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Checklist for evaluating chemical safety assessment in applications for authorisation

Introduction

This checklist is designed to support Risk Assessment Committee (RAC) rapporteurs in their evaluation of an application for authorisation for the use of an Annex XIV substance. It is intended to enable a rapporteur to establish what information is and *is not* presented by the applicant and therefore help in identifying key issues that should be addressed during opinion-making, as well as helping to formulate requests for additional information.

Importantly, the checklist is not intended as definitive guidance or a set of minimum information requirements. Rather, it provides a means to read an application in a structured manner in order to:

- identify and scrutinise the assumptions made by the applicant;
- spot gaps in data or analysis;
- conclude whether the methodology used by the applicant in their exposure assessment and risk characterisation is appropriate and sufficiently justified;
- summarise the evidence-base on which RAC can form an opinion.

The checklist has been written to be as consistent as possible with the opinion justification template. The checklist is a non-exhaustive document that will be updated by the ECHA Secretariat from time-to-time based on the experience gained from the evaluation of applications.

1. General information on the scope of the 'use applied for'

This section of the checklist focuses on the applicant's description of the use applied for and any tasks presented in contributing scenarios? This description could consist of narrative (text) descriptions or appropriate photos, videos and diagrams.

a) What is the tonnage used per year?
   - Does the exposure scenario describe foreseeable future use of the substance (in particular greater but also reduced tonnage)?

b) Will the 'use applied for' concern Downstream Users (DUs) and what is their relationship to the applicant(s)?

c) Is the scope of the 'use applied for' broad or narrow?

d) How many workplaces (sites) are included?

e) Does the applicant clearly describe all relevant exposures i.e. worker (industrial and professional user), environmental, article service life and consumer?

- How many workers are directly exposed and what is the size of the general population that is indirectly exposed?

2. Hazard Assessment

This section of the checklist is focused on whether or not the applicant clearly describes the hazard properties, endpoints and reference values used in their assessment. This section of the checklist is linked to sections 1, 2 and 3 of the opinion justification template.

2.1 Scope of the assessment

a) Has the applicant used, and correctly referenced, all relevant RAC reference derived no effect levels (DNEL) or dose-response values for:

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

b) Has the applicant provided hazard data for other endpoints where this is relevant for comparison with potential alternative substances?

3. Exposure assessment

This section of the checklist is focused on the extent to which an applicant has described the relevant operational conditions (OCs) and risk management measures (RMMs) outlined in their exposure scenario/s? This section also focuses on the extent to which an applicant's exposure estimation is based on reliable / representative data, robust methodology and is appropriately documented. This section of the checklist is linked to sections 4 and 6 of the opinion justification template.

3.1 Worker (industrial and professional) contributing scenarios

a) Where an exposure scenario consists of contributing scenarios, is it clear which aspects of the use / which tasks are covered by each contributing scenario?

b) Is the overall sequence of worker activities clear?

3.1.1 Operational conditions

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

b) Are the operational conditions (OCs) sufficiently described? For example, are the process conditions such as volume, concentration of the Annex XIV substance, temperature, pressure, flow rate clearly described?

c) Is the frequency and duration of each task described?

d) Is it clear how many workers are involved in each of the tasks and whether any of the workers undertake multiple tasks leading to additional exposure?

3.1.2 Risk Management Measures

a) Are any parts of the task automated?

b) Are the hierarchy of control principles[1] applied in the implementation of RMMs?

c) Are the risk management measures (RMMs) sufficiently described? For example, do descriptions include an estimate of the effectiveness of each RMM and a justification for achieving this level of effectiveness? Is compliance with other relevant standards mentioned (e.g. EN standards for PPE)? Specifically:

- Evidence of containment within closed / semi-closed systems
- Intended effectiveness (performance specification) of local exhaust ventilation, fume cabinets or general mechanical ventilation systems e.g. from design or commissioning report and evidence that these performance specifications are achieved.
- Type and effectiveness of personal protective equipment (PPE):
    i. respiratory protective equipment (respirator and cartridge);
    ii. gloves (material and breakthrough time);
    iii. other PPE used (e.g. protective clothing, boots, googles).

d) Do descriptions of RMMs outline what regular checks, maintenance, replacement of parts or other controls (e.g. training / monitoring / air-flow indicators) are in place to ensure the stated effectiveness of RMMs.

e) Are relevant organisational controls such as access rights, procedures, training etc. described?

f) Does the applicant demonstrate that they ensure that the exposure is reduced to as low a level as is technically and practically possible, particularly for non-threshold substances. Have applicants outlined plans, or made commitments in their application, to further improve risk management?

3.1.3 Exposure estimation

[1] Hierarchical system used to minimise or eliminate exposure to chemical hazards. Controls are categorised, in order of decreasing effectiveness, as elimination, substitution, engineering controls, administrative controls and personal protective equipment (PPE).

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

b) Does the exposure scenario include tasks leading to potentially high exposure situations (e.g. maintenance, sampling, filling and transfer)

c) Is exposure in each worker contributing scenario appropriately estimated and documented?

- Modelling data. Is the model applicable to the task and substance? Are input parameters and outputs available? Are any deviations from default assumptions clearly stated and justified?
- Measurement data. Does the applicant provide relevant contextual information with monitoring data, e.g.:
  i. sampling protocol [static, personal or biomonitoring] including the location of sampling/measurement devices,
  ii. analytical method used, including the limit of detection,
  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).
- Are datasets, or relevant third party reports available in an annex to the CSR?
- Are exposure estimates corrected to time-weighted averages (usually 8 hours)?
- Are exposure estimates expressed both with and without PPE?
- Is measurement data supported/corroborated by modelling data, or *vice versa*?
- 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?
- 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?

d) Does the applicant describe the potential for combined exposure (aggregated exposure from the performance of a number of contributing scenarios during one shift, or exposure from other uses / processes of the same substance)? Is it justified that exposure from more than one source (task or process) will not occur?

- Is the period for combined exposure credible and appropriate (shift average)
- If there are different types of workers is it clear which type of worker performs each task?

3.2 Environmental contributing scenarios (industrial and professional)

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

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

c) Are RMMs for each environmental compartment sufficiently described e.g. are they accompanied by an estimate of their effectiveness (and a justification for this level of effectiveness)? Specifically:

- What type of emissions abatement technology is used (and why)?
- What maintenance regimes or other controls (e.g. training / monitoring) are in place to ensure the effectiveness stated?

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

- Modelling data. Does the applicant justify the appropriateness of any model/release factor used? Are any deviations from default assumptions clearly stated and justified? Are models, including spERCs (specific environmental release categories), appropriately referenced (e.g. spERC fact sheet) and used within their applicability domain? Are model input parameters and outputs available (as Annex to the CSR)?
- Measured data. Does the applicant provide relevant contextual information alongside monitoring data e.g.
  i. number of samples,
  ii. duration, frequency and dates of sampling,
  iii. sampling and analysis methodology?
  iv. limit of detection and quantification,
- Are datasets, model output files or relevant third party reports available in an annex to the CSR?
- Do emissions to air consider point source and fugitive emissions?
- Where any other data / methodology has been used to support or derive release estimates (e.g. mass balance approaches) has this been sufficiently described?
- Other existing assessments. Where relevant, does the applicant take account of relevant existing assessments for the Annex XIV substance e.g. EU Risk Assessment Reports?

e) Is indirect exposure to humans via the environment (general population exposure) included in the assessment e.g. exposure via air, drinking water and food.

- Are deviations from default assumptions in guidance clearly described and justified?

3.4 Consumers (where relevant e.g. for PBT/vPvB substances)

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

3.5 Article service life (where relevant)

Is exposure estimation for industrial, professional and consumers users of articles clearly described and justified? Has modelling or measurement data been supported sufficiently i.e. taking into account relevant principles as described above for worker exposure?

4. Risk Characterisation

This section of the checklist is focused on the extent to which an applicant has described their risk characterisation. This section of the checklist is linked to section 8 of the opinion justification template.

4.1 Worker (industrial and professional) contributing scenarios

a) Does the applicant undertake risk characterisation for all relevant endpoints and tasks? For non-threshold substances, is excess risk reported from the dose-response relationship without any further correction for the length of the "assessment/review period"?

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

4.2 Environmental contributing scenarios (industrial and professional)?

a) Does the applicant undertake risk characterisation for indirect exposure to humans via the environment

b) Does the applicant describe and justify deviations from default model assumptions?

5. Specific considerations for "upstream" and "multi-site" applications (under development)

This section of the checklist outlines specific considerations that are relevant for the evaluation of "upstream" and "multi-site" applications for authorisation. Upstream and multi-site applications are efficient if well prepared and focussed at an appropriate scale. However, they are difficult to evaluate without sufficiently "representative" exposure scenarios, which can lead to them being considered as having high

uncertainty.

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 workplaces that are intended to be covered by the authorisation.

As these types of applications are the focus of ongoing discussions 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 workplaces 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 workplace "scale", including number of workers e.g. small companies vs large companies; several production lines vs single production line.
    - Range of workplace "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 workplaces 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 workplaces 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 workplaces with measured data as a proportion of the total number of workplaces (also taking into account potential variability in workplace scale and process technology). Is contextual information on the RMMs implemented at each of the workplaces with measured data available?
    - Geographical variability across member states and potentially in relation to proximity of workplaces to areas of high/low population density.

b) Has the applicant understood and described the additional uncertainly introduced to their risk assessment as a result of the scale of the application?

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

6. Hazard and risk of alternatives

This section of the checklist focuses on the extent to which an applicant has considered 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). This section of the checklist is linked to sections 7.3 and 7.4 of the opinion justification template.

a) Does the applicant describe 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? At least a comparative hazard assessment of alternatives would be expected.

7. Uncertainties

This section of the checklist focuses on the extent to which an applicant has understood and detailed the uncertainties in their exposure estimation and risk characterisation. This section of the checklist is linked to multiple sections of the opinion justification template.

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

b) Related to 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 workplaces is OC, RMM and exposure data from?)

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

8. Application of opinion trees

Which outcome do you consider to be appropriate and what are the consequences in terms of:

a) Conditions

b) Monitoring arrangements

- With immediate effect (monitor, review, improve = further minimisation)?
- On review?

c) Advice to SEAC on the review period?

d) If RAC should advise the Commission not to grant the application, what is the justification?

e) Are there alternative courses of action that RAC could take?

- strict interim measures
- review conditions