

Guidance for Industry and other stakeholders

Visit of a delegation from the Brazilian
Ministry of Environment and Institute of
Environment and Renewable Natural
Resources to ECHA
15 April 2013

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Team leader, Guidance Team; Unit A2 - Guidance
and Forum Secretariat
European Chemicals Agency



What does REACH say?

- ECHA
 - Provides **technical and scientific** guidance and tools for the operation of REACH for:
 - Industry, especially SMEs
 - Other stakeholders
 - (Provides **support to the helpdesks**)
 - Provides **assistance to registrants**
 - Provides **explanatory information** on REACH to other stakeholders

...and what does CLP say?

- ECHA
 - Provides **technical and scientific** guidance and tools for the operation of CLP for industry
 - Provides **technical and scientific** guidance for the operation of CLP for competent authorities
 - Provides **assistance to helpdesks** established by Member States

...and what does the Biocidal Products Regulation say?

- ECHA
 - Provides **technical and scientific** guidance and tools for the operation of this regulation for the application of this Regulation by the Commission and Member States' competent authorities and **providing support to national helpdesks**
 - Provides advice and assistance to applicants, in particular to SMEs, for the approval of an active substance or its inclusion in Annex I to this Regulation or for a Union authorisation;
 - Prepares explanatory information on this regulation

...and what does the PIC Regulation say?

- ECHA
 - Provides with the agreement of the Commission and after consultations with Member States, assistance and technical and scientific guidance and tools for the industry in order to ensure the effective application of this Regulation;
 - Provides with the agreement of the Commission, the designated national authorities of the Member States with assistance and technical and scientific guidance in order to ensure the effective application of this Regulation

Partners of the ECHA Secretariat

- Non-institutional partners (accredited stakeholders)
- ECHA Committees & Forum
- European Commission and MSCAs
- Third country representatives invited by the ECHA Management Board

Guidance

- To assist stakeholders in implementing their obligations – but not legally binding
 - Historically, first versions were developed by the Commission and agreed with industry, NGOs, MSCAs and ECHA (RIPs) to ensure broad support of all important players
 - Guidance management has been handed over to ECHA and today new (versions of these) guidance documents are developed by ECHA itself

ECHA Guidance shows the “safest” way for industry to implement the Regulations within ECHA’s remit.

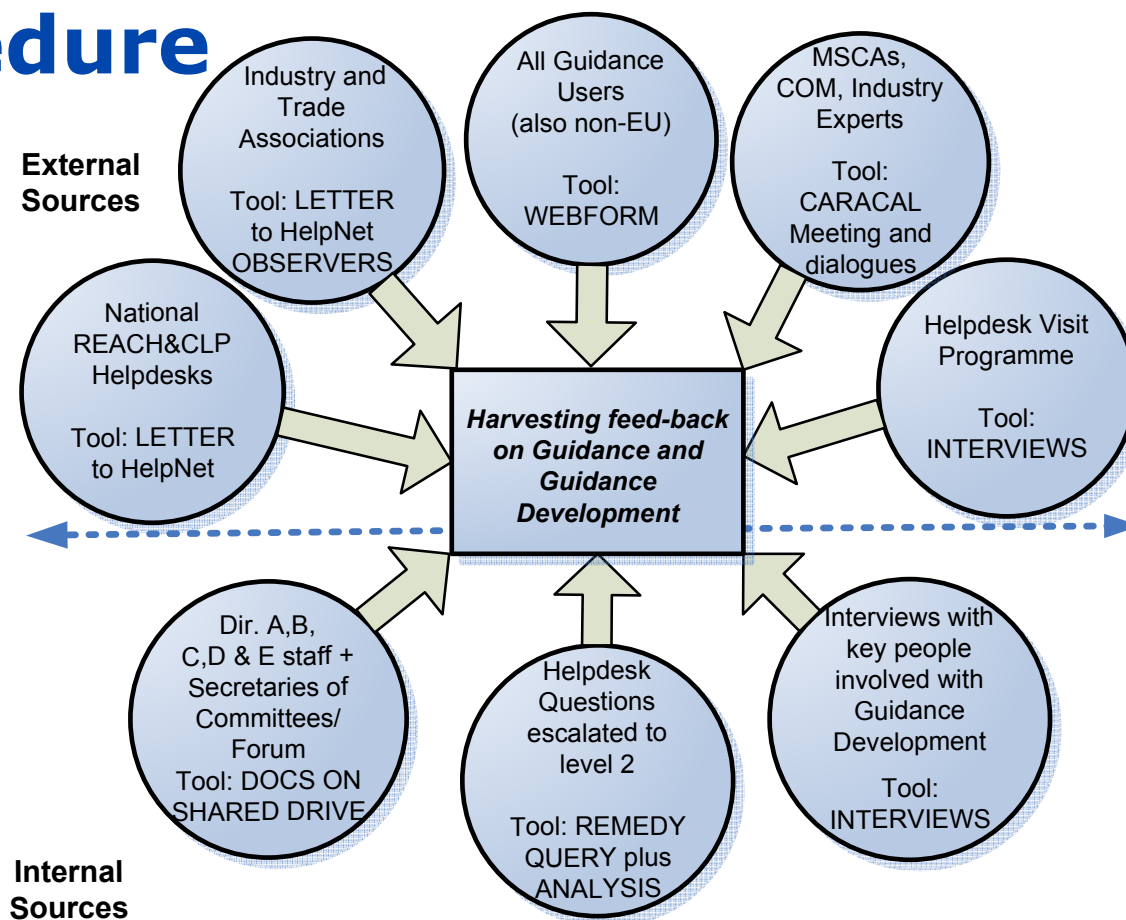
Consultation procedure



How are ECHA Partners involved?

1. Initiation of the consultation procedure
2. Consultation of ECHA partners
 - Partner Expert Group
 - Committees and/or the Forum
 - European Commission and the MSCAs
3. Main interim documents prepared at different stages of the consultation process published on the ECHA website

1. Initiation of the consultation procedure



1. Initiation of the consultation procedure (web-form)

Feedback on ECHA Guidance Documents

As a user of the ECHA [Guidance Documents](#), you are invited to provide your comments on your experience of working with them. ECHA is seeking to continually improve the service it provides to its customers and the quality of the guidance that is available on REACH. For any enquiries on REACH or press enquiries please [contact ECHA](#).

Comments would be welcomed in relation to:

- a) the "accessibility" of guidance documents e.g. the ease of finding the information you need;
- b) the specific guidance documents mentioned below by selecting the guidance document and appropriate chapter of the guidance document; or
- c) on any other guidance document not specified in (b) or to make general remarks.

Comments are collected within the framework of guidance update and revision. Please note ECHA cannot reply to these comments.

Compulsory fields are marked with an asterisk (*)

Please provide us with your contact information.

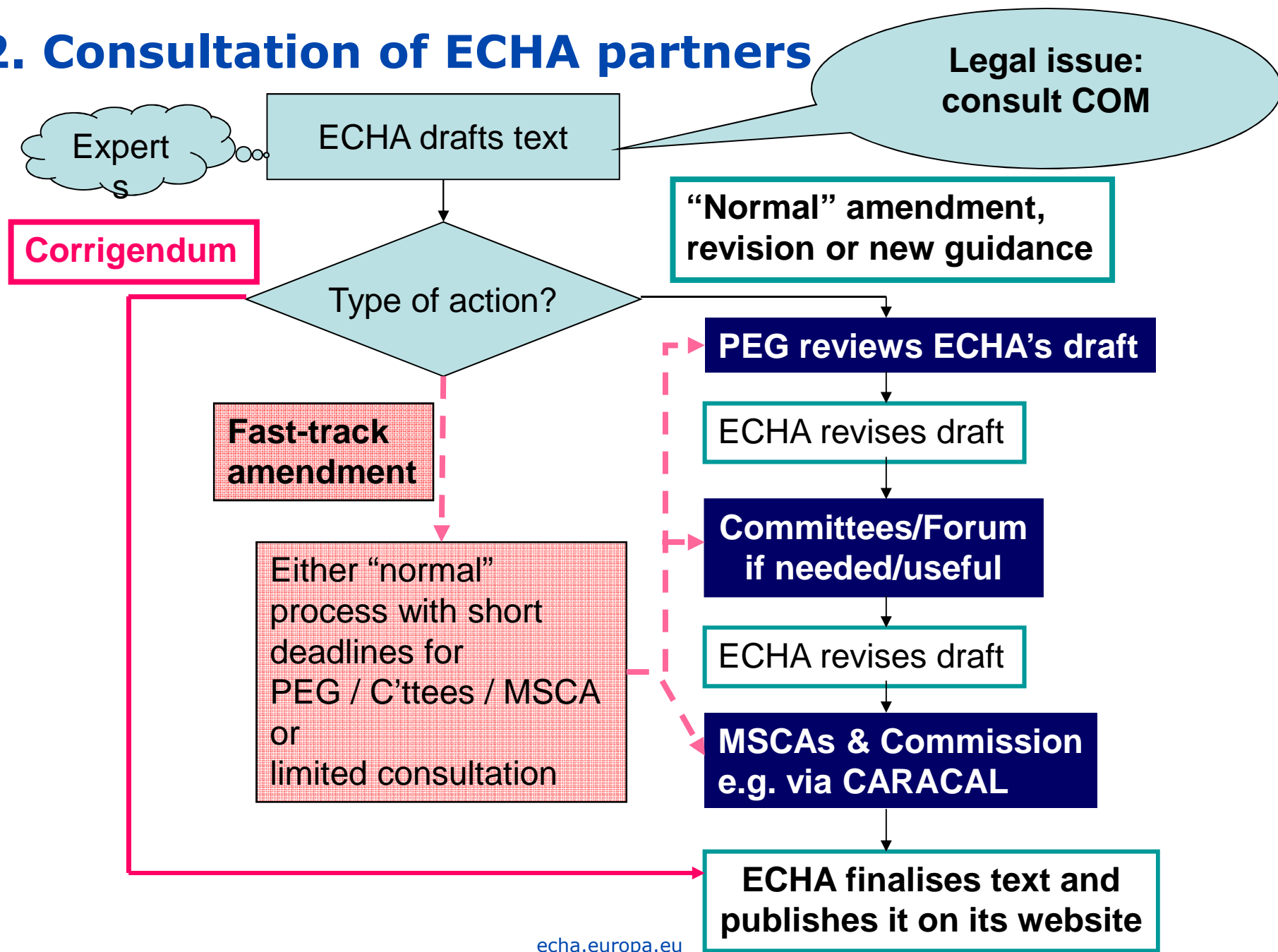
Title	Select ▼
* First Name	<input type="text"/>
* Last Name	<input type="text"/>
* Email	<input type="text"/>
* Country	Please select country.. ▼
Name of company	<input type="text"/>

Please provide some information on your organisation.

* Please provide the size of company or organisation	<input type="radio"/> less than 250 employees <input type="radio"/> 250 employees or more
* Your role under REACH	Please select ▼
If you selected "Other", please specify	<input type="text"/>
My comments are related to:	Accessibility ▼

<https://comments.echa.europa.eu/comments cms/FeedbackGuidance.aspx>

2. Consultation of ECHA partners



Consultation of ECHA partners

- Partner Expert Group “PEG”
 - Nominations by MSCAs, Stakeholder Organisations or ECHA
 - Established by ECHA
 - A meeting will be convened as part of the consultation process
- Committees and/or Forum
 - ED will be advised by the ECHA Secretariat/PEG on their involvement
 - To avoid disagreement at the end
 - To feed in top-level expertise
- Consultation of MSCAs and the Commission
 - Obligatory for amendments, revisions and new guidance

Outcome of a consultation

- A stakeholder consultation
 - Involves all stakeholders, including Commission, MSCAs, industry, enforcement authorities – **and is transparent**
 - Should meet deadlines while achieving buy-in
 - All efforts will be made to reach consensus for achieving the basic objective:

Guidance that is acceptable to

- **those applying it,**
- **those using it, and**
- **those enforcing REACH and CLP**

3. Publication of main interim (and final) documents

- The results of consultation of the Partner Expert Group “PEG”, Committees and/or Forum and CARACAL can be seen on the ECHA website:
 - Comments made
 - ECHA response – including reasons when rejected
 - Resulting draft text for next stage of consultation and final text of the guidance after completion of the process.

How to find ECHA guidance and view consultation status on new guidance



ECHA website – (live hyperlink?)

- <http://echa.europa.eu/>

ECHA website – (em Português!):

- <http://echa.europa.eu/pt/>

Guidance = (part of) Support



The screenshot shows the ECHA (European Chemicals Agency) homepage. At the top, there is a navigation bar with links: Document library, News and Events, Press, Contact, and a language dropdown set to English. Below this is the ECHA logo and a search bar with a magnifying glass icon and a link to 'Advanced search >'. A horizontal menu contains several items: About Us, Regulations, Addressing Chemicals of Concern, Information on Chemicals, Chemicals in our Life, and Support. The 'Support' item is circled in red, and a red arrow points to it from the right. Below the menu, there is a section for 'ECHA > Homepage' with social media icons and a visitor count of 330. The main content area is divided into two columns. The left column features a news alert dated 13 December 2012 titled 'ECHA starts publishing dossier evaluation decisions', which states that from this date onwards, ECHA's dossier evaluation decisions on compliance checks and examination of testing proposals will be available on the Agency's website. Below this are sections for 'News Alerts' and 'Press Releases'. The 'News Alerts' section contains two items: one dated 07 December 2012 titled 'SEAC concludes on scientific opinions for two restriction proposals' and another dated 07 December 2012 titled 'RAC adopts seventeen scientific opinions'. The 'Press Releases' section contains two items: one dated 12 December 2012 titled 'ECHA to start publishing comments during CLH public consultations' and another dated 04 December 2012 titled 'Preliminary results of enforcement project point to high rates of non-compliance among chemical formulators'. The right column features a 'Search for Chemicals' section with a checkbox for 'I have read and I accept the legal notice' and a search input field. Below this is a blue banner for 'ACT NOW! REACH 2013' with a magnifying glass icon. Further down are several links: Document Library, REACH IT, IUCLID 5, CHESAR, Identify your obligations, ECHA-term, and Publications. At the bottom right, there is a link to 'Committee for Socio-Economic Analysis Registered Substances'.

Document library | News and Events | Press | Contact | English

ECHA
EUROPEAN CHEMICALS AGENCY

Advanced search >

About Us | Regulations | Addressing Chemicals of Concern | Information on Chemicals | Chemicals in our Life | **Support**

ECHA > Homepage

13 December 2012
ECHA starts publishing dossier evaluation decisions
From the 13 December 2012 onwards, ECHA's dossier evaluation decisions on compliance checks and examination of testing proposals will be available on the Agency's website.

Search for Chemicals
☐ I have read and I accept the legal notice
Name, EC or CAS No

ACT NOW!
REACH 2013

> Document Library
> REACH IT
> IUCLID 5
> CHESAR
> Identify your obligations
> ECHA-term
> Publications

Committee for Socio-Economic Analysis
Registered Substances

News Alerts
07 December 2012
SEAC concludes on scientific opinions for two restriction proposals
The ECHA Committee for Socio-economic Analysis (SEAC) has concluded that it has no basis to support the Danish proposal to further restrict four already classified phthalates (DEHP, DBP, BBP, and DIBP). SEAC's opinion is based on the June Committee for Risk Assessment opinion (RAC) which said that the available data does not indicate a current risk from combined exposure to the four phthalates. The SEAC opinion therefore confirms its draft opinion of June 2012.

Press Releases
12 December 2012
ECHA to start publishing comments during CLH public consultations
Starting with the next public consultation on 18 December 2012, ECHA will publish comments received during the public consultation on proposals for Harmonised Classification and Labelling (CLH) while it is ongoing. The Agency has done this to make the consultation process more transparent and efficient. From now on, interested parties will be able to read and respond to comments submitted within the 45-day public consultation. ECHA encourages parties concerned to submit comments early during the consultation period to allow sufficient time for the public to react and provide comments.

07 December 2012
RAC adopts seventeen scientific opinions
The Committee for Risk Assessment (RAC) has adopted fifteen opinions for harmonised classification and labelling (CLH), one opinion at the Executive Director's request concerning the safety of a plant protection product (Article 77 (3)) and an opinion on the restriction proposal of Chromium VI in leather compounds.

04 December 2012
Preliminary results of enforcement project point to high rates of non-compliance among chemical formulators
The preliminary results of REACH-EN-FORCE-2 were presented to the participants of the 13th plenary meeting of the Forum which took place from 27 to 30 November 2012 in Helsinki. The project looked at the obligations of formulators of mixtures and the quality of safety data sheets (SDSs).

30 November 2012
ECHA updates its CSR illustrative example with IUCLID and Chesar data files

Guias = (uma parte do) Apoio



ECHA
EUROPEAN CHEMICALS AGENCY

Pesquisa avançada >

Acerca da ECHA | Regulamentos | Gestão de substâncias químicas que suscitam preocupação | Informação sobre substâncias químicas | Os produtos químicos na nossa vida | **Apoio**

ECHA > Apoio > Orientação sobre a implementação dos Regulamentos REACH e CRE

Orientação sobre a implementação dos Regulamentos REACH e CRE

Estes documentos foram desenvolvidos com a participação dos interessados (indústria, Estados-Membros e ONGs) no quadro de projectos geridos pela Comissão. O objectivo destes documentos é facilitar a aplicação do REACH através da descrição de boas práticas no cumprimento das obrigações.

Guias de Orientação

A lista abaixo indica todos os Guias de Orientação actual ou futuramente disponíveis, neste sítio Web. Estes documentos foram desenvolvidos com a participação dos interessados (Indústria, Estados-Membros e ONGs) no quadro de projectos geridos pela Comissão. O objectivo destes documentos é facilitar a aplicação do REACH através da descrição de boas práticas no cumprimento das obrigações.

> [Mais](#)

Fichas técnicas de orientação

A Agência Europeia dos Produtos Químicos vai publicar uma série de Fichas Informativas. As Fichas Informativas apresentam uma panorâmica geral estruturada dos documentos de orientação REACH publicados pela Agência e incluem um resumo dos aspectos mais importantes, informações bibliográficas e outras referências.

> [Mais](#)

Guias práticos

Estes documentos apresentam informações concretas sobre os requisitos dos Regulamentos REACH e CRE e sobre as melhores práticas a adotar para os cumprir.

> [Mais](#)

Formatos

Guias de orientação resumidos

The European Chemicals Agency (ECHA) is producing a series of shortened versions of the REACH Guidance Documents in order to make the corresponding Guidance Documents published by the Agency more accessible for industry.

> [Mais](#)

Procedimento de consulta

Consult the different steps of updating and developing Guidance documents.

> [Mais](#)

Identifique as suas obrigações

O Navigator é uma ferramenta que ajuda os fabricantes, os importadores, os utilizadores a jusante, os distribuidores de substâncias químicas e os produtores ou importadores de artigos a determinar as suas obrigações no âmbito do REACH.

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ECHA > Support



Support



- > [Document Library](#)
- > [Publications](#)

Guidance



- > [Guidance on REACH and CLP implementation](#)



- > [Identify your obligations](#)



- > [Practical examples of exposure scenarios](#)



- > [Information Toolkit](#)



- > [Information for Registrants](#)



- > [Small and Medium Enterprises](#)



- > [Webinars](#)



- > [ECHA Helpline](#)



- > [Frequently Asked Questions](#)

Dossier Submission Tools



- > [REACH-IT](#)



- > [IUCLID 5](#)



- > [CHESAR](#)



- > [Restriction](#)



- > [Authorisation](#)



- > [Socio-economic analysis in REACH](#)



- > [CLH](#)




- > [National Helpdesks](#)

Guidance on REACH and CLP implementation


Guidance documents aim at facilitating the implementation of REACH and CLP by describing good practice on how to fulfil the obligations. They are developed with the participation of many stakeholders: industry, Member States and NGOs.

Guidance Documents

 These documents have been developed with the participation of many stakeholders: Industry, Member States and NGOs. The objective of these documents is to facilitate the implementation of REACH by describing good practice on how to fulfil the obligations.


[Read more](#)

Guidance in a nutshell

 The European Chemicals Agency (ECHA) is producing a series of shortened versions of the REACH Guidance Documents in order to make the corresponding Guidance Documents published by the Agency more accessible for industry.

[Read more](#)

Fact Sheets

 Fact Sheets provide a structured overview of Guidance documents. They include a summary of the key aspects, bibliographic information and other references.


[Read more](#)

Consultation procedure table

 Consult the different steps of updating and developing Guidance documents.


[Read more](#)

Practical Guides

 These documents provide practical information on REACH and CLP requirements and best practice on how to fulfil them.


[Read more](#)

Identify your obligations

 With this tool you can determine your obligations under REACH and find the appropriate guidance on how to fulfil them.

[Read more](#)

Formats

 Industry and authorities can download templates here to use in the context of REACH and CLP.

[Read more](#)

Orientação sobre a implementação dos Regulamentos REACH e CRE

Estes documentos foram desenvolvidos com a participação dos interessados (Indústria, Estados-Membros e ONGs) no quadro de projectos geridos pela Comissão. O objectivo destes documentos é facilitar a aplicação do REACH através da descrição de boas práticas no cumprimento das obrigações.

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[> Mais](#)

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[> Mais](#)

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[> Mais](#)

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[> Mais](#)

Procedimento de consulta



Consult the different steps of updating and developing Guidance documents

[> Mais](#)

Identifique as suas obrigações



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[> Mais](#)

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+ Chemicals in our Life

- Support

- Guidance on REACH and
CLP implementation

> Identify your
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> Practical Guides

> Formats

> FAQs

> Information toolkit

> Webinars

> Information for
registrants

+ Dossier Submission Tools

+ Helpdesks

> Practical examples of
exposure scenarios

> Small and Medium-sized
Enterprises (SMEs)

> Restriction

Guidance on REACH

The list below contains all the **Guidance Documents** which are available, or will be available, on this website. These documents have been developed with the participation of many stakeholders: Industry, Member States and NGOs. The objective of these documents is to **facilitate the implementation of REACH** by describing good practice on how to fulfil the obligations.

Some of these documents have been or will be translated into 21 official EU languages. You can access the translations from this webpage: use the language menu on the top right corner of the page.

Search all Guidance documents

[Feedback Form](#)

Guidance on REACH

Guidance on CLP

> **Guidance on information requirements and chemical safety assessment**

> **Guidance for Annex V**

> **Guidance on registration**

> **Guidance for monomers and polymers**

> **Guidance on data sharing**

> **Guidance for identification and naming of substances under REACH and CLP**

> **Guidance on the compilation of safety data sheets**

> **Guidance on requirements for substances in articles**

> **Guidance on the preparation of an application for authorisation**

> **Guidance on Socio-Economic Analysis – Authorisation**

- + [Acerca da ECHA](#)
- + [Regulamentos](#)
- + [Gestão de substâncias químicas que suscitam preocupação](#)
- + [Informação sobre substâncias químicas](#)
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 - > [Formatos](#)

Guias de orientação relativos ao Regulamento REACH

A lista abaixo indica todos os Guias de Orientação actual ou futuramente disponíveis, neste sítio Web. Estes documentos foram desenvolvidos com a participação dos interessados (indústria, Estados-Membros e ONGs) no quadro de projectos geridos pela Comissão. O objectivo destes documentos é facilitar a aplicação do REACH através da descrição de boas práticas no cumprimento das obrigações.

Parte destes documentos já está ou estará traduzida em todas as línguas da Comunidade Europeia.

[Pesquisa em todos os guias de orientação](#)

[Formulário para comentários](#)

Guias de orientação relativos ao Regulamento REACH

Guias de orientação relativos ao Regulamento CRE

> [Documentos de orientação sobre os requisitos de informação e avaliação da segurança química](#)

> [Guia de orientação sobre o Anexo V](#)

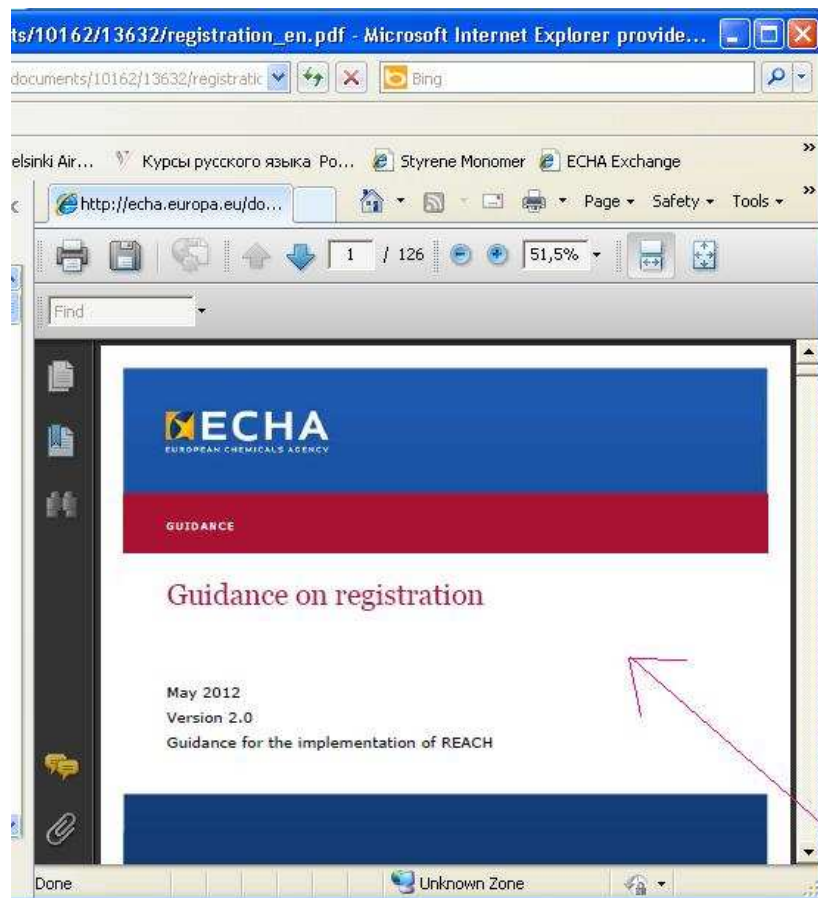
> [Guia de orientação sobre o registo](#)

> [Documento de orientação para a identificação e designação de substâncias no REACH e CRE](#)

> [Guia de orientação para monómeros e polímeros](#)

> [Guia de orientação sobre partilha de dados](#)

> [Guia de orientação sobre a elaboração de fichas de dados de segurança](#)



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ation > Guidance Documents > Guidance on REACH

REACH

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[Search all Guidance documents](#)

[Feedback Form](#)

[Guidance on CLP](#)

[Information requirements and chemical safety assessment](#)

[Annex V](#)

Guidance on registration

Reference name:	<i>Guidance on registration</i>
Description:	This document describes when and how to register a substance under REACH. It consists of two parts: one on Registration tasks and obligations and the other on the preparation of the Registration Dossier.
	download full PDF document (02.05.2012)

[Guidance for monomers and polymers](#)

Orientações sobre o registo

Maio de 2012

Versão 2.0

Orientações sobre a implementação do Regulamento REACH



Guias ao Regulamento REACH

Atualização actual ou futuramente disponíveis, neste sítio Web. Estes documentos
destinados a interessados (indústria, Estados-Membros e ONGs) no quadro de projectos
destinados a facilitar a aplicação do REACH através da descrição de boas

disponibilizada em todas as línguas da Comunidade Europeia.

[Pesquisa em todos os guias de orientação](#)

[Formulário para comentários](#)

to REACH

Guias de orientação relativos ao Regulamento CRE

requisitos de informação e avaliação da segurança química

Orientações sobre o registo

Este documento descreve quando e como se
deve registar uma substância de acordo com
o REACH. Divide-se em duas partes: uma
centra-se nas tarefas e obrigações de registo
e a outra na preparação do Dossiê Técnico.

[descarregar documento PDF](#)
Integral (Atualizado 02/05/12)

Identificação e designação de substâncias no REACH e CRE

e polímeros



The screenshot shows the ECHA website interface. At the top is the ECHA logo and a search bar. Below the logo is a navigation menu with tabs: About Us, Regulations, Addressing Chemicals of Concern, Information on Chemicals, Chemicals in our Life, and Support. The 'Support' tab is selected. Below the navigation menu is a breadcrumb trail: ECHA > Support > Guidance on REACH and CLP implementation > Consultation Procedure. To the right of the breadcrumb trail are social media icons and a '12' icon. On the left side of the page is a sidebar menu with expandable sections: About Us, Regulations, Addressing Chemicals of Concern, Information on Chemicals, Chemicals in our Life, and Support. The 'Support' section is expanded, showing sub-items: Guidance on REACH and CLP implementation, Identify your obligations, Consultation Procedure, Guidance Documents, Guidance in a Nutshell, Guidance Fact Sheets, and Practical Guides. The 'Consultation Procedure' item is selected. The main content area has the title 'Consultation Procedure' and a paragraph explaining the process: 'If ECHA identifies a need for updating existing guidance or for developing new guidance, it will prepare a corresponding draft, potentially involving external experts. Based on this draft, the consultation will follow the following steps:'. Below this are three bullet points: 'Consultation of a Partner Expert Group (PEG);', 'Consultation of ECHA's Committees and/or Forum, where relevant;', and 'Concluding consultation of the European Commission and Member States Competent Authorities via the meeting of the Competent Authorities for REACH and the CLP Regulations (CARACAL)'. A paragraph follows: 'In order to ensure that the guidance updating process will be kept transparent and open to participation by relevant partners drafts of the different consultation steps will be published on this webpage.' Below this is a link: 'More information on the "Consultation procedure on Guidance" is readily available.' At the bottom of the main content area are two icons: a clipboard with a checklist and a clipboard with a checklist and a checkmark. To the right of the first icon is the text 'Ongoing Consultations' and to the right of the second icon is the text 'Closed Consultations'.

<http://echa.europa.eu/Web/guest/support/guidance-on-reach-and-clp-implementation/consultation-procedure>

Thanks for your attention

Questions?