ECHA ¹ Guidance from the Pre-registration website ²	CONCAWE Additional guidance for petroleum substances ³
Page "Pre-registration" 4 http://echa.europa.eu/pre-registration en.asp	
Pre-register to benefit from extended deadlines	
REACH, the new EU chemicals regulation, requires that chemical substances on their own, in preparations and those which are intentionally released from articles have to be registered to the European Chemicals Agency (ECHA). The regulation applies to substances manufactured in, or imported to the EU in annual quantities of 1 tonne or more per company, unless the regulation indicates otherwise.	Manufactured or imported petroleum substances are "chemical substances" in the definition of REACH and have to be registered. Petroleum substances are recognised UVCBs (substances of Unknown or Variable composition, Complex reaction products or Biological materials) and as such treated as equivalent to monoconstituent substances, NOT as multi-constituent substances.
The obligation to register applies from 1 June 2008. The chemicals currently on the EU market which meet the definition of phase-in substances should be pre-registered between 1 June and 1 December 2008. Companies who pre-register their substances can benefit from extended registration deadlines. The deadline depends on the tonnage band and the hazardous properties of the substance. The staggered deadlines are:	Petroleum substances listed in the Official Journal of the European Commission OJ 84 of 5 April 1993 are recognised as being phase-in substances. However, some of these substances are the result of blending processes. According to the ECHA these blends have a dual nature. Depending on the circumstances they can be regarded (and registered) as substances or treated as preparations. See the letter from the ECHA for details: http://212.3.246.155/Common/GetFile.asp?DocID=14 119&logonname=guestC&mfd=off Under certain conditions also substances not listed in OJ 84 of 5 April 1993 can be registered as phase-in substances (see REACH Article 3(20)(b)). This could apply to polymerisates if the conditions of REACH

¹ **European Chemicals Agency** Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland; Tel.: +358 9 6861 80, Fax +358 9 6861 8210, http://echa.europa.eu | info@echa.europa.eu | http://echa.europa.eu/pre-registration_en.asp; Status: 1 June 2008 Version of 25 June 2008

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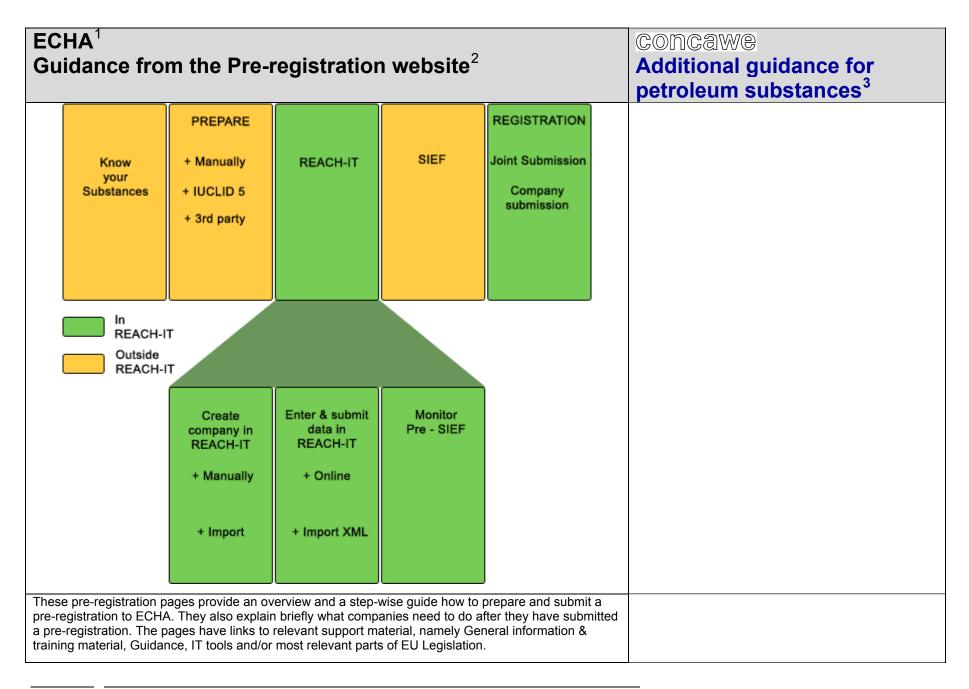
⁴ Please note that it has not been possible to copy the hyperlinks in the original ECHA guidance document into this document.

ECHA ¹	concawe
Guidance from the Pre-registration website ²	Additional guidance for
	petroleum substances ³
	Article 3(20)(b) are met.
• 30 November 2010,	Practically all petroleum substances fall into the tonnage band ≥ 1000 t/a. The registration deadline for phase-in petroleum substances manufactured or imported in volumes ≥ 1000 t/a is 30 November 2010.
• 31 May 2013 or	
• 31 May 2018	
Pre-registration is free and simple	
Pre-registration requires only limited data and there is no fee associated to it. A pre-registration file for a substance consists of:	
Substance Identity: EINECS number, CAS numbers and names of the substance	
envisaged deadline and tonnage band for the registration	
name and contact information of a Contact person or Third party Representative who will act as the contact point in data sharing	The contact person does not have to be a natural person. It is possible to use the name of a function or a department.
	The e-mail address can also be a corporate or a specially created functional mailbox. The latter is the preferred option.
A pre-registrant should also provide when applicable substance identification of any relevant substances which may facilitate the risk assessment and data sharing of the substance	This refers to substances that could be used for read-across of substance properties.
	Such information is not mandatory and in the case of petroleum substances not necessary, since CONCAWE has already carried out extensive work on grouping substances in "substance categories" for the purpose of read-across. A list of these categories will be made available on the CONCAWE website.

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ECHA ¹ Guidance from the Pre-registration website ²	Concawe Additional guidance for petroleum substances ³
From an inventory to a registration	
The process from knowing your REACH roles and substances to registration has several steps. The roles are explained in the Actors section of the About REACH web page on the Guidance website . The seven steps are presented in the graph below. Each of the steps has its own web page. The preparation, company account creation and submission of a pre-registration file steps can be carried out by different methods. All the potential options are explained first on the generic page for the step. More details are given on the option specific page.	

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Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
The buttons above the "Further information"-heading will allow you to navigate easily from one step to another.	
Guidance	
Practical Steps for Pre-registration guide is a hands-on guide for companies preparing for pre-registration	See CONCAWE document "Practical steps for REACH pre-registration - Additional guidance for petroleum substances".
Guidance on data sharing endocument describes data sharing mechanisms for phase-in and non phase-in substances under REACH:	
o Section 3. Pre-registration	
Glossary provides a listing and explanation of the key terms used in the REACH guidance.	
Guidance website is a single point of access to general and detailed technical guidance on REACH.	
IT Tools	
REACH IT Portal	
IUCLID 5 website	
IUCLID 5 leaflet en gives an overview of the IUCLID 5 IT tool.	
Legislation	
REACH Regulation	
o Art. 3.1 - Definition, chemical substance	
o Art. 3.3 - Article	
o Art. 3.20 - Definitions - phase-in substance	
Art. 7 - Registration and notification of substances in articles	
o Art. 5 - No data no market	

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Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
Art. 23 - Specific provisions for phase in substances	
Art. 28 - Duty to pre-register for phase-in substances	
A) Sub-page "What to know"	
http://echa.europa.eu/pre-registration/whattoknow_en.asp	
What you need to know	
Know your REACH role/s	
When you start preparing for REACH you should first know what roles your company may have in relation to its substances. The following roles are relevant for pre-registration:	
Manufacturer / importer of substances	For manufacturers and importers of petroleum substances:
	Under certain circumstances blended petroleum substances (e.g. gasoline, CAS RN 86290-81-5, EINECS number 289-220-8) can be registered as substances, in other circumstances they have to be dealt with as preparations. For detailed guidance see the letter from the ECHA dated 7 May 2008: http://212.3.246.155/Common/GetFile.asp?DocID=14 119&logonname=guestC&mfd=off
	For importers (1):
	See also the joint CONCAWE/Cefic paper on the definition of the importer under REACH:
	http://212.3.246.155/Common/GetFile.asp?DocID= 14009&logonname=guestC&mfd=off
	Note : There are two issues which may require amendments to the document. They are clearly marked in the document on the CONCAWE

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ECHA ¹ Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³ Internet website. For importers (2):
	A list of CAS RNs/EINECS numbers has been posted on the CONCAWE website that CONCAWE member companies have identified as suitable identifiers for traded (imported) petroleum substances.
Producer / importer of articles	
Only representative	
Downstream user	
Distributor	
Data holder	
If you are a manufacturer or importer of substances which fall within the scope of REACH you need to register them. The registration requirement applies also to producers and importers of articles if substances are intentionally released from their articles.	
Companies that are not established in the EU have no obligations under REACH and can not preregister and register. However, a non-EU manufacturer of substances, preparations or articles whose products are imported into the EU can appoint an Only Representative. The Only Representative will then carry out the REACH obligations including pre-registration linked to the imported substances. An only representative would not need to be appointed in the event that the importer had already registered the substance, as outlined above.	
Downstream users and distributors who buy their substances (or articles which intentionally release substances) from EU suppliers or non-EU suppliers who have nominated an Only Representative do not need to pre-register and register. However if they buy from other non-EU suppliers they will be considered as importers under REACH and they have to pre-register and register as importers.	
If a downstream user or a third party is holding data on substances it can inform ECHA with the intention of participating to exchange of information with the registrants. The REACH IT portal has a separate functionality for these Data holders .	

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ECHA ¹ Guidance from the Pre-registration website ²	CONCAWE Additional guidance for petroleum substances ³
Know your substances	
You need to know all chemical substances your company manufactures, imports and/or uses. Establishing this knowledge is a critical step in getting ready for REACH. You may compile your inventory using any solution that suits your company size, commercial activity and information systems.	Note: Imported petroleum products may contain additives, octane boosters, biofuels etc Under REACH such petroleum products are always regarded as preparations. Their components need to be registered independently if the accumulated volume of a component is 1 t/a or more.
An example of steps to be taken is given below. A web based Navigator tool and REACH Guidance Documents available on the guidance website give useful advice on interpreting tonnage information, identification of substances and many other aspects that may help you in prepare for REACH.	
Create an inventory of substances	CONCAWE strongly suggests to follow the advice and to create an inventory of substances.
	Imported petroleum products may contain additives, octane boosters, biofuels etc Under REACH such petroleum products are <u>always</u> regarded as preparations. Their components need to be registered independently if the accumulated volume of a component is 1 t/a or more.
	CONCAWE therefore suggests to include in the inventory imported petroleum products and their components.
o on their own	
o in preparations	Some petroleum substances are the result of blending processes. According to the ECHA these blends have a dual nature. Depending on the circumstances they can be regarded (and registered) as substances or treated as preparations. See the letter from the ECHA for details: http://212.3.246.155/Common/GetFile.asp?DocID=14 119&logonname=guestC&mfd=off
o those intentionally released from articles	

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ECHA ¹ Guidance from the Pre-registration website ²	CONCAWE Additional guidance for petroleum substances ³
2. Consider exemptions for substances and uses in the inventory	
 review your substances and their uses in relation to Articles 2 and 15 as well as Annexes IV and V of the REACH regulation; further information is available in the Guidance on Registration 	
3. Compile data based on volumes	Strictly speaking the volume triggers are:
o = 1 tonne	1 t/a or more
o = 10 tonnes	10 t/a or more
o =100 tonnes	100 t/a or more
o = 1000 tonnes	1000 t/a or more
4. Understand the sources of the substances	
manufactured by your company	Some petroleum substances are the result of blending processes. According to the ECHA these blends have a dual nature. Depending on the circumstances they can be regarded (and registered) as substances or treated as preparations. See the letter from the ECHA for details: http://212.3.246.155/Common/GetFile.asp?DocID=14 119&logonname=guestC&mfd=off
o purchased from an EU company	In this particular case no registration is required as the supplier (or his supplier etc.) will have to register the substance. If in doubt it may be advisable to check with the supplier what his intentions with respect to the registration of the substance are.
o purchased from a non-EU supplier and imported to the EU by your company	
o purchased from a non-EU supplier who has nominated an Only Representative	
Be prepared to pre-register all substances you manufacture in or import to the EU and those which are intentionally released from articles if the annual amount is one tonne or more.	
Further information	
Documents and web pages below help you to understand the topics covered and/or provide access to	

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ECHA ¹ Guidance from the Pre-registration website ²	CONCAWE Additional guidance for petroleum substances ³
relevant tools. The en-icon indicates that the linked material is available only in English.	
General information & training material	
REACH guidance website assists industry and authorities to understand their obligations under REACH and provides guidance on how to fulfil them. It contains 5 sections: About REACH, Navigator, Guidance documents, Formats and REACH Legislation.	
Navigator tool	
Guidance on registration endocument describes the registration and data sharing mechanisms for phase-in and non phase-in substances under REACH. The document is currently being translated. The translations are foreseen to be published in autumn 2008.	
Guidance	
Practical Steps for Pre-registration guide is a hands-on guide for companies preparing for pre-registration E.	
Guidance for identification and naming of substances in REACH document describes how to name and identify a substance under REACH:	
Section 3. Framework for substance identification in REACH	
Section 4. Guidance for substance identification and naming in REACH	
Guidance on data sharing endocument describes data sharing mechanisms for phase-in and non phase-in substances under REACH:	
o Section 3. Pre-registration	
Substances in article document emassists producers and importers of articles in identifying whether or not they have obligations under REACH. The document is foreseen to be published by 1 June.	
Legislation	
REACH Regulation	

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ECHA ¹ Guidance from the Pre-registration website ²	CONCAWE Additional guidance for petroleum substances ³
o Art. 2 Application	
o Art. 3 - Definitions	
Art. 15 - Substances in plant protection and biocidal products	
Art. 24 - Notified substances	
Annex IV - Exemptions from the obligation to register in accordance with article 2(7)(a)	
o Annex V - Exemptions from the obligations to register in accordance with article 2(7)(b)	
B) Sub-page "Preparation"	
http://echa.europa.eu/pre-registration/prepare_en.asp	
Good preparation will ensure an easy pre-registration	
A pre-registration can be only carried out electronically via the REACH-IT portal on the ECHA website. To ensure an easy submission of your files please ensure that you have all necessary information in hand before you enter the REACH-IT pre-registration module.	
You can prepare your substance data already now for either:	
Online pre-registration - by manually compiling required data,	Option 1: This is the recommended tool for pre- registering a small number of petroleum substances
IUCLID 5 pre-registration - by entering your substance data in IUCLID 5, or	Option 2: This is the recommended tool for "bulk uploading" of pre-registration information that has already been created in IUCLID 5, i.e. the submission of pre-registration XML files for a large number of substances.
XML pre-registration - by entering your substance data in your company IT system that allows you to create an XML file in the required format	Option 3: This is the recommended tool for "bulk uploading" of pre-registration information that has not yet been created in IUCLID 5, i.e. the submission of pre-registration XML files for a large number of substances. A tool "Excel to XML" has been developed by

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ECHA ¹	concawe
Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
	CONCAWE and Cefic and is available free of charge on the CONCAWE Internet website (http://www.concawe.org/Content/Default.asp?Pag eID=480).
If you need to pre-register only a few substances and you are not currently using IUCLID 5, an on-line pre-registration via REACH-IT could be your preferred option. Pre-registration using IUCLID 5 or the XML option may be more practical for companies who will pre-register many chemical substances. The IUCLID 5 and XML option allows submission of pre-registration information of several substances defined by their EC numbers in a single file.	Both the IUCLID5 plug-in for pre-registration and the Excel to XML tool will generate a pre-registration XML file. The use of XML files (instead of online pre-registration) is the superior option for controlling, tracking and updating pre-registrations. This is independent of the number of substances to be registered!
	Therefore even for a relatively small number of substances options 2 and 3 may be preferable.
B-1) Sub-sub-page "Manual preparation"	
http://echa.europa.eu/pre-registration/prepare/manualpreparation_en.asp	
Prepare for manual online submission	= Option 1
If you are planning to enter your pre-registration data manually online to the REACH-IT system make sure that you have the following information easily accessible.	
Substance Identification: EINECS number, CAS numbers and names of the substance	A list of CAS RNs/EINECS numbers has been posted on the CONCAWE website that CONCAWE member companies have identified as suitable identifiers for traded (imported) petroleum substances.
Substance Identification of any relevant substances you would consider relevant for read across, grouping or QSAR purposes for your substance	
The envisaged registration deadline and the tonnage band for the substance	
Whether you will take part in the data sharing yourself or use a third party representative on your behalf. If you will use a third party make sure you have his contact information available.	

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	nce from the Pre-registration website ²	Additional guidance for petroleum substances ³
or vei	sification if the substance is carcinogenic, mutagenic or toxic to reproduction category 1 or 2 ry toxic to aquatic organisms which may cause long term adverse effects in the aquatic onment (R50/53)	
o In	accordance with the Classification and Labeling Directive (67/548/EEC)	
Further	information	
	s and web pages below help you to understand the topics covered and/or provide access to ools. The [en]-icon indicates that the linked material is available only in English.	
General i	information & training material	
	egistration Q&A [en](192 kb) is a compilation of general, IUCLID 5 and REACH-IT related tions and answers.	
to ead and 1	CS number (European Inventory of Existing Chemical Substances) is a registry number given ch chemical substance commercially available in the European Union between 1 January 1971 8 September 1981. The inventory was created by Directive 67/548/EEC concerning the ing of dangerous substances	
the su public (http:/	cumber -The EC-number, i.e. the EINECS, ELINCS or NLP number, is the official number of ubstance within the European Union. The EC-number can be obtained from the official cations of EINECS, ELINCS and NLP the website of the European Chemicals Bureau //ecb.jrc.it) in the sub-section "ESIS" The EC-number consists of 7 digits of the type x1x2x3-x6-x7. The first digit is defined by the list to which the substance belongs (EINECS, ELINCS NLP).	
	INECS= European INventory of Existing Commercial chemical Substances is available in the European chemical Substances Information System (ESIS)	
o NI	LP= no-longer polymer". The list of "no-longer polymer" substances is available in ESIS	
o El	LINCS = European List of Notified Chemical Substances	
Guidance	e	
	rical Steps for Pre-registration guide is a hands-on guide for companies preparing for pre-tration 🚨	

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Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
Guidance for identification and naming of substances in REACH endocument describes how to name and identify a substance under REACH:	
Section 3. Framework for substance identification in Reach	
o Section 4. Guidance for substance identification and naming in REACH	
Guidance on data sharing document describes the registration and data sharing mechanisms for phase-in and non phase-in substances under REACH:	
o <u>Section 3. Pre-registration</u>	
IT Tools	
REACH IT Portal enis the tool to be used for submitting pre-registration files and other data to ECHA.	
Legislation	
REACH Regulation	
Art. 4 - General provisions - third party representative	
Art 8 - Only representative of a non-community manufacturer	
<u>Directive 67/548/EEC</u> - Classification and Labelling of hazardous substance	
B-2) Sub-sub-page "IUCLID 5"	
http://echa.europa.eu/pre-registration/prepare/IUCLID5 en.asp	
Prepare your substance in IUCLID 5	= Option 2
The creation of a substance dataset in IUCLID 5 includes the definition of the substance identification and provision of the legal entity information . Substances listed in the EC inventory can be downloaded from the IUCLID web site and imported into your IUCLID 5 installation.	A list of CAS RNs/EINECS numbers has been posted on the CONCAWE website that CONCAWE member companies have identified as suitable identifiers for traded (imported) petroleum substances.

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ECHA ¹ Guidance from the Pre-registration website ²	CONCAWE Additional guidance for petroleum substances ³
Detail advice on substances creation in IUCLID 5 is available in the IUCLID 5 User's manual on the IUCLID 5 website.	petroleum substances
IUCLID 5 Pre-registration plug-in	
The IUCLID 5 software as such does not include the possibility to create pre-registration files. However, you can add a plug-in to your IUCLID 5 installation that can generate the required XML files , which you can use to pre-register. The pre-registration plug-in can generate files for a single substance or for several substances (bulk pre-registration).	
Further information	
Documents and web pages below help you to understand the topics covered and/or provide access to relevant tools. The en-icon indicates that the linked material is available only in English.	
General information & training material	
Pre-registration Q&A	
IUCLID 5 training page	
Guidance	
Practical Steps for Pre-registration guide is a hands-on guide for companies preparing for pre-registration	
Guidance for identification and naming of substances in REACH endocument describes how to name and identify a substance under REACH:	
Section 3. <u>Framework for substance identification in Reach</u>	
Section 4. <u>Guidance for substance identification and naming in REACH</u>	
Guidance on data sharing endocument describes data sharing mechanisms for phase-in and non phase-in substances under REACH:	

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Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
o Section 3. <u>Pre-registration</u>	
IT Tools	
REACH IT Portal enis the tool to be used for submitting pre-registration files and other data to ECHA.	
IUCLID 5 website	
IUCLID 5 plug-in makes it easy to enter the required data from IUCLID 5 to REACH-IT for submission of a pre-registration file	
XML format	
IUCLID 5 leaflet engives an overview of the IUCLID 5 IT tool.	
Legislation	
REACH Regulation	
Art. 111 - Formats and software for submission of information to the Agency	
B-3) Sub-sub-page "Other software"	
http://echa.europa.eu/pre-registration/prepare/othersoftware en.asp	
Prepare your substance files in your preferred software for	= Option 3
submission in XML format	A tool "Excel to XML" has been developed by CONCAWE and Cefic and is available free of charge on the CONCAWE Internet website (http://www.concawe.org/Content/Default.asp?PagelD=480).
Pre-registrants who do not want to enter a pre-registration manually online or use IUCLID 5 can prepare for a pre-registration by using any software that can generate XML files that complies with the format specified by ECHA.	A list of CAS RNs/EINECS numbers has been posted on the CONCAWE website that CONCAWE member companies have identified as suitable identifiers for traded (imported) petroleum

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	substances.
The XML format can be downloaded from the IUCLID 5 website.	
Pre-registration XML format	
A pre-defined file format is essential for XML files to be imported to the REACH-IT system to ensure that the submitted pre-registration data is valid and can be correctly entered to the pre-registration database. The XML-files generated by a third-party-software will be in the same format as those generated by the IUCLID 5 pre-registration plug-in.	
Further information	
Documents and web pages below help you to understand the topics covered and/or provide access to relevant tools. The en-icon indicates that the linked material is available only in English.	
General information & training material	
Pre-registration leaflet	
Pre-registration Q&A en (\$\mathbb{E}\$192 kb) is a compilation of general, IUCLID 5 and REACH-IT related questions and answers.	
Guidance	
Guidance for identification and naming of substances in REACH endocument describes how to name and identify a substance under REACH. The document is currently being translated. The translations are foreseen to be published in autumn 2008.	
Section 3. Framework for substance identification in Reach	
Section 4. Guidance for substance identification and naming in REACH	
Guidance on registration endocument describes the registration and data sharing mechanisms for phase-in and non phase-in substances under REACH:	
Section 2.2 Main principles of pre-registration of phase-in substances	
o Section 1.7 When to register?	

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ECHA ¹	ROMRAWIA
	concawe
Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
Guidance on data sharing endocument describes data sharing mechanisms for phase-in and non phase-in substances under REACH: Section 3. Pre-registration	
IT Tools	
REACH IT Portal	
IUCLID 5 website enis the access point to download the software. It contains all support documents, training material and access to IUCLID 5 Service Desk.	
XML format enthat can be used to generate export files for data exchange with REACH-IT	
Legislation	
REACH Regulation	
Art. 111 - Formats and software for submission of information to the Agency	
Further information	
Documents and web pages below help you to understand the topics covered and/or provide access to relevant tools. The en-icon indicates that the linked material is available only in English.	
General information & training material	
Pre-registration leaflet	
Pre-registration Q&A en (\$\mathbb{E}\$192 kb) is a compilation of general, IUCLID 5 and REACH-IT related questions and answers. Translated versions of the document will be available shortly.	
EC-number -The EC-number, i.e. the EINECS, ELINCS or NLP number, is the official number of the substance within the European Union. The EC-number can be obtained from the official publications of EINECS, ELINCS and NLP the website of the European Chemicals Bureau (http://ecb.jrc.it) in the sub-section "ESIS" The EC-number consists of 7 digits of the type x1x2x3-x4x5x6-x7. The first digit is defined by the list to which the substance belongs (EINECS, ELINCS and NLP).	A list of CAS RNs/EINECS numbers has been posted on the CONCAWE website that CONCAWE member companies have identified as suitable identifiers for traded (imported) petroleum substances.
o EINECS= European INventory of Existing Commercial chemical Substances is available in the	

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ECHA ¹ Guidance from the Pre-registration website ²	CONCAW® Additional guidance for petroleum substances ³
European chemical Substances Information System (ESIS)	
NLP= no-longer polymer". The list of "no-longer polymer" substances is available in ESIS	
ELINCS = European List of Notified Chemical Substances	
Guidance	
Practical Steps for Pre-registration guide is a hands-on guide for companies preparing for pre-registration E.	
Guidance for identification and naming of substances in REACH endocument describes how to name and identify a substance under REACH:	
Section 3. Framework for substance identification in Reach	
 Section 4. Guidance for substance identification and naming in REACH 	
Guidance on registration endocument describes the registration and data sharing mechanisms for phase-in and non phase-in substances under REACH. The document is currently being translated. The translations are foreseen to be published in autumn 2008.	
 Section 2.2 Main principles of pre-registration of phase-in substances 	
o Section 1.7 When to register?	
Guidance on data sharing endocument describes data sharing mechanisms for phase-in and non phase-in substances under REACH:	
o Section 3. Pre-registration	
IT Tools	
REACH IT Portal	
IUCLID 5 website	
Legislation	

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Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
REACH Regulation	
Art. 111 - Formats and software for submission of information to the Agency	
C) Sub-page "Account creation"	
http://echa.europa.eu/pre-registration/createaccount_en.asp	
Company Account in REACH-IT is essential for pre- registration	See the step by step guidance on the CONCAWE website.
A pre-registration can only be carried out electronically via the REACH-IT portal on the ECHA website. Before you start pre-registering substances, you need to sign-up and create an account for your company in REACH-IT.	
Signing up your company is a simple process. You will be guided through the following steps:	
Create a REACH-IT account	
Provide company information	
Enter your company billing information for later use during registration	
Add information about contact persons within the company	
Validate the entered data	
You can provide your company information either:	
by uploading it to REACH-IT if you have a Legal Entity definition file (LEO) in IUCLID 5, or	
directly entering it in the REACH-IT application	
When the first user of your company has signed up, he becomes the account manager for your company in REACH-IT. He can create additional user accounts for other users in the company and define their user profiles.	
Further information	
Documents and web pages below help you to understand the topics covered and/or provide access to	

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ECHA ¹ Guidance from the Pre-registration website ²	CONCAW® Additional guidance for petroleum substances³
relevant tools. The en-icon indicates that the linked material is available only in English.	
IT Tools	
REACH IT Portal en is the tool to be used for submitting pre-registration files and other data to ECHA.	
REACH_IT Training material will be made available by 1 June 2008.	
REACH_IT User Guide will be made available by 1 June 2008.	
IUCLID 5 website	
IUCLID 5 End User Manual	
D) Sub-page "Submission"	
http://echa.europa.eu/pre-registration/submission_en.asp	
REACH-IT guides you through pre-registration steps	
A pre-registration can only be carried out electronically via the REACH-IT portal on the ECHA website. To ensure an easy submission of your files please take the necessary steps to have all required information in hand before you enter the REACH-IT pre-registration module.	
You can submit your pre-registration by either:	
manually entering online the required data in REACH-IT,	Option 1: This is the recommended tool for pre- registering a small number of petroleum substances
using the pre-registration plug-in of IUCLID 5 to generate an XML file and import it to REACH-IT for submission, or	Option 2: This is the recommended tool for "bulk uploading" of pre-registration information that has already been created in IUCLID 5, i.e. the submission of pre-registration XML files for a large

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	number of substances.
using your company IT system to create an XML file and import it to REACH-IT for submission	Option 3: This is the recommended tool for "bulk uploading" of pre-registration information that has not yet been created in IUCLID 5, i.e. the submission of pre-registration XML files for a large number of substances.
	A tool "Excel to XML" has been developed by CONCAWE and Cefic and is available free of charge on the CONCAWE Internet website (http://www.concawe.org/Content/Default.asp?PagelD=480).
The XML file specifications are available on the IUCLID 5 website.	Note: The XML specifications are not sufficient to guarantee the generation of XML files compliant with REACH-IT (e.g. some field validations are not described in these specifications).
If you need to pre-register only a few substances and you are not currently using IUCLID 5, an on-line pre-registration via REACH-IT could be your preferred option. Pre-registration using IUCLID 5 or the XML option may be more practical for companies who will pre-register many chemical substances. These options allow a submission of pre-registration information for several substances defined by their EC number in a single file.	Both the IUCLID5 plug-in for pre-registration and the Excel to XML tool will generate a pre-registration XML file. The use of XML files (instead of online pre-registration) is the superior option for controlling, tracking and updating pre-registrations. This is independent of the number of substances to be registered!
	Therefore even for a relatively small number of substances options 2 and 3 may be preferable.
D-1) Sub-sub-page "Online"	
http://echa.europa.eu/pre-registration/submission/manually_en.asp	
Enter and submit your pre-registration online	= Option 1
An entry of pre-registration information online consists of the following seven steps:	
Entry of the substance identification	A list of CAS RNs/EINECS numbers has been

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ECHA ¹ Guidance from the Pre-registration website ²	Additional guidance for petroleum substances posted on the CONCAWE website that CONCAWE member companies have identified as suitable identifiers for traded (imported) petroleum substances.
Entry of the identification of similar substances if applicable	Such information is not mandatory and in the case of petroleum substances not necessary, since CONCAWE has already carried out extensive work on grouping substances in "substance categories" for the purpose of read-across. A list of these categories will be posted on the CONCAWE website.
Entry of the envisaged registration deadline and tonnage band	
Selection of a contact person if relevant or identification of a Third Party Representative if relevant	
Entry of any additional remarks for the other pre-SIEF participants	
Validation and submission of the pre-registration	
Online pre-registration is possible for phase-in substances with or without an EC number. It can never cover more than one substance at a time.	In other words, bulk uploading of pre-registration information is NOT possible for substances without an EC (EINECS) number. In the case of petroleum substances this could apply for polymerisates, provided the conditions of Article 3(20)(b) have been met (CAS RNs 64741-72-6 and 68783-11-9 as members of the naphtha category; CAS RNs 64741-71-5 and 68783-10-8 as members of the gas oils categories).
All pre-registration information except the substance identification can be updated at a later stage. This allows you to fill in for example the identifiers of relevant substances after you have submitted your pre-registration file. Pre-registrations can be inactivated until 1 December 2008 but they cannot be deleted.	
Entering pre-registration information manually may take about 10 min per substance.	
Further information	

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Documents and web pages below help you to understand the topics covered and/or provide access to relevant tools. The en-icon indicates that the linked material is available only in English.	
IT Tools	
REACH IT Portal en is the tool to be used for submitting pre-registration files and other data to ECHA.	
D-2) Sub-sub-page "Import XML"	
http://echa.europa.eu/pre-registration/submission/importxml_en.asp	
Import your pre-registration file in XML format for submission	= Option 2
You can submit your pre-registration as a bulk upload by selecting the bulk upload page in REACH-IT. On this page you will be asked to locate the pre-prepared XML file from your computer. Then you can upload and submit it. The submission of a bulk file will generate a report from which the user can see if any errors were encountered during the process.	
An XML-pre-registration can only be conducted on phase-in substances identified with an EC number. Bulk files may contain one or more substances.	
All pre-registration information except the substance identification can be updated at a later stage, and this allows you to fill in for example the identifiers of relevant substances after you have submitted your pre-registration file. Pre-registrations can be inactivated until 1 December 2008 but they cannot be deleted.	
Uploading and submitting a bulk pre-registration file prepared with either IUCLID 5 or your company IT-tool may take about 15 minutes.	
Further information	
Documents and web pages below help you to understand the topics covered and/or provide access to relevant tools. The en-icon indicates that the linked material is available only in English.	
General information & training material	
IUCLID 5 training page in the Get Support section of the IUCLID 5 website provides video	

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Guidance from the Pre-registration website ²	Additional guidance for
	petroleum substances ³
tutorials and presentations that will help you to get started in using the software.	
IT Tools	
REACH IT Portal enis the tool to be used for submitting pre-registration files and other data to ECHA.	
IUCLID 5 website	
E) Sub-page "Pre-SIEF"	
http://echa.europa.eu/pre-registration/pre-SIEF en.asp	
Pre-SIEF (Substance Information Exchange Forum)	
The REACH-IT module will allow a pre-registrant to see who else has pre-registered the same substance. The information is displayed on a substance specific pre-SIEF page. This page provides the following information:	
General information:	
substance identification	
identification of similar substances, if applicable (substances which may facilitate the risk assessment of the substance)	
Company specific information:	
contact information as specified during pre-registration (the third party representative or the company contact person or the company's general contact details)	
the envisaged registration deadline	
the pre-registration number	
the remarks for the other pre-SIEF participants	
Companies who have pre-registered a substance will automatically become listed on the pre-SIEF page	

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	concawe
Guidance from the Pre-registration website ²	Additional guidance for
	petroleum substances ³
of this substance.	
To initiate discussions after pre-registration, a pre-registrant can volunteer on the pre-SIEF page to become SIEF formation facilitator.	CONCAWE has volunteered as the SIEF Formation Facilitator (SFF) for all relevant petroleum substances.
ECHA will publish by 1 January 2009, a list of pre-registered substances on its website. The list will comprise of all substances that have been pre-registered by 1 December 2008. For each substance the following information is displayed:	It must be emphasised that the full composition of a SIEF will only be known after 1 January 2009. However, even after 1 January 2009 it is possible that a late pre-registrant joins a SIEF.
	Before 1 January 2009 the Pre-SIEF webpages in the ECHA's REACH IT system will provide snapshots of those who have already pre-registered. The information in the Pre-SIEF webpages shows more data than just the identity of the pre-registrants, but it is obviously only available to pre-SIEF members, i.e. legal entities that have already pre-registered.
Substance identification: EINECS number, CAS number and names of the substance	
Substance identification of the similar substances, if applicable	
The first envisaged registration deadline	
Further information	
Documents and web pages below help you to understand the topics covered and/or provide access to relevant tools. The en-icon indicates that the linked material is available only in English.	
General information & training material	
SIEF Facilitator - REACH IT will allow Pre-Registrants to volunteer to be "SIEF Formation Facilitator" by identifying this at pre-registration. The SIEF Facilitator initiates and conducts discussions after pre-registration, and facilitates the exchange of the information and data required to form a SIEF. (See Section 4.5.2 of the data sharing guidance).	CONCAWE has volunteered as the SIEF Formation Facilitator (SFF) for all relevant petroleum substances.
Guidance	
Guidance on data sharing endocument describes data sharing mechanisms for phase-in and non	

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phase-in substances under REACH:	petroleum substances
Section 4. Formation of substance information exchange forum (SIEF)	
Legislation	
REACH Regulation	
Art. 28.4 Publication of a list of pre-registered substances	
F) Sub-page "SIEF"	
http://echa.europa.eu/pre-registration/SIEF en.asp	
Substance Information Exchange Forum (SIEF)	
A SIEF (Substance Information Exchange Forum) will be formed for each pre-registered substance with the same identity. The participants in a SIEF are all pre-registrants (potential registrants, (early) registrants and the data holders). A SIEF has no prescribed legal form, but is a forum to share data and other information on a given substance. Participants in a SIEF are free to organize themselves in consortia or other forms of agreements as they see fit to carry out their obligations under REACH.	CONCAWE has volunteered as the SIEF Formation Facilitator (SFF) for all relevant petroleum substances. CONCAWE will offer a legal framework for the mandatory as well as the voluntary collaboration. The latter concerns the possibility for registrants to extend the collaboration beyond the legal minimum. For further information on CONCAWE's intentions see section "Collaboration with registrants that are not CONCAWE Member Companies" on the CONCAWE Internet website: http://www.concawe.org/Content/Default.asp?PageID =469
After 1 January 2009 a SIEF is formed when pre-registrants have agreed in a pre-SIEF that they manufacture or import the same substance. SIEF members need to nominate a Lead Registrant. They will share and assess data and prepare common parts of the registration (joint submission). Any SIEF member receiving a request for information that involves vertebrate tests must respond within 1 month. Compensation for sharing data is agreed among the respective SIEF members.	It must be emphasised that the role of the SIEF Formation Facilitator (SFF) and of the Lead Registrant originate from two completely different concepts. 1. The SFF manages communication and collaboration among SIEF participants. 2. The Lead Registrant submits joint information

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	(at least the legally required minimum as defined in Article 11 of REACH).
	CONCAWE member companies will volunteer for the role of the Lead Registrant.
All SIEF Participants shall:	CONCAWE has volunteered as SIEF Formation
React to requests for information from other participants	 Facilitator (SFF) and will manage the SIEF processes. For further information on CONCAWE's
Provide other participants with existing studies upon request	intentions see section "Collaboration with registrants that are not CONCAWE Member
Potential Registrants shall:	Companies" on the CONCAWE Internet website: http://www.concawe.org/Content/Default.asp?PageID
Request missing information from other SIEF participants	=469
Collectively identify needs for further studies to comply with registration requirements	CONCAWE intends to establish collaboration of all pre-registrants of substances belonging to the
Make arrangements to perform the identified studies	same category of petroleum substances (e.g. the category "Low Boiling Point Naphthas/Gasoline). The SIEFs of substances in the same category will be combined to "Super-SIEFs".
Agree on classification and labelling	
Data Holders:	
Must respond to any query from potential registrants if they hold the data relating to this query	
Are not entitled to request data	
SIEFs shall remain operational until 1 June 2018	
Further information	
The information here below helps you to understand the topics covered and provides access to relevant documents, tools and web pages. The en-icon indicates that the linked material is available only in English.	
General information & training material	
REACH FAQ enthe Frequently Asked Questions on REACH cover issues raised frequently by industry but also questions on very specific aspects of REACH, which ECHA feels will be interesting.	

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to the stakeholders.	
 Data-holders - Any person holding information/data relevant to a phase-in substance and willing to share these data. They can express their intention of participating to exchange of information with the registrants to ECHA. Data holders must respond to any query from potential registrants if they hold data relating to this query. 	
 Lead registrant is the registrant acting with the agreement of the other assenting registrants. The lead registrant submits the "joint submission". In case of a phase-in substance, the lead registrant will be one of the registrants who plans to submit his registration file before the first registration deadline. In other words, the lead registrant is likely to be a Manufacturer or Importer that has to register by the first registration deadline. 	
Guidance	
Guidance on data sharing endocument describes data sharing mechanisms for phase-in and non phase-in substances under REACH:	
o o Section 4. Formation of substance information exchange forum (SIEF)	
Legislation	
REACH Regulation	
Art. 29 Substance Information Exchange Fora	
Art. 30 Sharing of data involving test	
G) Sub-page "Registration"	
http://echa.europa.eu/pre-registration/registration_en.asp	
Registration	
When potential registrants in a SIEF have shared and assessed the available data they will prepare the common parts of their registration file, a so called joint submission. The other parts of their registration file will have to be submitted separately. A joint submission consists of:	CONCAWE has volunteered as the SIEF Formation Facilitator (SFF) for all relevant petroleum substances.
	CONCAWE intends to establish collaboration of all

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	pre-registrants of substances belonging to the same category of petroleum substances (e.g. the category "Low Boiling Point Naphthas/Gasoline). The SIEFs of substances in the same category will be combined to "Super-SIEFs".
	CONCAWE will offer a legal framework for the mandatory as well as the voluntary collaboration. The latter concerns the possibility for registrants to extend the collaboration beyond the legal minimum. For further information on CONCAWE's intentions see section "Collaboration with registrants that are not CONCAWE Member Companies" on the CONCAWE Internet website: http://www.concawe.org/Content/Default.asp?PageID=469 Specific guidance for Lead Registrants and "coregistrants" of petroleum substances (Who submits exactly what and when?) will be issued by CONCAWE during the course of 2009.
the classification and labelling	
Study Summaries	
Robust study summaries	
Proposal of testing where listed in the relevant annexes	
Whether the relevant information (Art. 10 (a)) has been reviewed by an assessor (on a voluntary basis)	
It may also contain if companies so decide:	
Guidance of safe use of the substance	This information will be part of the comprehensive package that CONCAWE intends to make available to all registrants of relevant petroleum substances.
Chemical Safety Report when required	
Indication as to which of the information has been reviewed by an assessor.	

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Guidance from the Pre-registration website ²	Additional guidance for petroleum substances ³
The company acting as a Lead Registrant for the substance will submit the joint submission. The joint submission is made on behalf of the other registrants.	
The lead registrant has to specify:	
Their names, address, phone number, fax number and e-mail address	
Parts of the registration which apply to other registrants	
Any other registrant shall identify the Lead Registrant submitting on his behalf specifying:	
His name, address, phone number, fax number, and e-mail address	
Parts of the registration which are submitted by the Lead Registrant	
Each registrant needs to refer in his own registration dossier to the Lead Registrant acting on his behalf. The company specific information that must be submitted separately consists of:	
Identity of manufacturer or importer of the substance	
Detailed information on the identity of the substance	
 Information on the manufacture and use(s) of the substance including all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories 	
for substances in quantities of 1 to 10 tonnes, exposure information	
After receiving a submission number from the European Chemicals Agency each company must pay a relevant registration fee. A registration is complete when the registration fee has been received by the Agency. Only then a registration number will be sent to the registrant.	
Further information	
The information here below helps you to understand the topics covered and provides access to relevant documents, tools and web pages. The en-icon indicates that the linked material is available only in English.	
General information & training material	
REACH - The new EU chemicals legislation leaflet gives an overview of the REACH requirements	

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to EU comp	anies.	
Information regulation in	for exporters to the European Union leaflet en gives an overview of the REACH relation to non-EU companies.	
	en The Frequently asked questions on REACH cover issues raised frequently by also questions on very specific aspects of REACH, which ECHA feels will be interesting holders.	
lead registra will be one o deadline. In	ant is the registrant acting with the agreement of the other assenting registrants. The ant submits the "joint submission". In case of a phase-in substance, the lead registrant of the registrants who plans to submit his registration file before the first registration other words, the lead registrant is likely to be a Manufacturer or Importer that has to he first registration deadline.	
Guidance		
phase-in an	n registration endocument describes the registration and data sharing mechanisms for d non phase-in substances under REACH. The document is currently being translated. ions are foreseen to be published in autumn 2008.	
o <u>1.6.3 Su</u>	bstances exempted from the REACH Regulation	
o <u>1.6.4 Su</u>	bstances exempted from registration	
o <u>1.6.5 Su</u>	bstances regarded as registered	
Guidance or	n data sharing	
o <u>Section</u> 8	8 Registration: Joint submission	
IT Tools		
REACH IT FECHA.	Portal enis the tool to be used for submitting pre-registration files and other data to	

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