

## Summary of status of ECHA guidance updates on the REACH regulation relevant to the 31 May 2018 registration deadline not finalised before 31 May 2016 – this update as at 14/06/2016

Note: Drafts already on the ECHA website can be viewed at: <u>http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach</u>

Guidance title	Scope of update	Draft(s) already on website? Y/N(expected date)	Tentative date of publication of final version	Further notes
Guidance on Registration	Update to take account of IUCLID upgrade, release of new versions of REACH-IT and Chesar, reviewed TCC process, strengthening of the OSOR principle and changes brought about the Implementing Act on data sharing	Y	October 2016	
Guidance on data sharing	Full revision of the Guidance mainly to take into account and implement the provisions laid down in the Commission Implementing Regulation (EU) 2016/9 on joint submission and data sharing	Y	December 2016 /January 2017	
Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA), Chapter R.15: Consumer exposure assessment	General update, including alignment with updated Chapter R.12 on use description, incorporation of relevant parts of Chapter R.17 on exposure estimation from articles (the rest of which to be obsoleted)	Y	June 2016	Note the title of previous versions of this document was "Consumer exposure estimation"

Guidance on IR&CSA, Chapter R.7a Endpoint specific guidance; Section R.7.3 (Sensitisation)	Full revision addressing the content of Section R.7.3 related to skin and respiratory sensitisation	Y	September 2016	Date for publication delayed to await publication of the corresponding revised REACH Annex
Guidance on IR&CSA, Chapter R.7a Endpoint specific guidance; Section R.7.4, Acute Toxicity	Update of the complete section, particularly to address a data waiving option for acute oral toxicity by prediction from repeated-dose toxicity for the 2018 > 10 t.p.a. registrations	Y	September 2016	Publication together with R.7.3 above
<i>Guidance on IR&amp;CSA, Part</i> <i>D, Framework for</i> <i>exposure assessment</i>	Complete re-draft of the document to take account of experience in exposure scenario building	Y	July 2016	Note previous version of this document were entitled "Exposure scenario building"
Guidance on IR&CSA, Chapter R.14, Occupational exposure assessment	Update to change the scope of the guidance from exposure estimation to exposure assessment, address observations from dossier evaluation and update the information on exposure estimation tools	Y	July 2016	
<i>Guidance on IR&amp;CSA, Chapter R.7.a: Section R.7.5 Repeated Dose Toxicity</i>	This update is to specifically address route of administration	Y	January 2017	
Guidance on IR&CSA, Chapter R.11 and Part C (both on PBT assessment) and PBT assessment related sections of Chapters R.7b and R.7c	Addressing recent scientific developments in the field and outcome from the PBT Expert Group's discussions	Y	May 2017	

Guidance on Nanoforms	<b>New</b> appendix to the <i>Guidance on registration</i>	Y	May 2017	
Guidance on information requirements for nanomaterials for human health	(Update of Appendix R7-1 to Chapter R.7a and Appendix R7-2 to Chapter R.7c "Recommendations for Nanomaterials" of the Guidance on IR&CSA)	Y	May 2017	Guidance on information requirements for nanomaterials for human health
Guidance on information requirements for nanomaterials for the environment	(Update of Appendices R7-1 to Chapter R.7a and R.7b and Appendix R7-2 to Chapter R.7c "Recommendations for Nanomaterials" of the Guidance on IR&CSA)	Υ	May 2017	Guidance on information requirements for nanomaterials for the environment
Guidance on read-across for nanoforms	<b>New</b> appendix to the <i>Guidance on</i> IR&CSA Chapter R.6, QSARS and grouping of chemicals	Υ	May 2017	
<i>Guidance for identification and naming of substances under REACH and CLP</i>	Partial update (new annex only) to describe the Substance Identity Profile concept and the relevance of its definition by registrants to fulfilling the registration obligations	N (June 2016)	December 2016	
(Guidance on requirements for substances in articles)	(Update to further align with conclusions of case C-106/14, re-introduce /replace examples and take account of other experience)	N (June/July 2016)	(January 2017)	(Note this update is not relevant to the 2018 registration deadline – this entry for information only)