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Coal-tar pitch high temperature (CTPHT), transitional arrangements and way forward under REACH

REACH-SEA report of scoping study

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Abstract

Coal-tar pitch high temperature (CTPHT), transitional arrangements and way forward under REACH

REACH-SEA report of scoping study

A restriction or authorisation within the European legislation REACH is not the most appropriate option to reduce the risks of the emission of PAHs. These emissions, primarily caused during production- and combustion processes, are not adequately controlled by this legislation. This is the result of a study by RIVM to the possibilities of REACH to the PAH-emissions caused by the use of coal-tar pitch (CTPHT) in for instance the aluminium industry. According to RIVM, emission control via national and European legislation, like Integrated Pollution Prevention and Control (IPPC), is the first instrument to consider. In IPPC best available techniques for many industries, including the aluminium industry, are described to reduce emissions as much as possible. The aim of REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) is to protect man and environment against the risks of chemicals.

Coal-tar pitch is formed during the treatment of coal-tar and is used in for instance the aluminium industry. RIVM and TNO have been analysing the use of coal-tar pitch before and concluded that the PAH-emissions can possibly result in a risk to man and environment. PAHs are Polycyclic Aromatic Hydrocarbons, the safety of the chemicals can not be guaranteed. These chemicals have a slow degradation in the environment, accumulate in the food chain and are carcinogenic.

Reason for this study was the change from the old chemical legislation into REACH. In 2008 REACH got into force. The results of this study will be used for the so-called transitional dossier for coal-tar pitch.

Key words:

REACH, CTPHT, socio-economic analysis, restriction, PAH

Rapport in het kort

Steenkoolteerpek (CTPHT), opties voor transitiedossier en mogelijkheden binnen REACH REACH-SEA rapport van verkenningstudie

Een beperking of autorisatie binnen de Europese wetgeving REACH is niet de meest geëigende manier om de risico's aan te pakken van PAK-emissies. Deze emissies, die vooral vrijkomen tijdens productie- of verbrandingsprocessen, worden namelijk niet goed ondervangen in deze wetgeving. Dit blijkt uit onderzoek van het RIVM naar de mogelijkheden van REACH voor PAK-emissies die vrijkomen bij het gebruik van steenkoolteerpek (CTPHT) in onder andere de aluminiumindustrie. Volgens het RIVM kunnen deze PAK-emissies beter gereguleerd worden binnen de nationale en de Europese IPPC-wetgeving (Integrated Pollution Prevention and Control). IPPC beschrijft de best beschikbare productietechnieken, waaronder die van aluminium, om problemen met emissies zo veel mogelijk te beperken. Het doel van REACH (Registratie, Evaluatie, Autorisatie en beperking van Chemische stoffen) is mens en milieu te beschermen tegen de risico's van chemische stoffen.

Steenkoolteerpek komt vrij bij de bewerking van steenkool en wordt gebruikt in onder andere de aluminiumindustrie. RIVM en TNO hebben eerder het gebruik van steenkoolteerpek geanalyseerd en vastgesteld dat de PAK-emissies een mogelijk risico vormen voor mens en milieu. PAK's zijn Polycyclische Aromatische Koolwaterstoffen waarvan de veiligheid niet kan worden gegarandeerd. Ze worden slecht afgebroken in het milieu, hopen zich op in de voedselketen en zijn kankerverwekkend.

Aanleiding voor het onderzoek is de overgang van de oude wetgeving naar REACH, die in 2008 in werking is getreden. De resultaten worden gebruikt bij het zogeheten transitiedossier voor steenkoolteerpek.

Trefwoorden:

REACH, CTPHT, sociaal-economische analyse, restrictie, PAK

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Summary

The Netherlands is rapporteur for Coal-tar pitch, high temperature (CTPHT) of the 3rd priority list of Council Regulation 973/93/EEC on the evaluation and control of the risks of existing substances (Existing Substances Regulation or ESR). To finalise the work on CTPHT the Netherlands has to make a transitional Annex XV restriction report.

The CTPHT dossier is the first dossier, in the Netherlands, for which a strategic evaluation of REACH instruments is performed. An important element of the study was to experiment and learn on 'how to organise the work under REACH'. A multidisciplinary team was formed to explore the various REACH instruments and procedures. Experts from the Ministry of Housing, Spatial Planning and the Environment (VROM) and the National Institute for Public Health and the Environment (RIVM) participated in the team. All participants supported the way this work was organised. It was very valuable to start the scoping process with a multidisciplinary team in which policy makers can learn from the technical experts and vice versa. Also the iterative process with discussions in several stages was welcomed by all people involved.

It is concluded that it is very important to set a clear aim of the scoping study. Especially in the case of CTPHT with a link to the broad Polycyclic Aromatic Hydrocarbon (PAH) discussions, there is a need for a well defined scope of the study. This scoping study can be considered as a kind of pre-Annex XV dossier. It is advisable that the Member States or the European Commission perform a scoping study before putting a substance on the Register of Intention.

For CTPHT three possible strategies for limiting the risks were explored:

1. Can restrictions be justified to address the identified risks of CTPHT? Identify other possible risk reduction measures in time before 1 December 2008.
2. Examine whether the authorisation instrument can be used to reduce PAH emissions related to CTPHT.
3. Discuss which other possibilities within/beyond REACH are available to develop an overall PAH strategy.

It is concluded that both the restriction and the authorisation procedure are not the most appropriate options to reduce the risks of CTPHT. Emission control via Integrated Pollution Prevention and Control (IPPC) and national legislation is the first instrument to consider for the main applications (industrial point sources).

The following recommendations are made:

- The transitional dossier should give direction, e.g. to indicate at which emission levels safe use can be guaranteed.
- To perform a further scoping study to PAH emissions sources that can be tackled by REACH (screening of all REACH instruments) and the possible impact of the REACH instruments on the overall PAH levels.
- To carefully follow the registration process under REACH. Dependent on the registrations a dossier or substance evaluation should be considered.

1 Introduction

1.1 Current status of CTPHT

NL is rapporteur for Coal-tar pitch, high temperature (CTPHT) of the 3rd priority list of Council Regulation 973/93/EEC on the evaluation and control of the risks of existing substances (Existing Substances Regulation or ESR). In Table 1 an overview of the current status of CTPHT dossier under the ESR and the need for further action is given.

Table 1. Current status of CTPHT dossier and need for further action with regard to transitional measures.

Elements	Current status of dossier	Action/decision
Risk assessment: information on hazard and risk of CTPHT	Risk Assessment Report (RAR) endorsed by TCNES	Information from the RAR should be transposed to transitional Annex XV Restriction report before 1 December 2008
Need for further information and/or testing (Conclusion i in RAR) for the use and related risks of CTPHT as binder for coal briquetting, clay pigeons and heavy duty corrosion protection	Deadline for data submission 28 September 2008, no information received by now	Further data should be received by 28 September 2008. Eventual follow-up actions will be kept outside the scope of the transitional dossier: the available time left does not allow for developing a restriction proposal, when considered appropriate
Need for limiting the risks for workers (Conclusion iii in RAR)	Risk reduction strategy (RRS) report endorsed by 15 th Risk Reduction Strategy Meeting, 22-24 April 2008	Information from the RAR should be transposed to transitional Annex XV Restriction report before 1 December 2008
Need for limiting the risks for environment and man indirectly exposed via the environment (Conclusion iii in RAR)	Risk reduction strategy is not yet addressed	Make a transitional Annex XV restriction report before 1 December 2008: this report should describe whether restrictions can be justified to address the identified risks for the environment and man indirectly exposed via the environment of CTPHT or/and identify other possible risk reduction measures

To finalise the work on CTPHT the Netherlands has to make a transitional Annex XV restriction report in which information from the finalised RAR and the finalised RRS on workers can be uploaded. In the RAR also a need for limiting the risks for environment and man indirectly exposed via the environment, is identified. For these risks a risk reduction strategy still has to be developed.

1.2 Possible strategies under REACH

In this scoping report possible risk reduction strategies under REACH will be discussed. This document gives the outcome of the strategic discussions on the way forward of the CTPHT dossier under REACH. The discussions will not solely focus on the specific transitional requirements related to the CTPHT dossier, but also explore other possible strategies for limiting the risks related PAH emission from CTPHT or other sources:

1. possibilities of restriction of CTPHT or other possible risk reduction measures in the transitional dossier;
2. possibility of authorisation of CTPHT through a SVHC dossier;
3. possibilities within/beyond REACH to develop an overall PAH strategy.

Option 1 concerns the work that needs to be done to submit the transitional dossier to the European Chemical Agency (ECHA), before 1 December 2008. According to article 136.3 of the REACH Regulation the Member State that has not forwarded by 1 June 2008 the risk evaluation and, where appropriate the strategy for limiting the risks, amongst others, shall (1) initiate the restriction process or (2) document how the identified risks can be addressed by other means than restrictions. The key question at option 1 is whether restrictions can be justified to address the identified risks of CTPHT or to identify other possible risk reduction measures in time before 1 December 2008.

In option 2 the possibility of an authorization of CTPHT under REACH is discussed. In the RAR the production of CTPHT and the main applications of coal tar pitch are selected for the risk characterization. No risk characterisation is made for the other CTPHT uses. Based on the hazard assessment of CTPHT (persistent bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and carcinogenic, mutagenic or toxic for reproduction (CMR)) it may however be possible to initiate the authorisation process under REACH. Option 2 examines whether the authorisation instrument can be used to reduce PAH emissions related to CTPHT or to replace CTPHT by suitable alternatives.

Finally, in option 3 it will be discussed which other possibilities within/beyond REACH are available to develop an overall PAH strategy. Originally the Netherlands intended to evaluate, within the ESR, the overall risks due to multiple PAH sources and to develop an overall PAH risk reduction strategy. CTPHT was selected as priority substance to trigger this discussion, but due to legislative constraints the evaluation and control of risks was limited to the production and downstream use of CTPHT itself. The contribution of CTPHT to the overall PAH emissions is small; it may be more effective to look to all PAH sources instead of focusing on CTPHT. It is recommended to look from a wider perspective to possibilities to reduce the overall PAH emissions and exposure.

Table 2. Overview on three options for risk reduction strategies.

Option	Task	Aim	Scope
1. Restriction or/and other risk reduction measures (transitional dossier)	Examines whether restrictions can be justified to address the identified risks of CTPHT or/and identify other possible risk reduction measures, before 1 December 2008	Reduce the identified risks of CTPHT	Identified risks of CTPHT; 5 scenarios (87% use of CTPHT)
2. Authorisation all CTPHT uses through SVHC dossier	Examine whether the authorisation instrument can be used to reduce PAH emissions related to CTPHT and/or to replace CTPHT by suitable alternatives	Reduce PAH emissions related to CTPHT production/use; replace CTPHT by suitable alternatives	All CTPHT uses
3. Strategy on all PAH sources	Examine possibilities within/beyond REACH to reduce the overall PAH emissions	Reduce overall PAH emissions; reduce impact on human health and environment	All PAH sources (within and outside scope REACH)

In any case the transition dossier needs to be finalised before 1 December 2008.

1.3 Organisation of work

The CTPHT dossier is the first dossier, in the Netherlands, for which a screening of REACH instruments is performed. An important element of the study was to experiment and learn on 'how to organise the work under REACH'. A multidisciplinary team was formed to explore the various REACH- instruments and procedures. Experts from the Ministry of VROM and RIVM participated in the team. To create an open setting for information exchange and learning it was decided not to invite industry and other relevant parties to the discussions at this stage.

Step 1. Kick-off meeting multidisciplinary team (March 2008)

A kick-off brainstorm meeting was organised to discuss the key-questions of the dossier. At this meeting a summary was given of the results of the risk characterisation and a discussion followed on the pros and cons of different (REACH) instruments and procedures. The discussion was very lively, but also somewhat chaotic as different perspectives and levels of information were brought to the table. It was decided to prepare a scoping document in order to structure the information and to discuss the scoping document at the follow-up meeting of May 2008.

Step 2. First draft scoping document (March – May 2008)

In the first draft scoping document the relevant information in the RAR-CTPHT and REACH regulation was summarised and a first screening of the REACH instruments was made. The draft document was only used for internal purposes.

Step 3. Blank canvas interviews (May 2008)

To prepare for the follow-up meeting 'blank canvas' interviews with all members of the multidisciplinary team in groups of 2/3 persons were organised. The characteristic of a 'blank canvas' interview is that there are no documents and the structure of the interview is open. This allows the interviewer to attune to the perceptions and information level of the interviewed person(s) and prevents less active 'downloading' of information.

The interviews helped:

1. to get an impression of different perspectives, divergent opinions et cetera;
2. to focus the minds of the interviewed persons to the key questions in the study;
3. to get the project group at a same information level.

Step 4. Second meeting multidisciplinary team (May 2008)

To allow for a lively and open discussion it was decided not to present the first draft scoping document at the follow-up meeting. Only the annexes to the scoping document, with a summary of the relevant background information, were submitted to the project team before the meeting. Much effort was put in the structuring of the meeting. Due to the design of the meeting there were good constructive discussions and clear conclusions could be drawn.

Step 5. Second draft scoping document (May – July 2008)

The results of the interviews and the discussion in the second meeting were incorporated in the second draft scoping document (also only for internal purposes). This document was send around to all members of the multidisciplinary team for written comments.

Step 6. Go/no-go decisions on follow-up (July 2008)

The conclusions drawn by the multidisciplinary team were presented at a meeting of representatives of the responsible Ministries (Breed Stoffen Overleg) and at this meeting go/no-go decisions were taken on the follow-up of the dossier.

Step 7. Prepare final scoping document (July – August 2008)

The final scoping document gives the outcome of the strategic discussions on the follow-up of the Coal Tar Pitch High Temperature (CTPHT) dossier under REACH. Contrary to the draft

documents, the final document is written in way that the discussions and results of this study can be shared with others, i.e. colleagues from other EU Member States.

1.4 Structure of the report

After this first chapter with the introduction, chapter 2 will give a short summary of the background information on CTPHT. All information in this chapter is taken from the RAR, more details and more references can be found in the RAR (ECB, 2008). The three identified options will respectively be discussed in chapters 3, 4 and 5.

2 Background information on CTPHT

2.1 Production and use

Within the European Union, high temperature coal tar pitch is produced by ten companies at eleven sites in nine countries. The total European Union production capacity in 2004 was 1,127,000 tonnes. The actual production output of coal tar pitch in that year was about 817,800 tonnes. Import from outside the EU was reported to be about 91,600 tonnes per year and export was about 355,600 tonnes per year. The total consumption of coal tar pitch in the EU from these figures is estimated to be about 554,000 tonnes per year.

Coal tar pitch is mainly used as binding agent in the production of carbon electrodes, anodes and Søderberg electrodes for instance for aluminium industry. It is also used as binding agent for refractories, clay pigeons, active carbon, coal briquetting, road construction and roofing. Furthermore small quantities are used for heavy duty corrosion protection. A summary of marketing and use information, including information implemented risk management measures (RMM) and the availability of suitable alternatives, is given in Table 3.

The production of CTPHT and the main applications of coal tar pitch (anodes and electrodes) are selected for the risk characterization, primarily because lower emissions for the other sources are expected. Moreover, the amounts of coal tar pitch used in the smaller applications are decreasing. The risk assessment focuses on the PAHs that are emitted by industrial point sources. For the use and related risks of CTPHT as binder for coal briquetting, clay pigeons and heavy duty corrosion protection more information is asked from industry (conclusion i, need for further information and/or testing). At the time of finalising this document no additional information received from industry as requested.

Table 3. Information on marketing and use, implemented RMM and availability of alternatives.

Application	% of total sales	Trends	Implemented RMM	Availability of alternatives
Anodes (anode production, aluminium production applying prebakes (with and without) anode baking, aluminium production with Søderberg technology)	71.3	The share of Søderberg anodes used for aluminium production is decreasing and is currently less than 10%. The major part of the total aluminium production is nowadays produced by prebake technologies.	All sites are covered by the IPPC directive. Best Available Techniques (BAT) should be used.	Since more than ten years a new technology has been developed at bench-scale based on inert anodes to replace CTPHT-bound carbonated anodes, but this technology is still immature and costly. Therefore it can be expected that CTPHT will be used for more than decades in the primary aluminium smelters.

Application	% of total sales	Trends	Implemented RMM	Availability of alternatives
Electrodes (graphite electrode production, production of steel, silicon, etc., applying electric arc furnaces with Søderberg electrodes)	18.0			
Refractories	5.0		The pitch industry now proposes pitches with a higher softening point resulting in much lower benzo(a)pyrene contents (300 ppm instead of 20,000 ppm).	
Road construction	0.2	The amount of pitch used for these application decreases as it is replaced by petroleum pitch on account of the lower PAK content.	Most European countries have banned the use of coal tar pitch in road construction by law or agreement between trade unions and road building companies.	Only very particular applications such as anti-kerosine coatings for parking lots, airfields, taxi ways and fuel stations still use pitch emulsions
Active carbon	1.7	More and more produced outside the EU. Processed in closed vessels with controlled emissions		No
Heavy duty corrosion protection	1.0	Corrosion protection with pitch based products is declining and the phasing out is predicted in the next few years	EU ban on use of coal tar (pitch) containing coatings on ships and quays	Suitable alternatives available
Roofing	0.7	The amount of pitch used for these application decreases as it is replaced by petroleum pitch on account of the lower PAK content		Suitable alternatives available

Application	% of total sales	Trends	Implemented RMM	Availability of alternatives
Clay pigeons	1.3	Some manufacturers claim to produce environmentally friendly clay pigeons by applying petroleum pitch (or no binder) in order to meet the EEC environmental protection directives	Replacement of CTPHT by petroleum pitch by more than 80%	Suitable alternatives available
Coal briquetting	0.9	Replacement by other binding agents	In some countries the use of CTPHT is forbidden. Market linked to dedicated and captive users in mining countries where retired miners have rights on solid fuels provided by the former state owned companies	Suitable alternatives available

2.2 Classification

The proposed classification for CTPHT is different from the current classification according to Annex 1 of 67/548/EC (see Annex 2.2). According to the proposed classification CTPHT meets the criteria for mutagenic category 2, carcinogenic category 1 and toxic for reproduction category 2. CTPHT meets the criteria for PBT and vPvB (see also Annex 1).

2.3 Information on hazard and risk

Table 4 gives the overall results of the risk characterisation for environment and man indirectly exposed via the environment. For all sites and scenarios conclusion iii (need for limiting the risk) is drawn. Further information can be found in Annex 2.

All emissions of PAH, in the selected scenarios, are related to industrial point sources. Most critical endpoint is the exposure to PAH of people living nearby these industrial point sources. People are exposed via inhalation of polluted air or via consumption of contaminated food. The risk characterisation for man indirectly exposed via the environment is based on exposure levels at 100 m distance from the point sources. The actual exposure of people may be much lower.

Further, it is important to notice that also at regional background levels of PAH an unacceptable risk is concluded. Significant higher exposure levels, than the regional background levels, are estimated for the primary aluminium production scenario. Within this scenario large differences in emissions and related risks are found. This can probably be explained by the use of different techniques and operational conditions. Also higher predicted environmental concentrations, than the regional background levels, are calculated for the generic scenarios (graphite electrode production and ferro-alloy industry). It is however expected that based on site specific information no significant higher environmental concentrations than background levels will be calculated. Therefore, it is estimated that for the other scenarios (production of CTPHT, graphite electrode

production, and ferro-alloy industry) the exposure is in the same order of magnitude as the regional background.

From the risk assessment it can be concluded that contribution of the production and use of CTPHT to the regional background levels of PAH is very small. There are several studies with an overview of PAH sources presented in the risk assessment report, but these studies do not lead to a congruent picture (see Annex 3). Figure 1 shows the current and projected emission of benzo(a)pyrene from several sources.

Table 4. Summary results of risk characterisation of CTPHT for the environment and man indirectly exposed via the environment.

	Air	Water	Sediment	Terrestrial	Man indirect	Secondary poisoning.	Exposure scenario
Production CTPHT	x	iii	iii	ii	iii	x	site specific
Primary AL production	x	iii	iii	ii	iii	x	site specific
Graphite electrode production	x	ii no emissions to water	ii no emissions to water	ii	iii	x	generic
Ferro-alloy industry applying electric arc furnaces with Söderberg electrodes	x	iii	iii	ii	iii	x	generic
Regional background	x	iii	iii	ii	iii	x	

x = no risk characterisation; no Predicted No Effect Concentration (PNEC) available
 ii = there is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already
 iii = there is a need for limiting the risks; risk reduction measures which are already applied shall be taken into account.
 ... most critical end point
 ... significant higher PEC than regional levels, for some of the sites; large differences in emissions and related risks

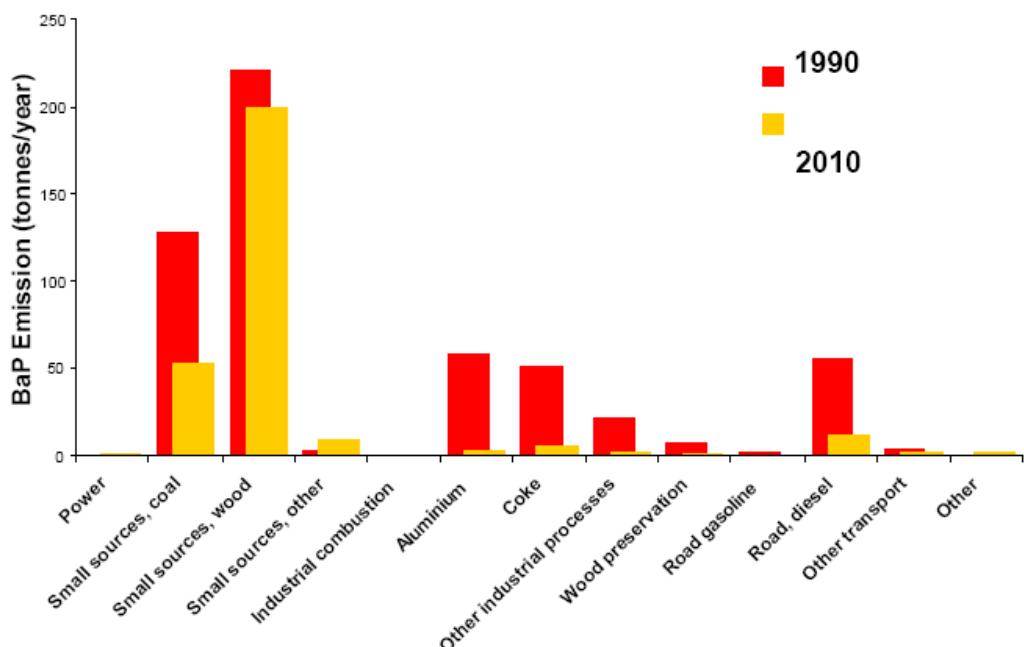


Figure 1. Current and projected emissions of benzo(a)pyrene for the EU15+6 accession countries (Holland et al., 2001).

3 Option 1. Restriction or other measures (transitional dossier)

3.1 Introduction

Option 1 concerns the work that needs to be done to submit the transitional dossier. This dossier should initiate the restriction process or document how the identified risks of CTPHT can be addressed by other means than restrictions. Aim of this part of the scoping is to address the identified risks of CTPHT for environment and man indirectly exposed via the environment. The risks for workers have already been addressed under the Existing Substance Regulation (ESR).

The screening is based on the available data in the RAR of CTPHT and discussions with the members of the multidisciplinary team. The requirements for a restriction dossier are given in Annex 4. A restriction shall be considered when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives. Four key-questions are discussed trends and information on alternatives (section 3.2), existing measures and measures in the pipeline (section 3.3), justification for Community wide action (section 3.4) and justification that restriction is the most appropriate risk management option (section 3.5).

3.2 Trends and information on alternatives

There is no full overview in the RAR of alternative substances. As mentioned earlier in Table 3 it will take several decades before alternatives to CTPHT can be used in the production of anodes. For the electrode production and the use in the ferro-alloy industry it is not clear if alternatives are available.

There are several techniques available for the production of anodes and electrodes. The technique which is used partly determines the emissions of PAH. At some plants very low PAH levels are found. Sometimes an explanation for the differences can be found (use of prebaked anode instead of Søderberg anodes; no emission to the water compartment), but at this stage there is no detailed understanding of the techniques and operational conditions leading to low PAH emissions.

Also several techniques can be used for the production of ferro-alloys (carbo-thermic and metallo-thermic reduction) and there are three types of furnaces used for the production (electric arc furnace, electric resistance furnace, blast furnace). In the RAR no information is given if the techniques and types have the same functionality, use the same amount of CTPHT and have different PAH emission levels.

3.3 Existing measures and measures in the pipeline

At this stage there is no evidence that the existing measures (permitting via IPPC and national legislation) and measures in the pipeline (registration under REACH) will be sufficient in addressing the identified risk. Risks are identified in the risk assessment report. This means that based on the available information, it may be concluded that the implemented Risk Management Measures (RMM) and operational conditions are not sufficient to control the risks. For the scenarios based on site specific data there is a high level of evidence that the risks are not

adequately controlled. For the scenarios based on generic data there is a low level of evidence that the risks are not adequately controlled.

At this stage it is not known why permitting via the IPPC directive or national legislation seems not to be sufficient to control the risks. This may be due to:

- an information problem (Competent Authorities do not know the risks related to the emission levels);
- an enforcement problem (emission levels in permits are exceeded);
- a technical problem (no better alternatives available);

or the result of:

- the permitting procedure that takes into account both risks and socio-economic considerations.

Since very low PAH levels are found at some plants it can be concluded that the relevant IPPC BAT reference document is outdated due to technological improvements. This BAT reference document will be revised within the next years. In the transitional dossiers it should be indicated whether the current emission levels in the BAT reference document are sufficient and at which emission levels no concern related to PAH emissions is identified.

Finally, registration under REACH can also be seen as a risk management measure in the pipeline: the industry will most likely submit registrations of substances with included chemical safety assessments showing that for production and uses the risks are adequately controlled. At this moment it is unknown whether industry will register all CTPHT uses and whether it will introduce further risk management measures or stricter operating conditions where risks are identified. Dossier- or substance evaluation, of registered substances under REACH, may provide the evidence whether or not implemented risk management measures are sufficient.

3.4 Justification for Community wide action

Although the hazard properties of CTPHT (CMR, PBT, vPvB) justifies Community wide action, such an action can not be justified because data on the extent of the risks (population affected, number of people affected, area of environment affected etc) related to CTPHT production and uses is not specified in the RAR.

Restriction measures for CTPHT to reduce overall PAH emissions to environment and PAH exposure on humans can also not be justified. Large non-industrial emission sources are the domestic combustion of solid fuels, the use of coal tar-based products (creosote) for wood preservation and road transport. The emissions of these three sources together can amount 54%-89% of the total PAH emission to air. Because the contribution of the production and use of CTPHT to the total PAH emissions is very small compared to these non-industrial emission sources, these measures are not proportionate.

Another possible justification for Community wide action can be that there is a (large) differences between member states with regard to permits which may lead to a distortion of the internal market. There is however no indication for such a distortion of the internal market. Also most companies are covered by the IPPC directive, so the level of playing field in the European market should be comparable.

3.5 Justification most appropriate risk management option

In general restrictions are not the most appropriate risk management option when unacceptable risks are concluded due to single emissions/exposure from industrial point sources; emission control via IPPC or national legislation (permitting) is the first instrument to consider. Further

measures, beyond permitting via IPPC and national legislation, can only be justified when there is sufficient evidence that the existing instruments will not be effective in addressing the identified risks. In section 3.3 it is concluded that the existing instruments seems not be sufficient to control the risks but there is not sufficient evidence to conclude the opposite. It should be possible to adequately control the risks at the production and main use of CTPHT.

An other possible risk management option is authorisation under REACH. The Authorisation instrument is, however, not targeted to the *identified* risks of CTPHT as it affects all uses of CTPHT. This instrument will be further discussed under option 2 (chapter 4).

Finally, voluntary action by industry would also be a possibility. There will be no time to initiate a voluntary programme, by industry and to incorporate the conditions of this programme in the transitional dossier. This process can be initiated parallel to the finalising of the transitional dossier.

3.6 Conclusion

The identified risks of CTPHT are all related to industrial point sources. Emission control via IPPC or national legislation (permitting) is the first instrument to consider for industrial point sources. Further measures, beyond permitting via IPPC and national legislation, can only be justified when there is sufficient evidence that the permitting instrument will not be effective in addressing the identified risks. A better understanding of the implemented risk management measures and operational conditions is needed to understand better the reason that the identified risks are not adequately controlled by the existing instruments.

The relevant BAT reference document for the scenarios at risk will be revised the next years. The transitional dossier may provide information to enable permitting authorities to assess the local situation. It is relevant to indicate in the transitional dossier whether the current emission levels in the BAT reference document are sufficient and at which emission levels no concern related to PAH emissions is identified.

Because the contribution of CTPHT to the overall PAH emissions is very small, Community wide restrictions seem not to be the most appropriate risk management option; an alternative documentation should be submitted to the Agency before 1 December 2008. The transitional dossier should give direction, e.g. to indicate at which emission levels safe use can be guaranteed.

4 Option 2. Authorisation through an SVHC dossier

4.1 Introduction

In Option 2 the possibility of an authorisation of all CTPHT uses under REACH is discussed. In the RAR the production of CTPHT and the main applications of coal tar pitch are selected for the risk characterization. No risk characterisation is made for the other CTPHT uses. Based on the hazard assessment of CTPHT (PBT, vPvB and CMR) it may be possible to initiate the authorisation process under REACH. Option 2 examines whether the authorisation instrument can be used to reduce PAH emissions related to CTPHT or to replace CTPHT by suitable alternatives.

The screening for a substance of very high concern (SVHC) dossier is based on the available data in the RAR of CTPHT and discussions with the members of the multidisciplinary team. Relevant background information on other uses of CTPHT is given in Annex 3.

The requirements for a SVHC dossier are given in Annex 5. A SVHC dossier shall be considered when a substance is identified as a CMR, PBT, vPvB or a substance of equivalent concern. The extent of the authorisation in relation to the relevant production and uses of the substance is an important aspect in deciding whether the authorisation is preferred. A manufacturer, importer or downstream user shall not place a substance included in Annex XIV on the market, unless authorisation for that use has been granted. This means that the production of CTPHT itself solely for export and imported articles containing CTPHT are not covered by the authorisation instrument. On the other hand the requirements from REACH articles 31.9 and 33 may have an impact on the import of articles due to demands of downstream users for 'REACH-proof' articles.

4.2 Arguments pro initiating the authorisation process

CTPHT clearly meets the SVHC criteria. One of the basic principles of REACH is that the use of chemicals with this kind of hazards should be avoided as much as possible. If CTPHT is listed on Annex XIV, it will not be placed on the EU market, unless a company has an authorisation. For this authorisation, a company has to make an Annex XV dossier in which the need for authorisation is clearly stated and a social economic analysis is made.

Suitable alternatives exist for the use of CTPHT in smaller applications as binder in coal briquetting, clay pigeons and heavy duty corrosion protection. It is already the intention of industry to phase out these applications. The authorisation instrument may be used to ensure that this uses will indeed be phased out.

Note that imported articles will not be covered by this authorisation. If CTPHT is placed on the candidate list, notifications requirements (article 7.2) apply for the producer and importer of articles. This may be an important instrument to get information on the use of CTPHT in imported articles. On the other hand the lack of covering imported articles distort the level playing field of the internal market because authorisation will have a major impact on in EU produced articles. An option could be to restrict imported articles in parallel with an authorisation decision.

4.3

Arguments contra initiating the authorisation process

The inclusion of a substance in Annex XIV can be an effective instrument to address the identified risks where suitable alternatives are available, as no authorisation will be granted in this case. For CTPHT, it may be difficult to provide sufficient justification for this route. For the main applications of CTPHT in the primary aluminium production and the production of electrodes and anodes there seems to be no suitable alternatives. Therefore there is no guarantee that the authorisation instrument will be effective in addressing the identified risks. The socio-economic benefits will very likely outweigh the risk for the mentioned uses and authorisation will probably be granted. On the other hand in granting an authorisation strict conditions on PAH emissions can be required.

Also for the production of CTPHT a risk is identified. Because production processes are not covered by a possible Annex XIV listing, this is may be not the most suitable way to control emission from industrial production processes. Regulatory action through other legislation (like IPPC) seems most obvious.

Because import articles containing CTPHT are not covered by a possible Annex XIV listing and restriction in parallel would not be supported, this is may be not the most suitable way to control emissions from articles. Therefore, it may in practice not be possible to regulate diffuse sources with the authorisation instrument. The restriction instrument is probably the preferred route to phase out these smaller CTPHT uses. There are both risk(management) and market based considerations that justify Community wide restrictions:

- difference in national legislation may lead to a distortion of the internal market;
- the possibilities for emission control at diffuse emission sources are often limited;
- also imported articles may be covered;
- the instrument can be targeted to specific uses and the conditions of the restrictions can be specified.

It will take about two years before a decision on restrictions is taken and about four years before the measure is implemented. For authorisation it will also take at least about two years before a decision is taken. It is questionable whether time and money should be spent –either by restriction or authorisation- on problems that may solve themselves within a couple of years and for which at this moment a risk is not identified.

4.4

Conclusion

To our opinion, authorisation for CTPHT is not the most suitable way forward. The main reason is that at this moment and in the near future, alternatives for the main applications (anodes, electrodes) are not available. Due to the lack of alternatives, authorisation for these applications will be granted. In this case regulatory action through other legislation (like IPPC) seems most obvious.

For the smaller applications of CTPHT, alternatives are available. For the applications the restriction procedure looks more logic and should seriously be considered. Industry is claiming to phase out these applications already, but thus far no concrete information or agreements are given by industry.

If the authorisation route is to be considered further it is important to gather further information on available alternatives.

5 Option 3. Strategy on all PAH sources

It was planned that in Option 3 the other possibilities within/beyond REACH to develop an overall PAH strategy, would be discussed. Originally the Netherlands intended to evaluate, within the ESR, the overall risks due to multiple PAH sources and to develop an overall PAH risk reduction strategy. CTPHT was selected as priority substance to trigger this discussion, but due to legislative constraints the evaluation and control of risks was limited to the production and downstream use of CTPHT. The unintended emission of PAHs due to processing or burning is outside the scope of the ESR and also outside the scope of REACH.

Some preliminary discussions took place on the need for an overall PAH-strategy. The risk characterisation shows that the regional background levels of PAH are of concern. There are several studies with an overview of PAH-emission sources, but these studies do not lead to a congruent picture. It is plausible that the main sources of PAH are outside the scope of REACH (related to unintentional sources: wood burning).

It is concluded that a further scoping study to PAH emissions sources that can be tackled by REACH (screening of all REACH instruments) and the possible impact of the REACH-instruments on the overall PAH levels, is needed for decision making on follow-up actions. This study should be performed in line with this CTPHT scoping study (involvement of multidisciplinary team and staged approach)

6 Conclusion and recommendations

6.1 General

All participants supported the way this work was organised. It was very valuable to start the scoping process with a multidisciplinary team in which policy makers can learn from the technical experts and vice versa. Also the iterative process with discussions in several stages was welcomed by all people involved.

It is very important to set a clear aim of the scoping study. Especially in the case of CTPHT with a link to the broad PAH discussions, there is a need for a well defined scope of the study.

Unfortunately it appears that a good overview on the (legal) possibilities outside the scope of REACH is lacking. And also at this moment, there is no effective way of bringing the conclusions of studies like this to the colleagues responsible for the other instruments like IPPC.

This scoping study can be considered as a kind of pre-Annex XV dossier. It is advisable that the Member States or the European Commission perform a scoping study before putting a substance on the Register of Intention.

6.2 CTPHT dossier

In Annex 6 a comparison between restriction, authorisation and other possible risk reduction measures is summarised. In the previous chapters it is concluded that both the restriction and the authorisation procedure are not the most appropriate options to reduce the risks of CTPHT. Emission control via IPPC and national legislation is the first instrument to consider for the main applications (industrial point sources). Industry is already reducing or phasing out the use of CTPHT in smaller applications.

The following recommendations are made:

- The transitional dossier should give direction, e.g. to indicate at which emission levels safe use can be guaranteed.
- To perform a further scoping study to PAH emissions sources that can be tackled by REACH (screening of all REACH instruments) and the possible impact of the REACH-instruments on the overall PAH levels.
- To carefully follow the registration process under REACH. Dependent on the registrations a dossier or substance evaluation should be considered.

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Annex 1. Classification and labelling

Current Classification according to Annex I:

Classification	:	Carc. Cat. 2
Symbol	:	T
R-phrases	:	45
S-phrases	:	53-45
Notes	:	H (pitch)

Proposed classification

Decisions by the Technical Committee on Classification and Labelling (TC-C&L) in October 2006 for physical and human health endpoints.

Classification	:	Mut. Cat 2; Carc. Cat. 1; Repro. Cat. 2.
Symbol	:	T; Xi
R-phrases	:	41, 43, 45, 46, 60-61
S-phrases	:	53 - 45
Notes	:	H (pitch)

There are insufficient data available on the sensitising properties, mutagenicity and toxicity for reproduction of CTPHT itself. However, it is proposed to classify CTPHT as a skin sensitisier, a category 2 mutagen, and as toxic to reproduction (category 2), because CTPHT contains substances which are classified as such (see section 1.7.2.1 of Annex VI of Directive 67/548).

PBT assessment

Most of the PAHs in CTPHT have a DT₅₀ value both in soil and sediment > 125 days, which means that CTPHT meets the P (Persistent) and vP (very persistent) criteria.

In several studies conducted with different fish species BCF values for fluorene, anthracene, phenanthrene, fluoranthene and pyrene were measured > 2000. For anthracene, phenanthrene and fluoranthene the BCF values were even > 5000 (Linder et al., 1985; De Voogt et al., 1991; De Maagd et al., 1996; and Weinstein and Oris, 1999). This means that CTPHT meets the B (bioaccumulative) and vB (very bioaccumulative) criterion.

For all the EPA 16 PAHs the aquatic NOEC values are < 0.01 mg/l, which means that CTPHT also meets the T criterion.

In view of the fact that most of the (higher molecular) PAHs are present in > 0.1% (see section 1.2) it can be concluded that CTPHT meets the vP, vB and T criteria and hence is considered as a PBT and vPvB substance.

Annex 2. Results risk characterisation

	Identified risk		Characteristics	Remarks	Uncertainties
Production	Air	x		The PEC is in the same order of magnitude as the regional background levels.	High level of evidence for PEC/PNEC ratio and ELR: exposure assessment based on site specific data. The emission data on PAH do not concern the production of coal tar pitch per se, but the whole process of coal tar processing.
	Water	iii: RR 4	1/2 out of 8 sites		
	Sediment	iii RR 8, 41	2 out of 8 sites		
	Terrestrial	ii			
	Man via environment	iii ELR $10^{-4} - 10^{-5}$	8 sites		
	Secondary poisoning	x			
Aluminium production	Air	x		Large differences between PEC values; at some sites the PEC is significant higher than the regional background levels	High level of evidence for PEC/PNEC ratio and ELR: exposure assessment based on site specific data.
	Water	iii RR 0.2-3386	13 out of 21 sites	Sites not at risk have no emissions to water	
	Sediment	iii RR 0.6-12019	13 out of 21 sites	Conclusion ii applies for all prim. Aluminium plants using prebaked anodes without an anode plant on site (x sites)	
	Terrestrial	ii			
	Man via environment	iii ELR $10^{-3} - 10^{-7}$	20/21 sites ...	See remarks air	
	Secondary poisoning	x			
Ferro-alloy industry, applying electric arc furnaces with Søderberg electrodes	Air	x	Exposure assessment based on generic scenario. Number of sites 2-10	The PEC is in the factor 20 above regional background levels?	Low level of evidence for magnitude PEC/PNEC ratio and ELR: exposure assessment based on generic scenario
	Water	iii RR 10			
	Sediment	iii RR 69			
	Terrestrial	ii			
	Man via environment	iii ELR $10^{-3} - 10^{-4}$			
	Secondary poisoning	x			
Production of graphite electrodes	Air	x	Exposure assessment based on generic scenario. Number of sites unknown	The PEC is factor 4 above regional background levels?	Low level of evidence for magnitude PEC/PNEC ratio and ELR: exposure assessment based on generic scenario
	Water	ii			
	Sediment	ii			
	Terrestrial	ii			
	Man via environment	iii ELR $10^{-4} - 10^{-5}$			
	Secondary poisoning	x			

x: no PNEC; no conclusion; ELR: order of magnitude of estimated excess lifetime risk; RR: risk ratio

Annex 3. Contribution of sources to Regional PAH levels

Summary

Overall, it can be concluded that a consistent description of the emissions and emission sources of PAH to air is not available. The reasons for this are caused for instance by the different ways to express total PAH emissions (6 Borneff, 16 PAH, et cetera), the different classifications into categories (e.g. does anode baking belong to other processes or to non-ferrous metals) and other striking differences (e.g. the emissions of brake and tyre wear). A recent overview of the PAH emissions to air in the EU is not available and the data available is only based on a few EU countries. Nevertheless, it seems that the largest emission sources to air are non-industrial, like domestic combustion, the use of coal tar-based products and road transport. For the emission to surface water even less data is available. Some industrial point sources can be large emission sources of PAH. Compared to (industrial) point source data, the emission via atmospheric deposition seems more important.

Emissions to air

Emission data of PAH to air are scarce. The data for PAH (16 PAH, 6 Borneff) are available for the 15 OSPAR member countries and B(a)P data are available for Germany (see Table 3.1-Table 3.5). The UK data presented in Table 3.4 and Table 3.5 are actually based on the same reference, but the published figures are dissimilar. The difference is mainly caused by the traffic emissions for naphthalene, which are 1,153,360 kg/y and 34,100 kg/y according to the UK National Atmospheric Emissions Inventory (NAEI) and Department for Environment, Food and Rural Affairs (DEFRA), respectively. Most likely, the largest emission of the NAEI is correct (RAR Naphthalene).

Large non-industrial emission sources are the domestic combustion of solid fuels, the use of coal tar-based products (creosote) for wood preservation and road transport. The emissions of these three sources together can amount 54%-89% of the total PAH emission to air, dependent on the references (see Table 3.1-Table 3.5). PAH emissions from wood preservation will reduce due to the entry into force of EU directive 2001/90/EC in 2003. The Directive prohibits the use coal tar based products for wood preservation through spraying and dipping, which consequently is expected to be phased out in the European Union. Therefore emission from this source is also expected to reduce considerably. The contribution of the industrial emissions of the aluminium and steel industry to the total PAH emissions are not unimportant with values up to 22%. For the Netherlands these industrial emissions are very low, mainly because probably a large part is grouped under 'other processes'. In 2001, in the Netherlands about 500 tonnes have been emitted to air for the total PAH 10 (Duyzer, 2002). In the Netherlands consumers (35-64%), traffic and transport (20-35%) and agriculture (12-21%) are the main PAH sources to air (Duyzer, 2002). The importance of agriculture is not confirmed by the emission data presented in Table 3.2 for 1998. According to the EU Working group on PAHs (EC, 2001), the UK seems to be quite representative of the majority of the European countries and as an example, the trend of the sum of the 16 EPA PAH in the UK between 1990 and 2002 is shown in Figure 3.1.

Similarly Table 3.6 illustrates, again using UK data, the generally downward trend currently being observed within the European Union as a whole. The estimated B(a)P emissions for 1990 and 1995, and the forecast emissions for 2010, represent a 'business as usual' scenario¹. PAHs emissions have decreased significantly since 1990. Between 1990 and 1995, the estimated total emissions of B(a)P had decreased by over 50 %. The main reduction was in the emission from natural fires and open agricultural burning which decreased by 90% from 1990 levels because of the ban on stubble burning in England and Wales. During 2002, the largest source of PAH was

¹ In respect of emissions: Business as usual should be interpreted as: human activity (industry, transport, domestic consumption, etc.) continue forecasted growth, there is no new legislation introduced that would affect emissions, existing legislation is fully implemented.

road transport combustion, contributing 52% to the total emissions. Other major sources include domestic combustion and non-ferrous metal production. The UK B(a)P emission is forecast to further decrease by 2010 to 16.4 tonnes (see Table 3.6). The emission from vehicles is forecast to decrease under the 'business as usual' scenario, due mainly to stricter emission regulations which require e.g., the use of catalytic converters, and improved maintenance and vehicle condition. The emissions from anode baking (within the process of primary aluminium production) are predicted to decrease sharply as a result of improved abatement equipment which was brought on-stream during the last 10 years and the implementation of the IPPC Directive with introduction of BAT effective from 2007. The emission from domestic coal combustion is forecast to decrease between 1990 and 2010 due to a decrease in the quantity of coal burned (Figure 3.2). However, these sources are still likely to be responsible for a significant proportion of the forecast 2010 emission, which is spread across several sectors: vehicles (24%), industrial combustion (24%), domestic combustion (18%), and natural fires (18%).

Table 3.1 PAH emissions to air (6 Borneff) in 15 OSPAR member countries¹⁾ (year 1990) (OSPAR, 2001) ³⁾.

No	Source	PAH (t/y)	(%)
1	Industrial processes - iron and steel production - non ferro metal industry (primary aluminium and anode baking) - asphalt industry - other processes	131 378 112 16	2% 5% 1% 0.2%
2	Industrial combustion	78	1%
3	Power generation	14.6	0.2%
4	Commercial, institutional and domestic combustion	4,220	54%
5	Solvent use wood preservation (coal tar-based products) ²⁾	1,820	23%
6	Traffic emissions	955	12%
7	Other (waste incineration)	5.69	0.1%
	Total	7,730	

- 1) Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, the UK
- 2) The use of carbolineum in wood preservation is being phased out in the EU. There are also restrictions on the use of creosoted wood according to EU directive 2001/90/EC
- 3) Data original from Berdowski et al. (1997)

Table 3.2 PAH emissions to air (6 Borneff) in The Netherlands for 1998 (CCDM, 2000).

No	Source	PAH (kg/y)	(%)
1	Industrial processes - iron and steel production - non ferro metal industry - petroleum industry - inorganic and organic chemicals - other processes (mainly metal-electro)	258 98.5 66.3 3.7 35,800	0.2% 0.1% 0.1% 0% 33.8%
2	Industrial combustion	169	0.2%
3	Power generation	86.2	0.1%
4	Domestic combustion	8,270	7.8%
5	Commercial, institutional combustion	16.6	0%
6	Solvent use wood preservation (coal tar-based products)	27,400	25.9%
7	Road transport - combustion - brake and tyre wear	4,402 28,600	4.2% 27.0%
8	Non-road transport	714	0.7%
9	Other (waste treatment, agricultural combustion)	16.2	0%
	Total	105,900	

Table 3.3 Benzo(a)pyrene emissions to air in UK (1995)¹⁾ and Germany (1994)²⁾.

No	Source	Germany (kg/y)	%	UK (kg/y)	%
1	Industrial processes - iron and steel production: sinter plants - iron and steel production: coke production - iron and steel production: electric arc furnaces - non ferro metal industry (primary aluminium / anode baking)	52 1,090 257 2,578	0.4% 8% 2% 19%	- 1,100 - 16,200	- 2.5% - 36.4
2	Industrial combustion	27.8	0.2%	5,000	11.2%
3	Power generation	5.5	0%	-	-
4	Domestic combustion - coal - oil - wood	3,992 3,383 1,940	29% 25% 14%	2,200 - 1,200	4.9% - 2.7%
5	Solvent use wood preservation (coal tar-based products)	157	1.2%	460	1%
6	Traffic emissions	266	1.9%	7,700	17.3%
7	Other (natural fire)	-	-	2,900	6.5%
	Total	13,751		44,460	

1) Figures derived from EC (2001)

2) Figures derived from Gandrass and Salomons (2001)

Table 3.4 PAH emissions to air (sum of the 16 EPA PAHs) in the UK for 1999 (UK National Atmospheric Emissions Inventory (NAEI, 2001).

No	Source	PAH (kg/y)	(%)
1	Industrial processes - iron and steel production (coke, sinter and combustion) - non ferro metal industry (aluminium) - refineries / petroleum industry - other processes (chemical industry, cement, collieries etc.)	100,618 277,349 4,502 8,792	3.8 10.4 0.2 0.3
2	Industrial combustion (others)	154,792	5.8
3	Power generation	3,164	0.1
4	Domestic combustion	522,754	19.6
5	Commercial, institutional combustion	588	0.02
6	Solvent use wood preservation (coal tar-based products)	72,765	2.7
7	Road transport	1,293,513	48.6
8	Non-road transport	4,764	0.2
9	Other: waste treatment (incineration) natural fires agriculture (combustion)	123,425 94,920 640	4.6 3.6 0.02
	Total	2,663,035	

Table 3.5 PAH emissions to air (sum of the 16 EPA PAHs) in the UK for 1999 (UK Department for Environment, Food and Rural Affairs (DEFRA).

No	Source	PAH (kg/y)	(%)
1	Industrial processes - iron and steel production - non ferro metal industry (aluminium) - petroleum industry - other processes	22,303 277,349 4,593 80,855	1.6% 19.6% 0.3% 5.7%
2	Industrial combustion (others)	166,756	12.4%
3	Power generation	3,162	2.2%
4	Domestic combustion	540,123	38.2%
5	Commercial, institutional combustion	2,692	0.2%
6	Solvent use wood preservation (coal tar-based products)	102,564	7.3%
7	Road transport - combustion - brake and tyre wear	114,490 48.5	8.1% 0%
8	Non-road transport	4,146	0.3%
9	Other waste treatment (incineration) natural fires	298 94,920	0% 6.8%
	Total	1,414,300	

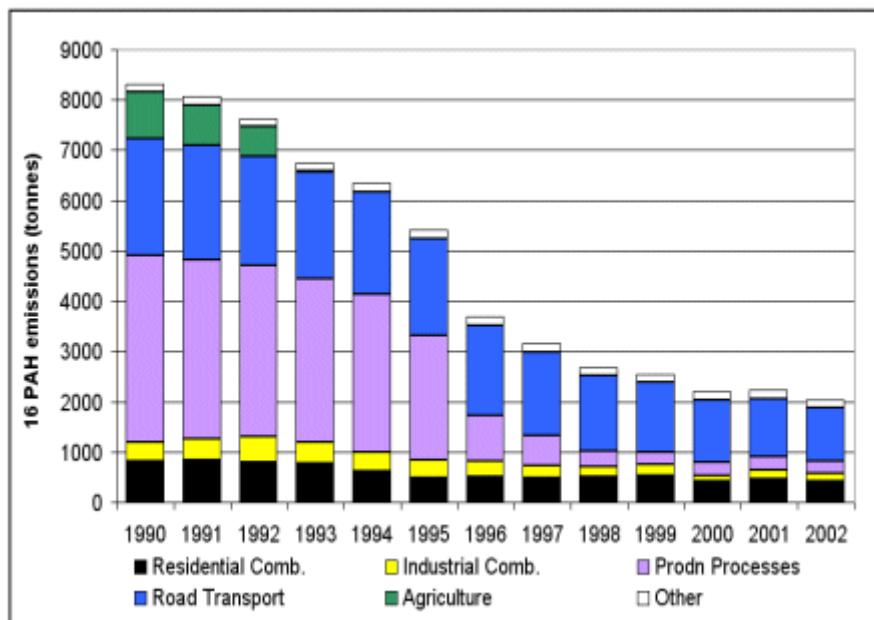


Figure 3.1 Atmospheric Emission of the sum of the 16 EPA PAHs in the UK between 1990 and 2002 (NAEI, 2004).

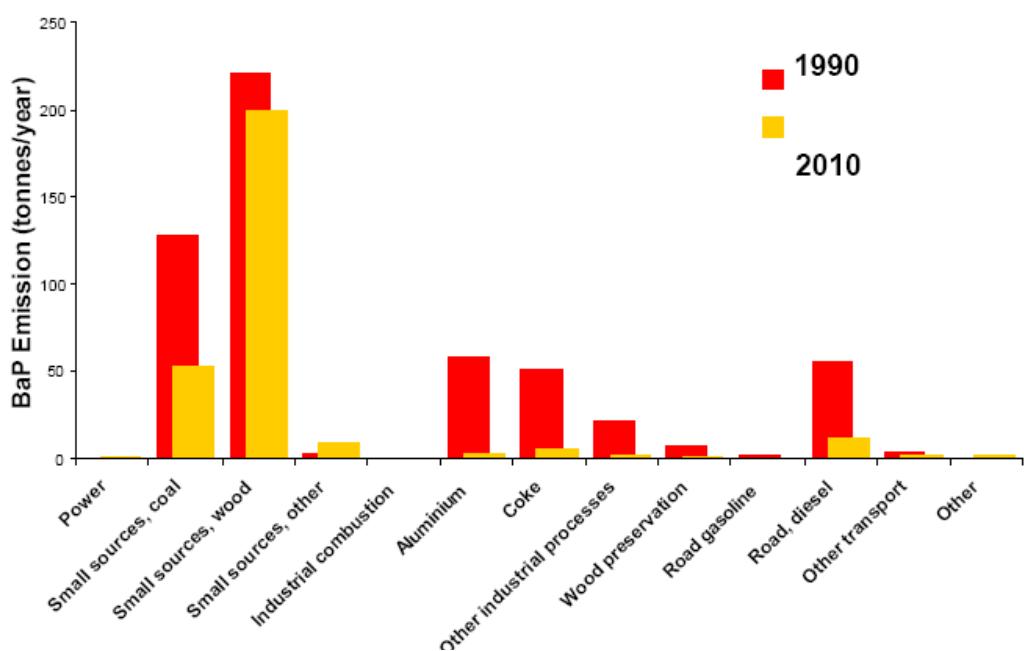


Figure 3.2 Current and projected emissions of Benzo(a)pyrene for the EU15+6 accession countries (Holland et al., 2001).

Table 3.6. Summary of benzo(a)pyrene emissions in the UK measured in 1990 and 1995 and estimated for 2010 (EC, 2001).

BaP Emissions	1990		1995		2010 Estimated	
	Emission (tonnes)	% Contribution to total BaP Emissions from sources in this table	Emissio n (tonnes)	% Contribution to total BaP Emissions from sources in this table	Emission (tonnes)	% Contribution to total BaP Emissions from sources in this table
Vehicles – diesel	1.4	1.7	2.0	5.4	3.3	20.0
Vehicles – gasoline	8.5	10.6	5.7	15.5	0.7	4.0
Natural fires / open agric. Burning	31	38.7	2.9	7.8	2.9	17.5
Creosote use	0.06	0.07	0.06	0.16	0.06	0.4
Aluminium production	1.9	2.4	1.4	3.9	0.03	0.2
Anode baking	22.7	28.3	14.8	40.3	1.0	5.9
coke production	1.3	1.6	1.1	2.9	1.1	6.7
Domestic wood combustion	1.2	1.5	1.2	3.2	1.2	7.1
Industrial wood combustion	0.1	0.2	0.1	0.4	0.2	1.0
Domestic coal combustion	5.3	6.6	2.2	6.1	1.9	11.3
Industrial coal combustion	6.3	7.8	4.9	13.3	3.8	23.3
other sources	0.4	0.5	0.4	1.0	0.4	2.4
Total BaP Emission	80.2	100	36.8	100	16.4	100

Emissions to water

PAH can be emitted to surface water directly or indirectly via a sewage treatment plant by (industrial) point sources and via atmospheric deposition. Information on PAH emission to surface water for the EU is limited to the European Pollutant Emission Register (EPER) database.. Based on the emission estimates for 1998 in the Netherlands, road transport is considered to be by far the largest emission source to water, followed by emissions from agriculture and consumers. The emission from industry is relatively small.

The EPER (2004) reports PAH emission of the different point sources for 2001 (see Table 3.8). The largest industrial emission sources to water are the pre-treatment of fibres or textiles, based on the EPER data.

Based on both measurements and model calculation Duyzer (2003) determined the total burden of surface waters in the Netherlands (excluding North Sea) by atmospheric deposition of three PAH (anthracene, phenanthrene and benzo(a)anthracene). The total emission in the Netherlands to surface water via atmospheric deposition of these three PAH was more than 25,000 kg/y).

Table 3.7 PAH emissions to water (tonnes/year) in the Netherlands for 1998 (Harmelen et al., 1999).

	Agriculture	Refineries	Industry	Waste treatment	Road transport	Consumers	Public service	Effluent STP	Emission via air and soil	Total
PAH (Borneff 6)	0.623	0.001	0.051	0.000	15.3	0.001	0.001	1.51	3.20	21.1

Table 3.8 PAH emissions to water in the EU for 2001 (The European Pollutant Emission Register (EPER, 2004)).

Source	Direct (kg)	Indirect via STP (kg)
Industrial processes		
- iron and steel production	10,271	381
- petroleum industry	558	151
- basic organic chemicals	1519	16
pharmaceutical products	0	36
- pre-treatment fibres or textiles	0	12,284
Industrial combustion	1,022	6
- Installations for the production of carbon or graphite	21	0
- Slaughterhouses, plants for the production of milk other animal or vegetable raw materials	267	77
- Industrial plants for pulp from timber or other paper or board production	6	0
Waste disposal	259	80
	6	0
Total	13,923	13,031

Annex 4. Requirements annex XV restriction dossier

Proposal

The proposal shall include the identity of the substance and the restriction(s) proposed for the manufacture, placing on the market or use(s) and a summary of the justification.

Information on hazard and risk

- The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report.
- Evidence shall be provided that implemented risk management measures (including those identified in registrations under Articles 10 to 14) are not sufficient.

Information on alternatives

Available information on alternative substances and techniques shall be provided, including:

- information on the risks to human health and the environment related to the manufacture or use of the alternatives,
- availability, including the time scale,
- technical and economical feasibility.

Justification for Restrictions at Community Level

Justification shall be provided that:

- action is required on a Community-wide basis,
- a restriction is the most appropriate Community wide measure which shall be assessed using the following criteria:
 - (i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;
 - (ii) practicality: the restriction must be implementable, enforceable and manageable;
 - (iii) monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

Socio-economic assessment

The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

Information on stakeholder consultation

Information on any consultation of stakeholders and how their views have been taken into account shall be included in the dossier.

Annex 5. Requirements annex XV authorisation dossier

Dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern according to Article 59 of REACH.

Proposal

The proposal shall include the identity of substance(s) concerned and whether it is proposed to be identified as a CMR according to Article 57(a), (b) or (c), a PBT according to Article 57 (d), a vPvB according to Article 57(e), or a substance of equivalent concern according to Article 57(f).

Justification

A comparison of the available information with the criteria in Annex XIII for PBT according to Article 57(d), and vPvBs according to Article 57(e), or an assessment of the hazards and a comparison with Article 57(f), according to the relevant parts of Section 1 to 4 of Annex I shall be completed. This shall be documented in the format set out in Part B of the Chemical Safety Report in Annex I.

Information on exposures, alternative substances and risks

The available use and exposure information and information on alternative substances and techniques shall be provided.

Annex 6. Comparison of restriction, authorisation instrument and other possible measures

	Restriction	Authorisation	Address identified risks by other means
Action needed to finalize the transition dossier	Prepare annex XV Restriction dossier before 1 December 2008	Prepare annex XV SVHC dossier before 1 December 2008	<ul style="list-style-type: none"> • Document information on hazard and risk • Document how the identified risks can be addressed
Dossier requirements	<ul style="list-style-type: none"> • Restriction proposal, see Annex 4 • Document in format part B of the Chemical Safety Report 	<ul style="list-style-type: none"> • Proposal for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern, see Annex 5 • Document in format part B of the Chemical Safety Report 	<ul style="list-style-type: none"> • No format given to document how identified risks can be addressed if no restrictions are proposed • Document information on hazard and risk in format part B of the Chemical Safety Report
Applicability of instrument	<ul style="list-style-type: none"> • Where there is an <u>unacceptable</u> risks for human health or the environment arising from the <u>manufacture</u>, use or placing on the market of substances, which needs to be addressed at Community wide basis • Risks/concerns that cannot be addressed with restrictions: <ul style="list-style-type: none"> • Unacceptable risks related to unintentional sources • Scenarios for which other risk management measures are more appropriate • Scenarios not at risk 	<ul style="list-style-type: none"> • Where substances meet criteria for SVHC • Prohibition for <u>all uses</u> • Obligations for manufacturer, importer and downstream user related to the placing on the market and use of substances of very high concern <p>Concerns that cannot be addressed with authorizations:</p> <ul style="list-style-type: none"> • Concerns related to the manufacturing of substances 	<ul style="list-style-type: none"> • Will be filled if other RMO are considered most appropriate
Expected workload for MS in preparing the dossier	<ul style="list-style-type: none"> • High, especially if no suitable alternatives are available. • The MS should make the case: provide all necessary information for decision making 	<ul style="list-style-type: none"> • Median • Most work has to be done by other parties in the follow up once the dossier is submitted 	<ul style="list-style-type: none"> • Low
Follow up once the dossier is submitted	<u>Restriction procedure</u> <ul style="list-style-type: none"> • The submission of the dossier initiates the restriction procedure • The restriction procedure 	<u>Procedure for inclusion substance in candidate list</u> <ul style="list-style-type: none"> • The submission of the dossier initiates the procedure for inclusion 	

	Restriction	Authorisation	Address identified risks by other means
	<p>will take approximately 18 months after submission of the dossier</p> <ul style="list-style-type: none"> • If the restriction is agreed – Comitology procedure - Annex XVII will be amended accordingly 	<p>of the substance in the candidate list for inclusion in Annex XIV; length of procedure 3-6 months</p> <p><u>Procedure for inclusion substance in Annex XIV</u></p> <ul style="list-style-type: none"> • The agency shall, taking into account the opinion of the MSC, recommend priority substances to be included in Annex XIV specifying the issues in article 58.1 • If the inclusion of the substance is agreed – Comitology procedure - Annex XIV will be amended accordingly <p><u>Procedure for granting authorizations</u></p> <ul style="list-style-type: none"> • Industry should submit application for authorization if he wishes to continue to use or place on the market for certain uses after the sunset date. Provide information on alternatives and show that the socio-economic benefits of the use of the substance outweigh the risks • The submission of an application for authorization initiates the procedure for granting authorizations • The procedure will take approximately 18 months • If a authorization is granted this will be published in the OJ 	
Role submitter in follow up dossier	<ul style="list-style-type: none"> • No formal role 	<ul style="list-style-type: none"> • No formal role 	
Role of interested parties (including MS) in follow	<ul style="list-style-type: none"> • Submit SEA or related information • Comment on draft SEAC-opinion 	<ul style="list-style-type: none"> • Submit comments on intended recommendation of Agency to include substance in Annex 	

	Restriction	Authorisation	Address identified risks by other means
up dossier		XIV	
When do the measures enter into force?	<ul style="list-style-type: none"> Expected entering into force 24 months² after publication of the restriction in the OJ – 1 June 2012 	<ul style="list-style-type: none"> First substances to be included in recommendation of the Agency to the candidate list for Annex XIV in 1 June 2009. Expected first sunset dates³ (X months after inclusion of substance in Annex XIV) 	
HERO's ⁴	<ul style="list-style-type: none"> Unacceptable risk related to diffuse sources, combined exposure, consumer products Substances with alternatives available for the relevant uses 	<ul style="list-style-type: none"> SVHC with suitable alternatives available for most uses. 	
LERO's ⁵	<ul style="list-style-type: none"> An unacceptable risk is concluded for a small number of industrial point sources No suitable alternatives available are available for the uses at risk. 	<ul style="list-style-type: none"> SVHC with no suitable alternatives available for most uses. 	
When can the work be considered successful?	<ul style="list-style-type: none"> When the restriction proposal is agreed and the identified risks are addressed 	<ul style="list-style-type: none"> When the substance is included in the candidate list When the substance is included in Annex XIV When the substance is replaced by alternative. 	<ul style="list-style-type: none"> When the identified risks are properly addressed

² X months after inclusion of the substance is included in Annex XVII. The transitional arrangements are specified for the substance. Under the Marketing and Use Directive a period of 24 months after publication of the restriction is considered reasonable; period to allow industry to change their procedures.

³ Y months (more than 18 months) after the inclusion of the substance in Annex XIV. The transitional arrangements specified for the substance

⁴ Substances with High Expected Regulatory Outcome

⁵ Substances with Low Expected Regulatory Outcome

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