commission considered this application to be in conformity.

Therefore, the Commission considers this ground for review to be unfounded.

2. Alleged manifest error of assessment of the risks to human health and the environment and breach of Article 60(4) of REACH

In your request you claim that the authorisation Decision is vitiated by a manifest error of assessment of the risk arising from the uses applied for, for two reasons: firstly, because the risk assessment only covered the carcinogenic and reprotoxic properties of the two lead chromate pigments and did not cover their hazardous properties for the aquatic environment; secondly, because the risk assessment did not assess exposure to those substances due to paint degrading in time or due to heat.

With regard to the first point, it should be noted that the requirement to conduct a risk assessment for the use(s) applied for is limited to the hazards listed in Annex XIV. From a literal reading of Article 60(4) of REACH it could appear that a risk assessment covering all hazards for human health and the environment arising from the use of the substance has to be performed in order to conclude whether the risk is outweighed by the socio-economic benefits. However a conclusion on the interpretation of a provision cannot rely only on a literal reading of the provision in isolation, but it has to take into account its context and objectives of the Regulation as a whole.

Article 60(4) is part of the authorisation system provided for in Title VII of REACH and it sets the conditions for granting an authorisation under the so-called "socio-economic route". Article 62(4) of REACH lists the information that must be included in an application for authorisation, i.e. the information that the applicant needs to submit in order to demonstrate that the conditions for authorisation are met. This article specifies in point (d) that a chemical safety report (CSR) (which is the document that contains the chemical safety assessment, including the risk assessment) must be submitted "*covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV*" (emphasis added). Therefore, in order to conclude whether the socio-economic benefits outweigh the risks, Article 60(4) cannot be interpreted as requiring the applicant to conduct a risk assessment wider than the one Article 62(4)(d) requires him to submit in order to demonstrate that the conditions for authorisation are met.

Furthermore the above understanding is the only possible interpretation of Article 60(4) in the light of the objectives of the REACH authorisation requirement set out in Article 55 of the Regulation, which are to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern ('SVHC') are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. Therefore until substitution is viable, the purpose of authorisation is to properly control the risks from SVHC. For that purpose Title VII establishes a procedure to list in Annex XIV the substances whose use should be subject to authorisation, which is based on the

intrinsic properties referred to in Article 57. The existence of such properties, which are specified in Annex XIV, is the reason for the listing of the substance in that Annex and for the automatic ban that applies after the 'sunset date' unless an authorisation is granted. An Annex XIV listing intends to protect human health or the environment from the hazards specified in that Annex. Hence, it is only logical that the requirements in Article 60(2) relating to the risk assessment and, in the case of Article 60(4), to the risk-benefit assessment of the Annex XIV substance relate only to the intrinsic properties at the basis of the identification of the substance as an SVHC indicated in that Annex, and are intended specifically as assessments of whether those risks are adequately controlled or socio-economically tolerable in specific instances.

Moreover, contrary to your claim¹⁰, there is no difference in the scope of the risk assessment submitted for an authorisation under Article 60(2) of REACH (so-called “adequate control route”) or under Article 60(4) (“socio-economic route”). Therefore the argument that “under Article 60(4) a comprehensive assessment is necessary because the substance included in Annex XIV will always be used in ways that do not exclude a risk for human health and the environment” does not find a basis in the REACH Regulation. Furthermore the argument seems arbitrary, as you do not explain why the risks arising from hazards not listed in Annex XIV for a particular substance would be more relevant if the risks from the hazards that are listed in that Annex are not adequately controlled.

You also argue¹¹ that the risk assessment for applications for authorisation under Article 60(4) should cover all the hazards of the substance because this is necessary in order to be able to assess whether possible alternatives would result in an overall reduction of the risks. However, the requirement under Article 60(5) to assess whether transfer to alternatives results in reduced overall risks for human health and the environment does not mean that a comprehensive risk assessment has to be performed for the purpose of the risk/benefit comparison required in Article 60(4), which is limited to the Annex XIV intrinsic properties. Furthermore, that requirement in Article 60(5) cannot be interpreted as requiring a comprehensive risk assessment for all the hazards of the Annex XIV substance as well as of all the possible alternatives being assessed, and the REACH Regulation does not require this either. As mentioned before, Article 62(4) requires a CSR only for the substance for which an authorisation is being applied for, and regarding the risks related to the intrinsic properties listed in Annex XIV. Indeed, the *Guidance on the preparation of an application for authorisation*¹² clarifies that for the purpose of assessing the alternatives it is important not only to consider the risks that resulted in the requirement for authorisation based on the substance properties listed in Article 57 but also all other possible risks resulting from the Annex XIV substance and the alternative. However the Guidance also clarifies that for doing so the applicant is not required to provide a chemical safety assessment for each of the alternatives but to compare the potential risks of possible alternatives to those of the substance listed in Annex XIV. The level of effort that needs to be put into this comparative assessment going beyond the documentation of available information will be a matter of judgment for the applicant. For example, the comparison of hazard profiles may indicate that the alternatives present a clearly lower level of risk. In these cases, no additional assessment may be necessary. In other cases the possible alternatives may not be technically or economically feasible so whether they would result in an overall reduction of risks to human health and the environment would not constitute an element for consideration.

¹⁰ Par. 112

¹¹ Par. 111

¹² *Guidance on the preparation of an application for authorisation*, https://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf/6571a0df-9480-4508-98e1-ff807a80e3a9, Section 3.7.1

It is worth noting the practical implications of your interpretation of Article 60(4). As established above a CSR is not required neither by Article 60(2) nor by Article 62(4)(d) for hazards other than the ones listed in Annex XIV. Performing such a wide risk assessment (covering all potential risks from all hazards of the substance) would require many resources and would be disproportionately burdensome for the applicant vis-à-vis the relief sought. With regard to the authorisation Decision under discussion, the SEAC concludes that the socio-economic benefits largely outweigh the risk of continued use. While the quantified benefits of the continuation of each use amount to hundreds of millions of euros¹³ based on a conservative assessment (i.e. mainly based on substitution costs, but not considering other relevant impacts such as job losses or welfare loss borne by downstream users due to lower quality of the paint), the health impact associated with the risk amounts to a few thousand euros¹⁴. Even if it was considered that the risks from other hazards should have to be taken into account (*quod non*), it should be noted that the RAC acknowledged that the predicted environmental exposure levels were much lower than the background environmental concentrations and, on that basis, it seems unreasonable to expect that any impacts associated with potential risks to the aquatic environment may make up for such a difference. Thus, even if the potential risks to the aquatic environment were taken into consideration in the benefit-risk comparison, it would not have changed the validity of the conclusion that the socio-economic benefits outweigh the risk from continued use, therefore the relevant criterion under Article 60(4) would still be met.

An additional argument you put forward to support this ground for review¹⁵ is the wording of Article 62(5)(a) and Annex XVI to REACH, which refers to the socio-economic analysis in applications for authorisation under Article 60(4) REACH. Firstly, it should be noted that Annex XVI provides that *“the level of detail and scope of the SEA, or contributions to them, shall be the responsibility of the applicant for authorisation”* (emphasis added). Reference to the risks to human health and the environment is made in Annex XVI, in particular in the 7th indent of the list of elements that may be included in a socio-economic analysis in an authorisation application (*“in the case of a proposed restriction or a refused authorisation, the benefits for human health and the environment (...). For example, worker health, environmental performance and the distribution of those benefits, for example, geographically, population groups,”*). The Commission interprets the above mentioned provisions of Annex XVI, and in particular the use of the term *“may”* regarding the list of elements of a socio-economic analysis, as meaning that the scope of the analysis, including information on the costs for human health and the environment of a granted authorisation, has to be determined on a case-by-case basis.

¹³ For use 2 of C.I. Pigment Yellow 34: €522-€1,700 million; for use 2 of C.I. Pigment Red 104: €336-€1,099 million; for use 3 of C.I. Pigment Yellow 34: €130-€426 million; for use 3 of C.I. Pigment Red 104: €84-€274 million; for use 5 of C.I. Pigment Yellow 34: €20-€65 million; for use 5 of C.I. Pigment Red 104: €2-€6.6 million; for use 6 of C.I. Pigment Yellow 34: €5-€16 million; for use 6 of C.I. Pigment Red 104: €0.5-€1.6 million.

¹⁴ For use 2 of C.I. Pigment Yellow 34: circa €1,500 per year; for use 2 of C.I. Pigment Red 104: circa €1,500 per year; for use 3 of C.I. Pigment Yellow 34: circa €2500 per year; for use 3 of C.I. Pigment Red 104: circa €1000 per year; for use 5 of C.I. Pigment Yellow 34: circa €40,000 per year; for use 5 of C.I. Pigment Red 104: circa €15,000 per year; for use 6 of C.I. Pigment Yellow 34: circa €32,000 per year; for use 6 of C.I. Pigment Red 104: circa €14,000 per year.

¹⁵ Par. 112

With regard to the environmental hazards, in the case at hand, the CSR included, for each of the six exposure scenarios¹⁶, relevant environmental contributing scenarios describing the grounds for calculating the estimated releases to water, air, soil and waste and providing the modelled predicted environmental concentrations of lead for all the relevant environmental targets (freshwater, freshwater sediment, marine water, sewage treatment plant and agricultural soil). In all cases the information provided indicated that either there are no emissions to the environment or these result in environmental concentrations which are orders of magnitude below the background concentrations in the environment, thereby indicating that the environmental exposure to the substances is negligible.

As indicated in section 9.0.2.1. of the CSR submitted by the applicant "Environment Scope and type of assessment", a quantitative environmental risk characterisation was done as regards the risks for the environment associated to the uses of the two pigments. The basis for the assessment are explained in that section, including the use of the "added risk approach" (given that lead and chromium are naturally occurring elements found in environmental media) and taking into account the dissolution of these metals from the two pigments, as calculated using test results applying the OECD transformation dissolution protocol. The same section of the CSR also provides justification for the approach chosen whereby for the risk assessment of C.I. Pigment Yellow 34 and C.I. Pigment Red 104, lead was identified as the leading substance indicator given that the content of lead in the pigments is higher than the chromium content by a factor of 4, the dissolution from the pigments is higher by a factor of 4 to 100 and the Predicted No-Effect Concentrations (PNECs) for lead are generally lower. In this respect it is highlighted that PNECs and PEC regional for lead were taken from the voluntary Risk Assessment Report¹⁷ for lead and that conservative PNECs (reference values for the environmental risk assessment) had been selected.

The second point raised is that the risk assessment in the application was limited to the risk of release of the substance during the use of the mixture containing it and did not assess exposure due to paint degrading with time or due to heat. This claim is unfounded as the CSR in the application did consider not only environmental emissions from the uses applied for, but also from relevant aspects related to the service life of the articles containing the pigments:

- section 9.4.1 of the CSR addresses environmental emissions due to the sanding of painted / coated articles;
- section 9.5.1 of the CSR addresses in its environmental contributing scenario 1 (ECS1) the leaching from painted metal surfaces (machines, vehicles, structures, signs, road furniture, coil coating) during service life;
- section 9.5.2 deals with the sanding of painted/coated articles;
- section 9.5.3 examines leaching from painted road marking during service life;
- section 9.8.1 contains the ECS for use of colour premixes and pre-compounds in the application of hotmelt road marking;

¹⁶ E.g., for exposure scenario 1 - Section 9.1.1 of the CSR. *Environmental contributing scenario 1: Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use*

¹⁷ Boreiko, C., Battersby, R. (2008). Voluntary Risk Assessment Report on Lead and some inorganic Lead compounds. Testing laboratory: ILZRO and EBRC Consulting. Report no.: not available. Owner company: LDAI Lead Risk Assessment Working Group. Report date: 2008-03-04.

- section 9.9.1 contains the ECS for industrial service life of coloured plastic or plasticised articles, including hotmelt road marking;
- section 9.10.1 contains the ECS for service life of coloured plastic and plasticised articles, including hotmelt road marking (leaching), and
- section 9.10.2. contains the ECS for removal of hotmelt road marking.

For each of the environmental contributing scenarios the rationale underlying the emission factors is described, the different exposure estimation tools are defined¹⁸ and the calculated environmental concentrations and associated risk assessment ratios are provided. These scenarios address releases not only of painted articles due to leaching, but also leaching from plastic articles as well as release of particulates due to maintenance operations (e.g. sanding).

Thermal decomposition of the pigment in the paint is not addressed as their decomposition is highly unlikely under any reasonably foreseeable, non-accidental environmental condition, given that the two lead chromate pigments subject to the application for authorisation are highly heat stable inorganic compounds (this being one of the main reasons for being the pigment of choice for the described uses), with stability up to 300°C according to the applicant, which allows the thermal processing during plastic manufacture and in certain coating operations.

Finally, you claim that the absence of an assessment of the indirect exposure of man via the environment in the application is contrary to the wording of Article 60(4) in as far as it requires an assessment of “the risk to human health or the environment”.

The CSR provides justification as to why it is not possible to develop a precise estimation of exposure to man via the environment for lead but, in any event, the risk characterisation conclusions for each of the environment contributing scenarios described in the CSR state that *"under the conditions of this contributing scenario, the local concentrations and associated risk characterization ratios due to the use of C.I. Pigment Yellow 34 and C.I. Pigment Red 104 are orders of magnitude lower than the background concentrations of lead for all environmental compartments assessed"*. Given that the calculated contribution to environmental concentrations of lead from the described industrial, professional and article service life scenarios is claimed to be below background environmental concentrations it does seem reasonable to accept that the exposure of man via the environment (due to the use of the pigments) was not included.

The fact that an assessment of exposure of man via the environment was not performed and was not considered applicable due to very low environmental exposures is acknowledged and confirmed by the RAC in the opinions, and no conditions or monitoring arrangements to address this matter are recommended in them. The Commission services have examined the information and justifications in this regard provided in the CSR by the applicant and have no reasons to disagree with neither the applicant nor the RAC.

In your request you contest the conclusion of the RAC that, since the predicted environmental exposure levels are much lower than the background environmental concentrations, the absence of a risk assessment of indirect exposure of man through the environment can be accepted. In other words, you argue that the REACH Regulation requires the indirect risk of man via the environment to be calculated also in cases where

¹⁸ essentially EUSES or specific SpERCs

the predicted environmental exposures are considered to be negligible because they are at or below the background environmental concentrations.

In the Commission's view this is not supported by the letter and the spirit of the REACH Regulation. Section 5 of Annex I to REACH, which sets out the requirements for conducting an exposure assessment, provides that "*An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable*" (emphasis added) (section 5.2.4). In the case at hand the outcome of the assessment of risks to man via the environment is considered negligible and thus it would not affect the overall risk/benefit comparison. Consequently, the Commission has accepted that the assessment of indirect exposure of man via the environment is not evaluated.

In view of the above, the Commission considers this ground for review as unfounded.

3. Alleged breach of Article 60(4) and (5) and Article 64(2) of REACH¹⁹

In your request you allege that the authorisation Decision is vitiated by an error of law in the interpretation of the notion of suitable alternative in the meaning of Article 60(4) and (5) of REACH and a manifest error of assessment of the information submitted by third parties under Article 64(2) of the Regulation.

3.1. Error of law in interpreting the notion of suitable alternative²⁰

The request alleges that the Commission erroneously interpreted the notion of technical feasibility and economic feasibility of alternatives.

3.1.1. Technical feasibility²¹

Regarding technical feasibility, you firstly contend that the assessment made by the applicant was erroneous because it covered all the individual properties of the substances irrespective of their function, whereas what should have been assessed, in your view, are the characteristics of the substances which are necessary for their function. On the one hand, you argue that the approach followed by the Commission excludes any alternative that would not achieve all the technical criteria of the two substances in question at the same level of performance. On the other, you claim that the notion of substitution under EU competition law rules cannot be taken into account when implementing the REACH Regulation.

Concerning the first argument, it should be noted that the analysis of alternatives focused on six technical properties the two substances confer (i.e. chroma, opacity, heat stability, weather fastness, shade and dispersibility) that, according to the applicant, allow the paints and coatings to which they are added to perform a number of functions (i.e. in terms of their durability, reliability, signal and contrast, and quick drying). The applicant assessed the performance of over thirty identified potential alternative pigments against the above technical properties and concluded that none of the alternatives could provide the same level of quality for all of them. In other words, while some alternatives (such as the pigment PY184, bismuth vanadate) allow meeting some of the technical properties identified as necessary by the applicant, not all of them were satisfied (in the example of

¹⁹ Par. 118-175

²⁰ Par. 123-146

²¹ Par. 124-139

PY184, the shade, opacity and weather fastness of the resulting application would be compromised). The SEAC in its opinions, and subsequently the Commission when deciding on the application, considered that the approach followed by the applicant was appropriate.

In your request you claim that since the application does not identify the function of the pigments and the minimum requirements needed to achieve that function at the same level of performance, it is not possible to compare the technical characteristics of the different alternatives being assessed. In the Commission's view, this interpretation of Article 60(4) and (5) of REACH has no basis in the legal text. When assessing potential alternatives, a reference should be the function that the Annex XIV substance in question performs. The *Guidance on the preparation of an application for authorisation* states that technical feasibility of an alternative "is based on the alternative fulfilling or replacing the function of the Annex XIV substance" and that it is "therefore closely linked to the function that the Annex XIV substance performs"²². While the Guidance recognises that it may be possible to develop technical requirements on the function that must be fulfilled for an alternative to be technically feasible, this is not a mandatory condition for an analysis of alternatives. Your argument that comparing the technical characteristics of the substance with those of others, without knowing the minimum requirements to be achieved, inevitably leads to the finding that the alternative substance cannot be considered technically feasible²³, is incorrect. By taking as a reference the technical requirements met by the Annex XIV substance necessary for its desired function, the alternatives should be assessed against those requirements, as it was done in the case at hand. Furthermore, the wording of Article 60(5)(b), which requires the Commission to also take into account in its assessment "including: ... the technical and economic feasibility of alternatives for the applicant", further indicates that the notion of feasibility of alternatives is relative, as the legislator required the Commission to consider also the applicant's perspective in its assessment. In the case at hand, the analysis of alternatives provided by the applicant²⁴ showed that for some of the above mentioned six technical functions, different alternative substances met some of them to the same level as the two Annex XIV substances, but none of the potential alternatives listed met all of them. It should be noted that the Commission acknowledged in the authorisation Decision the difficulties to fully ascertain the lack of suitable alternatives for the entire scope of the uses covered by the description of uses in the application, and, accordingly, it imposed a number of limitations (in Article 1(1) and (2) of the Decision) on the authorisation holder and its downstream users as to the scope of the uses authorised.

The second argument you raise is that the SEAC erred in law when assessing the alternatives by referring to a recent Commission merger Decision which considered that bismuth vanadate and lead chromates belong to different product markets²⁵. You consider that by not contradicting the SEAC's statement in its authorisation Decision, the Commission also erred in law.

Firstly, in the Commission Decision there is no particular reference to the paragraph you refer to in the SEAC opinions. The argument in question is provided by the SEAC in its opinions as an additional element confirming their conclusion that bismuth vanadate is not a technically suitable alternative to the two lead chromate pigments.

²² Section 3.6

²³ Par. 131

²⁴ Appendix I to Analysis of Alternatives

²⁵ Par. 133-139

The Commission does not share your views that the notion of relevant product market and substitutability under competition law is not relevant for the assessment of alternatives under the REACH Regulation. Whereas the product characteristics and function on their own are indeed not sufficient to define the relevant product market, and that also other considerations may play a role in the market responsiveness to relative price changes, a similar reasoning holds for the notion of suitable alternative under REACH, which is not determined only by the technical characteristics of the substance and its function, but also by its economic feasibility, its availability, its hazard properties and overall risks. In that regard, in the Commission's view an assessment about the substitutability between two substances made under competition policy may provide useful insights for the purpose of assessing the technical and economic feasibility of a substance under the REACH Regulation. It would however not be the only aspect to be taken into account.

In the Commission's view the fact that REACH authorisation and competition policy have different aims does not justify excluding that the concept of relevant product market in competition policy may provide relevant input for assessing alternatives under REACH.

3.1.2. Economic feasibility²⁶

In your request you contend that the authorisation Decision is based on an erroneous interpretation of the notion of economic feasibility. You claim that the SEAC erred in accepting the applicant's assessment of economic feasibility, which allegedly relied solely on cost comparison based on prices. You contend that such an analysis is contrary to the recommendation of the *Guidance on the preparation of an application for authorisation*.

The Commission would like to recall that Article 60(5) obliges to take into account also the economic feasibility of the alternatives for the applicant when assessing whether suitable alternatives are available. While REACH does not prescribe any particular way of assessing the economic feasibility, the ECHA Guidance²⁷ explains how to determine the economic feasibility of alternatives. Indeed, as claimed in paragraph 141, the Guidance notes that '*one criterion for an alternative to be economically feasible is ... using the alternative should result in generating gross profit*'. However, contrary to your claim, the Guidance does refer to it as one criterion but not as the only (defining or sufficient) criterion, thus even if this criterion is fulfilled, this does not necessarily mean that the alternative is economically feasible. It is also worth noting that this criterion is not always relevant, as in certain cases the use of the substance would not be related to a profit-generating activity. In fact, the Guidance establishes that: "*The basis of determining the economic feasibility of alternatives can be called a costs analysis. This identifies the costs associated with the Annex XIV substance and compares this to possible alternatives, calculating the comparative costs between them. The analysis should also include possible changes in revenues due to substitution. Such revenues should be deduced from the costs.*" It further explains that "*the costs and revenues should reflect only the uses applied for*". Finally, the Guidance summarises the process as "*perform a comparative costs analysis of current use of the Annex XIV substance versus the alternative/s*". Thus, both the applicant and the SEAC applied the cost comparison approach as recommended by the ECHA Guidance.

²⁶ Par. 140-146

²⁷ ECHA's Guidance on the preparation of an application for authorisation, p. 74, p. 75, p. 76

Note that, even though economic feasibility does not need to be assessed in depth when no technically feasible alternative exists, as concluded by the SEAC, the applicant provided an assessment of the implications of not being able to use the substance that underpins the conclusion on economic feasibility. The assessment, which was backed by the SEAC, is based mainly (but not only) on the direct and the associated costs of substitution that would be passed on to the direct end users (the link between the economic feasibility and the substitution costs assessments is set out in page 16 of the opinions of Use 3). The assessment relies not only on a comparison of prices between the substances and the alternatives, as you claim, but on a broader cost comparison, which also includes the need for a higher amount of the alternative pigment, the need for more layers in order to achieve the same characteristics and the need for repainting (i.e. need for additional quantities, at higher prices). Furthermore, by estimating the impacts of non-use, the assessment already accounts for the potential loss of revenues, loss of the market, and thus loss of the profits. In addition, note that comments from stakeholders during the opinion and the decision making processes confirmed that alternatives are more expensive and, for those stating that an alternative can be used at an acceptable cost, no substantiated and quantitative data were provided that would modify the SEAC's or, subsequently, the Commission's conclusion on the economic feasibility. On this basis, Article 60(5) was considered as fulfilled. Finally you do not establish in your request that a different assessment approach would lead to the opposite conclusion, i.e. that alternatives are economically feasible.

Based on the above, the Commission considers this ground for review as unfounded.

3.2. *Manifest error of assessment of the information submitted by third parties under Article 64(2)*²⁸

In your request you contend that the authorisation Decision breaches Article 64(2) of REACH in that it failed to take properly into account crucial information submitted during the public consultation and it is vitiated by an error of assessment of certain submissions to the public consultation conducted by ECHA.

3.2.1. Failure to take properly into account relevant contributions to the public consultation

In your request you allege that the Commission did not give sufficient weight to “key submissions” to the public consultation which, in your view, unequivocally revealed that technically and economically feasible alternatives are available. In support of that claim you refer to submissions from the paints and coatings sector claiming that most of its customers have successfully substituted to lead chromate free formulations or are prepared to do so. In the request it is claimed that the SEAC did not make a critical assessment nor gave adequate weight to the submissions by major actors on the market and downstream users, but that it merely summarised the contributions and concluded by agreeing with the applicant on the lack of technically feasible alternatives. You also argue that if lead chromates were necessary for niche applications, as claimed by a number of submissions from downstream users, then the scope of the uses for which authorisation was applied for should have been limited to such niche applications.

The Commission would like to recall again Article 60(5), which provides that the technical and economic feasibility of alternatives **for the applicant** should also be taken into account when assessing whether suitable alternatives are available (emphasis added).

²⁸ Par. 147-165

In this case, the assessment is made from the point of view of the downstream users of the applicant. The fact that other stakeholders have substituted or are prepared to do so does not necessarily mean that the alternatives are suitable for the downstream users of the applicant. In that regard, the quoted submission by Akzo Nobel²⁹ to the public consultation refers to the existence of suitable alternatives meeting the requirements of the customers of that company, who are not necessarily the same as those of the authorisation holder. In addition, the quoted submission by BASF³⁰ to the consultation refers to “most of our customers”, which indicates that the alternatives are not suitable for all their customers. Contrary to your claims, all submissions to the public consultation have been taken into account by the SEAC during their evaluation and this has been properly documented in the related opinions. As evident from the SEAC opinions, the submissions of stakeholders, including those pointed in your request, have been used by the SEAC to challenge or validate the applicant's assessment, as well as in reaching the final conclusions and pointing out any uncertainties.

Thus, the Commission considers this ground for review as unfounded.

3.2.2. Failure to critically assess certain contributions to the public consultation³¹

In your request you refer to over 100 submissions from downstream users claiming that there were no technically and economically feasible alternatives to lead chromates, and claim that the SEAC assessment of those submissions lacked a critical analysis and scientific perspective. In particular, the legitimacy and credibility of those submissions is put in doubt because many of the submitters requested their identity not to be disclosed, many submissions were similar in wording and content, the actual number of companies who actually submitted such comments is not known, and the arguments submitted should have been considered as irrelevant.

Concerning the companies who submitted the comments, it is common practice in ECHA's public consultations not to seek justification from companies for requesting anonymity in the publication of the results. There may be legitimate reasons for such requests, in particular if the comments are submitted by customers of the applicant, as recognised by Article 118 (2)(d) of REACH. Therefore the Commission does not consider that such requests should put into question in any way the legitimacy and credibility of the submission.

As to the content of the submissions, the fact that the wording of different submissions is the same should neither question their legitimacy nor their credibility. Although from a practicality and efficiency point of view it is obviously preferable for public authorities to receive joint comments from operators who share the same view on a particular matter, the fact that this does not happen, as often similar contributions are submitted by different operators, does not invalidate in any way the quality or credibility of the information submitted.

According to information from ECHA, 23 entities have submitted a total of 149 comments on a confidential basis. In the Commission's view, this fact does not put into question the legitimacy or the credibility of the submissions, either.

Finally, regarding the content of those submissions, you consider the main arguments of the comments should have been rejected because they are based on an erroneous

²⁹ Par. 151

³⁰ Par. 149

³¹ Par. 149-165

interpretation of the notion of alternative. On the one hand, you refer to the arguments put forward under the third ground for review (error of law in interpreting the notion of suitable alternative), and on the other hand you consider irrelevant the argument in those submissions that companies may need to exit the EU market if the authorisation is refused.

Concerning the first point, it suffices to refer to the reply in point 3.1. On the second point, the Commission notes that, in accordance with the *Guidance on the preparation of an application for authorisation*³², what is relevant for determining the economic feasibility of alternatives is the change in the applicant's costs and revenues as a result of the transfer to the alternative, and may include the economic impacts of the transferral within the supply chain. Furthermore, the same Guidance does advise to '*... take account of economic consequences of any related changes in the production volume*'. While the Commission agrees that possible relocation outside the EU is more relevant for the non-use scenario part of the application, the inclusion of such an argument in the submissions by some third parties does not invalidate those comments, in as much as they do include relevant information on the technical and economic feasibility of alternatives.

Thus, the Commission considers this ground for review as unfounded.

3.3. *Manifest error of assessment of the national rules relating to road markings*³³

In your request you contend that the Commission erred in its assessment of the existing obligations at national level to use lead chromates in road markings. On the one hand, you argue that the applicant's claim that some national regulations require the use of lead-based paints in road marking is not supported by evidence. On the other, you consider that the prohibition of the use of lead chromate-based paints in road marking in some Member States is in itself enough proof that technically and economically feasible alternatives exist for that use.

Concerning the first argument, it should be noted that the technical requirements about the paints to be used in road markings in Member States are set out by the latter. In your request, you quote a short extract of the analysis of alternatives³⁴ to show that the applicant allegedly did not justify why the two lead chromate pigments are required for road marking. In the view of the Commission, this argument is not supported by the evidence you have provided, given that the analysis of alternatives for that use is not limited to referring to the colours as such, but a detailed description of the performance characteristics required in paints for this use, and comes to the conclusion that none of the potential alternatives identified meet all those characteristics.

Regarding the reference made to the comments submitted by Sweden in the public consultation conducted by ECHA³⁵, the authorisation Decision acknowledges that lead chromate pigments are not used in all Member States for road marking, and that the use of lead-based paints for that purpose is banned in some cases, whereas in other cases other colours than yellow and red are used. You claim that the fact that in some Member States the use of lead-based paints is banned demonstrates there are suitable alternatives³⁶. In that regard the Commission notes that the prescription of the performance characteristics of the paints used for road markings is a matter of general

³² Section 3.8

³³ Par. 166-175

³⁴ Par. 166

³⁵ Par. 168

³⁶ Par.174

road safety policy which is outside the scope of an authorisation Decision under the REACH Regulation. Road marking systems and traffic conditions are very diverse, and the technical characteristics required from paints used for that purpose may differ accordingly. Therefore the fact that in a particular Member State the yellow and red colours are not used in road markings in no way demonstrates that there are suitable alternatives to the two lead chromate pigments everywhere in the EU, because the use of a different colour is a choice made by that Member State against the background of its national situation, which is beyond the scope of the authorisation decisions adopted under Article 60 of REACH. This conclusion became clear in discussions with Member States during the decision-making process, which showed that Member States have different approaches to road markings, depending on many different factors such as traffic density, weather conditions, and frequency for renewing road markings.

In your request you also claim³⁷ that the fact that no submission was made by the national bodies that allegedly impose the use of lead chromates questions the accuracy of the claim that the lead chromate pigments are necessary for road markings. In that regard it suffices to say that the lack of any submissions from national bodies does not in itself demonstrate anything at all, neither in favour nor against the applicant's claims.

In view of the above, the Commission considers this ground for review unfounded.

4. Alleged breach of the obligation to state the reasons under Article 296 TFEU³⁸

In your request you contend that the Commission Decision breaches the obligation to state the reasons because it does not provide an assessment of the lack of suitable alternatives within the meaning of Article 60(4) and(5), and merely summarises the conclusions of the RAC and the SEAC opinions. Furthermore you allege that the Decision lacks logic and contains internal inconsistencies, by granting the authorisation in spite of the uncertainties identified in the applications and the acknowledgment that there are difficulties in fully ascertaining the lack of technically feasible alternatives. You also claim the SEAC did not provide sufficient justification for its conclusion that no technically suitable alternatives are available³⁹.

Firstly, it should be pointed out that the legislator gave the SEAC the task to assess the availability, suitability and technical feasibility of alternatives⁴⁰. Recital 102 of the REACH Regulation further clarifies the role of the ECHA Scientific Committees, i.e. "*take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence*". Therefore the opinion of the SEAC in the context of Article 60(4) of REACH constitutes an independent, scientific judgment about the merits of an application for authorisation in the light of the conditions set out in the legal text. By referring to the opinion of the SEAC, and expressing its agreement with it as regards the Committee's conclusions on whether the socio-economic benefits from the use of the substance outweigh the risks to human health and the environment and, albeit to a limited extent, on whether there are suitable alternatives available, the Commission provided the justification of its Decision with regard to the assessment of those conditions set out in Article 60(4) of the Regulation. In the Commission Decision, the

³⁷ Par. 171

³⁸ Par. 176-185

³⁹ Par. 176-181

⁴⁰ Article 64(4)(b) of REACH

agreement of the Commission with the assessment of the SEAC is reflected in Recitals 6 and 7 (“(...) *the six uses applied for should therefore be authorised, (...)*”) in conjunction with recital 12. The wording of Recital 7 makes it clear that the Commission reviewed and agreed with the SEAC conclusions referred to in the previous Recital. By referring in this manner to the SEAC opinions the Decision provided a clear and sufficient motivation of the aspects of why it considered that the conditions for granting an authorisation under Article 60(4) REACH were met. In addition, the Commission notes that during the decision-making procedure, in view of the questions raised by some Member States in the REACH Committee, it conducted further enquiries as regards the technical and economic feasibility of alternatives for the uses applied for. In particular the Commission had requested clarifications from the applicant concerning the uses covered by the application, and the technical and economic drivers that determine the choice of the substance to be used by downstream users. The Commission had also enquired with Member States about any national requirements or bans on the use of lead chromate pigments in road markings. The information provided in the application, by third parties and Member States, and in particular the difficulties to fully ascertain the lack of suitable alternatives for the entire scope covered by the description of the uses applied for, led the Commission to depart from the SEAC opinions as regards the existence of suitable alternatives for the applicant and its downstream users and to conclude that this condition was only met for some of the uses covered in the description of uses in the application, as per the analysis of alternatives presented in the application. Accordingly, the Commission imposed a number of limitations in Article 1(1) and (2) as to the scope of the authorised uses, and provided a justification for that decision in Recital 12 of the authorisation Decision, as explained in Recital 12, and set a limitation.

The Commission does not agree with your claim that the Decision lacks logic and contains internal inconsistencies. According to that view, any shortcoming identified in an application for authorisation should inevitably lead to a refusal of an authorisation. Should that logic prevail, the Commission should refuse authorisations in a majority of cases, since more often than not uncertainties have been reported by the Committees in the assessment of the risks, in the analysis of alternatives or in the socio-economic analysis. As explained before (*supra* point 1.1), in the Commission’s view the fact that Article 60(9)(d) of REACH generally provides for the possibility to impose conditions in the decision (“*any conditions under which the authorisation is granted*”) constitutes an acknowledgement by the legislator that applications may potentially contain shortcomings that can be addressed in the decision provided that do not compromise the conformity of the application. An authorisation should be refused where the shortcomings put into doubt whether the conditions for granting an authorisation are met, which in the Commission’s view was not the case in the present application.

Concerning the SEAC opinions themselves, the Commission does not agree that they lacked reasoning and logic as a whole. Concerning the analysis of the technical feasibility of alternatives, which is the part of the SEAC opinions you are concretely referring to in support of your claim⁴¹, your conclusion that the SEAC limited itself to agreeing with the applicant without further justification is incorrect. In its opinions, the Committee reflected the assessment made by the applicant in its analysis of alternatives, the different views (in favour and against) expressed in the public consultation, as well as the applicant’s comments to the public consultation submissions. The fact that contradictory claims were made by different stakeholders in the public consultation should not require the Committee to launch an in-depth market study to verify which stakeholders are right and which are wrong. Such contradictory statements do not prevent

⁴¹ Par. 180

the Committee from drawing conclusions based on an overall assessment of the available evidence. However, while the Commission found that the SEAC's evaluation with regard to the alternatives were sufficient to exclude the existence of suitable alternatives for the uses applied for as analysed in the applicant's analysis of alternatives, it also found that the description of the uses applied for was broader than the scope of the analysis of alternatives. Accordingly, the Commission imposed limitations (in Article 1(1) and (2) of the authorisation Decision) as to the scope of the uses authorised.

In view of the above, this ground for review must be dismissed.

5. Alleged breach of the precautionary principle under Article 191 TFEU⁴²

In your request you contend that the Commission Decision is in breach of the precautionary principle because it granted an authorisation despite the fact that it was allegedly not in conformity and the assessment raised uncertainties and difficulties in fully ascertaining the lack of technical feasibility of alternatives. Since the arguments you provide in support of your claim have already been dismissed (*supra* points 1.1 and 3.1.1), this claim must be dismissed as unfounded.

6. Incompatibility with the Dubai Declaration on International Chemicals Management⁴³

In the request you contend that the Decision is incompatible with the Strategic Approach to International Chemical Management (SAICM) adopted by the International Conference on Chemicals Management (ICCM) in February 2006 in Dubai, and in particular the commitments undertaken by the ICCM members under the Global Alliance to Eliminate Lead in Paint (GAELP).

Recital 15 of the Commission Decision clarifies that the authorisation is not incompatible with the main goals of those instruments. The SAICM and the GAELP do not directly impose legally binding obligations upon the EU, but set out general political goals towards improvement of chemicals management and, in particular regarding lead in paints, towards reduction of exposure to such paints and their elimination over time, with the target year of 2020. Such political commitments are implemented through the existing EU law but cannot legally limit the power of the Commission to grant an authorisation in accordance with EU legislation. Furthermore, by including the two lead chromate pigments in Annex XIV to the REACH Regulation with the sunset date of 21 May 2015, while subjecting the use of those substances after this date to close scrutiny via the authorisation requirement, the EU took a policy decision to phase out the uses of those substances where technically and economically suitable alternatives are available. The fact that the Commission has authorised certain uses of those substances to continue after May 2015, in accordance with the conditions set out in REACH, is only an implementation of that policy decision. Finally, the imposition of a number of conditions in the authorisation Decision (e.g. application of additional risk management measures to protect workers, limitation of the maximum annual quantities of pigments authorised, obligation for downstream users to provide updated information on the status of the

⁴² Par. 182-185

⁴³ Par. 186-199

suitability and availability of alternatives) is in the spirit of the political commitments set out in the GAELP to phase out the use of lead in paints over time.

Furthermore, the review reports for uses in road marking are to be submitted in November 2017, while for other uses in November 2020, when the authorisations are to be reviewed in accordance with Article 61(1) of REACH, unless the Commission conducts an earlier review in accordance with Article 61(2) of REACH.

Finally, it should also be noted that in line with Article 69 (2) of REACH, the European Chemicals Agency (ECHA) is considering whether the use of lead chromate pigments in articles poses a risk to human health or the environment that is not adequately controlled and if that is the case it must prepare a dossier for initiating a restriction procedure of these pigments in articles.

This ground for review should therefore be dismissed.

Conclusion

For the afore-mentioned reasons, the internal review of Decision C(2016) 5644 has led to the conclusion that the Commission has neither infringed any of the provisions of the REACH Regulation referred to in the request for internal review, neither any of the obligations under the TFEU or under international law referred to in the request. Accordingly, the grounds put in the request for internal review have to be dismissed as unfounded.