



Risk Management Option Analysis Conclusion Document

Substance Name: Fluoranthene

EC Number: 205-912-4

CAS Number: 206-44-0

Substance Name: Pyrene

EC Number: 204-927-3

CAS Number: 129-00-0

Substance Name: Benz(a)anthracene

EC Number: 200-280-6

CAS Number: 56-55-3

Substance Name: Chrysene

EC Number: 205-923-4

CAS Number: 218-01-9

Substance Name: Benzo(k)fluoranthene

EC Number: 205-916-6

CAS Number: 207-08-9

Substance Name: Benzo(ghi)perylene

EC Number: 205-883-8

CAS Number: 191-24-2

Substance Name: Phenanthrene

EC Number: 201-581-5

CAS Number: 85-01-8

Authority: Germany

Date: June 2017

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020¹.

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority (eMSCA). In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

¹ For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation>

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Extender oils containing polycyclic aromatic hydrocarbon (PAH) constituents are included in Annex XVII (entry 50) of the REACH regulation. This entry limits the concentration of benzo(a)pyrene, benzo(e)pyrene, benz(a)anthracene, chrysene, benzo(b)fluoranthene, benzo(j)fluoranthene, benzo(k)fluoranthene and dibenzo(a,h)anthracene in extender oils for tyres to 10 mg/kg in sum of all listed constituents or if the concentration of benz(a)pyrene is more than 1 mg/kg in extender oils. Further consumer products, toys and childcare articles shall not be placed on the market for supply to the general public if their rubber or plastic part come into direct contact as well as prolonged or short-term repetitive contact with human skin or oral cavity under normal or reasonably foreseeable conditions of use. This latter restriction concerns consumer products containing more than 1 mg/kg of the listed PAHs and toys and childcare articles containing more than 0.5 mg/kg are restricted. PAHs, listed in entry 50 of Annex XVII are addressed due to their human health hazardous properties (mainly carcinogenicity) and are not restricted due to their environmental hazard yet.

The following PAHs are listed in Annex VI of CLP:

- Benz(a)anthracene (601-033-00-9): Carc. 1B, Aquatic Acute 1, Aquatic Chronic 1
- Chrysene (601-048-00-0): Muta. 2, Carc. 1B, Aquatic Acute 1, Aquatic Chronic 1
- Benzo(k)fluoranthene (601-036-00-5): Carc. 1B, Aquatic Acute 1, Aquatic Chronic 1

These classified PAHs are covered by Annex XII Entry 28 of EU regulation 2006/1907.

Annex III of REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on persistent organic pollutants (POPs) and amending Directive 79/117/EEC includes PAHs with Benzo(k)fluoranthene as indicator substance.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	
<i>Harmonised classification and labelling</i>	
<i>Identification as SVHC (inclusion into Candidate List)</i>	X
<i>Restriction under REACH</i>	
<i>Other EU-wide regulatory measures</i>	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Identification as a substance of very high concern and inclusion into the Candidate List

In 2009 the Member State Committee (MSC) evaluated the SVHC-properties of coal tar pitch, high temperature (CTPHT). The substance contains a number of PAHs as constituents, among them the PAHs considered in this RMOA. The MSC agreed on the identification of CTPHT as substances of very high concern meeting the criteria set up in REACH Art. 57 d) and e) because it contains PAHs with these properties in individual concentrations ≥ 0.1 % (w/w) (table 1). CTPHT was included into the Candidate List.

Table 1: Conclusions on the fulfilment of the (v)P-, (v)B-, and T-criteria of Annex XIII for 7 PAH-constituents of CTPHT, covered within this RMOA.

Substance	Intrinsic properties According to Art. 57d, e	Classification/CLP
Fluoranthene (CAS 206-44-0)	PBT, vPvB,	-
Pyrene (CAS 129-00-0)	PBT, vPvB	-
Benzo(a)anthracene (CAS 56-55-3)	PBT, vPvB	Carc. 1B, Aquatic Acute 1, Aquatic Chronic 1
Chrysene (CAS 218-01-9)	PBT, vPvB	Carc. 1B, Aquatic Acute 1, Aquatic Chronic 1
Benzo(k)fluoranthene (CAS 207-08-9)	PBT, vPvB	Carc. 1B, Aquatic Acute 1, Aquatic Chronic 1
Benzo(ghi)perylene CAS (191-24-2)	PBT, vPvB	-
Phenanthrene	vPvB	-

Including these PAHs into the Candidate List would be the formal confirmation of their SVHC status. This would create a common understanding among all REACH-stakeholders concerning the PBT/vPvB properties of these PAHs.

The eMSCA experts expected that registrations of relevant UVCB containing these PAHs will be updated with respect to their constituent levels since Candidate List substances have to be considered in exposure assessments to guarantee a safe use.

Candidate listing would trigger follow up activities:

- For articles containing one or more of these seven PAH, inclusion into the Candidate List would trigger the obligation to inform downstream users and consumers, if these PAHs are present in an article at a concentration > 0.1 % (Art 33).
- Producers or importers need to notify uses in articles, if the prerequisites of Article 7 are fulfilled.
- Potentially stimulation of a more general risk reduction strategy for UVCBs containing PAH-constituents.

The information gathered as a follow up to the Candidate listing of the individual PAHs might facilitate the decision making process for possible further regulatory action for UVCB substances.

The Candidate listing of PAHs, covered within this RMOA would give a strong signal that substances, containing these PAHs as constituents should be substituted or the PAH content needs to be decreased. Since the inclusion of the seven PAHs in the Candidate List facilitates the communication within the supply chain, this might lead to the decision of a producer or downstream user to switch to a less hazardous alternative.

A subsequent authorisation process for the seven PAHs is meaningless to date.

However, the authorisation of UVCBs containing one or more of the seven PAHs might be a suitable regulatory measure. It seems reasonable to identify the most efficient risk management activity in a separate RMO analysis for PAH-containing UVCBs. This could be done either on an individual substance level or via a group based approach.

3.2 Restriction under REACH

UVCB substances containing PAHs are used in a wide variety of uses with high tonnage bands. Taking into account the high economic value of some of the uses, a general restriction covering all PAH-containing products might thus not be appropriate.

A restriction for specific uses of PAH containing substances, e.g. UVCBs, leading to significant emissions into the environment or humans might be an appropriate regulatory option in the future. Thus, restriction of certain PAH-containing UVCBs could be a subsequent action after inclusion into the Candidate List.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

As stated in section 3.1 inclusion of fluoranthene, pyrene, benz(a)anthracene, chrysene, benzo(k)fluoranthene, benzo(ghi)perylene and phenanthrene into the Candidate List will be the first appropriate step to formally recognise and raise awareness concerning the PBT/vPvB properties of these PAHs. Subsequent risk management option analyses for UVCBs containing these PAHs as constituents, either based on single PAH constituents or in a constituent grouping approach (e.g. block method) seem to be reasonable. Moreover, a strategy needs to be developed how to efficiently regulate PAH-containing UVCBs.

Follow-up action	Date for follow-up	Actor
Annex XV dossier for identification of benz(a)anthracene as SVHC	2017	DE-CA
Annex XV dossier for identification of chrysene as SVHC	2017	DE-CA
Annex XV dossier for identification of phenanthrene as SVHC	2018	Other MSCA
Annex XV dossier for identification of pyrene as SVHC	2018	Other MSCA

Annex XV dossier for identification of fluoranthene as SVHC	2018	Other MSCA
Annex XV dossier for identification of benzo(k)fluoranthene as SVHC	2018	Other MSCA
Annex XV dossier for identification of benzo(ghi)perylene as SVHC	2018	Other MSCA
RMOAs for UVCBs containing PAHs as constituents	2017 ff.	