ECHA
EUROPEAN CHEMICALS AGENCY

# Authorisation Handbook

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# Table of Contents

**LEGAL NOTICE**

This document aims to assist national helpdesks and users with their obligations under the REACH/CLP Regulation. However, users are reminded that the text of the REACH/CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regards to the use that may be made of the information contained in this document.

| Version | Changes | Date |
|---|---|---|
| Version 0 | First edition | October 2022 |
| Version 1 | Revision of links and addition of new Q&As under 'General/procedure' and 'Technical instructions for specific Annex XIV entries'. | May 2023 |



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# 1. Introduction

The aim of the authorisation process (Article 55, REACH) is to:

i. Ensure that the risks related to substances of very high concern (SVHCs) are properly controlled throughout their life cycle;

ii. Promote the progressive replacement of SVHCs by suitable alternatives (less dangerous substances, new technologies and processes), where technically and economically feasible alternatives are available.

# 2. Authorisation process

The authorisation process can be seen as a **three-phase process**:

- **Phase I** – Identification of Substances of Very High Concern (SVHC)
- **Phase II** – Prioritisation and recommendation of SVHCs for inclusion in the Authorisation List (Annex XIV)
- **Phase III** – Applications for authorisation


**Figure:** Visual overview of the three phases of the authorisation process (see infographic)

The route to authorisation starts when a Member State or ECHA, at the request of the European Commission, proposes a substance to be identified as an SVHC by submitting an Annex XV dossier. Following identification of a substance as an SVHC (Article 57), it is added to the Candidate List (Article 59) for potential inclusion in the Authorisation List (Annex XIV, REACH).

ECHA regularly assesses the substances from the Candidate List to determine which ones should be included in the Authorisation List as a priority. Based on ECHA's recommendations (Article 58), the European Commission decides on the substances to be included in the Authorisation List (Annex XIV) and on the final entries (sunset date, latest application date, review period, exemptions).

When a substance is placed on the Authorisation List (Annex XIV), companies may submit an application for authorisation to ECHA for specified uses (Article 56), to continue using the substance after the sunset date.

**Links:** Application for authorisation infographic, Substances of very high concern identification, Recommendation for the Authorisation List and Applications for authorisation

**N.B. Authorisation (including the Candidate list) and Restriction processes** are two separate processes with different aims:

- Authorisation: ultimate aim to progressively substitute SVHCs by safer alternatives. Uses can be authorised for a limited review period beyond the sunset date according to the conditions laid out in Article 60.

- Restrictions: The general provisions for the List of restricted substances (Annex XVII, REACH) are outlined in Article 68. The criteria for -introducing a restriction are not as straightforward as for the authorisation process. Annex XVII to REACH also includes all the restrictions that were established under the previous legislation.

Consequently, each of these lists are separate entities imposing different obligations to EU/EEA-based companies. A substance might be present in both authorisation and restrictions processes, albeit for different uses.

**Links**: Integrated Regulatory Strategy infographic, Restriction - ECHA (europa.eu) HelpNet Restriction Handbook

# 3. Phase I: Substance of Very High Concern identification and inclusion to the Candidate List

**Who:** Member States or ECHA at the request of the European Commission, inform all interested parties of their **intention** to propose a substance for identification as a **substance of very high concern (SVHC)** and submit an Annex XV dossier. Interested parties can submit comments or provide further information during the consultation period. When comments are received that provide new information or challenge the SVHC identification, the proposal is referred to the Member State Committee. If the committee does not reach a unanimous agreement, the European Commission will, if required take the final decision on the identification of the substance as an SVHC. Stakeholders/companies can subscribe to ECHA Weekly in order to be informed about any future updates of the Candidate list and related news on the authorisation and restrictions processes.

**What:** The **intention** is published in the Registry of SVHC Intentions (RoI), on ECHA's website. The proposal is prepared and submitted according to the requirements set out in Annex XV to REACH and it is published on ECHA's website. If no comments challenging the identification of the substance as an SVHC are received, the substance is included directly in the **Candidate List**.

**Links:** Phase 1: SVHC identification, Registry of SVHC intentions (RoI), consultations in the authorisation process, Preparing & submitting an SVHC dossier, Guidance on the preparation of an Annex XV dossier for SVHC identification, Current consultations on SVHC identification, Previous consultations on SVHC identification, and ECHA Weekly subscription

## a. Information on Substances of Very High Concern

Under the REACH authorisation process, a substance can be identified as a Substance of Very High Concern (SVHC) and placed in the Candidate List when it fulfils one or more of the criteria specified in Article 57 of the REACH Regulation:

- Substances meeting the criteria for classification as **carcinogenic, mutagenic or toxic for reproduction (CMR)** category 1A or 1B in accordance with the CLP Regulation.
- Substances which are **persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)** according to REACH Annex XIII.
- Substances on a case-by-case basis, that cause an **equivalent level of concern** as CMR or PBT/vPvB substances. This includes for example endocrine disrupting chemicals or respiratory sensitisers.

**Links**: Candidate List of substances of very high concern for authorisation, reason for inclusion in the Candidate List and Information on Candidate List substances in articles - ECHA (europa.eu)

### b. Obligations resulting from the inclusion of SVHCs in the Candidate List

Companies may have legal obligations resulting from the inclusion of substances in the Candidate List. The Candidate List obligations are effective from the date of inclusion and refer to the listed substances on their own or in mixtures and also to their presence in articles.

The inclusion of a substance in the Candidate List of SVHCs sets **notification obligations** (Article 7(2), REACH) and **communication obligations** (Article 33, REACH) for EU/EEA-based producers/ importers or suppliers of articles containing an SVHC in a concentration above 0.1% (w/w).

Moreover, the SCIP notification obligation (Waste Framework Directive) applies to all articles placed on the EU/EEA market containing an SVHC in a concentration above 0.1% w/w.

**Links**: Candidate List obligations, Information on Candidate List substances in articles and SCIP notification obligation

### c. Updates of the Candidate List

The Candidate List is updated each time substances are identified as SVHCs, following Articles 57 and 59 of REACH. This is normally done **twice per year** (usually in June/July and in December/January).

**Links:** Adding substances to the candidate list

## 4. Phase II: Prioritisation of SVHCs and recommendation for inclusion in the Authorisation List

**Who:** ECHA regularly assesses the substances from the Candidate List to determine which ones should be prioritised for inclusion in the **Authorisation List**. ECHA's draft **recommendation** is submitted for a public consultation (related to uses, volumes, transitional arrangements and possible exemptions), which typically runs for three months once every one to one and a half years. The Member State Committee provides an opinion on the draft recommendation to ECHA. ECHA finalises the recommendation and the European Commission decides on the substances to be included in the Authorisation List.

**What:** Recommendations are prepared and submitted at least every second year based on the principles for the prioritisation approach based on Article 58(3). Relevant information on uses and volumes of the substance in the scope of authorisation is collected from registration dossiers, from comments received during the SVHC consultation or other sources.

The draft recommendation includes:

- **Sunset date** from which the placing on the market and the use of a substance is prohibited, unless an authorisation is granted or the use is exempt from authorisation;
- **Latest application date** by which applications must be received if the applicant wants to continue placing the substance on the market or using it after the sunset date;
- **Review periods** for certain uses, if any;
- **Uses exempted** from the authorisation requirement, if any.

**Links**: Phase II: Recommendation for inclusion in the Authorisation List, Recommendation for inclusion in the Authorisation List, General prioritisation approach: practical implementation examples, principles for the prioritisation approach, Recommendations for inclusion in the Authorisation List and ECHA's general responses on issues commonly raised in consultations on draft recommendations.

## A. Information on substances in Annex XIV (Authorisation List)

In any particular prioritisation round, the relative priority assigned to a substance needs to be considered in the context of that particular round. In subsequent prioritisation rounds, each substance that is not already included or recommended for inclusion in Annex XIV will be reassessed, taking into account any new information relevant for the prioritisation. Priority substances that have already been submitted to the European Commission as part of a recommendation for inclusion of SVHCs in Annex XIV are no longer considered by ECHA in the context of the future prioritisation rounds.

A substance that has been included in the Candidate List will remain in that list regardless of whether it also gets included in Annex XIV (Authorisation List).

**Links**: Authorisation List

## B. Obligations resulting from the inclusion of SVHCs in Annex XIV (Authorisation List)

Once an SVHC is included in the Authorisation List (Annex XIV, REACH) it is subject to the **authorisation obligations** (Article 56, REACH).

For **substances**, the placing on the market and use is not allowed within the EU/EEA after its sunset date unless covered by an authorisation or a timely submitted application for authorisation (i.e. before the latest application date), or unless an exemption applies. There is no tonnage threshold below which the placing on the market and use of an Annex XIV substance is exempted from the authorisation requirement.

For **mixtures**, the authorisation obligation under REACH applies to the import, placing on the market and use of a mixture containing an Annex XIV substance within the EU, unless the Annex XIV substance is present in the mixture below the concentration limits set out in Article 56(6) of REACH. When an Annex XIV substance is formulated into a mixture within the EU/EEA, this use is subject to authorisation.

For **articles**, the import, placing on the market or use of an article containing an Annex XIV substance is not subject to the authorisation requirement. When an Annex XIV substance is incorporated into an article within the EU/EEA, this use is subject to authorisation.

EU/EEA-based companies that are affected by the authorisation obligation and wish to continue

using an Annex XIV substance after its sunset date need to prepare an application for authorisation, submit it to ECHA before its latest application date and obtain a positive authorisation decision by the European Commission on their use.

**Links:** Application for authorisation

### C. Updates of the Annex XIV (Authorisation List)

The Annex XIV (Authorisation List) is updated by amendments of the REACH Regulation at irregular intervals, the timelines of which are in the remit of the European Commission.

**Links**: Amendments of the Authorisation List and Recommendations to amend Annex XIV entries

## 5. Phase III: Application for authorisation

**Who:** EU/EEA-based manufacturers, importers, downstream users or only representatives can submit an **application for authorisation** for one or more uses, and one or more (similar) substances. Authorisation holders can submit a **review report** to extend their authorisation beyond the expiry of the granted review period. ECHA launches a consultation on alternatives for each applicant/substance/use applied for, during which interested parties are invited to submit information on possible alternative for these uses, including information on risks, technical feasibility and costs. ECHA's **RAC & SEAC Committees** prepare the **opinion** on each use applied for and send it to the European Commission, the Member States and the Applicant within ten months from submission of the application. The **European Commission** prepares a draft **decision** within three months of receiving the final opinion, which is followed by a vote in the REACH Committee and the adoption procedure.

**What:** An **intention** to submit an authorisation application can be notified to ECHA by the Applicants and a teleconference-based information session can be requested to discuss case-specific aspects related to the authorisation application. Depending on the route for submitting an authorisation application (adequate control/ socio-economic) the assessment reports required in an application may include a **Chemical Safety Report (CSR), Analysis of Alternatives (AoA)**, **Socio-Economic Analysis (SEA)** and a **Substitution Plan (SP)**. Once the application is submitted and the authorisation fee is paid, ECHA prepares a document, the broad information of uses package, that will be used for launching the consultation on alternatives for each use applied for. An authorisation can be granted by the European Commission if the risks from using the substance are adequately controlled (adequate control route) or if the socio-economic benefits of using the substance outweigh the risks and there are no suitable alternatives available for the use (socio-economic route).

**Links:** Phase III: Application for authorisation, Applications for authorisation, Consultations in the authorisation process, Teleconference-based information session, Assessment reports and Broad information of uses package.

### a. Generic exemptions from authorisation

Generic exemptions from the authorisation requirement have been established:

- All **intermediate** uses: on-site isolated intermediates and transported isolated intermediates (Article 2(8)(b)) (non-isolated intermediates fall outside the scope of REACH);
- Uses of substances in **mixtures** below certain concentration limits (Article 56(6)(b)).
- Uses in **medicinal products** for human or veterinary use (Article 2(5)(a));
- Uses in **food or feedingstuffs** (Article 2(5)(b));
- Uses in **scientific research and development** (Article 56(3));

- Uses on **plant protection products** (Article 56(4)(a)) and **biocidal products** (Article 56(4)(b));
- Use as motor **fuels** (Article 56(4)(c)), as fuels in mobile or fixed combustion plants and as fuels in closed systems (Article 56(4)(d));

**Links**: Generic exemptions from the authorisation requirements

## b. Applying for an authorisation

EU/EEA-based companies affected by the authorisation obligation that are not covered by any relevant exemptions need to develop a strategy on how to proceed. **Manufacturers**, **importers** or **downstream users** of an Annex XIV substance as well as duly mandated **only representatives** can apply for an authorisation (Article 56(1)) and be holders of a granted authorisation. Potential applicants are also encouraged to make use of ECHA's partners' service for applicants (including companies, consortia, industry associations, consulting companies) to find suitable **partners** for their authorisation application.

Companies can benefit from the transitional arrangements of Art. 58(1)(c)(ii) of REACH if they submit their application to ECHA in the latest or in any of the earlier submission windows. Alternatively, a downstream user may continue their use of an Annex XIV substance provided that their use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use (Article 56(2)).

To better plan the Committees' workload, ECHA has established specific timelines, so-called submission windows (quarterly in February, May, August and November), for submitting applications for authorisation.

ECHA's authorisation web pages provide step-by-step guidelines in preparing and submitting an authorisation application.

The **current status** of all applications for authorisation (and review reports) submitted to ECHA that have undergone consultation, as well as **Statistics** on the received applications for authorisation, adopted RAC & SEAC opinions and authorisation decisions per Annex XIV substance are provided on the ECHA website.

**Links**: Develop an application strategy, ECHA's partners' service, How to apply for authorisation step-by-step, Submission windows, Adopted opinions and previous consultations on applications for authorisation, Evaluating applications, Working procedure for RAC & SEAC for developing opinions on applications for authorisation, Common approach of RAC & SEAC in opinion development on applications for authorisation, European Commission – Authorisation decisions, Adopted opinions and previous consultations on applications for authorisation and Statistics on received applications for authorisation and review reports

## c. Review report

In order to continue using an Annex XIV substance after the end of the review period of an authorisation granted by the European Commission, **authorisation holders** must submit a review report at least 18 months before the expiry date of the review period. This ensures continued use of the Annex XIV substance after the expiry of the review period until the issuing of the Commission decision on the review report, in analogy to the transitional arrangements described under Article 58(1)(c)(ii) of REACH for the original authorisation applications.

As part of the review reports, the authorisation holders should update all documents submitted in the original application that have changed and submit any other elements required by the conditions or monitoring arrangements of the authorisation decision.

Alternatively, actors which are not themselves authorisation holders may submit a new authorisation application to extend their authorisation beyond the review period. However, in this case the transitional arrangements under Article 58(1)(c)(ii) of REACH no longer apply. Whether the company which is no longer covered by an authorisation would need to cease using the Annex XIV substance is an issue for the National Enforcement Authorities.

**Links**: Review report of an authorisation

### d. Downstream user notification of authorised uses (article 66)

EU/EEA-based downstream users using an Annex XIV substance on the basis of an authorisation granted to an actor up their supply chain for that use (Article 56(2)), must notify their authorised use to ECHA within three months of the first supply of the substance after the publication date of the European Commission's decision in the Official Journal (Article 66(1)).

More than one authorised use of the same Annex XIV substance can be included in one downstream user notification per legal entity. If the authorisation decision requires downstream users to submit to ECHA specific data, e.g. on exposure, they will need to attach a file (see format for reporting monitoring data) to their notification by the deadline set in the decision.

Links: Technical guidelines on submitting an Article 66(1) downstream user notification for authorised video, downstream users authorised use, Format to report DU occupational exposure data, Overview of all DU notifications received to date by ECHA.

## 6. Guidelines

Useful support is offered by the guideline documents available on ECHA's website. The links to the most relevant documents for each phase of the authorisation process are listed below:

**Phase I**

- Guidance on the preparation of an Annex XV dossier for the identification of SVHCs: This ECHA Guidance document describes how the authorities (Member States Competent Authorities or the European Chemicals Agency) can prepare a dossier in accordance with Annex XV to identify an SVHC under REACH.
- Guidance on requirements for substances in articles: This ECHA Guidance document assists producers, importers and suppliers of articles in identifying how to fulfil their obligations under REACH, in particular in relation to registration/ notification (Article 7) and supply chain communication (Article 33).

**Phase II**

- Prioritisation of SVHCs for inclusion in the Authorisation List (Annex XIV): This document describes prioritisation as part of the recommendation step in the context of authorisation and sets out the principles of ECHA's prioritisation approach, with a particular focus on the Article 58(3) criteria.
- Preparation of draft Annex XIV entries for substances to be included in Annex XIV: This document describes how ECHA prepares the draft Annex XIV entries, including considerations on the transitional arrangements, review periods, any applicable exemptions and their conditions.

**Phase III**

- Factsheet on applications for authorisation: This document provides a brief overview of the main elements of the application for authorisation process under REACH.
- Guidance on the preparation of an application for authorisation: This ECHA Guidance document provides a detailed overview of the authorisation process, and guidance on how to prepare and submit an application for authorisation for the use of an Annex XIV substance, including considerations on the analysis of alternatives and substitution plan.
- Guidance on Socio-Economic Analysis – Authorisation: This ECHA Guidance document provides a detailed description on how to perform the socio-economic analysis as part of an application for authorisation for the use of an Annex XIV substance.
- Guide - How to apply for authorisation: This guide provides potential applicants with practical advice on how to prepare a 'fit-for-purpose' application for authorisation. It describes the key issues to be considered when developing an application strategy and the essential elements that should be included in an authorisation application, illustrated by examples from previous applications.
- Guide – How to develop use descriptions in applications for authorisation: This guide explains how to define the scope of the use applied for and how it should be developed and described in an authorisation application, including the supporting justification that should be provided.
- Checklist for preparing an application for authorisation of a review report: This checklist aims to support potential applicants in the preparation of an application for authorisation or authorisation holders in the preparation of a review report. It includes sections relevant to the three assessment reports (CSR, AoA, SEA) and a section dedicated to review reports.
- How to prepare an application for authorisation: This manual provides technical assistance in the preparation of an application for authorisation and its submission to ECHA, outlining the relevant IUCLID sections and required fields.

# 7. Q&As

Below, the complete list of all Q&As concerning authorisation available on ECHA's website. It is possible to search the ECHA Q&As by topic (e.g. REACH), scope (e.g. Authorisation) and chapter (e.g. Authorisation Procedure; authorisation Scope; Format and content of Authorisation; Authorisation fees and invoicing; Analysis of Alternatives; Technical instructions for specific Annex XIV entries; Changes of legal entity; review reports; Article 66). It is also possible to search a specific Q&A number, or keywords using the 'search' option.

## a. General / Procedure

- Q&A 124 - Are any substances already subject to authorisation?
- Q&A 125 - Where do I find the candidate list?
- Q&A 126 - How is a substance included in the Candidate List?
- Q&A 127 - How is a substance from the Candidate List included in the "Authorisation List"?
- Q&A 128 - How are authorisations granted for substances on the "Authorisation List"?
- Q&A 129 - In which language do Applications for authorisation have to be submitted to ECHA?
- Q&A 567 - Who can apply for an authorisation?
- Q&A 568 - Can an Only Representative apply for an authorisation?
- Q&A 569 - Will only the person who submitted the authorisation application to ECHA benefit from the granted authorisation?
- Q&A 570 - Who will decide on the granting and conditions of an authorisation?

- Q&A 571 - Will my application be processed if I submit it outside the submission windows?
- Q&A 572 - Why should I submit the application before the Latest Application Date?
- Q&A 573 - Will my application be processed if I submit it after the Latest Application Date?
- Q&A 574 - Are end points related to the intrinsic properties of Annex XIV more critical than other end points?
- Q&A 575 - Can the decision taken by the Commission be different for the several uses included in my application?
- Q&A 576 - How RAC and SEAC work together? Can they disagree with each other?
- Q&A 577 - Can a distributor be considered as the immediate Downstream User (DU) in the context of article 56(1) (e) and apply for an authorisation?
- Q&A 578 - Can a Downstream User apply for uses upstream in the supply chain?
- Q&A 579 - I use an Annex XIV substance in a mixture. Should the information in the application be presented for the mixture or for the substance?
- Q&A 580 - May an authorisation be reviewed before the expiry of the period for which it has been granted for?
- Q&A 581 - What rights does the applicant have to challenge the decision of the Commission?
- Q&A 582 - Who will enforce the authorisation decisions and how?
- Q&A 583 - What other key sources of information might ECHA use when evaluating Applications for authorisation?
- Q&A 584 - When will I receive the decision of the Commission after I have submitted my application?
- Q&A 749 - Are there clear criteria on which the opinions will be based and which could provide more certainty about the outcome of the application?
- Q&A 750 - As a downstream user relying on an authorisation granted to a manufacturer/importer up in my supply chain, will I receive a unique authorisation number for all the authorised uses?
- Q&A 757 - Can restrictions be applied on the use of Annex XIV substances in articles?
- Q&A 758 - Can an Only Representative apply for an authorisation on behalf of several companies located outside the EU?
- Q&A 915 - Will ECHA inform the applicant if it has accepted the justifications for claiming certain information confidential?
- Q&A 919 - How is the time-limited review period set in authorisation decisions?
- Q&A 1358 - I am a downstream user of an Annex XIV substance and the European Commission has not yet decided on the application for authorisation submitted by a company up my supply chain covering my use. The sunset date of the substance has passed.
    a) Do I have to stop using the substance?
    b) Do I have to notify my use to ECHA?
- Q&A 1441 - I am a downstream user of an Annex XIV substance and the European Commission has decided to grant an authorisation for my use to a company up my supply chain. Do I have to notify my use to ECHA?
- Q&A 1656 - What environmental release information will ECHA publish as part of the opinions on applications for authorisation?
- Q&A 1657 - The authorisation decision states as a condition that a monitoring programme needs to be established so that the first measurements shall be performed at the latest by a particular date in spring 2020. Due to Covid-19 emergency, it will not be possible to finalise these monitoring programmes within the deadlines of the decision. What should we do?
- Q&A 1853 - If the Commission decides not to grant or decides to withdraw an authorisation, will there be a possibility of transitional arrangements allowing the phasing out of the not authorised use of the substance?
- Q&A 2005 - Does the inclusion of a substance in the Candidate List (SVHC status) trigger the need to update the Safety Data Sheet (SDS)?

## b. Scope

- Q&A 130 - Does the use of a substance listed on Annex XIV require an authorisation when contained in a mixture at a concentration below that specified in Article 56(6) (a) and (b) of REACH?
- Q&A 563 - Is there any tonnage threshold below which Annex XIV substances are exempted from the authorisation requirement?
- Q&A 564 – Does the authorisation requirement apply to the use of substances in articles?
- Q&A 565 – Does the authorisation requirement apply to a substance in Annex XIV that is present as an impurity in another substance or mixture?
- Q&A 566 – Does the authorisation requirement apply to a substance in Annex XIV that is present as an impurity in another substance or mixture?
- Q&A 585 – Does the authorisation requirement apply to a substance in Annex XIV that is present as an impurity in another substance or mixture?
- Q&A 844 - Does the authorisation requirement apply to a substance in Annex XIV that is present as an impurity in another substance or mixture?
- Q&A 1027 - Article 2(5), subparagraphs (a) and (b), and Article 56 subparagraphs (4)((a), (b), and (c)) and (5)((a) and (b)) of REACH exempt from the authorisation requirement a number of uses in products (medicinal products, food or feedingstuffs, plant protection products, biocidal products, motor fuels, cosmetic products and food contact materials, respectively) within the scope of, or covered by, the sector-specific Union legislation specified in those provisions. 1. Do these exemptions cover the incorporation of the Annex XIV substance into the product during the manufacturing process? 2. Do these exemptions also cover the life-cycle steps (such as formulation) preceding the incorporation of the substance into the product in question?
- Q&A 1028 - Article 56 (4)(d) of REACH contains an exemption from the authorisation requirement for the use as fuels in closed systems. Does this exemption also cover the life-cycle steps (such as formulation) preceding this end-use?
- Q&A 1029 - Does an application for authorisation for the use of a substance in a medical device regulated by the sector-specific legislation referred to in Article 60(2) 2nd subparagraph of REACH have to be submitted for a substance for which Annex XIV specifies human health hazards only? Does this exemption cover the incorporation of the Annex XIV substance into the product during the manufacturing process? If so, are the life-cycle steps preceding the incorporation of the substance in the medical device subject to authorisation?
- Q&A 1030 - Article 56 (3) of REACH exempts from the authorisation requirement the use of a substance in scientific research and development (SRD). Does this exemption also cover the life-cycle steps (such as formulation) preceding the end-use in SRD?
- Q&A 1031 - Is the manufacture of a substance, whether for export or placing on the EU market, subject to the authorisation requirement?
- Q&A 1153 - Does the exemption for the use of Annex XIV substances in scientific research and development under Article 56(3) of REACH also apply to sampling activities for further quality control analysis?
- Q&A 1219 - Does the exemption from the authorisation requirement for substances in mixtures (Article 56(6)b of REACH) depend on their classification in any hazard class or only the hazard classes for which the substance was included in the authorisation list?
- Q&A 1442 - Does the exemption for the use of Annex XIV substances in scientific research and development (SRD) under Article 56(3) of REACH also apply to analytical activities using in vitro diagnostic (IVD) medical devices (as defined in Directive 98/79/EC) at a laboratory scale?
- Q&A 1443 - Does the exemption for the use of Annex XIV substances in scientific research and development (SRD) under Article 56(3) of REACH also apply to the use of an Annex XIV substance in upstream life-cycle stages to produce in vitro diagnostic (IVD) medical devices?
- Q&A 1498 - Does the exemption for the use of Annex XIV substances in scientific research and development (SRD) under Article 56(3) REACH also apply to Annex XIV substances used together with or incorporated in SRD articles?

- Q&A 1565 - Are uses in Product and Process Orientated Research and Development (PPORD) exempted from the authorisation requirement?

## c. Format and content of authorisation

- Q&A 586 - What is the format for authorisation applications?
- Q&A 587 - How can an applicant submit an application to ECHA?
- Q&A 588 - In which language shall I submit my application for authorisation to ECHA?
- Q&A 589 - What will ECHA do if it receives applications that contain documents in more than one official EU language?
- Q&A 590 - What is meant by the "Broad Information on Uses" package and what does it contain?
- Q&A 591 - Will the applicant's name be made public?
- Q&A 592 - How can I provide in my application a "complete" and a "public" version of sections 9 ("Exposure assessment") and 10 ("Risk characterisation") of the Chemical Safety Report (CSR) covering the uses applied for?
- Q&A 593 - Do I need to update my Chemical Safety Report (CSR)?
- Q&A 594 - How can an applicant provide information in its application which should not be made publicly available?
- Q&A 595 - What is a joint application?
- Q&A 596 - Is a joint application easier to submit and manage than separate applications?
- Q&A 597 - Can an additional legal entity join a group of applicants after the submission of a joint application?
- Q&A 598 - What is a subsequent application?
- Q&A 599 - How will ECHA communicate with the applicant once an application has been submitted?
- Q&A 912 - I consider that the substance that I will apply for has a threshold. What if RAC disagrees with my assessment?
- Q&A 913 - In a joint application, can confidential information from a joint applicant made secret to the other applicants?
- Q&A 914 - Can I submit a single application covering several substances?
- Q&A 1151 - When commenting the draft opinions of RAC and SEAC, can I submit additional or new data that I had not provided when the committees were preparing them?
- Q&A 1723 - If a suitable alternative is available in general -- but not technically or economically feasible for the applicant -- and it therefore submits a substitution plan, can an authorisation be granted under the socio-economic route?

## d. Authorisation fees and invoicing

- Q&A 600 - How is the fee for an application for an authorisation calculated?
- Q&A 601 - Application for one applicant and one substance only
- Q&A 605 - How will ECHA calculate the fee and send the invoice in the case of joint applications?
- Q&A 606 - How will the applications be invoiced and paid?
- Q&A 607 - The Fee Regulation (EC No 340/2008) related to the fees for Applications for authorisation has been amended by Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013. Updated articles 8(2) and 9(2) state that "the Agency shall issue one invoice covering the base fee and any applicable additional fees". How will these additional fees be levied?
- Q&A 608 - Is there a fee for confidentiality claims in Applications for authorisation?
- Q&A 826 - Will ECHA consider one exposure scenario for article service life as equivalent to one use for determining the fee?

## e. Preparing for authorisation application

- Q&A 609 - What is the purpose of the teleconference based information sessions?

- Q&A 610 - When and how can I request a teleconference based information sessions?
- Q&A 611 - How can I have access to the Lead Registrant's Chemical Safety Report (CSR) data if he is not taking part in the application for authorisation? What can I do if the data owner refuses to give me access to its data? Can I use the information available on ECHA's dissemination website?
- Q&A 612 - Will a pre-submission information session (PSIS) be available for the whole group of applicants participating in a joint application or will there be a separate PSIS for each co-applicant?
- Q&A 751 - How should I develop the 'uses applied for' and exposure scenarios in my application?
- Q&A 752 - Which DNEL should I use?
- Q&A 756 - How many pages should an application contain?
- Q&A 916 - Would the application be in conformity according to Article 62(4)(d) of REACH if it took as a premise the 'Reference DNEL' or 'dose response relationship' adopted by RAC and published on ECHA's website?
- Q&A 950 - Do I need to include Part A in the Chemical Safety Report (CSR), when I submit it as part of my application for authorisation?

## f. Analysis of alternatives

- Q&A 613 - Do I need to consider also Substances of Very High Concern (SVHC) in my Analysis of Alternatives?
- Q&A 614 - How will the ECHA Committees (RAC and SEAC) take into account third parties' comments submitted during the public consultation on alternatives?
- Q&A 615 - What is the scope of the Analysis of Alternatives and the Socio-economic Analysis? The applicant's perspective or the society as a whole?
- Q&A 616 - I will submit an Analysis of Alternatives for a threshold substance. I have R&D activities to develop and implement safer alternatives that are neither suitable nor available yet. Can I submit a Substitution Plan with my application?
- Q&A 617 - Is it appropriate to provide a socio-economic analysis under the adequate control route?
- Q&A 753 - How should the "economic feasibility" criteria be interpreted?
- Q&A 754 - What is the level of details needed for the analysis of alternatives?
- Q&A 755 - Should I consider in my socio-economic analysis the aspects outside the EU?
  Q&A 1859 - I am preparing an application for authorisation and I am considering using the profits of my operation as the basis for showing the benefits of authorisation. However, in the past couple of years my company has made a loss. What should I do?

## g. Technical instructions for specific Annex XIV entries

- Q&A 618 - The entry for Hexabromocyclododecane (HBCDD) indicates 2 EC entries and 5 CAS entries. How should the substance identification sections (1.1 and 1.2) in an IUCLID application for authorisation dossier be filled in?
- Q&A 805 - Can an application for authorisation for chromium trioxide cover the use of the chromic acids and their oligomers generated from adding chromium trioxide to water?
- Q&A 1566 - The entries for 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (entry 42) and 4-Nonylphenol, branched and linear, ethoxylated (entry 43) cover several substances each. How should the substance identification sections (1.1 and 1.2) in an IUCLID application for authorisation dossier be filled in?
- Q&A 1567 – The substance I use has been identified as 'nonylphenol ethoxylated' (CAS# 9016-45-9). Should I consider that this substance is listed under entry 43 of the Authorisation list?
- Q&A 2004 - The substance I use has been identified as 'nonylphenol ethoxylated' (CAS# 9016-45-9). Should I consider that this substance is listed under entry 43 of the Authorisation list?
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## h. Changes of legal entity

- Q&A 1239 - What is a change of legal entity that needs to be notified for applications for authorisation or granted authorisations?
- Q&A 1240 - Does a change of corporate name of an applicant or an authorisation holder need to be notified to ECHA and how?
- Q&A 1241 - Can an application for authorisation or a granted authorisation be transferred?
- Q&A 1242 - How can I notify a change of legal personality regarding an application or an authorisation?
- Q&A 1243 - Do I have to pay a fee when notifying my change of legal entity?
- Q&A 1246 - The application was submitted before the Latest Application Date. If the legal entity changes, do the transitional arrangements set out in Article 56(1)(d) of REACH continue to apply to the legal successor?
- Q&A 1247 - What will ECHA and the European Commission do and by when, following a notification of a change of legal entity regarding i) a pending application or ii) authorisation decision?
- Q&A 1248 - How should an applicant or an authorisation holder inform ECHA about a legal entity change?
- Q&A 1249 - I am preparing an application for authorisation while knowing that a change of legal entity will take place in the near future. How should I address this in the application?
- Q&A 1250 - Does a change of an Only Representative (OR) concerning an application for authorisation or a granted authorisation need to be notified to ECHA and how?

## i. Review reports

- Q&A 1360 - What is difference between a Review Report and the Application for Authorisation?
- Q&A 1361 - I have submitted my Review Report on time i.e. at least 18 months before the end of the review period. The Commission has not issued its decision before the end of the review period. Can I continue to use the substance according to the authorisation decision until the Commission issues its decision?
- Q&A 1362 - I have submitted my Review Report too late i.e. less than 18 months before the end of the review period. The Commission has not issued its decision before the end of the review period. Can I continue to use the substance according to the authorisation until the Commission issues its decision?
- Q&A 1363 - Can I submit a Review Report for a use that has not been authorised?
- Q&A 1364 - Can I narrow down the scope of the authorised use in a review report to be more specific?
- Q&A 1365 - In the Review Report, can I split my use which was originally authorised into two or more specific, more narrowly defined different uses?
- Q&A 1366 - Will ECHA's Scientific Committees use the information gathered from the downstream user notifications (based on REACH Article 66) during the evaluation?
- Q&A 1367 - Will ECHA's Scientific Committees use information from enforcement authorities?
- Q&A 1368 - Will I be able to submit another Review Report after this one as a result of a new Commission's decision?
- Q&A 1369 - I was unable to demonstrate adequate control of risks for a threshold substance in the original application that I submitted originally. Will I need to do so in the Review Report?
- Q&A 1370 - How will I submit the Review Report?
- Q&A 1858 - I am holding an authorisation based on an application which specifies a particular tonnage of an Annex XIV substance that can be used. It is likely that this use will increase. What should I do?

## j. Article 66

- Q&A 1794 - How can I update my downstream user notification of authorised uses?
- Q&A 1807 - How do I cease all notified uses of a substance for which I have sent a Downstream User notification of authorised uses?
- Q&A 1829 - How can I attach information collected from monitoring programmes to my downstream user notification of authorised uses?