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Checklist for evaluating socio-economic analysis in applications for authorisation

1. Rationale

This checklist is designed to support SEAC rapporteurs in the appraisal of applications for authorisation. The checklist has two objectives: it should enable the rapporteur to establish what is and what is *not* presented in the SEA and help in identifying the key issues of the application. Importantly, the checklist is not a firm guideline. Rather, it provides a means to go through a dossier in a point-by-point manner in order to:

- identify and scrutinise the assumptions made by the applicant;
- spot gaps in data, research, or analysis;
- conclude whether the methodology of the SEA is appropriate and proportionate;
- establish the evidence based on which SEAC can form an opinion.

The checklist was formulated so that it is possible to draw on the opinion template document as much as possible. I.e., for points that can be "ticked off", there is a standard wording in the template. The checklist is a non-exhaustive document that will be updated by the Secretariat, as more applications are evaluated.

2. Scope of problem/justification for continued use

This section scrutinises whether or not the applicant clearly describes why they need to continue the use of the applied-for-use (AFU) substance.

2.1 What will happen to the applicant's business, if authorisation is not granted?

a) Does the applicant clearly describe the purpose and scope of the AFU?

b) Are scenarios and alternatives discussed reasonable and credibly assessed?

c) For upstream applications: has the applicant described what happens to clients down the supply chain?

d) For downstream applications: has the applicant described what their competitors (in the same branch using the same or alternative substances) are likely do in the same situation. In other words, is this applicant one among many users or not?

3. Analysis of alternatives

This section aims at summarising the extent to which the technical and economic feasibility of alternatives is described and compared to the applied-for-use substance (AFU). This section is linked to section 7.1 & 7.5 of the justification template.

3.1 Has the applicant considered whether there are available alternatives?

a) Has the application seriously considered whether there are alternatives?

b) Are the alternatives available and technically feasible?

3.2 Which options have the applicant considered to substitute the AFU?

a) Switch substances; if so to what?

b) Adapt technologies or processes, develop new ones;

c) Use additional inputs;

d) Switch products;

e) Import products;

f) Change product specification;

g) Stop producing.

3.3 Why are the available alternatives identified as not suitable?

a) Technical infeasibility of substitutes:
   - Technical performance, efficiency, resource requirements;
   - Product qualities (durability, aesthetics, etc.);
   - Environmental & health risks.

b) Political scope limits the applicant to substitute (national defence, patents, etc.)

c) Legal, regulatory requirements or technical standards of alternative products (approval)

d) Limited market potential of alternatives

e) AFU used in a system
   - What is the lifetime of that system?
   - Does a different system exist that provides the same functionality?
   - What limits the choice of using a different system?

f) Economic infeasibility – cost of substitution
   - Cost difference between AFU and alternative;
   - Cost difference between systems, processes, etc.;
   - Is economic feasibility assessed at the level of the product / supply chain?
   - Profitability/Competitive position;

4. Impact assessment

This section aims at establishing whether the benefits of continued use have been demonstrated (does not apply for threshold substances for which adequate control is demonstrated). This section is linked to section 8 of the Justification template.

4.1 Non-use scenario

a) Indicated response to denied authorisation
   - Use of the best alternative as described in §3;
   - Complete or partial shutdown of site(s);
   - Relocation or going out of business;
   - Is non-use scenario as described by the applicant convincingly demonstrated?

b) Economic impacts of non-use included in the assessment
   - Loss in applicant's/upstream/downstream profits (or producer surplus);
   - Loss in applicant's/upstream/downstream value added foregone;
   - Loss in applicant's/upstream/downstream revenues.

c) Social impacts of non-use included in the assessment
   - Unemployment costs;
   - Loss in consumer surplus;
   - Other social impacts quantified (e.g., distributional impacts).

4.2 Applied-for-use scenario

a) Human health impacts (as scrutinised by RAC)
   - Excess risk quantified based on the dose-response function endorsed by RAC?
   - Which (if any) adjustments have been made (frequency/duration), do those match up with the task description (batches, shifts, etc.)
   - Have all relevant health endpoints as described in Annex XIV been identified?
   - Are the assumptions about the population at risk sensible?
   - Which (if any) values have been used for monetisation of risks?
   - Has the applicant done a sensitivity analysis and (if so) what are the results of a worst-case scenario (i.e., how much uncertainty pertains to the cost estimate?)

b) Environmental and other relevant impacts (as scrutinised by RAC)
   - Have environmental impacts been identified?
   - (If so) how are those impacts valued?
   - Have other impacts been assessed/quantified?

c) Scope of analysis
   - Is the temporal and spatial scope of the application clearly described?
   - Have costs and benefits been adjusted to the base year (sunset date)?
   - Have all the impacts been assessed over the entire review period applied for?
   - Has discounting been done properly?

- Does the impact assessment appear to be exhaustive?
- Are methods and assumptions appropriately described?
- Have uncertainties been assessed/quantified?

5. Review period (RP)

This section reviews the justification of the review period applied for by the applicant. It addresses the questions for setting the review period and links the checklist to other relevant documents including the review period paper and the opinion trees. This section is linked to section 10 of the justification template.

5.1 Rigor of analysis

a) Final ratio between benefits and costs (B/C ratio) of granting the authorisation
   - By how many orders of magnitude do the benefits outweigh the costs?
   - Are the assumptions made to arrive at the B/C ratio clearly stated and plausible?
   - How likely is it that the B/C ratio is smaller than one, if other (reasonable) assumptions are made?
   - How credible is it that the indicated B/C ratio persists throughout the RP?

b) Are the uncertainties:
   - clearly described by the applicant?
   - to some extent quantified (e.g. by indicating max/min values)?
   - so large that the actual B/C ratio is not unlikely to be smaller than one?

5.2 Justification of the review period applied for

a) Are any of the criteria for a long RP met:
   - The investment cycle is demonstrably long (meaning >7 years);
   - Costs of alternatives are very high and unlikely to change over the RP;
   - It is unlikely that alternatives become available within a normal RP;
   - Possible alternatives require legislative measures;
   - Remaining risks are demonstrably low and socio-economic benefits are high.

b) Deficiencies in the assessment of:
   - the cost the applicant would have to bear in the non-use scenario;
   - impacts on the wider economy (e.g., overstating social costs of unemployment;
   - impacts on human health and/or the environment.

c) Incomplete assessment of impacts on human health and the environment;

d) Uncertainty pertaining to either to the number of people at risk, including workers and the general population (i.e., impacts to man via the environment);

e) Deficiencies in the monetisation of identified health and environmental impacts (i.e. understating the social costs of granting the authorisation).

f) Credibility, commitment and level of detail of activities that aim at progressively replacing the substance by suitable alternatives.