12 May 2017 Version 1.1

Checklist for preparing an application for authorisation or a review report

Introduction

This checklist is meant to support applicants in the preparation of an application for authorisation (AfA) for the use of an Annex XIV substance or authorisation holders in the preparation of a review report.

The checklist includes sections relevant to the three assessment reports: the chemical safety assessment (described in a chemical safety report), the analysis of alternatives (AoA) and the socio-economic analysis (SEA). The checklist also includes a section relevant to review reports, which is only relevant to authorisation holders that wish to continue using an Annex XIV substance after the date of the review period specified in their authorisation decision. As part of the review report, the authorisation holder should update the assessment reports submitted in their application, and prepare an explanatory note outlining what progress the authorisation holder has made in terms of substitution of the Annex XIV substance for the authorised use and what other factors relevant to the authorisation that have changed since the application.

In combination with other available guidance, the checklist will help the applicant/authorisation holder to identify the **key relevant information** to include in an application/review report and to what level of detail it should be described and substantiated with supporting material.

The use of this checklist by an applicant/authorisation holder should help to reduce the likelihood that ECHA's scientific committees for risk assessment (RAC) and socio-economic analysis (SEAC) will request additional information at short notice during their evaluation.

The checklist does not replace other relevant guidance documents or set "minimum information requirements". This is because RAC and SEAC recognise that the minimum information necessary to describe and appropriately justify an application/review report will vary depending on the specifics (and complexity) of an individual application/review report.

As a rule, applicants/authorisation holders should prepare 'fit for purpose' applications/review reports that focus on the information and analysis which is strictly necessary to justify their application/review reports. This should not be interpreted as

meaning that applications/review reports by upstream actors can legitimately contain less information or analysis than applications/review reports for similar uses by downstream users. Rather, applicants/authorisation holders should ensure that all applications/review reports are supported by reliable, representative and transparent data in combination with appropriate analytical methodology, irrespective of scale.

Please note that this checklist is a non-exhaustive document that will be updated from time-to-time by ECHA.

General information

Ensure that the application contains a suitable general description, including the function of the substance and a description of the context (i.e. industrial process) it is used within.

a) Does the Chemical Safety Report (CSR) contain a clear narrative description of all of the tasks described in exposure scenarios and contributing scenarios, including their duration, frequency and location?

- In addition to text, this description could consist of appropriate photographs, videos and diagrams.
- Do not assume that readers of your documents will have any prior detailed knowledge of your use / process.

b) Does the Analysis of Alternatives (AoA) contain a clear description of the function of the Annex XIV substance?

c) Where the application is made by an upstream actor for uses further down the supply chain, is the relationship between the applicant and the downstream users (DU) clear?

d) Does the application describe how many different sites (DU and / or applicant) are included within the scope of the application?

- Where applicable, this should include a description of how these sites vary in terms of their size, capacity, process technology and how are these sites distributed across EU Member States.[1]

e) Does the application describe the tonnage (tonnage range) used per year (overall and per site)? Does the exposure assessment take account of any planned or foreseeable changes to OCs and RMMs in the future (in particular the use of greater but also reduced tonnage)?

f) Does the exposure assessment describe all relevant exposures, i.e. worker (industrial and professional user), general population (via the environment), article

[1] Information on how exposure to workers and releases to the environment differs between sites is also likely to be relevant.

service life, consumer uses and environmental receptors? The exposure assessment should also aim to quantify the following (particularly for applications for non-threshold substances):

- How many workers are directly and indirectly exposed (i.e. bystanders)?
- What is the size of the general population that is indirectly exposed?
- What is the size of the consumer population exposed?

g) For applications by "upstream actors", has any relevant supply chain communication and information received been described? For example, this information may relate to the operational conditions and risk management measures of downstream users, workplace exposure concentrations, environmental releases, technical requirements of customers, potential alternatives, the suitability of alternatives, and socio-economic costs or benefits of continued use.

Chemical Safety Assessment

1. Hazard Assessment

Ensure an appropriate description of the hazard properties, endpoints and reference values used in the assessment.

1.1 Scope of the assessment

a) Does the CSR report hazard data for all relevant endpoints, routes of exposure and potentially exposed populations i.e. derived no effect levels (DNEL), dose-response values or predicted no effect concentrations (PNECs)? Where an alternative to a RAC reference DNEL or dose-response is proposed, this will need to be described in sufficient detail to allow RAC to evaluate it. Specifically consider:

- relevant hazard endpoints (more than one can be listed in Annex XIV);
- relevant routes of exposure (inhalation, dermal, oral);
- potentially affected populations (workers, consumers, general population).

b) Where this is relevant for the analysis of alternatives, is data on other hazard endpoints included?

2. Exposure assessment

Ensure an appropriate description of relevant operational conditions (OCs), risk management measures (RMMs) and exposure estimation.

2.1 Worker (industrial and professional) contributing scenarios

a) Where an exposure scenario consists of several contributing scenarios, is it clear which tasks and workers are covered by each contributing scenario?

b) Is the overall sequence of tasks clear?

c) Does the exposure scenario include tasks leading to potentially high exposure situations (e.g. planned and unplanned maintenance and cleaning operations, sampling, filling and transfer, waste water treatment)?

d) Does each contributing scenario describe a set of OCs (including process technologies) and RMMs with similar exposure potential?

- Is there a justification for grouping different OCs and RMMs within the same contributing scenario?
- Process technologies with different inherent exposure potential (such as automated and manual processes) should not be included within the same contributing scenario.

2.1.1 Operational conditions

a) Are the choice/s of PROC codes justified, particularly if they are relevant for exposure estimation?

b) Are the operational conditions (OCs) sufficiently described?

- Are process conditions relevant to exposure such as volume/mass, concentration of the Annex XIV substance, temperature, pressure, flow rate, location of process (indoor or outdoor) described?
- Are these conditions sufficiently similar within individual exposure or contributing scenarios to allow evaluation of related exposure information?

c) Is it clear how the task is performed, and with what equipment? For example, sampling from a process can be undertaken using a variety of different equipment (open vs closed sampling), with different potential for exposure.

d) Is the frequency and duration of each task described from an individual worker's perspective (considering both a reasonable worst-case and a typical scenario)?

e) Is it clear how many workers are involved in each of the contributing scenarios and whether any of the workers undertake tasks described in different contributing scenarios leading to combined exposure?

2.1.2 Risk management measures

a) Is it clear which, if any, parts of the task are automated?

b) Are risk management measures (RMMs) described in relation to the hierarchy of control principles[2], particularly for non-threshold substances? Is it justified why a

[2] Hierarchical system used to minimise or eliminate exposure to chemical hazards as described in the Chemical Agents Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC). Protection and prevention measures that should be used by employers to reduce risks to a minimum include, in order of decreasing effectiveness (priority): substitution, engineering controls (that avoid or minimise release, such as closed systems), collective protection measures at source (e.g. adequate local extraction or general

higher tier of control cannot be applied (e.g. is it clear why PPE is the only remaining option for risk management)?

c) Are RMMs sufficiently described? For example, do descriptions include information (and justification where relevant) on the appropriateness and effectiveness of each RMM? Where relevant, consider providing:

- Evidence of containment within closed / semi-closed systems[3].
- Details of the intended effectiveness (performance specification) of local exhaust ventilation, fume cabinets or general mechanical ventilation systems (e.g. from the design or commissioning report) and evidence that these performance specifications are achieved.
- Details of the type and effectiveness (e.g. APF) of personal protective equipment (PPE), including compliance with appropriate EN quality standards:
  i. respiratory protective equipment (respirator and cartridge);
  ii. gloves (material, generic or substance-specific breakthrough time);
  iii. other PPE used (e.g. protective clothing, boots, googles).

d) Do descriptions of RMMs outline what preventative maintenance, regular checks, replacement of parts or other controls (e.g. training / monitoring / air-flow indicators) are in place to ensure that the stated effectiveness of RMMs is achieved in practice? *For applications by upstream actors, can these types of organisational RMMs be included in the exposure scenario to ensure that downstream users comply with them?*

e) Are other relevant organisational controls, such as access rights, standard operating procedures, permit to work systems, minimum training requirements etc. described?

f) Where relevant, are any plans to further improve risk management described?

2.1.3 Exposure estimation

a) Are all appropriate routes of exposure considered in each contributing scenario, e.g. inhalation and dermal routes of exposure?

b) Is exposure appropriately estimated and documented?

- Where **measurement / monitoring data** is presented, has it been explicitly linked to the OCs and RMMs described in the relevant exposure scenario or contributing scenario? As such, appropriate contextual information should always be included alongside monitoring data, e.g.:

ventilation), administrative (organisational) controls (such as hygiene measures and demarcation of risk areas) and individual protection measures, including personal protective equipment (PPE).

[3] The guidance and principles for demonstrating "strictly controlled conditions" under article 18(4)(a) to (f) may be useful when considering this.

i. sampling type [e.g. stationary monitoring, personal monitoring, biomonitoring] including details of any relevant standard/protocol followed and the location of sampling/measurement devices,
ii. analytical method used, including the limit of detection and/or quantification,
iii. sampling duration / volume in each location,
iv. number of measurements,
v. date of measurement,
vi. task(s) performed during measurements (or relevant to measurements).

- Has the choice of measurement type been justified, noting that personal monitoring is generally preferable to stationary monitoring and that it is not always possible to link biomonitoring data to specific workplace exposures?
- Could measurement data be supported / corroborated with appropriate modelling data, or *vice versa*, particularly where available data are limited (e.g. limited sampling occasions or data only available for a small sub-set of individual [downstream user] sites that could undertake the use)?
- Where **modelling data** is presented, has it been explicitly linked to the OCs and RMMs described in the relevant exposure scenario or contributing scenario? Equally, has the appropriateness of the models "applicability domain" for both the task and the substance been described? Input parameters and outputs should be reported (potentially in an annex to the CSR)? Have any deviations from default modelling assumptions been clearly stated and justified?
- Have datasets, or relevant third party reports, been provided in an annex to the CSR.
- Have exposure estimates been expressed both with and without the use of PPE (i.e. exposure before any after the efficiency of any PPE is taken into account).
- Has the methodology used to correct exposure estimates for either duration, frequency or effectiveness of RMMs been clearly described e.g. correction of monitoring data to a time-weighted average (usually 8 hours).
- Is it clear what releases represent e.g. are release estimates typical (e.g. average / median), reasonable worst-case or worst-case (maximum) release levels? Where possible, release estimates should be expressed as both typical (realistic) and reasonable worst-case estimates and the underlying variability of the release estimates should be clear; both should be considered during subsequent risk characterisation and impact assessment.
- If measurement data for the substance in question are not available, is data on analogous (similar physico-chemical properties in the same or an equivalent process) measurement data provided and well justified? Note that

use of analogous data for in an application for authorisation is only expected in exceptional circumstances.

c) Where applicable, is combined exposure estimated (aggregated exposure from the performance of a number of contributing scenarios during one shift, or exposure from other uses / processes using the same substance)? Biomonitoring can be a useful approach to estimate combined exposure across routes and tasks, but cannot always be linked to a DNEL or dose-response.

2.2 Environmental contributing scenarios (industrial and professional)

a) Is the choice of ERC justified, particularly if it is used as the basis for release and exposure estimation? Note that default ERC release factors can be refined using a SPERC or site-specific information on the efficiency of RMMs.

b) Are the OCs sufficiently described e.g. tonnage used, number of operating days per year?

c) Are the RMMs used to prevent release to environmental compartments (e.g. air, water and soil) sufficiently described? For example, do descriptions include an estimate of the effectiveness of each RMM and a justification for this level of effectiveness? Specifically:

- For each type of potential release (point, diffuse and fugitive), which types of technical or organisational RMMs are used to prevent release (and why)?
- Do descriptions of RMMs outline what preventative maintenance, regular checks, replacement of parts or other controls (e.g. training / monitoring) are in place to ensure the stated effectiveness of RMMs? *In applications by upstream actors, can these organisation RMMs be included in the exposure scenario to ensure that downstream users can comply with them?*

d) Are releases to each environmental compartment (air, water, soil) appropriately estimated and justified?

- Where **measurement / monitoring data** is presented has it been explicitly linked to the OCs and RMMs described in the environmental contributing scenario? As such, appropriate contextual information should always be included alongside monitoring data, e.g.:
  i. number of samples,
  ii. duration, frequency and dates of sampling (and process underway during sampling),
  iii. sampling and analysis methodology
  iv. limit of detection and / or quantification,
- Where modelling data is presented, has the model / default (e.g. ERC / SPERC) been shown to be applicable to the OCs, RMMs and substance? Is the model appropriately referenced e.g. Is the SPERC factsheet available in an

Annex? Are model input parameters and outputs are available (as Annex to the CSR)?

- Have datasets, or relevant third party reports, been made available in an annex to the CSR?
- Where relevant, have releases to air been considered from both point and fugitive sources?
- Is it clear what exposures represent e.g. are exposure estimates typical (e.g. average / median), reasonable worst-case or worst-case (maximum) exposure levels? Where possible, exposure estimates should be expressed as both typical (realistic) and reasonable worst-case estimates and the underlying variability of exposure estimates should be clear; both should be considered during subsequent risk characterisation and impact assessment.
- If measurement data for the substance in question are not available, is data on analogous (similar physico-chemical properties in the same or an equivalent process) measurement data provided and well justified? Note that use of analogous data in an application for authorisation is only expected in exceptional circumstances.
- Have other data or approaches (e.g. mass balance approaches) been used to support or derive release estimates? Where applicable, have such approaches been described in sufficient detail for RAC to evaluate their reliability i.e. sufficient information on calculation steps and assumptions should be available?
- Other existing assessments. Where relevant, have other existing assessments for the Annex XIV substance e.g. EU Risk Assessment Reports been cited and discussed?

e) Has indirect exposure to humans via the environment (general population exposure) been included in the assessment e.g. exposure via air, drinking water, food and, where relevant, ingestion of dust, soil or other non-foods.

- As the default (Tier I) assumptions in the EUSES model for general population exposure are inherently conservative (reasonable worst-case risk assessment scenario), consider if refinement of general population exposure assessment is necessary to ensure that risks and impacts (for non-threshold substances) are not overestimated in subsequent SEA. Alternatively, the EUSES model does not account for dust (particle) uptake, which for some chemicals can be important. If so, has the contribution by this route been assessed?
- Have any deviations from default assumptions in guidance been clearly described and justified? Where alternative exposure estimation methods (e.g. alternative air dispersion modelling or environmental monitoring) are used, have these methods and results been reported in sufficient detail to allow evaluation?

2.3 Article service life (where relevant)

a) Where this is relevant (i.e. when exposure to the Annex XIV substance is reasonably foreseeable), has human (direct and indirect) and environmental exposure related to industrial, professional and consumer uses of articles been clearly described and justified? Has modelling or measurement data been supported sufficiently i.e. taking into account relevant considerations as described above for worker / environmental exposure?

- Have any refinements from default modelling assumptions (such as the size of the population exposed) been described and justified?

2.4 Consumer uses (where relevant)

a) Consumer uses of CMR substances in a mixture above specific concentration limits are restricted under REACH. However, applications for authorisation for PBT/vPvB substances and substances of equivalent concern (identified under Article 57(f) of REACH) should consider human (direct and indirect) and environmental exposure from any consumer uses (e.g. in consumer products).

- Have OCs (e.g. concentration, duration of use) and RMMs (e.g. size and type of packaging, labelling on packaging, PPE provided or recommended, use instructions) been clearly described?
- Has human and environmental exposure estimation been clearly described and justified? Has modelling or measurement data been supported sufficiently i.e. as described above for worker / environmental exposure?

3. Risk Characterisation

Ensure a clear risk characterisation for the use.

3.1 Worker (industrial and professional) contributing scenarios

a) Has risk characterisation been undertaken for all relevant endpoints and tasks? For non-threshold substances, ensure that excess risk reported from the dose-response relationship does not include any correction for the length of the "assessment/review period".

b) Has risk characterisation been undertaken for combined (aggregated) exposure across different tasks (where workers are known to undertake multiple tasks)? Indirectly exposed workers (e.g. those not directly involved in tasks resulting in exposure to Annex XIV substance) should be taken into account where relevant.

3.2 Environmental (industrial and professional) contributing scenarios

a) Has risk characterisation for CMR or equivalent concern substances (identified on the basis of human health hazard properties) been undertaken for humans exposed indirectly via the environment? Have all relevant routes of exposure been taken into account i.e. inhalation and oral (drinking water and food) routes of exposure?

- Have any deviations from default assumptions (such as population exposed) been described and justified?

b) Has risk characterisation for PBT / vPvB substances (and equivalent concern substances for the environment where it is not possible to derive a threshold) been undertaken?

- Does risk characterisation comprise an emissions characterisation (as outlined in section 4.2 of Annex I of REACH), including an estimation of the amounts of substance released to the different environmental compartments from the use (in kg per year)?
- Have releases to the environment been used as the basis of a cost-effectiveness analysis (as described in the SEAC paper on the evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC)?
- Does the risk characterisation also justify how the RMMs applied, or recommended to downstream users, minimise exposures and emissions to humans and the environment, throughout the life-cycle of the substance?

c) Has risk characterisation for equivalent concern substances (identified on the basis of environmental hazard properties) where it is possible to derive a PNEC been undertaken for all relevant environmental compartments i.e. water, aquatic sediments, soil?

3.3 Article service life (where relevant)

a) Has risk characterisation for appropriate human populations been considered?

- Applications for authorisation for CMR substances and substances of equivalent concern for human health hazard properties (identified under Article 57(f) of REACH) should include risk characterisation for any population that is reasonably foreseen to be exposed (i.e. described as per section 3.3).
- Have any deviations from default assumptions (such as the size of the population exposed) been described and justified?

b) Has risk characterisation for PBT and vPvB substances in articles been considered?

- Does the risk characterisation comprise an emissions characterisation (as outlined in section 4.2 of Annex I of REACH) including an estimation of the amounts of substance released to the different environmental compartments from the use (in kg per year)?
- Have these emissions been used as the basis of a cost-effectiveness analysis (as described in the SEAC paper on the evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC)?
- Does the risk characterisation also justify how the RMMs applied, or recommended to downstream users, minimise exposures and emissions to humans and the environment, throughout the life-cycle of the substance?

c) Has risk characterisation for equivalent concern substances in articles (identified on the basis of environmental hazard properties) where it is possible to derive a PNEC been undertaken for all relevant environmental compartments i.e. water, aquatic sediments, soil?

3.4 Consumer uses (where relevant)

a) Has risk characterisation for consumer uses been undertaken?

- Consumer uses of CMR substances in mixtures are generally restricted under REACH and will not require risk characterisation.
- Substances of equivalent concern for humans (identified under Article 57(f) of REACH) should include risk characterisation for any population that is reasonably foreseen to be exposed (i.e. described as per section 3.4).
- Any refinements from default modelling assumptions (such as the size of the population exposed) should be described and justified.

b) Has risk characterisation for PBT and vPvB substances in consumer uses been considered?

- Does the risk characterisation comprise an emissions characterisation (as outlined in section 4.2 of Annex I of REACH) outlining an estimation of the amounts of substance released to the different environmental compartments from the use (in kg per year)?
- Have these emissions been used as the basis of a cost-effectiveness analysis (as described in the SEAC paper on the evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC)?
- Does the risk characterisation also justify how the RMMs applied, or recommended to downstream users, minimise exposures and emissions to humans and the environment, throughout the life-cycle of the substance?

c) Has risk characterisation for equivalent concern substances (identified on the basis of environmental hazard properties) where it is possible to derive a PNEC been undertaken for all relevant environmental compartments i.e. water, aquatic sediments, soil?

4. Specific considerations for applications by "upstream actors" and "multi-site" applications by downstream users

This section of the checklist outlines specific considerations for applications prepared by upstream actors and multi-site downstream user applications. These types of applications are efficient if well prepared and focussed at an appropriate scale. However, RAC may conclude that they contain significant uncertainties where, for example:

- *Uses, exposure scenarios or contributing scenarios are considered to be too "broad"[4];*
- *Where the data on exposure or releases are not considered to be representative (to the OCs and RMMs), reliable or are described in insufficient detail (e.g. no contextual data);*
- *There is uncertainty whether "sub-uses" within the scope of a broad use can be substituted more quickly than the remainder of the use".*

Representative data on exposure is needed to cover the range of process technology, scale (i.e. size of operation) and diversity of OCs and RMMs that could be implemented at the different sites that are intended to be covered by the authorisation.

As these types of applications are the focus of ongoing discussion, this section of the checklist should be considered to be under development.

a) Have the OCs and RMMs (worker and environmental) been justified as representative of all the sites that are intended to be covered by the authorisation e.g. by use of case studies, literature or other argumentation? The following aspects may be relevant:
    - Volumes of Annex XIV substance used.
    - Range of site "scale", including number of workers e.g. small companies vs large companies; several production lines vs single production line.
    - Range of site "process technology" e.g. industrial automation vs manual operations; serial production vs piece production; continuous vs batch processes.
    - Diversity/uniformity of RMMs (worker and environmental) at different sites e.g. containment, extent of automation, use of LEV, use of PPE, organisation controls.

b) Has a justification been provided as to why the exposure information presented should be considered to be representative of all the sites that are intended to be covered by the authorisation e.g. by use of case studies, literature or other argumentation? The following aspects may be relevant:
    - Explicit linkage between the OCs and RMMs (or groups of similar OCs and RMMs) described in an exposure scenario and the exposure data.
    - Number of sites / tasks with measured data as a proportion of the total number of sites (also taking into account potential variability in site scale and process technology). Is contextual information on the RMMs implemented at each of the sites with measured data available?
    - Geographical variability across member states and potentially in relation to proximity of sites to areas of high/low population density (relevant to indirect assessment of humans via the environment).

[4] WCS with highly variable OCs and RMMs leading to very different exposure potential.

c) Has the additional uncertainly, introduced because of the scale of the application, been discussed and its significance evaluated?

d) Where information has been aggregated / summarised has the methodology used for this been appropriately described? Has sufficient disaggregated data, with appropriate contextual information, be supplied to allow evaluation?

5. Uncertainties

Provide a clear description of the uncertainties in an exposure estimation and risk characterisation.

Have uncertainties relating to the following aspects been discussed and their significance investigated within a sensitivity analysis

a) Related to OCs (e.g. duration and frequency of tasks)

b) Related to the efficiency of RMMs (e.g. is supporting information available)

c) Related to exposure estimation data and methodology (e.g. sample size, variability of exposure data, analytical sensitivity, modelling methodology)

d) Related to representativeness of data, particularly for upstream applications (e.g. what proportion of the sites are OCs, RMMs and exposure data from?)

e) Related to risk levels (workers, consumers, humans via the environment).

Analysis of Alternatives/Socio-economic Analysis

6. Alternatives

6.1 Substance function and requirements

a) Has the purpose and scope of the use applied for been clearly described? Pay particular attention to the process, the function of the Annex XIV substance within the process and the requirements that possible alternatives need to meet.

6.2 Identification of alternatives

a) Have all efforts to identify potential alternative substances or technologies (e.g. literature reviews, trials, etc.) been reported?

b) Where short-listing is undertaken, have the selection criteria been clearly described and justified? Alternatives that are, or will be, used by other actors in the market should be considered.

6.3 Options to substitute the use applied for

Where relevant, have the following aspects been considered[5]?

a) Switch substances; if so to what?

b) Adapt technologies or processes, develop new ones;

c) Switch products;

d) Import products;

e) Change product specification;

f) Stop producing within the European Economic Area.

6.4 Feasibility of alternatives

Have the following aspects been considered in the assessment? An alternative suitable for one actor may not be suitable for another. However, if an alternative is used by other relevant actors (e.g. by competitors in the market) then any conclusion that it is not suitable for the applicant needs to be appropriately justified. Have the following elements be analysed?

a) Technical feasibility

- Performance (production efficiency, yield and scrap rate)
- Product quality (durability, aesthetics, etc.)
- Regulatory or technical standards (pre-market approval)

b) Economic feasibility – i.e. the cost of substitution – should be assessed at the level of the article / supply chain

- Cost difference between Annex XIV substance and alternative
- Cost difference between alternative systems, processes, etc.
- Impact on profits or competitive position / market potential of alternatives
- Annex XIV substance used in a system:
  i. What is the remaining lifetime of that system?
  ii. Does a different system exist that provides the same functionality?
  iii. What limits the choice of using a different system?

c) Other considerations in relation to feasibility (e.g. national defence, patents, etc.)

6.5 Hazard and risk of alternatives

Define the relative hazard and risk of alternative substances and technologies, particularly where alternatives are considered to be technically and economically feasible (where authorisation can only be granted if there is no overall reduction in risk from using an alternative).

[5] Points d), e), f), and g) are potential options that an applicant has in the event that an authorisation was not granted for their use. However, these options are not strictly 'alternatives' in the REACH sense.

a) Has the hazard, exposure and risk reduction potential of technically and economically feasible alternative substances, or alternative substances that are considered in their non-use scenario been described? At least a comparative hazard assessment of alternatives is expected.

7. Impact assessment

Ensure a clear description of the benefits of continued use outweighing the associated risks. This is not required when adequate control is demonstrated for a threshold substance. However, some of the below elements might be helpful to state even in case of adequate control.

7.1 Scope and boundaries of analysis

a) Has the temporal and spatial scope of the application been clearly described?

b) Have the costs and benefits been adjusted to a base year (e.g. sunset date)?

c) Have the relevant impacts been assessed over the same period?

d) Has discounting been appropriately applied?

e) Does the impact assessment distinguish between costs and benefits from the perspective of the applicant and of society as a whole.

f) Have methods and assumptions used for the assessment been appropriately described?

7.2 Applied-for-use scenario (continued use)

a) Human health impacts

- Have the relevant health endpoints as described in Annex XIV been assessed?
- Where available, has the excess risk for non-threshold substances been estimated based on the dose-response function published by RAC? Alternative dose-response relationships can also be used, but must be appropriately referenced and justified.
- Have additional health impacts, associated with endpoints other than those included in Annex XIV, been considered? The description of such health impacts are not a mandatory part of an application for authorisation, but could be useful when comparing the Annex XIV substance to potential alternatives.
- Have assumptions about the population at risk in terms of size and exposure level been credibly described and justified? Have both "reasonable worst case" and "typical/expected" assumptions been considered?
- Where available, has the monetisation of risks been based on willingness-to-pay reference values published by SEAC? Alternative values can also be used, but must be appropriately referenced and justified.

- Has a sensitivity analysis been undertaken? What are the results of a reasonable worst-case scenario compared to the expected/typical scenario, i.e. how much uncertainty pertains to the cost estimate?

b) Environmental and other relevant impacts (e.g. transport emissions)
   - Have any environmental impacts been deemed relevant? If so, have these impacts been qualitatively or quantitatively analysed?
   - If these impacts are quantified, ensure that the methodology is clearly described and justified.

7.3 Non-use scenario

Ensure a clear description of the non-use scenario. This is a description of what will happen if an authorisation is not granted.

a) Have various different options in response to non-authorisation (including both management options as well as the use of alternatives), been identified and credibly assessed? For example,
   - Use of the best alternative as described in the AoA
   - Complete or partial shutdown of site(s)
   - Relocation or going out of business

b) Has the non-use scenario, i.e. the applicant's best response to a denied authorisation, been clearly identified and described. Does this link to the conclusions reported in the AoA?

c) For applications by upstream actors, have the reactions on downstream users or other actors in the event that an authorisation is not granted been described?

d) For downstream applications, have the responses of competitors (in the same branch using the same or alternative substances) been described?

e) Have the economic impacts of non-use been included in the assessment? For example:
   - Impact on applicant's/upstream/downstream/competitors' profits (this may be an appropriate welfare measure in instances of permanent shut down or relocation);
   - Impact on applicant's/upstream/downstream/competitors' value added foregone (this may be an appropriate welfare measure in instances where a temporary shut-down would occur);
   - Note that changes in revenues alone are generally not an appropriate welfare measure

f) Have the social impacts of non-use been included in the assessment? For example,
   - Unemployment costs;
   - Loss in consumer surplus;
   - Other social impacts (e.g. distributional impacts).

- Wider economic impacts, where relevant (e.g. trade, competition and economic development)

8. Conclusions and review period

This section outlines key issues for the justification of the review period.

8.1 Rigour of analysis

a) Final ratio between benefits and costs of granting the authorisation

- Have the assumptions made in the SEA been clearly stated and justified?
- Have the relevant non-quantified impacts been taken into account when comparing benefits and risks?
- Do the benefits of continued use outweigh the risks, and by how many orders of magnitude?

b) Uncertainties and sensitivity analysis:

- Have uncertainties been clearly described?
- Have the consequences and significance of uncertainties been explored and to some extent quantified, e.g. by undertaking a sensitivity analysis and indicating max/min values?
- Have uncertainties pertaining to the number of people at risk, including workers and the general population (i.e., impacts to humans via the environment) been described and their significance assessed?

8.2 Justification of the review period

Ensure that there is sufficient information for SEAC to recommend the length of the review period.

a) Has the time needed to develop a suitable alternative been described and justified? Where relevant, is it clear when a suitable alternatives would become available?

b) Have the SEAC criteria for the recommendation of review periods been considered?

- Is the investment cycle demonstrably long (meaning >7 years); where relevant, is the remaining lifetime of capital-intense production factors or patent protection demonstrably long (meaning > 7 years)?
- Are the costs of alternatives very high and unlikely to change over the review period?
- Is it unlikely that suitable alternatives become available within a normal review period of 7 years?
- Do alternatives require legislative measures?
- Are the remaining risks low and the socio-economic benefits high?

c) Have any ongoing substitution activities been clearly described, including relevant R&D and timelines.

d) Where relevant, why it would be unreasonable to re-apply after a normal review period of 7 years?

Review report (for authorisation holders only, not for applications for authorisation)

This section of the checklist outlines specific considerations for the explanatory note to be submitted as part of a review report, if the use of the Annex XIV substance needs to continue after the end of the review period of the authorisation. The previous sections of this checklist are also relevant, as the authorisation holder needs to update the assessment reports submitted in the original application.

9. Explanatory note

9.1 Authorisation decision

a) If the Authorisation was granted basis of fulfilling one or more conditions or monitoring arrangements n (i.e. as specified in the Authorisation decision), does the explanatory note include details of how these conditions were achieved

- Related to exposure assessment
  i. worker exposure
  ii. to environment
- Related to operational conditional and risk management measured
  i. OCs/RMMs related to worker exposure
  ii. OCs/RMMs related to environmental releases
- Other conditions (e.g. related to supply chain communication or substitution)

b) If the Authorisation decision specified conditions for the Review report (i.e. relevant to information that should be included in the review report), does the explanatory note include details of how these conditions were achieved?

- Related to exposure assessment
  i. worker exposure
  ii. to environment
- Related to operational conditions and risk management measures
  i. OCs/RMMs related to workers' exposure
  ii. OCs/RMMs related to environmental releases
- Other condition (e.g. recommended by SEAC)

9.2 Changes implemented / progress made - independent of the conditions of the authorisation decision

a) Have any changes to the scope of the use since the original application been described?
   - Have any uses been substituted?

b) Have any changes relevant to the exposure assessment been identified, such as:
   - Change to toxicological profile of the substance identified in the Annex XIV (e.g. added endocrine disrupting properties)
   - Volume of the substance used and/or content of the Annex XIV substance in the material used
   - Sites covered (e.g. number or location)
   - Number of workers exposed
   - Duration and frequency of tasks
   - OCs and/or RMMs in place
   - Exposure assessment methodology (e.g. change of analytical method used, use of measurements rather than modelling, introduction of new monitoring, such as wipe testing)
   - Changes to worker exposure level and/or releases to the environment and consequent impact on risk characterisation - resulting from change to any of the elements mentioned above or any other relevant elements.

c) Has the AoA been updated , detailing, where relevant:
   - The identification of any new potential alternatives since the submission of the application?
   - Any new information on the alternatives assessed in the application (e.g. in terms of their technical feasibility, economic feasibility, hazard/risk profile or availability)
   - Any R&D that have been undertaken and what progress has been made on implementing alternative(s) since the application?
   - Progress against the substitution planning that was documented in the application? Were any changes necessary? What are the future substitution activities?

d) Have any changes to the SEA been identified, such as:
   - Has the non-use scenario changed?
   - Have the costs of continued use changed since the application (e.g. due to changes in production technologies or improved knowledge of hazards or exposure levels, developed valuation methodologies)?
   - Have the benefits of continued use changed (e.g. due to changes to substitution costs, the economic situation of the AH or its supply chain, the affected workforce, and/or the non-use scenario)?
   - Have the justifications for the duration of the review period changed in light of the substitution effort made?

9.3 Additional information

a) Have any enforcement activities by the Member State Authority related to the authorised use of the Annex XIV substance been described?