

## **SETTING THE REVIEW PERIOD WHEN RAC AND SEAC GIVE OPINIONS ON AN APPLICATION FOR AUTHORISATION**

### **1 Introduction**

In the case of applications for which the Committees for Socio-economic Analysis (SEAC) and Risk Assessment (RAC) intend to propose to the Commission that authorisation be granted, this note describes how the length of proposed review period will be determined. The note is based on a previous version (RAC/25/2013/08 and SEAC/19/2013/04), on the discussions held in June in RAC and SEAC and on the views of the Commission services received on 31 July 2013 on the length of the review period.

The Commission decides the length of review period based on the recommendation of RAC and SEAC. The duration of the time-limited review of any authorisation shall be determined on a case-by-case basis (Article 60(8)). The criteria for determining the length of the review period are technical and scientific in nature, based on the committees' consideration of the details of the application and are given below. The suggestions for the length of the review period are given as part of their opinions. SEAC's opinion will focus in particular on this aspect due to the socio-economic impact.

The committees will make the recommendation for the review period in a two-step process. First, the committee needs to establish if, in their opinion, the authorisation should be granted. Second, if they consider that the authorisation should be granted, the committees will give their recommendation on the length of the review period based on the information provided in the analysis of alternatives, the socio-economic analysis and the substitution plan, as provided by the applicant.

In its application, the applicant should provide clear justifications for the length of the review period considering his specific circumstances. The committees will also take into account the possible comments received during the eight week long public consultation on the broad information on use(s).

Procedurally, RAC would provide SEAC with its opinion on the remaining risk and – as appropriate – on the risks from possible alternatives as well as any considerations to be taken into account by SEAC in setting the length of the review period. SEAC would then consider this, after assessing the socio-economic factors and the availability and suitability of alternatives, when proposing the length of the review period in its opinion.

### **2. Establishing the length of the review period**

For efficiency and transparency, the committees will use a simple and clear approach, based on a normal length for the review period.

**A normal length of seven years is considered appropriate.** Taking into account the views of the Commission services this length is considered normally sufficient for the authorisation holders to take benefit from technical progress and to carry out scientific Research and Development activities in order to find and deploy technically and

economically feasible alternatives. The interlinks and complexities in the supply chain to find and diffuse substituting innovative technologies have also been criteria for setting the normal review. It is recognised that the preparation of the review report and the administrative process of deciding an authorisation is about three years. This (re-)application period, as well as the administrative capacity of ECHA and its scientific committees, have also been used as criteria to set the length of the review period of seven years. Overall, this length is considered long enough to allow the authorisation holders to continue looking for alternatives but not too long that it might provide a disincentive to finding substitutes.

The length of the review period could be made longer or shorter depending on the technical and scientific arguments given in the application for authorisation, in particular in the analysis of alternatives and the socio-economic analysis. The long review period would be 12 years.

As the length of the review period shall be determined on a case-by-case basis, the length can be adjusted. The following criteria and considerations are used as the starting point when setting long or short a review period. These may be revised or extended based on the experience gained on the evaluation of the applications for authorisation.

### **Long review period**

The following criteria and considerations would lead to a recommendation of a long review period (12 years):

- The applicant's investment cycle is demonstrably very long (i.e. the production is capital intensive) making it technically and economically meaningful to substitute only when a major investment or refurbishment takes place.
- The costs of using the alternatives are very high and very unlikely to change in the next decade as technical progress (as demonstrated in the application) is unlikely to bring any change. For example, this could be the case where a substance is used in very low tonnages for an essential use and the costs for developing an alternative are not justified by the commercial value.
- The applicant can demonstrate that research and development efforts already made, or just started, did not lead to the development of an alternative that could be available within the normal review period.
- The possible alternatives would require specific legislative measures under the relevant legislative area in order to ensure safety of use (including acquiring the necessary certificates for using the alternative).
- The remaining risks are low and the socio-economic benefits are high, and there is clear evidence that this situation is not likely to change in the next decade.

There may be exceptional cases (such as SVHCs in legacy spare parts where an exemption exists in other legislation) which might need a particular solution, also in view of Article 60(8). Thus, in some very particular and exceptional cases the Committees may propose a review period above 12 years.

### **Short review period**

In some other cases, the Committees may recommend to the Commission a shorter than the "normal" review period (e.g. four years) based on the following criteria and considerations:

- The Analysis of Alternatives is not thorough enough in demonstrating that no suitable alternatives will become available during the "normal" period or if the applicant has not made an effort to demonstrate why potential alternatives on the

market would not be suitable and available for him. This conclusion may also arise due to comments received during public consultation on the alternatives.

- Significant technical or scientific uncertainty related to the impacts of authorisation. In addition, or as an alternative to a short review period, additional conditions (and possible monitoring arrangements) could be recommended.
- The socio-economic benefits, as demonstrated by the applicant, are only slightly higher than the remaining risks and there are uncertainties about these estimates
- The applicant is seeking a 'bridging' authorisation to enable him to transition to an alternative which will become available over the shorter term.