

Comparison point	AUTHORISATION	RESTRICTION
Basics		
Legal basis in REACH	TITLE VII - AUTHORISATION	TITLE VIII - RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES
Aim	Ensure the good functioning of the internal market while assuring that the risks from Substances of Very High Concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. – REACH Art. 55 s. 1	‘Safety net’ under REACH for addressing unacceptable Union-wide risks to human health or the environment (cf. REACH Art. 68(1)) where risks have not been addressed by other REACH processes or Community actions
Pre-REACH	Did not exist – new process	Restrictions did already exist pursuant to <i>Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations</i>
List of substances	ANNEX XIV , available on ECHA website: LINK	ANNEX XVII , available on ECHA website: LINK
Eligible substances to be included in the list NOTE: <i>To be subjected to Authorisation or Restriction, the substance does not need to be registered under REACH, and there is no minimum tonnage band.</i>	SVHCs as defined in REACH Art. 57, which are included in the REACH Candidate List (LINK). Categories: <ul style="list-style-type: none"> a) Carcinogenic Cat. 1A or 1B according to Regulation (EC) No 1272/2008 (CLP) b) Mutagenic Cat. 1A or 1B according to CLP c) Toxic for reproduction Cat. 1A or 1B according to CLP d) PBT: Persistent, Bioaccumulative and Toxic according to Annex XIII e) vPvB: Very Persistent and Very Bioaccumulative according to Annex XIII f) Case-by-case basis: Equivalent level of concern substances, e.g. endocrine disruptors, respiratory sensitisers etc. 	Potentially any substance, including but not limited to SVHCs on the REACH Candidate List <i>The substance does not even need to be classified according to CLP!</i>

Comparison point	AUTHORISATION	RESTRICTION
<p>Basic principle / logic → burden of proof</p> <p>NOTE: <i>The proof of compliance with applicable authorisations and restrictions may be required towards national authorities (inspectors) in case of enforcement or towards customers under contractual arrangements, e.g. in case of internal audits.</i></p>	<p>Apply for authorisation for continued use after the Sunset Date</p> <ul style="list-style-type: none"> ✓ Applicant (future authorisation holder) to justify grounds for continued use via the authorisation process ✓ Authorisation holder and downstream users relying on upstream authorisation to prove compliance with Commission authorisation decision once in force 	<p>Comply with restriction conditions</p> <ul style="list-style-type: none"> ✓ Member State/ECHA to first justify grounds for imposing a restriction in Annex XVII ✓ User to prove compliance with restriction once in force
Time aspects		
Minimum time from regulatory intention to prohibition	~6 years (until Annex XIV Sunset Date)	~4 years (until inclusion in Annex XVII)
Schedule for updates	<p>No fixed schedule for Annex XIV updates by COM, but ECHA shall recommend substances for Annex XIV at least every second year (REACH Art. 58(3)).</p> <p>The ECHA Candidate List of SVHC for authorisation is currently updated at least every 6 months.</p>	No fixed schedule for updates by COM
Scope and limitations		
Scope of regulated activities	Authorisation only applies to the use of the Annex XIV substance as such, in a mixture or its incorporation into an article. Authorisation does not apply to manufacture of the substance.	May cover the manufacture, placing on the market or use of a substance on its own, in a mixture <u>or in an article</u> .
Limitation of applicability	Substances for which all uses have been prohibited under Title VIII (Restrictions) or by other Community legislation shall not be included in Annex XIV or shall be removed from it (REACH Art. 58(7)).	No restriction under Annex XVII can be added to uses subject to authorisation (Art. 58(5)), but uses of the Annex XIV substance in articles can be restricted in addition to authorisation (Art. 58(6) & 69(2)).
Import of articles containing the regulated substance as integral part	Out of scope (i.e. does not need authorisation) by virtue of the above scope of regulated activities, e.g. imported articles already treated with Cr(VI)	May be restricted if present in the article (e.g. for an Annex XIV substance if its use in articles poses a risk not adequately controlled, REACH Art. 69(2))

Comparison point	AUTHORISATION	RESTRICTION
<p>Exemptions (relevant for industry)</p> <p>NOTE: Further to the generic exemption / derogation cases listed, pursuant to REACH Art. 2(3) “Member States may allow for exemptions from the REACH Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence.” In this regard, an EDA Code of Conduct on REACH Defence Exemptions and Framework for Applying for a Defence Exemption from a Requirement of REACH have been adopted.</p>	<ul style="list-style-type: none"> ✓ Scientific research and development (REACH Art. 56(3)1 with Art. 3(23)) ✓ On-site isolated intermediates and transported isolated intermediates (REACH Art. 2(8)(b)) ✓ Use as fuels in closed systems (REACH Art. 56(4)(d), 2nd alt.) ✓ Use of substances present in mixtures below certain concentration limits / values (REACH Art. 56(6)) 	<ul style="list-style-type: none"> ✓ Scientific research and development (REACH Art. 67(1)2 with Art. 3(23)) ✓ On-site isolated intermediates (REACH Art. 68(1), 2nd subpar.) ✓ Annex XVII may foresee concentration limits / values and derogations for specified uses / applications to continue, e.g. cadmium plating entry 23 par. 7 for aerospace and other sectors whose applications require high safety standards.
Consequences for industry / end users		
<p>Downstream user action(s)</p> <p><i>Applies in case the use is in scope, no exemption applies and substitution is not possible</i></p> <p>NOTE: Pursuant to REACH Art. 31(9) suppliers shall update the Safety Data Sheet for a substance or mixture without delay once an authorisation has been granted or refused (lit. (b)) and once a restriction has been imposed (lit. (c)). Furthermore, pursuant to REACH Art. 65 the authorisation number shall be included on the label for a substance or mixture supplied for an authorised use. These should help the user to become aware of the authorisation decision or restriction. On the contrary, applicable restrictions are not necessarily part of the safe use information to be communicated under REACH Art. 33(1). Therefore, and in all cases, the user is advised to verify compliance with applicable authorisation and restriction requirements.</p>	<ul style="list-style-type: none"> ✓ Either: Apply for authorisation ✓ Or: Ensure coverage by upstream application for authorisation for your use (incl. compliance with any authorisation conditions) and notify ECHA (cf. REACH Art. 66) 	<ul style="list-style-type: none"> ✓ Comply with restriction entry in Annex XVII ✓ <i>Before adoption of restriction:</i> Participate in ECHA/Member State public consultations and calls for evidence to protect your continued-use case (ensure feasible restriction / advocate derogation)

Comparison point	AUTHORISATION	RESTRICTION
Obsolescence risk for M&P	Typically high/imminent because of the stated substitution aim, including Sunset Date and continuous review process	Case-by-case: Depending on the type of restriction the risk may range from vaguely long-term to imminent and high (e.g. in case of a space-relevant ban implying a substitution pressure).

Version history:

- Initial version of 3.11.2024, ref. RL-MPTB-2021-11-03-Comparison-AvsR
- Present version of 2.12.2024, ref. MPTB-RL-HO-0171: Including some editorial clarifications and restructuring of comparison points for improved readability

Disclaimer:

This is an overview of REACH authorisation vs. restriction processes as they stand today. It should be noted that the European Commission is currently planning a review of this dual system of authorisations and restrictions, in order to substantially reduce the need for individual authorisations. The Commission’s legal proposal – part of the intended REACH revision – has been delayed and is currently expected to be published and submitted in 2025 to the European Parliament and the Council for adoption into law.

This overview has been prepared by REACHLaw Ltd. under Contract No. 4000139751/22/NL/AS. The information provided and/or generated reflects the opinion of REACHLaw. It is not considered a requirement and any action to the described issue is subject to project or programme decision, nor a comprehensive treatment of the subject matter. The information is intended for guidance only and whilst it is provided in utmost good faith and has been based on the best information currently available and adequate technical standards, is to be relied upon at the user’s own risk. No representations or warranties are made with regards to its completeness, or accuracy and no liability will be accepted by REACHLaw, ESA nor any organisation participating in the MPTB or its taskforces for damages of any nature whatsoever resulting from the use of or reliance on the information.

Contact for further questions:

reach.officer@esa.int