EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL
Circular Economy and Green Growth
Sustainable Chemicals

DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Consumer, Environmental and Health Technologies
REACH
Chemicals

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25th Meeting of Competent Authorities for REACH and CLP (CARACAL)
15 November 2017

Concerns: **REACH Authorisation - Criteria for longer review periods**

Agenda Point: **Follow-up point**

Action Requested: **For information (document endorsed by the CARACAL CA Session on 15/11/2017)**

Disclaimer:
This document regards *only* policy guidance for considering review periods for "exceptional cases". Referring to a review period of 12 years improves readability of this document but it does not concern the criteria for the length of review periods specified in the following documents: SEAC/20/2013/03 and RAC/35/2015/08 //SEAC/29/2015/06.

Criteria for setting a review period longer than 12 years ("longer review period")

In accordance with Article 60(8) of REACH, the duration of the time-limited review period in authorisation decisions is to be determined on a case-by-case basis, taking into account all relevant information, including the elements listed in paragraph 4 of that Article i.e. regarding the risk, the socio-economic implications, the analysis of alternatives including third party contributions on alternatives and available information on risks of the alternatives, as appropriate.

Therefore, a review period longer than 12 years could be appropriate if all relevant information referred to in Article 60(8) of REACH justifies it. According to the RAC and SEAC document on criteria for the duration of the review period, review periods longer than 12 years could be considered in "exceptional cases". There is also an agreement among the Commission services and a large majority of Member States competent authorities that more specific criteria to justify such a longer review period in exceptional cases are needed. The purpose of this note is to provide indicative criteria, without prejudice to the requirements of REACH.

It should also be noted that, regardless of the length of the review period in a granted authorisation, the Commission may initiate a review at any time in line with Article 61 (2) if the circumstances of the authorisation have changed so as to affect the risk to human health or the environment or the socio-economic impacts, or new information on possible substitutes becomes available.

In order to consider a review period longer than 12 years, in addition to the criteria for a 12-year review period established in the document "Setting the review period when RAC and SEAC give opinions on an application for authorisation", two additional conditions should jointly be met:

- as evaluated by the RAC, the **risk assessment** for the use concerned should not contain any deficiencies or significant uncertainties related to the exposure to humans (directly or via the environment) or to the emissions to the environment that would have led the RAC to recommend additional conditions for the authorisation. In the case of applications for threshold substances, the appropriateness and effectiveness of the applied risk management measures and operational conditions should clearly demonstrate that risks are adequately controlled, and that the risk characterisation ratio is below the value of one. For applications for non-threshold substances, the applied risk management measures and operational conditions should be appropriate and effective in limiting the risks and it should be clearly demonstrated that the level of excess lifetime cancer risk is below $1x10^{-5}$ for workers and $1x10^{-6}$ for the general population[1]. For substances for which the risk cannot be quantified, a review period longer than 12 years should normally not be considered, due to the uncertainties relating to the assessment of the risk;

[1] See the ECHA Guidance on information requirements and chemical safety assessment (chapter R.8). Should the guidance be modified, these levels of risk may need to be adjusted.

and

- as evaluated by the SEAC, the **analysis of alternatives and the third party consultation on alternatives** should demonstrate without any significant uncertainties that there are no suitable alternatives for any of the utilisations under the scope of the use applied for and that it is highly unlikely that suitable alternatives will be available and can be implemented for the use concerned within a given period (that is longer than 12 years).

Update(s) on the feasibility and availability of alternatives may be required to be submitted as and if appropriate. The need for them, their timing and frequency should be determined on a case-by-case basis and considering the length of the allocated review period.

For the time being, the Commission is aware of the following cases falling under the second criterion:

a) the main function of a substance is to provide a source of a biologically essential inorganic micronutrient for human, plants, animal or microbial cells;

b) the substance is irreplaceable due to its specific atomic properties (e.g. boron used for capturing neutrons);

c) the substance is used in the production of spare parts for the repair of articles the production of which has ceased, where the Annex XIV substance was used in the production of those articles and the latter cannot function as intended without that spare part, or the use of a substance in the repair of such articles where that substance (on its own or in a mixture) was used in the production of those articles and the latter cannot function as intended without that substance or mixture;

d) the use of the substance has been authorised in accordance with other EU legislation (e.g. marketing authorisation, certification, type-approval), the substance being specifically referred to in the authorisation/certification granted and substitution, including the time needed for modification of the authorisation/certification/type-approval, would not be feasible within 12 years and would involve costs that would jeopardise the operations with regard to the use of the substance;

e) the substance is used in the production, repair and maintenance of equipment with a very long life-cycle in the defence sector, and the use of the substance is required up to several decades to ensure the operational capabilities of the military and the ability to comply with international obligations as partner nations at EU level and in a wider field, e.g. with NATO.

The above is a non-exhaustive list of examples, which may be further developed by the Commission and Member States on the basis of future experience.

This document is intended to provide policy guidance for considering the review period in authorisation decisions.