Commission Regulation (EU) 2021/979
Amending Annexes VII and XI to the REACH Regulation

Commission Regulation (EU) 2021/979 was adopted on 17 June 2021 and has been in effect since 8 January 2022. The objective of the amendments are to:

- Provide more clarity on the obligations of registrants and the role of ECHA
- Increase legal certainty of the evaluation practise
- Ensure that animal testing is performed at appropriately high dose levels
- Modifying general rules for adaptation concerning existing data, weight of evidence and read-across/grouping

The amendment will likely trigger REACH dossier updates. For your convenience, we have compared the differences between the old and new regulations:

ANNEX VIII

Section	Old	New
8.1., column 2 Skin corrosion/ irritation	-	An *in vivo* study for skin corrosion/irritation shall be conducted only if the *in vitro* study/studies under points 8.1.1 and/or 8.1.2 of Annex VII is(are) not applicable, or the results of this/these study/studies is/are not adequate for classification and risk assessment.
8.2., column 2 Serious eye damage/ eye irritation	-	An *in vivo* study for serious eye damage/eye irritation shall be conducted only if the *in vitro* study/studies under point 8.2.1 of Annex VII is/are not applicable, or the results of this/these study/studies is/are not adequate for classification and risk assessment.
8.6.1. Short-term repeated dose toxicity study (28 days)	The short-term toxicity study (28 days) does not need to be conducted if: — a reliable sub-chronic (90 days) or chronic toxicity study is available, […]	[…] if: - a reliable sub-chronic (90 days) or chronic toxicity study is available or proposed by the registrant, […]
	The sub-chronic toxicity study (90 days) (Annex IX, Section 8.6.2) shall be proposed by the registrant	The sub-chronic toxicity study (90 days) (Annex IX, Section 8.6.2) shall be proposed by the registrant, or may be required by the Agency
	For nanoforms toxicokinetics shall be considered including recovery period and, where relevant, lung clearance	For nanoforms without high dissolution rate in biological media, the study shall include toxicokinetic investigations on, among others, the recovery period and, where relevant, lung clearance. Toxicokinetic investigations do not need to be performed if equivalent toxicokinetic information on the nanoform is already available
9.3.1. Adsorption/ desorption screening	-	The study may not be waived on the basis of low octanol-water partition coefficient alone, unless the adsorptive properties of the substance are solely driven by lipophilicity. For instance, the study may not be waived on

		the basis of low octanol-water partition coefficient alone if the substance is surface active or ionisable at environmental pH (pH 4 – 9).

ANNEX IX

Section	Old	New
7.16., column 2 Dissociation constant	The study does not need to be conducted if: […]	The study does not need to be conducted if: […] **or based on the structure, the substance does not have any chemical group that can dissociate**
7.17., column 2 Viscosity	-	For hydrocarbon substances the kinematic viscosity shall be determined at 40 °C.
8.6.1 Short-term repeated dose toxicity study (28 days), […]	Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VIII requirements or if tests according to Section 8.6.2 of this Annex is proposed. In this case, Section 3 of Annex XI shall not apply.	*deleted*
8.6.2. Sub-chronic toxicity study (90-day)	The sub-chronic toxicity study (90 days) does not need to be conducted if: - a reliable short-term toxicity study (28 days) is available […]	[…] if: - a reliable chronic toxicity study is available or proposed by the registrant, […]
	For nanoforms toxicokinetics shall be considered including recovery period and, where relevant, lung clearance	For nanoforms without high dissolution rate in biological media, the study shall include toxicokinetic investigations on, among others, the recovery period and, where relevant, lung clearance. Toxicokinetic investigations do not need to be performed if equivalent toxicokinetic information on the nanoform is already available
9.3.2. Bioaccumulation in aquatic species, preferably fish	-	*[*added] 'The study may not be waived on the basis of low octanol-water partition coefficient alone, unless the potential for bioaccumulation of the substance is solely driven by lipophilicity. For

		instance, the study may not be waived on the basis of low octanol-water partition coefficient alone if the substance is surface active or ionisable at environmental pH (pH 4 – 9)
9.3.3. Further information on adsorption/desorption	-	[added] 'The study may not be waived on the basis of low octanol-water partition coefficient alone, unless the potential for bioaccumulation of the substance is solely driven by lipophilicity. For instance, the study may not be waived on the basis of low octanol-water partition coefficient alone if the substance is surface active or ionisable at environmental pH (pH 4 – 9)

ANNEX IX AND X

Section	Old	New
8.7., column 2 Reproductive toxicity	the substance is known to be a genotoxic carcinogen [added], and […]	[added] **meeting the criteria for classification both in the hazard class germ cell mutagenicity (category 1A or 1B or 2) and carcinogenicity (category 1A or 1B),**
	the substance is known to be a germ cell mutagen [added], and […]	[added] **meeting the criteria for classification in the hazard class germ cell mutagenicity (category 1A or 1B)**
	(no evidence of toxicity seen in any of the tests available)	(a comprehensive and informative dataset showing no toxicity in any of the tests available),
	If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.	If a substance is known to have an adverse effect on sexual function and fertility, meeting the criteria for classification in the hazard class reproductive toxicity (category 1A or 1B: May damage fertility (H360F)), and the available data are adequate to support a robust risk assessment, then no further testing for sexual function and fertility shall be necessary.
	If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and	If a substance is known to cause developmental toxicity, meeting the criteria for classification in the hazard class reproductive toxicity (category 1A or 1B: May damage the unborn child (H360D)), and the

	the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.	available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity shall be necessary.

ANNEX XI

Section	Old	New
1.1. Use of existing data	-	[Added]*:* 'Any data generated as from 1 June 2008 shall not be considered as existing data and shall not be subject to the general rules for adaptation laid down in this point (1.1).'
1.1.1.	*Data on physical-chemical properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)*	[Replaced by]*:* '1.1.1. Data on physical-chemical properties from experiments not carried out according to the test methods referred to in Article 13(3)';
1.2. Weight of evidence	There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion. There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3) or from an international test method recognised by the Commission or the Agency as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property. Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available: – further testing on vertebrate animals for that property shall be omitted, – further testing not involving vertebrate animals may be omitted. In all cases adequate and reliable documentation shall be provided.	'[…] when information from several independent sources together enable, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement. The justification must have regard to the information that would otherwise be obtained from the study that shall normally be performed for this information requirement. There may **also** be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3), **leading to a reasoned justification that they provide the information that would enable a conclusion on the information requirement**. Weight of evidence may lead to the conclusion that a substance has or has not a particular property. If there is sufficient weight of evidence, the information requirement is fulfilled. Consequently, further testing on vertebrate animals shall be omitted and further testing not involving vertebrate animals may be omitted. In all cases, the information provided shall be adequate for the purpose of classification, labelling and/or risk assessment, and

	When nanoforms are covered by the registration the above approach shall address the nanoforms separately.	adequate and reliable documentation shall be provided, including: — robust study summaries of the studies used as sources of information; — a justification explaining why the sources of information together provide a conclusion on the information requirement. […]'
1.5 Grouping of substances and read-across approach	The Agency, after consulting with relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances sufficiently in advance of the first registration deadline for phase-in substances.	Removed
	The similarities may be based on:	The similarities may be based on any of the following:
	-	Structural similarity for UVCB substances shall be established on the basis of similarities in the structures of the constituents, together with the concentration of these constituents and variability in the concentration of these constituents. If it can be demonstrated that the identification of all individual constituents is not technically possible or impractical, the structural similarity may be demonstrated by other means, to enable a quantitative and qualitative comparison of the actual composition between substances.
	In all cases results should: […] — have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), — cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and — adequate and reliable documentation of the applied method shall be provided.	In all cases, results shall fulfil all of the following conditions: […] — have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement, — cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter. In all cases, adequate and reliable documentation of the applied method shall be provided. Such documentation shall include:

		— a robust study summary for each source study used in the adaptation; — an explanation why the properties of the registered substance may be predicted from other substances in the group; — supporting information to scientifically justify such explanation for prediction of properties.'
3.1	Testing in accordance with *Sections 8.6 and* 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.	Testing in accordance with Section 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report. **Testing in accordance with Section 8.6.1 of Annex VIII may be omitted only for registrants producing less than 100 tonnes per year per manufacturer or importer, based on the exposure scenario(s) developed in the Chemical Safety Report.**
3.2(a)(ii)	(ii) a DNEL or a PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes ([1]); [1] For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of Section 8.7 of Annexes IX and X, a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study. For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of section 8.6 of Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study.	'(ii) […] For this purpose and without prejudice to column 2 of Sections 8.6 and 8.7 of Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study, and a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or an extended one-generation reproductive toxicity study.'