

Comparison point	AUTHORISATION	RESTRICTION
Pre-REACH	Did not exist – new process	Restrictions did already exist
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
List of substances	ANNEX XIV	ANNEX XVII
Eligible substances to be included in the list	SVHCs as defined in REACH Art. 57, which are included in the REACH Candidate List. Categories: <ul style="list-style-type: none"> ➔ CMR Cat. 1A or 1B ➔ PBT, vPvB ➔ Equivalent level of concern (ELOC) substances, e.g. endocrine disruptors, respiratory sensitisers etc. 	Any substances, incl. but not limited to SVHCs on the REACH Candidate List. The substance does not even need to be classified!
	The substance does not need to be registered under REACH, and there is no minimum tonnage band.	
Schedule for updates	No fixed schedule for Annex XIV updates by COM, but ECHA shall recommend substances for Annex XIV at least every second year (Art. 58(3)). ECHA Candidate List of SVHC for authorisation is currently updated every 6 months (not legally required).	No fixed schedule for updates
Minimum time from regulatory intention to prohibition	~6 years (until Annex XIV Sunset Date)	~4 years (until inclusion in Annex XVII)
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
Definition	Permission granted to a person (legal entity) to use (or place on the market for it) a substance included in Annex XIV of REACH after the Sunset Date specified therein on its own or in a mixture subject to a time-limited review period, which may be subject to conditions and/or monitoring arrangements (cf. Art. 60(9)). Authorisation applications are subject to a fee to be paid to ECHA.	Any condition for or prohibition of the manufacture, use or placing on the market (REACH Art. 3(31)) of a substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction, unless it complies with the conditions of that restriction. Hence, restrictions are flexible in that they may take the form of a ban or ‘only’ set specific conditions such as specific risk management measures or labelling requirements
Basic principle / logic ➔ burden of proof	Apply for authorisation for continued use after Sunset Date <ul style="list-style-type: none"> ➔ Applicant (future authorisation holder) to justify grounds for continued use via authorisation post Annex XIV inclusion ➔ Authorisation holder and downstream users relying on upstream authorisation to prove compliance with authorisation decision once in force 	Comply with restriction conditions <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
	NOTE: The prove 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.	

This is an overview of REACH authorisation vs. restriction processes as they stand today. It should be noted that the Commission is currently planning a reform of these processes as part of the intended REACH revision under its 2020 Chemicals Strategy for Sustainability (CSS); possible options go as far as merging the two processes or even removing the authorisation process completely. The Commission legal proposal is expected by the end of 2022.

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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)).
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. 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> .
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 CrVI	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))
Exemptions (relevant for industry)	Scientific research and development (REACH Art. 3(23))	
	On-site isolated intermediates and transported isolated intermediates (REACH Art. 2(8)(b))	On-site isolated intermediates (REACH Art. 68(1), 2 nd subpar.)
	Use as fuels in closed systems (REACH Art. 56(4)(d), 2 nd alt.)	Annex XVII may foresee concentration limits / values and <i>derogations</i> 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.
	Use of substances present in mixtures below certain concentration limits / values (REACH Art. 56(6))	
	If specified in Annex XIV: Uses or categories of uses provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled (REACH Art. 58(2)) – <i>no relevant case to date</i>	
NOTE: Further to these generic exemption / derogations, 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.		
Downstream user action(s) (if use is in scope, no exemption applies and substitution is not possible)	Either: Apply for authorisation	Compliance with the restriction entry in Annex XVII
	Or: Ensure coverage by upstream AfA for your use (incl. compliance with any authorisation conditions) and notify ECHA (cf. REACH Art. 66)	<u>Before adoption of restriction:</u> Participate in ECHA/Member State consultations to protect your continued-use case (ensure feasible restriction / advocate derogation)
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.		
Obsolescence risk for M&P	Typically high/imminent because of the stated substitution aim	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 ban implying a substitution pressure).

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