Industry Guidance

REACH Authorisation Guidance for Downstream Users

THE AUTHORISATION PROCESS AND OBLIGATIONS RELATED TO THE INCLUSION OF A SUBSTANCE IN THE "CANDIDATE LIST"

Disclaimer

The information contained in this paper is based on the understanding of the situation as of today and updates may be required in the near future once experience with authorisation applications is available. Therefore, it is intended as advice only and whilst the information is provided in utmost good faith and has been based on the best information currently available, is to be relied upon at the user's own risk. No representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted by any association nominated at the top of this document for damages of any nature whatsoever resulting from the use of or reliance on the information.

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INTRODUCTION

The goal of this document is to clarify and give practical tips to downstream users (DUs) dealing with substances of very high concern as defined in the framework of Title VII of the REACH Regulation (EC) No1907/2006 on the authorisation process.

Any **Substance** considered to be of **Very High Concern** (SVHC) pursuant to Article 57 of the REACH Regulation might be introduced in the "Candidate List". From this list, substances with very high health and/or environmental concerns will be prioritised for inclusion in Annex XIV of REACH. Once the European Commission (following the comitology procedure) has included the substance on the list given in **Annex XIV of REACH** and **the defined sunset date has passed**, the substance **cannot be placed on the market for a use or used** without the prior **authorisation** of the European Commission **unless that use is exempt from authorisation**.

REACH authorisation is a new, complex and expensive process;

- ***The regulation encourages change and the development of safer alternatives.***
- ***Authorisation is granted for a limited period, after which the applicant may re-apply.***
- ***It is clear that the quality of the application for authorisation (strength and simplicity) is key to the success of that application –and, depending on the substance and the particular applicant, the Socio-Economic Analysis (SEA) and Analysis of Alternatives (AoA) are very important.***

Authorisation aims to:

- guarantee that the risks relative to substances of very high concern are properly controlled throughout their life cycle, and
- promote the progressive replacement of these substances by other substances or by the implementation of new technologies if and when these are economically and technically available and feasible.

In the authorisation process, it is not substances as such that require authorisation, but the uses of those substances. Therefore, any use of a SVHC included in Annex XIV that is not authorised or exempt from authorisation is prohibited after the sunset date.

In the EEA, placing an Annex XIV substance on the market after the sunset date is subject to authorisation which is company-specific, supply chain-specific and use-specific.

Which substances are affected?

Authorisation relates to substances of very high concern, as defined in the REACH Regulation, Article 57 (a) to (f), i.e.:

- substances which are carcinogenic, mutagenic or toxic for reproduction (CMR) categories 1A and 1B (CLP Regulation)
- Persistent, Bioaccumulative and Toxic substances (PBT)
- very Persistent and very Bioaccumulative substances (vPvB)
- substances identified on a case by case basis whose health and environmental effects give rise to an equivalent level of concern to those above (for instance such substances may be substances having endocrine disrupting properties or having PBT/vPvB properties without fulfilling the PBT/vPvB criteria set out in Annex XIII of REACH).

The European Chemical Agency (ECHA) publishes on its website the list of substances identified as SVHC in the so-called "Candidate List" (CL). This CL is a "living document", typically updated twice per year, with new substances being added each time.

Substances recommended by ECHA to the Commission, for potential inclusion in Annex XIV are selected from this CL. Annex XIV is the list of substances subject to authorisation.
Alternatively, a restriction can also be proposed for SVHC substances.

Link to ECHA Recommendation:
http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

> ***Examples** of substances without a threshold that were recommended for inclusion on Annex XIV at the time of publication (2012) and that are known to be used in many industries include Chromium Trioxide, Sodium Dichromate, Potassium Dichromate, Trichloroethylene, Dichloroethane and MDA. Further details on the categories of substances that require authorisation can be found on ECHA's website*
>
> *link to Annex XIV: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list*

What is the impact of substances of very high concern (SVHCs) on article producers?

1. Notification of SVHCs in articles within 6 months after inclusion of a substance on the CL

According to Article 7(2) of the REACH Regulation (EC) No 1907/2006, producers and importers of articles have to notify to ECHA if the substance listed on the candidate list is present in their articles above 1tonne/year and in a concentration > 0.1% w/w. If the use of the SVHC in articles has already been covered in the registration dossier, or if no exposure to human or environment can be foreseen from that use, no notification by the article producer/importer needs to be submitted to ECHA.

http://echa.europa.eu/en/web/guest/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

2. Communication of SVHCs in articles immediately after inclusion on the CL

According to Article 33(1) and (2) of REACH, any supplier of an article containing a substance meeting the SVHC criteria in a concentration above 0.1% w/w shall provide:

- (1) the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article, including, as a minimum, the name of the substance.
- (2) the consumer (on his request) with sufficient information, available to the supplier, to allow safe use of the article, as minimum the name of the substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

3. SVHC on the authorisation list (Annex XIV):

For *imported* articles, the substances listed in Annex XIV that are an integral part of articles (as defined in Article 3(3) of the REACH Regulation) will not require an application for authorisation. However, substances in imported articles can still be subject to a restriction.

For articles *produced* in the EEA (European Economic Area), the substances listed in Annex XIV that are 1) an integral part of these articles will require an application for authorisation if the intention is to use the substance (in this case, use means incorporate it into the article) after the sunset date, unless an exemption applies to that (category of) use. This application can be submitted by the article producer or by the upstream supplier which has decided to cover the article producer's use in their application for authorisation.

2) used in the production process of the article but not included in the final article, will require an application for authorization covering the whole manufacturing process of the article.

Note: The use of the article containing an Annex XIV substance is not a use of a substance requiring an authorisation; however the article service life and its end of life shall be assessed in the exposure scenarios (Chemical Safety Report) provided in the application for authorisation covering the use of the substance.

Where articles are produced in the EEA before the sunset date and held in stock;

- ***There is a need to apply for the use of a substance but not for the use of articles* containing the substance. *Therefore, authorisation is not required when assembling parts of articles.***
- ***The whole life cycle (including the article service life) shall be covered in the CSR provided in the application for authorisation covering the substance use.***
- ***Articles (or parts of articles) in stock produced in the EEA* before *the sunset date can be supplied* after *the sunset date.***
- ***Communication obligations remain for substances listed on the CL contained in articles at more than 0.1%weight/weight.***

What is the authorisation procedure?

> ***The authorisation process for the use of an Annex XIV substance is independent of the registration process. Therefore, it is required no matter how low the tonnage might be.***
>
> ***For registration, only substances manufactured or imported in quantities of > 1 tonne per year are relevant. This means that there are substances that require authorisation but do not require registration!***

The authorisation may be granted or not. The ECHA Committees form an opinion which is sent to the Commission for decision-making.

> ***An application for authorisation may include a request for the length of time of continued use. However, the Commission decides on the time-limited review period.***
>
> ***If an authorisation application is denied, applicants can lodge an appeal against the adverse decision of the Commission before the European Court of Justice (in Luxembourg).***
>
> ***The authorisation may be reviewed or suspended by the Commission at any time, if information regarding possible replacement substances becomes available or the circumstances of the authorisation have changed.***

Timeline

The timeline for the authorisation process is very tightly controlled so it is necessary to take into consideration the time submission window period when defining your business strategy. ECHA has to receive the payment of the fees before the latest application date in order to ensure market continuity after the sunset date and before Commission's final decision.

Every applicant submitting a dossier after the latest application date has to stop using the substance after the sunset date until authorisation has been granted. On the other hand applicants, who have submitted an application before the latest application deadline specified in Annex XIV but have not yet received a decision, can still use the substance after the sunset date.

In order to clarify regulatory and procedural issues related to the application for authorisation, as well as the wording published for the public consultation on alternatives, the applicant may use the opportunity to meet ECHA during the pre-submission information session (PSIS); One session per applicant, requested to ECHA no later than 8 months before the submission is foreseen.

Hereafter, the timeline indicates the commenting period for stakeholders available from the publication of the Annex XV SVHC dossier until the decision given by the European Commission on the application for authorisation. All supporting information must be provided ONLY during the three

public consultation periods shown in Figures 1-4. It is strongly recommended that Downstream Users use the opportunity to comment. The information as described in the following table should be included in the comments. Downstream users can comment for example that some specific uses shall be exempt from authorisation or some uses need a longer review period. **Don't miss it!**

Deadlines must be respected.

ECHA / Commission	Third party
Notice that Annex XV dossier has been prepared placed on ECHA website (Article 59(4))	Comments invited from interested parties within specified time period (Article 59(4))
Substance placed on candidate list, recommendations for priority substances published on ECHA's website (Article 59(10))	Comments invited from interested parties, in particular on uses that should be exempted within 3 month time period (Article 58(4))
Substance placed on Annex XIV, applicant applies for authorisation, ECHA publishes information on broad uses on website (Article 64(2))	Information on alternatives invited from third parties within a specified time period (Article 64(2))
ECHA may request further information from third parties (Article 64(3))	Interested parties may still provide information on alternatives to ECHA (Article 61(2))
Granting of authorisation (Article 60)	
Review of authorisation (Article 61)	Comments invited from interested parties (Article 61, 64(2))

An authorisation dossier should include information provided by all actors of the supply chain.

- Application may be submitted by the manufacturers, importers, DUs or ORs
- Therefore, *communication* in the entire supply chain is important.
- All actors need to consider the level of involvement they may need in the authorisation process.

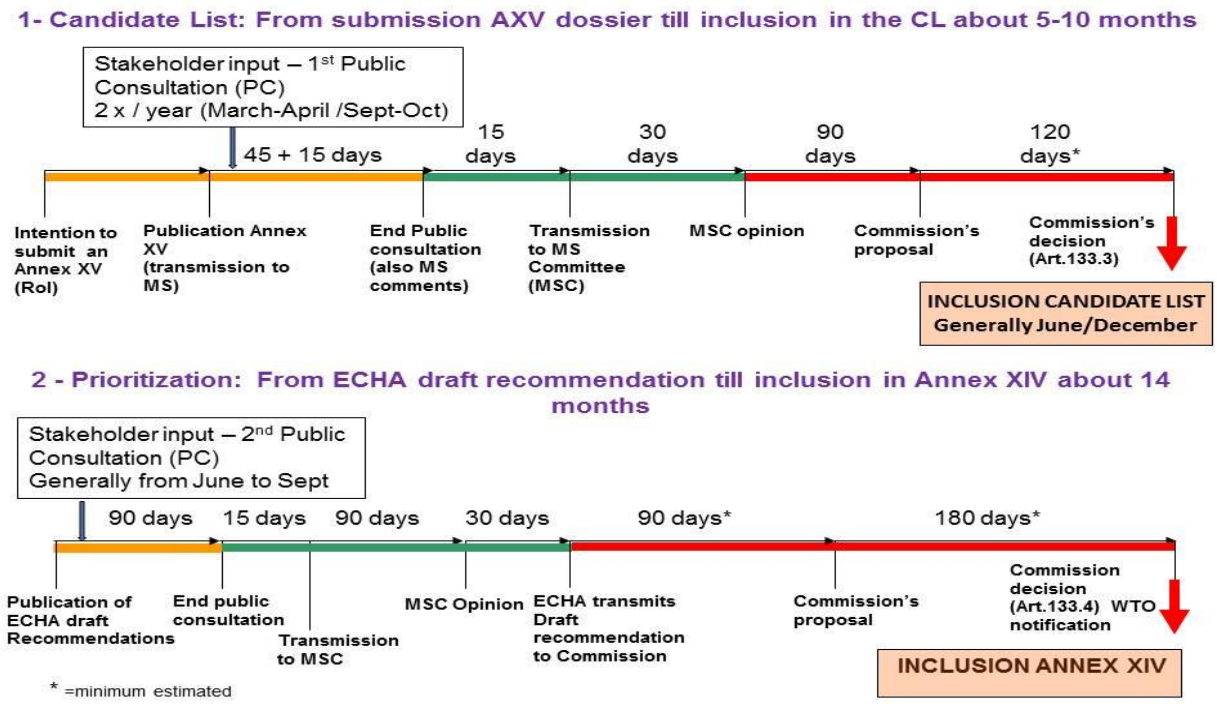
For instance, communication ensures the producer is aware that a DU is willing to support authorisation and thus keep the chemical on the market.

Figure1. "Candidate List" timeline: selection of substances for the "Candidate list".
From submission of the Annex XV dossier till inclusion in the CL, it takes approx. 5 to 10 months.

Figure2. Prioritisation timeline: substances selected by ECHA from the CL to enter Annex XIV
From the ECHA draft recommendation till inclusion in Annex XIV, it takes approx. 14 months.

Figure3. Application for authorisation submission window timeline: Time to submit your application
From notification till latest application date, it takes approximately 11 months.

Figure4. Authorisation granted or refused: Timeline for the evaluation and granting of the authorisation. From application submission till Commission final decision, takes up to 2 years.



Note on the first step: SVHC proposal

- There are 2 public consultations/year on SVHC proposals (generally one in March-April, then in Sept-Oct).
- If a general agreement is reached at the MSC, the substance goes directly (or not) to the "Candidate List" without any input from the Commission. => inclusion after 5 months is possible. If a single Member State disagrees on the opinion, the Commission will decide and inclusion of the substance into the "Candidate List" may take longer.
- Final inclusion on the "Candidate List" generally happens twice a year (in June and December).

Note on the second step: recommendation

- Public consultation for recommendation for inclusion in Annex XIV generally takes place from June to September.
- In case of no unanimous agreement at the MSC, REACH foresees an involvement of the Commission in the process.

Who can apply for an authorisation?

The requests for authorisation may be submitted by:

- the **manufacturers** or **importers** of the substances
- the **downstream users**, which may include formulators as well as end-users of the substance on its own or in a mixture and producers of articles
- the **Only Representative** (OR)
- any combination of these.

An application for authorisation can be submitted:

- for one or several uses
- for one or a group of (similar) substances

Depending on the complexity of the supply chain, it is highly recommended;

- ***To enter into contact with all actors involved (suppliers, customers, etc…)***
- ***To determine who has the best knowledge on the use of the substance and have them apply. This must be based on company specific internal business decision. It could be the M/I/DU or OR.***
- ***Once decided, ensure the applicant has all the information needed to cover your use and those of your DUs.***

A manufacturer/Importer or a non-Community manufacturer represented by an "only representative" may only sell the substance for a given use if he and the use are covered by a granted authorisation. Authorisation obtained by M/I/OR or by an immediate DU.

DUs may only use an authorised substance if the authorisation is granted to a company further up their supply chain and their uses are covered.

In cases where a downstream user uses the substance on the basis of the authorisation granted to his supplier, the downstream user shall notify ECHA within three months of the first supply of the substance (Art. 66(1)).
If none of the companies in the supply chain holds an authorisation, all users must cease use immediately after the sunset date until such time as they find another duly authorised supplier.

The downstream or end-user, the chemical manufacturer or any other actor in the supply chain can seek a joint authorisation for a substance. Therefore, the users will need to ensure that the use(s) of their supply chain are covered as well as their own.

In a joint application, some documents regarding the Socio-Economic Analysis (hereinafter SEA) and the Analysis of Alternatives (hereinafter AoA) will probably contain sensitive and individual commercial data that cannot be exchanged between competitors. Nevertheless SEA and AoA need to be as complete and meaningful as possible. A careful assessment and drafting of the Broad Information on Uses (BIU) statement by the applicant can provide good guidance for the detail of the AoA and SEA.

In any case, when multiple applicants are preparing applications partially or completely together, it is recommended that applicants provide a clear set of assessment reports per combination of applicant-use-substance i.e. one CSR/ES, one AoA, one SP, and one SEA is developed for each combination. This information shall be clearly identified in the IUCLID dossier (see Dossier Submission Manual – 22: How to prepare and submit an AfA using IUCLID 5)
http://echa.europa.eu/documents/10162/13653/data_submission_manual_22_application_authorisation_iuclid5_en.pdf

Strict measures have to be adopted in order to be compliant with Competition law (refer to Cefic document on *do's and don'ts – competition law*) and to protect Confidential Business Information (CBI).
http://www.cefic.org/Documents/IndustrySupport/Cefic%20REACH%20AUT%20Competition%20DO%20-%20DONT%20first%20edition%20DEC%2010.pdf) or
http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

- An authorisation granted to a ***Manufacturer or Importer*** of a substance could cover throughout the complete supply chain, all known uses specified in the AfA.
- An authorisation granted to a ***Formulator*** could cover throughout his complete supply chain all known uses of the mixture identified specifically in the AfA.
- An authorisation granted to a ***Producer of articles*** using the substance could cover his own use, and could also cover the placing on the market of the substance by his immediate supplier. Such an authorisation seems to be very limited in benefit but might be useful for simple cases where a unique use is confidential.
- An authorisation granted to a ***downstream user*** of the substance covers that use and that of his customers down his supply chain. This authorisation could also cover the placing on the market of the substance by the downstream user's immediate actor(s) supplied up his supply chain (i.e. manufacturers, importers or formulators from which the DU purchase the substance directly or via distributors), but no further up the supply chain. Therefore if the immediate supplied actor is the manufacturer or importer of the substance, that would cover the supply chain but if not, the upstream supply chain is **not** covered by the authorisation.
- ***Distributors*** are not users or DUs according to REACH Regulation-Art 3(13). There are not entitled to apply for an authorisation.

When and how can the downstream user contribute to the authorisation process?

> ***At each step, for each public consultation, the most effective method for commenting is via your industry sector groups, your trade association, at both national and European levels. They will consolidate inputs from their member companies to submit to the authorities during the public consultation. The earlier they receive this information the more effective it will be.***

1. **When the substance is included in the Registry of Intentions:**

   The authorisation procedure begins when a Member State or the European Chemicals Agency (on behalf of the European Commission) uses the possibility to publicly announce their intention to prepare an Annex XV dossier for identification of a SVHC via the Registry of Intentions. This publication allows stakeholders to start preparing their application for authorisation and business strategy.
   http://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions

   At this stage, REACH does not foresee an official process for industry to interact directly with ECHA. However, it is possible to provide relevant input via Member States or consultants of Member States who prepare the Annex XV dossier. *Providing information at this stage may lighten regulatory work on the substance or even prevent the proposal for the candidate list or indicate availability/development of other most relevant risk management option*.
   Companies should start gathering information on e.g. SEA and AoA to help and guide them on business strategy decision.

2. **When submission of an Annex XV dossier identifying SVHCs is published:**

   Once the Annex XV dossier has been published on the ECHA website, the downstream user has a **period of 45 days** to comment (Public Consultation Period). There are 2 public consultations (hereinafter PC) per year on SVHC proposals (generally one in March-April and one in September-October). Comments to the Agency usually relates to the identification of the substance as SVHC. Information on the uses of the substances (including data on tonnages per use and exposures or releases resulting from these uses), on the availability of safer alternative substances and techniques and the structure of supply chains is also welcome. ECHA will however rather consider this information when recommending SVHCs in the "Candidate List" for inclusion in the authorisation list (Annex XIV).
   More information is available at: http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp

3. **When the "Candidate List (CL) is published:**

   It is not possible to intervene but legal obligations need to be fulfilled (Article 33, Communication and Article 7(2), Notification).
   DUs are advised to monitor the information on ECHA website to check the biannual CL update.

4. **When the substance is proposed for prioritisation:**

   Indication of the substances on the candidate list to be included as a priority in Annex XIV.

The Agency will publish the list of priority substances on its website, proposed to be included in Annex XIV (Article 58(3)). Downstream users may submit their comments over **a three-month period** (Article 58(4)).
http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/consultation-on-draft-of-20-june-2012-of-echas-4th-recommendation.html

After that time, based on the comments received, the Member State Committee will prepare an independent recommendation for ECHA and they (ECHA) will prepare the opinion and transfer a final recommendation to the European Commission. The European Commission will finally decide according to the comitology procedure whether or not to include substances in Annex XIV, which exemptions should be granted and what should be the sunset date.

5. **When the substances is included in Annex XIV:**

No possibility to intervene on the process but at this point producers and users of Annex XIV substances *must* decide whether or not to make an application for authorisation for an/each individual use of the substance.

In addition there are further opportunities to comment during the process:

6. **When an application is submitted:**

- As an applicant, keep in contact with ECHA and the Commission.
- As a third party, comments on possible alternatives may be submitted during the public consultation on alternatives which is based on broad information on uses (BIU) that follows the submission of an application (Article 64(2)).

7. **When authorisation is granted:**

- As an applicant, keep the contact with ECHA and the Commission even after authorisation is granted
- As a third party, comments on possible alternatives may be submitted at any time.

How to define the authorisation strategy?

1. Produce an inventory for all substances and uses in your business (check the SDS)
2. Check the list of uses already exempted in Annex XIV, if any.
   http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf
3. Compare and highlight those substances used against the Registry of Intentions, Candidate list and Annex XIV. Substances included in the Candidate List will appear in the SDS of your suppliers after 6 months of inclusion on the Candidate List. Check the SDS.
4. Assess the importance of the substances for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures
5. Identify the actors within your supply chain.
6. Contact the suppliers (particularly the manufacturer/importer of the substance or mixture) to ascertain if they are considering substitutes or the development of alternatives.
7. Identify as much as possible who in the supply chain will be applying for an authorisation.
8. Contact the consortium or any working group on authorisation.

9. Decide on your own substance strategy i.e. authorisation, substitution (or exemption) and how it fits with your sourcing/supply chain strategy.

- ***Do not forget that an application for authorisation requires a lot of data, including some which may be available to registrants, manufacturers or other actors in the supply chain but not directly to the downstream user or end-user of a substance.***
- ***Some relevant information can be extracted from the Chemical Safety Report and are related to the threshold/non-threshold status, the DNELs and DMELs. It is highly recommended that all applicants use the same references to avoid choosing different authorisation route or using different DNEL references to proof adequate control.***
- ***However, depending on the length and transparency of the supply chain, information on the precise conditions of use and information on potential alternatives are often better known by the downstream users.***
- ***Therefore, communication within the supply chain plays a key role in gathering relevant information for the application for authorisation.***
- ***Collecting and generating data (e.g. for use in the Socio-economic Analysis (SEA)) is resource and time consuming and costly. Joint application can be considered if combined actions provide benefits and are in line with CBI concerns and legal constrains.*** **(refer to Cefic documents *-do's and don't – competition law).***
- ***As the application must be submitted at least 21 months (18+3 to define the BiU and pay the fees) before the sunset date, and a SEA takes about 1 year to put together; gathering all data needed for the dossier will take a minimum of 2 years.***
- ***Starting your SEA early is essential and should be part of the corporate/company decision-making process on whether to apply for authorisation or not.***

Two kinds of authorisation dossiers may be submitted

There are two ways to build an authorisation dossier depending of the recognition of a threshold concentration for the substance:

- For the threshold substances, by demonstrating that the risk from the use of this substance is adequately controlled throughout its life cycle (Article 60(2))
- For the non-threshold substances, by demonstrating that benefit is outweighing the risk. Meaning that the socio-economic advantages prevail over the risks to human health or the environment arising from the use of the substance, and that there are no appropriate replacement substances or technologies (Article 60(4))

For the SEA route, it is mandatory to demonstrate that socio-economic benefits outweigh the risks. Whereas for the adequate control route a socio-economic analysis (SEA) is recommended to be included in the application (see Appendix 1 of REACH for details on socio-economic analysis and dossier content).

Time limited authorisations (Review)

Authorisations are granted until a specific date by which the holder of the authorisation will have to resubmit an application (i.e. a review report). Review dates are set **on a case-by-case basis** and are driven by the information provided by the applicant, in particular the substitution plan and the analysis of alternatives.

To renew an authorisation, a **revised report must be sent to ECHA by the holder** at least **18 months** before the expiry date of the time limited review period defined in the authorisation decision.

This review report will then be processed and the authorisation may in certain circumstances be renewed.

The Commission may decide to withdraw, suspend or modify the authorisation **at any time** for the reasons below:

- if the circumstances have changed since the initial request was made (health or environmental hazard or socio-economic impact)
- if new information on possible replacement substances becomes available
- in the case of a serious and imminent risk for human health or the environment
- If an environmental quality standard is breached
- Uses of a substance that are subsequently prohibited or otherwise restricted under the Persistent Organic Pollutant Regulation (EC) No 850/2004 (hereinafter POPs Reg.) must be withdrawn from authorisation (for those uses). See Art 61.6 of REACH. If a substance is going to be banned with possible (time limited) exemptions under the POPs Reg. it should only be included in Annex XIV for the exempted uses.

The only route for appeal is the existing one for challenging decisions of the European Commission via the European Court of Justice

Authorisation exemption

The downstream users may request exemptions for their use(s) when the Agency publishes the list of substances recommended for authorisation on its website (Article 58(4) REACH). Check the publication of the ECHA's Annex XIV draft recommendations. The deadline for submitting this request is 3 months after publication.

Authorisation covers all the stages of the life cycle of a substance for a specific use. It is therefore not possible to get an exemption based on when a substance is exempted under other legislation and where only one stage of the life cycle is taken into consideration (e.g. only the production process). However, if a piece of legislation is prohibiting the use of substances in end products and if this prohibition has an impact throughout the complete life cycle (e.g. end-of-life legislation like ROHS or ELV), an exemption for this particular use *might* be worth to be considered. But at this stage, exemptions remain an open issue; more clarifications would be welcome in a following document.

Exemptions are most likely where the risk is properly controlled for specific uses, on the basis of other existing Community legislation (Article 58(2) REACH), or where it is based on Scientific Research, or Product/Process Oriented Research and Development (PPORD) (Article 56(3) REACH), ECHA and the EC presently state that such reference legislation must be substance specific.

Intermediates (but not catalysts) are exempt from authorisation for a specific applicant for as long the use fully complies with the definition of intermediates. A rejection of the intermediate status would automatically imply a need for a granted authorisation to pursue activities with this substance.

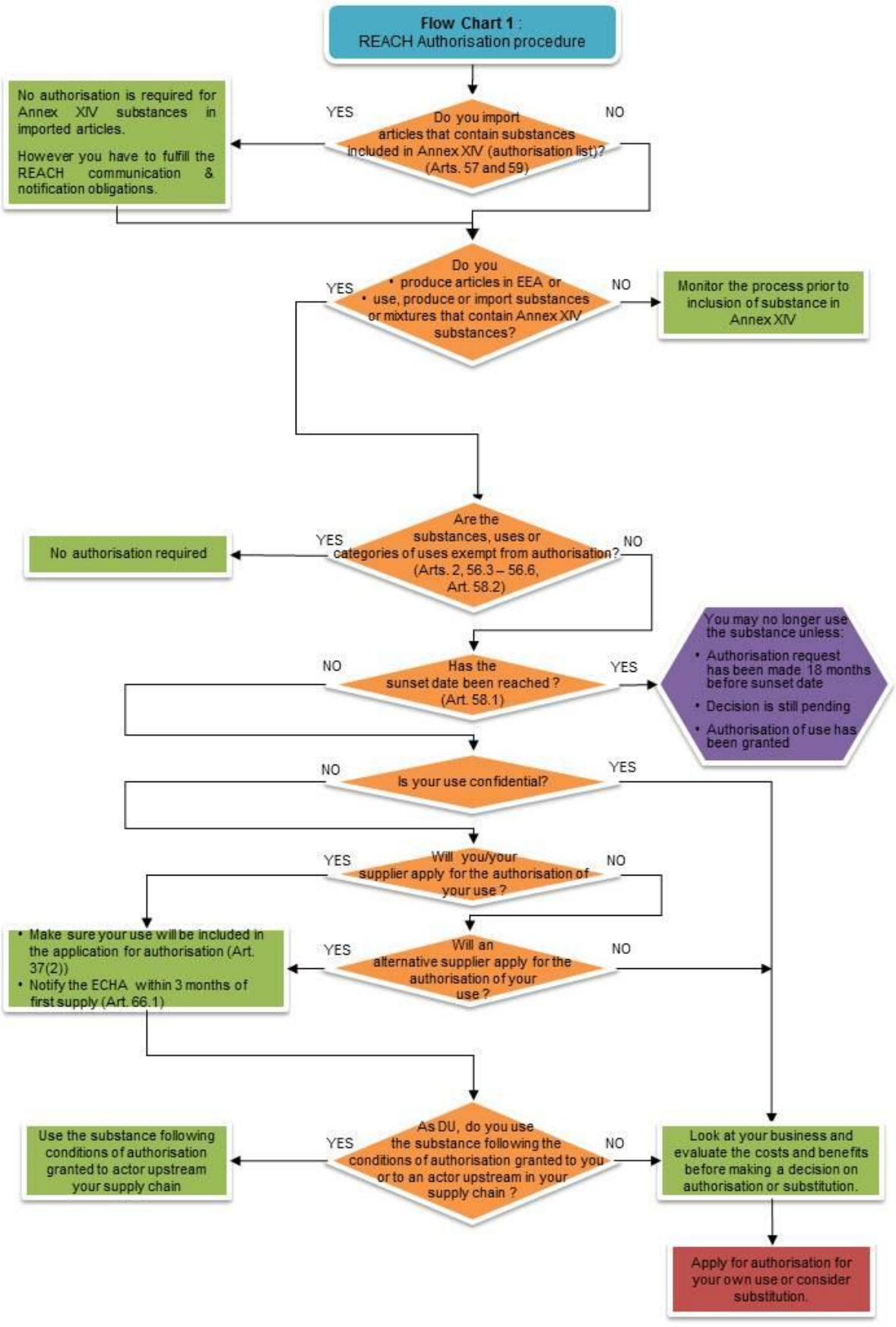
Based upon the knowledge existing in many industries today, an authorisation strategy relying on exemption is at risk of failure.

ECHA have provided a document listing generic exemptions from authorisation:
http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf.

Duties of downstream users (DUs) regarding authorisation

1. Once authorisation is granted, DUs shall notify the ECHA within three months from first time receiving the substance if this substance is used in accordance with the authorisation granted for that use (Article 66(1) REACH).

2. Holders of an authorisation, as well as DUs referred to in Article 56(2) REACH including the substances in a mixture, must include the authorisation number on the label before they place the substance or a mixture containing the substances on the market for an authorised use. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9) REACH. Where a substance is subject to authorisation it must also be mentioned in section 15.1 of the SDS.


Flow Chart 1 :
REACH Authorisation procedure
Do you import articles that contain substances included in Annex XIV (authorisation list)? (Arts. 57 and 59)
YES
NO
No authorisation is required for Annex XIV substances in imported articles.
However you have to fulfill the REACH communication & notification obligations.
Do you
• produce articles in EEA or
• use, produce or import substances or mixtures that contain Annex XIV substances?
YES
NO
Monitor the process prior to inclusion of substance in Annex XIV
Are the substances, uses or categories of uses exempt from authorisation? (Arts. 2, 56.3 – 56.6, Art. 58.2)
YES
NO
No authorisation required
Has the sunset date been reached ? (Art. 58.1)
NO
YES
You may no longer use the substance unless:
• Authorisation request has been made 18 months before sunset date
• Decision is still pending
• Authorisation of use has been granted
Is your use confidential?
NO
YES
Will you/your supplier apply for the authorisation of your use ?
YES
NO
• Make sure your use will be included in the application for authorisation (Art. 37(2))
• Notify the ECHA within 3 months of first supply (Art. 66.1)
Will an alternative supplier apply for the authorisation of your use ?
YES
NO
As DU, do you use the substance following the conditions of authorisation granted to you or to an actor upstream in your supply chain ?
YES
NO
Use the substance following conditions of authorisation granted to actor upstream your supply chain
Look at your business and evaluate the costs and benefits before making a decision on authorisation or substitution.
Apply for authorisation for your own use or consider substitution.

If you are submitting an application for authorisation, there are limitations on what can be included. Please refer to the recommendations and tips below.

When an application for authorisation is made for your own use, make sure the substance manufacturer intends to provide you with the substance in the long term.

List of recommendations for DUs and tips for authorisation

- Produce an inventory of all substances and uses in your business (check the Safety Data Sheet (SDS)).
- Compare and highlight those substances used by your company against the Registry of Intentions, "Candidate list" and Annex XIV. (CL is generally updated in June and December).
- Assess the importance of the substances for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures.
- Evaluate the costs and benefits to your business, industry, economy.
- Identify the actors within your supply chain.
- Contact the suppliers (particularly the manufacturer/importer of the substance or mixture) to ascertain if they are considering substitutes or the development of alternatives. R
- Identify who in your supply chain will be applying for an authorisation.
- Decide on your own substance strategy i.e. authorisation, substitution (or exemption) and how it fits with your sourcing/supply chain strategy.
- When a substance enters the "Candidate List", as DU, provide information on your use showing there is no risk handling this threshold substance. For non-threshold substance, a demonstration of no exposure may ensure to avoid prioritisation.
- Do not miss the public consultation period. All information has to be provided during the fixed time period.
- Investigate whether to limit your use of the targeted substances. Using potential alternatives should be carried out with the agreement of both customers and suppliers (fulfilling e.g. the technical/quality requirements).
- If you use an Annex XIV substance to produce an article, communicate your use upstream and check if your supplier has achieved an authorisation application number. If not, consider making your own application for authorisation of use.
- An authorisation application submitted by a DU can only cover the DU's uses, the uses of "his" downstream supply chain (i.e. your customers, their customers etc), and only the "placing on the market of the substance" by his immediate supplier (i.e. one level up his supply chain). A DU cannot cover other use up his supply chain.
- When determining the date to submit your application, don't forget to consider the three months period between the submission of the application and the official date of receipt (payment of the fee received and opening of the public consultation). Therefore it is recommended to submit your dossier at least 21 (18+3) months before the sunset date.

- Substitution of substances falling under the scope of authorisation (listed on the "Candidate List" and fulfilling the criteria for prioritisation) is recommended for new developments if technically and economically feasible. Consider the hazard profile of the replacement substance in your assessment.
- For existing products, if production of this product containing the targeted substance is going to cease prior to the sunset date, substitution will not be necessary for that use.
- For existing products, if production is going to continue after the sunset date, you will need to consider substitution of the substance requiring authorisation unless an authorisation for this specific use was obtained.
- Consider the contractual requirements between you and your supplier. You may want your supplier to inform you about their intentions to authorise or substitute the Annex XIV substance.
- Once authorisation is granted the review period may, in principle, be suspended at any time.
- As flexible strategy is needed in your business, do not entirely rely on the review period mentioned in the Commission's final decision.

Appendix 1

Writing a Socio-Economic Analysis:

This will involve comparing the benefit of no longer using the substance on the workforce, within the locality, and across the substance life cycle in comparison to the social and economic benefits from continued access to it.

Arguments could include:

- Adverse effect on other significant environmental impacts by changing the substance.
- Adverse effect on employment and economic prosperity in the EU at specific locations, regionally and nationally.
- Whether the risk will just be shifted to outside the EU because of the authorisation, rather than reduced.

Tools that can be used for SEA include cost-benefit analysis, macroeconomics and life cycle analysis amongst others. See: http://echa.europa.eu/documents/10162/13643/sea_authorisation_en.pdf

Content of the dossier to be sent to the Agency

All dossiers must contain:

- The identity of the substance(s);
- The name and contact details of the person(s) submitting the request;
- The use(s) for which the authorisation is being requested;
- The chemical safety report;
- The analysis of the replacement solutions, examining the risks as well as their technical and economic feasibility.

In the case of a request for an authorisation based on the socio-economic advantages provided by the use of this substance or if a substitute has been identified, the dossier must also contain:

- a substitution plan with an action timetable (under the adequate control route when suitable alternatives are available);
- a socio-economic analysis (under the SEA route in any case, and recommended on the adequate control route in case RAC concludes that adequate control has not been demonstrated by the applicant).

Fees

The fee stipulated in Title IX must be paid within 2 weeks after receiving ECHA's invoice.
The fee must have been paid and funds cleared by the final application date.
In all cases, there is a reduced fee for companies considered as SMEs according to REACH legislation.

Glossary and acronyms

AfA

Application for authorisation

AoA

Analysis of Alternatives

Annex XIII

Sets out the criteria for the identification of PBT and vPvB substances

Annex XV dossier

A dossier produced in compliance with Annex XV. This consists of two parts, a technical dossier and the Annex XV report. The Annex XV dossiers submitted for inclusion in the registry of intentions are under one of the three decision-making processes: identification of SVHC substances, restrictions or harmonised classification and labelling.

Annex XIV

List of substances subject to authorisation.

Article

An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

BIU

Broad information on uses

Candidate List

List of substance identified as being SVHC.

Competent authority

The authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

Distributors

Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.
Distributors may not import from outside the EU or repack the substances or preparation.

DNEL

Derived No Effect Level (substance with a threshold)

DMEL

Derived Minimal Effect Level (substance without a threshold)

Downstream user

Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user.

EC

European **C**ommission

ECHA

European **Ch**emicals **A**gency

EEA

European **E**conomic **A**rea. European Union which includes all the current 27 Member States plus Iceland, Liechtenstein and Norway.

Importer

Any natural or legal person established within the Community who is responsible for import.

Intermediate

Means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):

(a) Non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

(b) On-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

(c) Transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

LE

Legal entity is used to refer to such a natural or legal person having rights and obligations under REACH. (Details of legal aspects please refer to ECHA guidance on registration p20).

Manufacturer

Any natural or legal person established within the Community who manufactures a substance within the Community

MSCA

Member State Competent Authority (see above “Competent Authority”).

PBT

Persistent, Bioaccumulative and Toxic substance

PPORD

Product and process orientated research and development

Any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance

Preparation

Means a mixture or solution composed of two or more substances;

RAC

Risk Assessment Committee (or Committee for Risk Assessment)

RMM

Risk Management Measure

RMO

Risk Management Option

RoI

Registry of Intention, available at ECHA website: http://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions

SEA(C)

Socio-Economic Analysis (Committee)

Substance

Means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

SVHC

Substance of Very High Concern

Use

Means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization.

vPvB

Very Persistent, very Bioaccumulative substance