COMMENTS AND RESPONSE TO COMMENTS ON OEL: PROPOSAL AND JUSTIFICATION

All comments and attachments including confidential information received during the consultation have been provided in full to the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Although journal articles are not confidential, they are not published on the website due to Intellectual Property Rights.

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Last data extracted on 12.07.2022

Substance name: Polycyclic aromatic hydrocarbons
EC number: -
CAS RN: -

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
11.07.2022	Germany	Federal Institute of Occupational Safety and Health	National Authority	1

Comment received

Division 4 - Hazardous Substances and Biological Agents of the Federal Institute of Occupational Safety and Health submits the following comments on the draft scientific report of ECHA for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace.

p.10 + p. 84, Table 18: please check the concentration unit of ng/cm³. It should be likely corrected to ng/m³.

Chapters 5 and 6 of the report: Some more focus could be given to dermal exposure and dermal exposure monitoring as PAH are known to cause relevant dermal exposure at specific workplaces. The following publications are relevant for this exposure pathway. Some of them are already cited in the report:
A. Schäferhenrich, R. Hebisch, D. Holthenrich, K. Krutz, T. Göen: Messung von Hautbelastungen durch chemische Stoffe bei der Imprägnierung mit Holzschutzmitteln. 1. Auflage. Dortmund: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin 2012. ISBN: 978-3-88261-723-8, Seiten 197, Projektnummer: F 2053,
https://www.baua.de/DE/Angebote/Publikationen/Berichte/F2053.pdf
R. Hebisch, J. Karmann, A. Schäferhenrich, T. Göen, M. Berger, U. Poppek, M. Roitzsch, "Inhalation and dermal exposure of workers during timber impregnation with creosote and subsequent pro-cessing of im-pregnated wood", Environ. Res., 2020, 181, Art. 108877

It would be beneficial for the report to elaborate also some methods for dermal exposure monitoring, next to air- and biomonitoring.

Further comments:
We would like to draw attention to two research studies by the German environmental agency, which might be generally considered for the report and which have not been available during the call for evidence.

One recent report "Development of a chemical analysis concept for substances derived from coal and petroleum stream" (TEXTE 63/2022) is available under the following link: https://www.umweltbundesamt.de/sites/default/files/medien/479/publikationen/texte_63-2022_development_of_a_chemical_analysis_concept_for_substances_derived_from_coal_and_petroleum_stream.pdf

One report on intermediate uses of PetCo substances has not yet been published but is submitted for your consideration. We kindly ask that this document is treated as a confidential document. A publication is planned during this year.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment PetCo_Intermediates.pdf

ECHA/RAC Response

The error in the ERR tabke (ng vs µg) was corrected during the open consultation a few days after it was launched.

The reference to the report prepared by the German environmental agency was inserted and it is also described that in case of complex samples from coal and petroleum stream sample fractionation is needed after extraction and before analytical detection. However, to note that occupational exposure limits are set for concentrations at workplace air (see below paragraph) and therefore the methods described in the section 6.1 of the Scientific report are for airborne PAHs.

Dermal exposure monitoring methods are briefly mentioned in section of 6.1. However, detailed descibtion is not included to the Scientific report since there are no validated and standardised methods, nor any limit value is proposed for dermal exposure. Furthermore it is noted that the report is intended to support OEL settin under the OSH legislation, more specifically under the CMRD (Dir 2004/37/EC), which sets the legal framework, i.e. that limit values are set for concentration for a 'carcinogen or mutagen or reprotoxic substance' in the air, while dermal exposure is covered by a skin notation and overall exposure, if appropriate, by biological monitoring.

Date	Country	Organisation	Type of Organisation	Comment number
11.07.2022	Germany	Eurobitume	Industry or Trade Association	2

Comment received

P. 20, 5.2.2.4, 2nd paragraph states: "Commercial processing of coal leads first to coal-tars (see Figure 1), which are further processed to yield pitch, asphalt, ..."
Comment: the use of the word "asphalt" is misleading here, please change into "coal tar based binders". Asphalt and bitumen per definition are crude oil based and not related to coal tar based products.
P. 21, 5.2.2.5, 2nd paragraph states Bitumen was a by-product. Comment: Bitumen is not a by-product but purposely produced in oil refining.
Same paragraph later states "Application temperatures varies from 100 to 250 °C with different types of bitumen. Earlier, coal-tar pitch was used in roofing, flooring and road paving. However, coal-tar has been phased out in many countries starting in Finland, already in 1965. In Germany, the use of coal tar in asphalt paving ended in 1995. "
Comments: The stated temperature of 250 °C is beyond the maximum safe handling temperatures recommended by Eurobitume and our members. The use of bitumen

beyond is registered as "condition of use advised against". With regard to the use of coal tar in Germany clarification is needed. It might be that the year indicated is related to when the hot recycling of reclaimed asphalt containing amongst other coal tar binder ended. The use of coal tar as such must have ended decades before.
P. 24, 5.3, 2nd paragraph ends "Combustion products of petroleum or gas oil (vehicle exhaust), and asphalting may contain other toxic substances in much greater quantities than PAH."
Comment: Clarification is requested with regard to statement that "asphalting may contain other toxic substances in much greater quantities than PAH.".
P. 72, 8.1, 2nd but last paragraph states "Bitumen and coal tar fume condensates obtained at various temperatures were all found to be mutagenic in the Ames test (Binet et al., 2002). Metabolic activation was needed to obtain positive results."
Comment: Clarification is requested on the temperature applied in the study cited.

ECHA/RAC Response

The amendments for the section 5 that are proposed by Eurobitume have been made to the Scientific report.

Date	Country	Organisation	Type of Organisation	Comment number
11.07.2022	Belgium	Coal Chemicals Europe, a Cefic Sector Group	Industry or Trade Association	3

Comment received

The Cefic sector group "Coal Chemicals Europe (CCE)" (https://www.coalchemicals.org/) appreciates the opportunity to comment on the ECHA Scientific Report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace (10 May 2022). You can find our comments attached.

It is clear that PAHs are a complex topic. We are happy to provide any support in this and help propose European OEL-limits or biological markers for PAH exposure. Should you need any further information, please do not hesitate to contact us.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20220711 CCE comments on OEL for PAHs at the workplace.pdf

ECHA/RAC Response

There were numerous general and detailed comments which were implemented. However, suggestions concerning rewording of texts that were direct quotes of published assessments were not implemented. Nevertheless relevant counter arguments were quoted separately. The description on dermal absorption of PAH was elaborated.

Related to comments on the structure of the report or those suggesting moving texts from one place to another, we remind you that the ECHA report follows an established template in order to support RAC in its opinion-making. It becomes an Annex of the adopted RAC opinion and is forwarded to the Commission in the structure and format agreed.

Date	Country	Organisation	Type of Organisation	Comment number
08.07.2022	Germany	Institute for Occupational Safety and Health of the German Social Accident Insurance	National NGO	4

Comment received
p. 16/17 ECHA note – An attachment was submitted with the comment above. Refer to public attachment ECHA Scientific report PAH_IFA_2022-07-08.pdf
ECHA/RAC Response
The revisions to Tables 3 and 4 of the Scientific report were implemented.

Date	Country	Organisation	Type of Organisation	Comment number
06.07.2022	Sweden	Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals (NEG)	International NGO	5
Comment received				
See attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment NEG comments on ECHA PAH Draft July 2022.pdf				
ECHA/RAC Response				
There were numerous general and detailed comments which were implemented. The comments related to epidemiology were implemented and in particular the review of Rota et al. (2014) was described also as regards lung cancer results and the review of Sjogren et al. (2020) was added in the section of cardiovascular effects. As regards the comment relating to substances not having constituents, it is specifically noted that there are multi-constituent and UVCB substances which typically have multiple constituents: https://echa.europa.eu/support/substance-identification/what-is-a-substance Reference to this is added. Many PAH substances are such multi-constituent or UVCB substances and are covered by relevant entries both under REACH and CLP Regulations. Related to comments on the structure of the report or those suggesting moving texts from one place to another, it is noted that the ECHA report follows an established template in order to support RAC in its opinion-making. It becomes an Annex of the adopted RAC opinion and is forwarded to the Commission in the structure and format agreed. The studies of Archibong et al. on reproductive toxicity effects were added to section 7.8.2. and section 9.				

Date	Country	Organisation	Type of Organisation	Comment number
04.07.2022	Belgium	European Aluminium	Industry or Trade Association	6
Comment received				
On behalf of the European aluminium industry, we provide detailed comments on the indicated sections in the attached non-confidential paper. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20220704 Input on ECHA paper on PAH OELs.docx				

ECHA/RAC Response
The information about aluminium production industry in Europe has been corrected.

Date	Country	Organisation	Type of Organisation	Comment number
11.07.2022	France	French agency for food, environment and occupational health & safety	National Authority	7
Comment received				
Please see attached document ECHA note – An attachment was submitted with the comment above. Refer to public attachment Anses comments_ECHA OEL PAH public consultation_11072022.zip				
ECHA/RAC Response				
There were numerous general and detailed comments which were implemented. We acknowledge the comments related to the complexity of PAH mixtures and the consequent uncertainties of an approach using only one marker substance (BaP) for the protection of workers from the carcinogenic and other health effects of such complex mixtures. That is extensively described in the report, the merits and problems of alternative approaches are also described and the reasons for selecting the BaP approach are outlined. To reduce the uncertainties, the report also proposes the use of biomonitoring (3-OHBaP and 1-OHP), either as BLV or BGV. The report also underlines that the current entry of PAH in Annex 1 of CMRD is too restrictive and should be revised. The fact that BaP is proposed to be used as an indicator of cancer risk, not only of BaP itself, but of carcinogenic PAH mixtures, is made clear at the very beginning under the title “ECHA evaluation and recommendation” and in section 9 of the Scientfic report. The complexity of PAH mixtures also makes the database extremely large and not all individual studies can be summarised. Therefore an approach relying, when possible, on existing assessments, including those linked to PAH-related previous RAC opinions, was followed. However, some of the individual, particularly relevant studies indicated by ANSES were added to the report. In particular the epidemiological study by Singh et al. (2018) was added, although it is noted that it did not provide risk estimates by quantitative exposure metrics of BaP or other PAH in workplace air. Also the new study by Valiere et al 2022 was added and the description of external exposure monitoring methods was extended. It is also noted that due to the long latency time of cancer, existing incidence or mortality data inherently relates to past exposures which were usually higher than those experienced today. However, the meta-analysis of Armtrong et al. (2003,2004) used in the ERR derivation, compared linear and log-linear models and reported that at morerate to low relative risk, the results were close to each other.				

Date	Country	Organisation	Type of Organisation	Comment number
11.07.2022	Belgium	Concawe	Industry or Trade Association	8
Comment received				

Concawe welcomes the opportunity to comment the 10 May 2022 ECHA Scientific report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace.
Polycyclic aromatic hydrocarbons (PAH) are a large and complex family of organic chemistries among which are a subset of compounds with demonstrable environmental and human health toxicity concerns. It is the numerosity and diversity of these compounds that have created a challenge to their appropriate regulation, particularly as they tend to occur as or in complex mixtures. The European Commission has recently requested ECHA to evaluate the use benzo-a-pyrene (BaP) and/or its metabolites as marker for PAH exposure. BaP represents a relevant marker for PAH due to its established highly potent toxicity, its and its metabolites detectability by established methods, and its consistent presence in a variety of industrial PAH processes where multiple PAHs of concern exist.
We note that the report, in summary, concludes that BaP is considered as a suitable marker substance for carcinogenic PAH and that biomonitoring of PAH metabolites is also recommended.
With this exhaustive review process, and also to be technically able to support the implementation of any limit value, the report should have considered a more detailed review and a critical assessment of the various techniques available for both inhalation exposure and biological monitoring.
Section 6.1 (page 33) briefly describes inhalation exposure monitoring techniques and list the various available standards.
By comparison with other simple chemicals, these monitoring procedures are technically complicated, with two phase components, one for vapour, another for particulate aerosols and therefore not easy to apply in practice with workers. A more detailed review of the various characteristics (advantages, shortcomings etc.) of these detection methods would have been useful particularly having in mind a range of possibly proposed OEL values. Indeed, repeatability and reproducibility data of measurement methods are important for establishing OELs. Furthermore, we realise that the report doesn't recommend any specific limit value. However, extrapolating from the described excess life-time lung cancer risk of 1/100 000 in Table 18 a monitoring technique providing a level of quantification as low as 2 ng/m3 for BaP would be needed.
Considering the ISO 20581:2016 and EN 482:2021 standards requirement to have a quantifiable measurement method capable of detecting 10% of the considered limit value, none of the proposed methods or workplace detection is able to provide a limit of quantification at such low level (DFG Method 1 having the lowest BaP LOD of 1.6 ng/m3, nearly ten times the ideal LOD that can be achieved only with a sampling volume of 1200 l, that corresponds to a sampling duration of 10 h at 2 l/min). Additionally, because of that lack of method sensitivity and prolonged sampling times being necessary, the assessment of common short tasks on the order to 30 min – 2h is not possible. Other methods, used in the literature are probably available with a lower LOQ or LOD but have not been described in this ECHA report, for example Morales et al. (Environ Sci Pollut Res [2015] 22:5340–5349) demonstrate atmospheric BaP LOD of 1.0 pg/m3 using microwave-assisted extraction and concentration by nitrogen stream followed by HPLC and fluorescence detection. As a general comment, we noted there is also sometimes some confusion in the ECHA report, between PAHs present intrinsically in the substance, PAH present in the vapor phase/fumes (e.g. from hot bitumen uses) and PAHs produced by combustion.
Biological monitoring, in the form of PAH metabolites in post-shift urine, of exposure is an available assessment technique. However, in this specific case of occupational PAH exposure assessment, limitations and unknowns make its use in a regulatory context to be quite questionable. The first limitation is related to its relatively low sensitivity of validated techniques. If a significant relationship can be found at group level between ambient and biological monitoring, the overall detection limit remains even much higher than with inhalation exposure monitoring. As an example, the second line in Table 8

indicates the relationship between airborne BaP (0.07 µg/m3, 70 ng/m3) and urinary 3-OHBaP group suggesting this value to be a threshold for monitoring. The novel assays mentioned for 3-OHBaP are intriguing as they may overcome these detection limits- with reported LODs of 0.05 ng/L and 0.6pg/L. It is not clear whether these are considered validated methods, especially considering the noted instability of 3-OHBaP at low concentrations.

The introduction of urinary Tetraol-BaP as a stable metabolite with a LOQ of 0.02 ng/L urine is also attractive. However, due to its long urinary half-life (31.5 hrs; Barbeau et al., 2018) it is recommended that the best measuring time is post-shift end of week coupled with background measurement pre-shift beginning of week which may limit the utility in identifying acute exposure and differentiating workplace versus non-workplace exposure. Also, the Tetraol-BaP data was not correlated with ambient air levels. These biological metabolite methods are appealing due to their very low LOD, but it is not clear whether it is being proposed that these methods should be a surrogate to ambient air testing. Such an approach should proceed with caution as Pesch et al. (Arch Toxicol [2011] 85 [Suppl 1]:S29-S39) found no association between the external (air concentration of PAH) and the internal (1-OH in urine) dose in workers exposed to bitumen aerosols and vapours. They conclude "the small content of PAHs in vapours and aerosols of bitumen, the increasing use of additives to asphalt mixtures, the strong impact of smoking and their weak association with airborne bitumen limit the use of PAH metabolites as specific biomarkers of bitumen exposure." How well this conclusion applies to the BaP metabolites, 3OHBaP and Tetraol-BaP, and to substances other than bitumen is not clear.

A further complication stems from differences in the uptake dynamics from inhalation and via the skin (not discussed in the present ECHA report), with the latter being slower, and hence the timing of the urine collection becomes relevant. Conceivably, an optimal sample collection time could be at the end of the work week. A recommendation in that sense from ECHA would be helpful.

Another obvious limitation of biological monitoring is that exposure to PAH is ubiquitous, as stated by all authors, with measurable differences e.g. between smokers and non-smokers as well as variable dietary intake, making differentiating workplace exposure from non-workplace exposure challenging, especially given the half-lives of the proposed metabolic markers.

Importantly, as recognized in the document, inhalation is not the only route of exposure and it is acknowledged that dermal exposure is a significant and often primary route of PAH exposure. There is however no standardized technique for monitoring dermal exposure. We highly support ECHA's identification of suitable techniques in this vital area.

As a side comment, we also note that the petroleum industry is included as a "main industrial sector where workers are exposed to various PAH," which is not supported by data. For example, the statement in page 24 that there is high occupational exposure, amongst others, in petroleum refining is not supported by the data referenced in the report (Figures 3 and 4). While discussing crude-oil derivatives, it is stated "Coal tar contains much higher concentrations of PAH than bitumen… Exposure to coal tar among roofers was associated with a 35-times increase in dermal exposure to BaP and a 6-times increase to PAH" (page 21). Petroleum substances may indeed have PAH as constituents at very low levels, but occupational exposure is such that it cannot be qualified as being high in comparison with other industries and products: Importantly, there are risk management measures preventing such exposure. In the same paragraph in section 5.3, the sentence stating that "combustion products … and asphalting may contain other toxic substances in much greater quantities" is not relevant in this report as it doesn't explain what these other substances are although it is clear that combustion products contain other substances than PAH. Regardless, we appreciate the multiple notations within the text that demonstrate lower-than-other-industry BaP emissions and exposure (page 25)

and the market's preference for petroleum substances over historic substance for the "PAH level is significantly lower" and "more environmentally friendly" (page 77). ECHA note – An attachment was submitted with the comment above. Refer to public attachment PAH_RAC_OEL_Concawe.pdf
ECHA/RAC Response
There were numerous general and detailed comments which were implemented. The monitoring method description has been improved and it is highlighted that both particulate and vapour phases are collected. Dermal exposure monitoring methods are briefly mentioned in section 6.1. However, detailed description is not included to the Scientific report since there are no validated and standardised methods, nor any limit value is included to the OEL for dermal exposure (see further reasoning in the reply to comment nr 1). As a non-threhold mode of action is assumed, no OEL is proposed, while an exposure risk relationship (ERR) is derived for lung cancer. The ERR will be used in the later steps of the process, together with a socio-economic assessment as well as information on analytical feasibility of monitoring methods to set the ultimate OEL. This is standard practice under the EU OSH legislation in setting limit values (including for non-threshold carcinogens). Accordingly, more details were added concerning analytical sensitivity and complexity of the various monitoring methods needed to reach given detection levels.

PUBLIC ATTACHMENTS
1. Anses comments_ECHA OEL PAH public consultation_11072022.zip [refesr to comment No. 7]
2. PAH_RAC_OEL_Concawe.pdf [Please refer to comment No. 8]
3. 20220711 CCE comments on OEL for PAHs at the workplace.pdf [refers to comment No. 3]
4. ECHA Scientific report PAH_IFA_2022-07-08.pdf [refers to comment No. 4]
5. NEG comments on ECHA PAH Draft July 2022.pdf [refers to comment No. 5]
6. 20220704 Input on ECHA paper on PAH OELs.docx [refers to comment No. 6]

CONFIDENTIAL ATTACHMENTS
1. PetCo_Intermediates.pdf [refers to comment No. 1]