Authorisation and Restriction Newsletter

August 2010, N°1

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Cefic has published and is developing a number of guidance documents.

Please visit the REACH section of the Cefic website for more information: http://cefic.org/en/reach-for-industries-documents-and-tools.html

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The aim of this guide

REACH[i] aims at "ensuring a high level of protection of human health and the environment as well as the free movement of substances, on their own, in mixtures and in articles, while enhancing competitiveness and innovation. REACH should also promote the development of alternative methods for the assessment of hazards of substances" (Recital (1)).

A main objective is to establish a coherent registration system designed to identify relevant risk management measures based on hazard and risk information on new and existing chemical substances manufactured in or imported into the EU.

In parallel REACH Regulation provides the maintenance of the existing restriction system and the introduction of an authorisation process. So, both are regulatory instruments for authorities to manage the risks of hazardous chemicals under REACH. They ensure a Community wide control of substances.

The Authorisation process – a new tool within the Community chemicals legislation - starts with the identification of substances of very high concern (SVHC) by Member State Competent Authorities or the European Chemicals Agency, ECHA, (on behalf of the European Commission) by preparing a dossier in accordance with Annex XV. Decisions on prioritisation of these SVHCs and release of the final list of substances subject to authorisation: the official Annex XIV of REACH, is decided by the Commission through comitology procedure. Industry has to apply at ECHA for authorisation for uses of these substances. After an approval process (Commission through Comitology), the holder of an authorisation can use and place on the market the substance for the uses he was granted an authorisation.

The Restriction provision will be presented in the next release of the Newsletter.

The present Newsletter focuses on the Authorisation process by presenting the main documents, the actors and actions to be performed and the timeline of the process.

Authorisation – Title VII of REACH regulation

1. Aim of the authorisation process

The targets of the Authorisation process are substances of Very High Concern (SVHC).

As stated in Article 55 of the REACH Regulation, the Authorisation process aims at ensuring "the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable". To this end, all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

For all stakeholders, it is important to note that the authorisation process can occur in parallel from registration and evaluation processes. While registration gives the right to market a substance, authorisation process provides the right to marketing and using SVHCs for specific uses.

It is also important to realise that the Authorisation process under REACH comprises two distinct steps; the first one is related to the introduction of substances into the Annex XIV that is triggering the authorisation procedure, which is essentially a responsibility of Member States, ECHA and the Commission. The second one is the application for authorisation followed by granting (or not) of authorisation which is a Commission decision based on ECHA's committees' opinions. Authorisations will be granted if the applicant can demonstrate that the risk from the use of the SVHC is adequately controlled. The "adequate control route" does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.
If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies.

2. Substances: included and exempted

2.1 WHAT ARE THE SUBSTANCES COVERED BY THE AUTHORISATION PROCESS?

All substances of Very High Concern (SVHC) listed in Annex XIV of REACH are falling under the Authorisation process. Definition and identification of SVHCs are described by Art 57 and 59(1) of REACH, amended by the CLP Regulation.

The properties of SVHCs were initially defined in Article 57 of REACH.

These criteria are:

- Carcinogenic category 1 or 2: Substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;
- Mutagenic category 1 or 2: Substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;
- Toxic for reproduction category 1 or 2: Substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;
- Persistent, Bioaccumulative and Toxic: Substances which are persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII of this Regulation;
- Very persistent and very bioaccumulative: Substances which are very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII of this Regulation;
- Scientific evidence of probable serious effects to human health or the environment: Substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in

accordance with the procedure set out in
Article 59.

There is no tonnage threshold for a substance subject to authorisation.

Art 58 of Regulation (EC) N° 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (the so called CLP Regulation) provides amendments to REACH from1 December 2010.

Article 57(a), (b) and (c) shall be replaced by the following:

- *Substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;*
- *Substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;*
- *Substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008;*

2.2 WHAT ARE THE GENERAL EXEMPTIONS?

Some uses of substances are exempted from the provisions of authorisation by article 2 and Title VII of REACH. These uses of substances are already regulated under specific provisions.

The following uses of substances subject to authorisation are exempted[ii]

- Medicinal products for human or veterinary use
- Food or feeding stuffs including uses as food/feed additives and as flavouring in foodstuffs
- As on-site isolated intermediates and transported isolated intermediates
- Substances used for scientific research and development. PPORD activities may be exempted on a case by case basis only during the process of inclusion in Annex XIV
- Substances used for plant protection products, biocides,
- Motor fuel and certain fuels used in closed systems

However if a substance is manufactured or imported for the above mentioned uses as well as for other uses, the uses not described above are not exempted and have to fulfil the authorisation provisions.

For substances in preparation subject to Authorisation, the above list of uses ((a) to (f)) is also exempted if the substances are present in the preparation
below the lowest of the concentration limits, so that the preparation would not have to be classified as dangerous;
and below 0,1% weight by weight for PBTs, vPvBs and substances of equivalent concern.

Monomers to be used for polymer synthesis are exempted because they are regarded as intermediates. Polymers themselves however though exempted from registration and evaluation may be subject to authorisation.

Please note that uses in cosmetic products (Directive 76/768/EEC) and in food contact materials (Regulation (EC) N° 1935/2004) are not exempted from the authorisation procedure. The substances may be subject to authorisation not because of their hazards to human health covered already by the concerned legislation, but because they may meet the other criteria such as PBT or vPvB or equivalent concern.

IMPORTANT
It should be noted that the Manufacturing step does not require and Authorisation.

3. Main documents within the Authorisation process

3.1 THE REGISTRY OF INTENTIONS – THE RoI

It lists the intentions of Member States or ECHA (on behalf of the Commission) to submit Annex XV dossiers. The RoI gathers intentions for the publication on ECHA website of Annex XV dossiers and on top to the authorisation related process, the RoI is as well used for the restriction process or for the preparation of a harmonized classification.

3.2 ANNEX XV SVHC DOSSIER

A dossier produced in compliance with Annex XV. It is elaborated by a Member State to bring a substance on the candidate list. This consists of two parts, a technical dossier and the Annex XV report.

3.3 PUBLICATION OF ANNEX XV DOSSIERS ON ECHA WEBSITE

It lists the substances proposed as potential SVHC (provided via an Annex XV dossier); and which passed ECHA compliance check. ECHA publishes these substances on its website and all interested stakeholders are invited to provide comments. It is the aim of this process to provide information for the assessment to be made by the ECHA Member State Committee regarding the inclusion of these substances within the candidate list, and information on use, exposure and alternatives to be used by ECHA for the prioritisation for inclusion in Annex XIV.

3.4 CANDIDATE LIST

After the commenting period on Annex XV dossiers published on the ECHA website, for identification as potential SVHC, substances may be included in the Candidate List.

The Candidate list is a portal to Authorisation; it is the basis of the Annex XIV (the Authorisation List). Inclusion of Substances in the candidate list triggers some specific obligations for communication in the supply chain. For these substances, manufacturer has to provide information on SVHCs and uses in articles to Downstream Users and, on request, to consumers (REACH Art. 31 and 33 refer both directly to substances in the candidate list). Art. 7 (2) states that producers or importers of articles containing substances on the Candidate list shall notify the Agency if both the following conditions are met:
the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3.5 LIST OF SUBSTANCES PRIORITISED

A list of substances intended for authorisation; comprising of substances of the Candidate List prioritised by ECHA. These draft recommendations for inclusion in Annex XIV will be made public by ECHA. At this stage, interested parties are again invited to provide comments.

Please note that the first recommendation has been sent to the Commission on 1st of June 2009.

3.6 ANNEX XIV – SO-CALLED THE AUTHORISATION LIST

It is the list of substances subject to Authorisation, which is adopted further to a Commission's decision. When a decision is taken to include substances in Annex XIV, some information already available in ECHA's recommendation and additional ones will be given in the Authorisation List:

- Substance identity,
- Substance intrinsic properties of very high concern,
- Sunset date, date by when a substance can no more be used without authorisation
- Application date, date before which an application for authorisation for each use that is not exempted from the authorisation requirement must be made, in order to continue to use the substance for the specific use.
- Review period for uses, if appropriate and
- Exempted uses or categories of uses

4. Actors and their actions within the Authorisation process

4.1 ECHA: EUROPEAN CHEMICALS AGENCY – SO-CALLED THE AGENCY

- Develops and communicates an updated planning for submission dates of the Annex XV dossiers;
- Manages the Registry of Intention;
- Prepares of Annex XV dossier on request of the Commission – ECHA may also comment Annex XV dossiers;
- Includes and prioritises substances on the Candidate List;
- Makes recommendations to Commission to include Substances in Annex XIV;
- Compiles and publishes relevant information on Internet (Annex XV dossier preparation notification, Candidate list, recommendations for Annex XIV); (http://guidance.echa.europa.eu/authorisation_en.htm)
- Manages and keeps up to date a list of downstream users who have made a notification of using a SVHC substance. This registry can be accessed by Member States Competent Authorities.

Within ECHA, there is the Member State Committee, having, among others, the following task:

- Finds when possible an agreement on proposal for identification of SVHCs;
- Adopts an opinion on the recommendation of priority substances to be included in Annex XIV

4.2 COMMISSION: THE EUROPEAN COMMISSION

- May request ECHA to prepare an Annex XV dossier.
- Manages the meeting of Regulatory Committee;
- Adopts final decisions on inclusion/removal of SVHCs in Annex XIV;
- Grants or refuses Authorisation and publishes it in the Official Journal

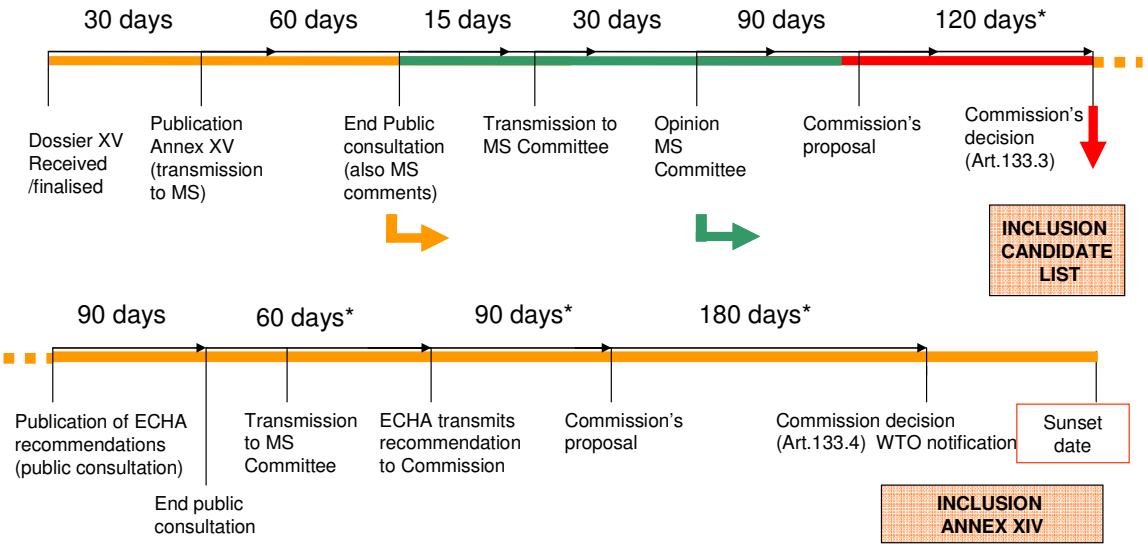
4.3 MEMBER STATES COMPETENT AUTHORITIES (MSCA)

- Prepare Annex XV dossier;
- Present their view to the Members State Committee on inclusion/removal of SVHCs in Annex XIV.

4.4 INTERESTED PARTIES: INDUSTRIES, MEMBER STATE AUTHORITIES, NGOS, GENERAL PUBLIC

- Make comments on Annex XV dossiers;
- Make comments on the draft recommendation for inclusion of SVHCs in Annex XIV;
- In particular, make specific comments on uses to exempt from Authorisation.
- Make specific comments on information on alternative substances or technologies

5. Main stages of the Authorisation process for inclusion of substances in Annex XIV



* = Minimum estimated

5.1 STAGE 1 - IDENTIFICATION OF SVHCS – ESTABLISHMENT OF THE CANDIDATE LIST

In the RoI, a Member State or the Agency (on request of the European Commission) indicates an intention, with an explanation, to submit an Annex XV dossier.

Proposals for substances to be considered as SVHC will be made via the submission of the Annex XV dossier for the substance. The dossier will contain among other information, a justification for the proposal why it is fulfilling the criteria to be a SVHC.
At that stage, interested parties can comment on substances for which such dossier have been presented. Dossiers and comments are reviewed by the Member States Committee and eventually agreed upon.

The outcome of this identification process is a list of substances, which are candidates for prioritisation – this list is called the Candidate List.
The Candidate List is published and periodically updated by ECHA on the Agency web site.

Introduction of Annex XV dossier

The Authorisation process starts when a Member State or the Agency (on behalf of the Commission) initiates work to submit an Annex XV dossier[iii].

This can be made in principle any time of the year. In practice, authorities are asked to respect some proposed schedule dates in order to keep the process manageable. There is an agreement on the dates … a pear to send Annex XV dossiers.

As previously stated, an Annex XV dossier suggests the identification of a substance as a SVHC. This dossier must be conform to the requirements (Section 2 of Annex XV), and must identify and justify which of the intrinsic properties listed in Art 57 of REACH the substance has.

It is recommended that the dossier includes any available information on uses, exposures and alternatives to facilitate the prioritisation process leading to ECHA recommendations for inclusion in Annex XIV.

However, please note that Annex XV dossiers are not only based on registration dossiers but also on 'existing' knowledge. So, substances outside the scope of the registration or substances not yet registered can be proposed for inclusion to the Candidate List.

First public consultation (on Annex XV dossiers)

A 45-days period offers the possibility to interested parties as well as Member States to comment and/or give additional information. The comments can only be done via the web form on the ECHA website, and it's mandatory to respect the different fields within the form.

Companies should use this possibility to provide comments on uses, exposures and alternatives, information which could be taken into account by ECHA in the priority setting. It is important to understand that this information will not affect the discussion whether the substance fulfils the requirements of SVHC.

Opinion of Member States Committee/ Decision of Commission

When the dedicated period is over and no comment has been made, the substance is placed automatically into the Candidate List.

However, if there is any comment, ECHA forwards the dossier to the Member States Committee (within 15 days) which has 30 days to reach unanimous agreement. If unanimity is reached, the substance is then included in the Candidate List by ECHA. If not, the Commission has to adopt a decision, following comitology procedure.

5.2 STAGE 2 - PRIORITISATION PROCESS BY AUTHORITIES – FROM CANDIDATE LIST TO ANNEX XIV

The aim of this stage is to determine a prioritisation among the substances in the Candidate List: to decide which substances will be included in the Annex XIV – the Authorisation list.

Again, in this step, interested parties are invited to submit comments.

At the end, decisions are taken on:

- whether or not the substance will be subject to authorisation;
- which uses of these substances will be exempted from authorisation;
- what will be the sunset and the application date

Publication of ECHA recommendations

At this stage of the process, ECHA will make in parallel:

- the prioritisation of substances listed on the current list of candidate substances for inclusion in Annex XIV.
- recommendations containing
    - substance identity,
    - intrinsic properties,
    - transitional arrangements: sunset date, application date, review periods for certain uses (if appropriate), and
    - exemption from authorisation requirements for certain uses or categories of uses (if appropriate).

In the first prioritisation exercise[iv], ECHA decided to use a pragmatic approach to assess criteria with a qualitative evaluation. The prioritisation criteria like the intrinsic properties, the nature of its uses and its volume supplied to uses are assessed in a weight of evidence approach. The number of criteria met and the extent to which the criteria are fulfilled are important factors to prioritise a substance. However, additional considerations, regarding 'regulatory effectiveness'[v], may also play an important role.

It should be noted that the decision not to prioritize a substance is only valid for the actual priority setting procedure. This substance may be re-considered in a later priority setting procedure.

Second public consultation

Due to REACH text and prior to the submission of recommendations to the Commission, ECHA must publish the draft recommendation with the prioritised substances on its web for comments by interested parties during a 3-month period.

The comments can, for example, be made on

- Exemptions of uses,
- Information on uses, alternatives and risk assessment,
- Socio-economic information,
- Grouping of Substances

After the consultation period, the Member State Committee gives an opinion on the recommendation drafted by the Agency.
In order to prepare the discussion within the Member States Committee, the appointed rapporteur (a Member State, optionally a working group) will draft the opinion on the recommendation and stakeholder inputs.
Then, the discussion starts and the Member States Committee will forward the opinion to the Agency.

Transfer of ECHA recommendations to Commission

ECHA forwards its recommendations of SVHC substances to the Commission in order to include those substances in the Authorisation list.

REACH provides that the Agency shall make its first recommendation of priority substances to be included on Annex XIV on 1 June 2009. The Agency shall make further recommendations for Annex XIV at least every second year. The current planning is approximately once per year, depending on the incoming dossiers and workload.

The final decision to include a substance in Annex XIV is taken by the Commission under a comitology procedure.

Please note that the presence of a substance listed in Annex XIV in articles manufactured outside the EU and placed on the market in the EU is not affected by the authorisation process. It only triggers the obligation of notification (after 01 June 2011) and of communication through the supply chain for such substances.

5.3 STAGE 3 - APPLICATION FOR AUTHORISATION BY INDUSTRY

Annex XIV (the official list of the substances subject to authorisation) is published.

Before placing on the market or using substances of very high concern included in this Annex XIV, a manufacturer, an importer or a downstream user has to apply for authorisation.

The application for authorisation should follow some strict rules:

- An application for authorisation is applicant specific (per Legal Entity).
- Manufacturers, importers as well as downstream users have to analyse the **availability of alternatives** (technology / process) and consider their risks, and the technical and economic feasibility of substitution.
- Applications for authorisation need to be made within a specific deadline for each use that is not exempted from the authorisation requirement.
- A fee has to be paid for each application, per substance and per use.

The ECHA RAC and SEAC Committees will provide expert opinions for all applications; these opinions can be commented by the applicant.

Authorisation applications must include among others a Chemical Safety Report if such report is not yet included in a registration dossier, an analysis of possible alternative substances or technologies, a substitution plan if alternatives are available, and a socio-economic analysis if no adequate control can be obtained (i.e. the case of PBT; vPvB and CMR without threshold effects).

When The *Guidance on authorisation will be available, Cefic will consider the necessity to come up with practical guidance for industry.*

5.4 STAGE 4 - GRANTING OF AUTHORISATION BY THE COMMISSION

Authorisation for a use of a substance will be granted if the applicant can demonstrate that the risk from this specific use is adequately controlled. If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies. Even if an applicant considers that the risk is adequately controlled, it would still be good to provide also evidence on socio-economic benefits outweighing the risks. This is due to the fact that one of the Committees might consider in their opinion that the risk is not adequately controlled. In such a case the application could be justified by the fact that the socio-economic benefits outweigh the risks.

For PBT and vPvB substances, or substances of equivalent level of concern or substances with no threshold concentrations, the 'adequate control route' does not apply.

Authorisation is time-limited and will be subject to review or to suspension at any time. Specifically an authorisation can be revised if changes occur on risk and socio-economic analysis, or if new information is made available on the substance or alternatives (replacement substances). The Commission can also decide to amend or withdraw the authorisation in a review process.

In accordance with Art 61 of REACH, the holder of an authorisation has to send a review report at least 18 months before the end of the revision period. The holder will then need to submit an update on analysis (alternatives, socio-economic, chemical safety report) depending on the situation.

According to Art 65 of REACH, holders of an authorisation, as well as downstream users who are including the substance subject to authorisation in a mixture, shall include the complete authorisation number on the label before they place the substance or the mixture containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 1999/45/EC. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9).

Glossary

Annex XIII
Criteria for the identification of PBTs and vPvBs

Annex XIV
List of Substances subject to Authorisation

Annex XV dossier
A dossier produced in compliance with Annex XV. This consists of two parts, a technical dossier and the Annex XV report. There are 3 different type of Annex XV: for substance of VHC, for restriction proposal, and for harmonised classification and labelling proposal

Annex XV report
A report produced as part of the Annex XV dossier according to the guidance and format outlined in the Guidance on identification of SVHC. Unless specified otherwise, it is implicitly assumed in the text that the Annex XV dossier in this guidance relates to the identification of SVHCs.

Annex XVII
Restrictions on the manufacturing, placing on the market and use of certain dangerous substances

Application date
A date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s).

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;

Candidate List
Candidate list of substances for eventual inclusion in Annex XIV

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

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

ECHA – the Agency
The European Chemicals Agency as established by REACH

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.

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

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;

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

Sunset date
The Annex XIV will specify for each substance included in that Annex the date (so-called the sunset date) from which the placing on the market and the use of the substance shall be prohibited unless an exemption applies or an authorisation is granted or an authorisation has been submitted before the application date also specified in Annex XIV, but the Commission decision on the application for authorisation has not been yet taken.

SVHC
Substance of Very High Concern which meets the criteria of Art 57 of REACH and has been included in the CL according to the procedure described in Art 59.

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.

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[i] REACH: Regulation (EC) No 1907/2006 of the European Parliament and of the council of 18 Dec 2006 concerning Registration, Evaluation, Authorisation and Restrictions of Chemicals – Entered into Force on 1 June 2007.
[ii] IMPORTANT NOTE: please read carefully REACH legal text and ECHA guidance on Authorisation for further and detailed information on exemptions
[iii] See REACH Art 59 (1&2)
[iv] See the 1 June 2009 ECHA paper on general approach for prioritization of SVHC for inclusion in the list of substances subject to Authorisation
[v] Situation may for instance occur where inclusion in Annex XIV will only require regulatory effort but most likely will not result in benefits for human health or the environment