

How to plan your registration

Introduction

The registration process takes time from pre-registration until you successfully submit your registration dossier. The time needed depends on your exact situation, and you need to consider several factors and steps to estimate how long registration takes. We recommend that you start preparing at least one year before the deadline even in the simplest cases.

Here we present the typical steps you need to consider in your planning. They will help you to analyse your own case, and make a solid plan to register in time. The steps are based on the split of registration into six phases under ECHA's REACH 2018 Roadmap.

Steps to registration

0 Preparatory phase

What		Estimated time	Ready
1.	Familiarise yourself with ECHA's support material at https://echa.europa.eu/reach-2018 .		
2.	Assign responsibility for REACH registrations to a nominated person in your company.		
!	The person nominated should know about chemical legislation and be familiar with the company procedures. They should have the full support of the management and enough resources.		



1 Know your portfolio

What		Estimated time	Ready
1.	Start from your product portfolio and make an inventory of the substances, mixtures and articles you manufacture, import or use.		
	Contact, for example, your colleague responsible for sales, examine your purchases, and ask colleagues from the manufacturing side for information.		
2.	For each substance, identify your REACH role for it (manufacturer, importer, downstream user, distributor, article manufacturer, article importer).		
3.	If you are not sure, check if your company has already registered the substances. Your colleagues dealing with legal or regulatory compliance, or quality issues could be potential sources of information.		
4.	Calculate the annual volumes for each substance to determine the registration need.		
5.	Confirm the identity of the substances in REACH terms. For this, you need access to expertise and services in analytical methods.		
6.	Check substance-by-substance whether they need to be registered, are covered by other legislation or are exempted.		
7.	Agree with your colleagues how you will communicate about registration-related issues. You may need their support and information from them to manage the registration process.		
8.	Prepare a draft work plan. Pay special attention to what you can cover internally and what you would need to outsource.		
9.	Determine resources and budget needed for registration for the substances. Reserve resources for post-registration activities(keeping your registration up-to-date, responding to authorities' requests).		
10	Present the registration plan to the management for endorsement, and ensure that you have their full support for it.		



2 Find your co-registrants

What	Estimated time	Ready
 Check that you have access to the company REACH-IT account: Check with your IT services that you have access to external sites, what are the rules for spam filtering, etc. Make sure that your username and password work in the application (https://idp-industry.echa.europa.eu/idp/). If you cannot log in, follow the instructions on the ECHA Accounts web page above. Make sure your contact details are up-to-date in REACH-IT so that your co-registrants can contact you. 		
Check if another company has already registered the same substance. You can see registered substances on our website at: https://echa.europa.eu/information-on-chemicals/registered-substances or in REACH-IT on the joint submission page. You find the contact details of your potential co-registrants in the pre-SIEF pages of REACH-IT.		

If your substance has not yet been registered, continue on page 4.

If your substance is already registered, skip to page 9.



→ If your substance has not yet been registered

2 Find your co-registrants

What		Estimated time	Ready
3.	Check if somebody already has the lead registrant role.		
	The lead registrant role cannot be claimed unilaterally, they need to operate with the consent of their co-registrants.		Ш
4.	If you have colleagues dealing with legal issues, consult them on issues related to SIEF cooperation, such as how to record communications, handle your company's confidential business information in the SIEF, and prepare for agreements with your coregistrants.		
5.	If not, contact your business association, chamber of commerce or similar to see if they can support you.		
6.	If nobody is active in the SIEF, take the initiative and contact your co-registrants.		
7.	Agree with your co-registrants on the substance identification profile of the joint submission.		

3 Get organised with your co-registrants

What	Estimated time	Ready
 Agree on ways to cooperate in your SIEF: Administrative aspects (meetings, handling financial issues). Cooperating with the substance consortium if it exists. Communication aspects. Gathering/generating the information needed for registration. Managing new members to the joint registration. Commitments beyond the registration deadline. 		
2. Prepare a draft cost-sharing agreement in the SIEF.		
Consult with internal lawyers and management on the SIEF management and cost-sharing aspects.		



 Discuss and agree in the SIEF. The cost-sharing agreement is mandatory in a SIEF, while agreeing on how the SIEF functions and how the responsibilities are shared is optional. 	
Usually, it is more efficient to have a written agreement also on the SIEF management aspects. Industry organisations have model SIEF agreements available.	
5. Adjust the internal budget to what the registration is expected to cost based on the known number of co-registrants.	

4 Assess hazards and risks

What		Estimated time	Ready
1.	Collect information: internal sources, literature, publicly available information.		
2.	Ask your downstream users about uses and information on the substance.		
3.	Compile all data the SIEF members have available and identify data gaps.		
!	The dataset compiled needs to be relevant for all the compositions of the joint registration.		
4.	Check 'similar substances' through the pre-SIEF pages in REACH-IT, if relevant. Data of these substances might be useful for read across.		
5.	Consider if alternative methods could be used to fill the data gaps.		
6.	If more information is needed for your registration, agree in your SIEF on how to generate that.		
	Alternatives to animal testing must be considered first!		



	7. If you do not have relevant expertise in-house, procure for the work needed to fulfil the data gaps	
	8. Order the work needed.	
	9. Analyse results with relevant experts.	
	10. Conclude on hazards and risks.	
Ì	11. Agree on classification and labelling in the SIEF.	
	You can opt-out for joint submission of information for three reasons (disproportionate cost, confidentiality issues, disagreement on data selection) if you can justify it.	
	12. If a chemical safety assessment is needed, agree whether it will be done jointly or individually.	
	13. Have the chemical safety assessment (CSA) conducted.	
	ECHA provides the Chesar tool for carrying out the chemical safety assessment for free. Chesar enables registrants to carry out their CSA in a structured, harmonised, transparent and efficient way.	



5 Prepare your registration as a IUCLID dossier

What		Estimated time	Ready
1.	Compare different options to submit: IUCLID, REACH-IT (not available for lead registrants) and ECHA Cloud services – which suits you best? Consult your IT services about your needs based on the number of users, system requirements, in-house IT structure and back-ups (for data and people).		
2.	 Make sure you have access to the route you have chosen IUCLID installation. ECHA Cloud services login. REACH-IT access. 		
3.	Type in the data.		
4.	Create your registration dossier (if you use IUCLID). Use the Validation Assistant and the dissemination plug-in to minimise issues at submission and to get a view on what data will be published. ECHA will also check some information manually. These checks are not covered in the Validation Assistant.		



6 Submit your registration dossier

What		Estimated time	Ready
1.	Agree on the submission plan with the SIEF (timing, reception of token).		
2.	Create the joint registration in REACH-IT and share the access token with your co-registrants (if you are a lead registrant).		
3.	With the token, join the joint registration in REACH-IT (if you are a member registrant).		
4.	Submit your registration dossier.		
5.	If you fail with your submission, follow the instructions in ECHA's communication. If unclear, seek advice from ECHA.		
6.	Re-submit.		
7.	Pay the fee within the deadline established in your invoice.		
	Check your REACH-IT account on a regular basis. It is ECHA's only means of official communication to you.		



→ If substance has already been registered

3 Get organised with your co-registrants

What		Estimated time	Ready
1.	You may have received emails from that company already. Otherwise, check from the Joint submission pages in REACH-IT.		
2.	Contact the lead registrant.		
3.	Confirm with your co-registrants that your substance fits in the substance identity profile of the existing registration and that the dataset is relevant for your substance. If you cannot agree on admission to the joint submission, you can file a dispute for access to the joint submissionwith ECHA.		
4.	Negotiate conditions to access the joint registration. Follow ECHA's advice for successful data-sharing negotiations on ECHA's REACH 2018 pages. If you already have data on a certain property, you may be able to opt-out for that property. There are three possible reasons: disproportionate cost, confidentiality issues and disagreement on data selection. A justification is required. If you cannot agree after making every effort, you can file a data-sharing dispute with ECHA.		



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During the planning process, you can seek support from your <u>national helpdesks</u>, ECHA or from your sector organisation/regional business association.