

REACH-Authorisation and Restrictions

Recital 22

The authorisation provisions should ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.

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Recital 72

To support the aim of eventual replacement of substances of very high concern by suitable alternative substances or technologies, all applicants for authorisation should provide an analysis of alternatives considering their risks and the technical and economic feasibility of substitution, including information on any research and development the applicant is undertaking or intends to undertake. Furthermore, authorisations should be subject to time-limited review whose periods would be determined on a case-by-case basis and normally be subject to conditions, including monitoring.

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Substances to be subject to Authorisation (Article 57)

- CMR categories 1 & 2
- persistent, bioaccumulative and toxic
- very persistent and very bioaccumulative
- endocrine disrupting properties

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Identification of substances subject to authorisation (Recital 77 and Articles 57 & 59)

- Substances identified as meeting the criteria for authorisation should be included in a candidate list for eventual inclusion in the authorisation procedure. (Annex XIV) Within this list, substances on the Agency's work programme should be clearly identified.
- Priority shall normally be given to substances with:
 - (a) PBT or vPvB properties; or
 - (b) wide dispersive use; or
 - (c) high volumes.

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Key Points on Authorisation

- Use of a substance should be authorised if the risks to human health or the environment arising from it are adequately controlled.
- If the risks cannot be adequately controlled, a use may only be authorised if its socio-economic benefits outweigh risks **and** there are no suitable alternatives.
- Authorisations will be subject to time-limited review without future prejudice; duration to be decided on a case-by-case basis.

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Authorisation and Substitution

All applications for authorisation shall include:

- an analysis of alternatives, considering their risks and technical and economic feasibility, including information about any relevant R&D activities.
- where suitable alternatives exist, a substitution plan, including timetable for proposed actions.

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Restrictions

- Even if Authorisation is granted it can be subject to restrictions on manufacture, placing on the market or use(s) which must be justified according to the procedure detailed in Annex XV.
- Substance restrictions are already included in Annex XVII. The long list includes asbestos, cement, benzene and at least two metals.

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Should EPMA members be concerned about Authorisation and Restrictions?

- Many substances will meet very high volume criteria for priority selection for inclusion in Annex XIV. But private assurance is that naturally occurring substances such as metals, ores & concentrates are NOT priority for Authorisation. Priority is PBT & vPvB
- Agency has limited capacity to undertake Authorisation. Substances will probably not be selected for Authorisation for a very long time (probably decades)