

ISO/TR 13121:2011-05 (E)

Nanotechnologies - Nanomaterial risk evaluation

Contents		Page
	Foreword	v
	Introduction	vi
1	Scope	1
2	Symbols and abbreviated terms	1
3	Summary of the process described in this Technical Report	3
4	Describe materials and applications	5
4.1	General	5
4.2	Materials descriptions	6
4.3	Materials sourcing	6
4.4	Manufacturing	6
4.5	Distribution	6
4.6	Use/reuse/maintenance	7
4.7	End of life/recycle/waste management	7
4.8	Questions to ask regarding the nanomaterial	7
4.8.1	Questions to ask regarding the description of nanomaterials	7
4.8.2	Questions to ask regarding the description of applications	7
5	Profiles of the nanomaterials' properties, hazards and exposures	8
5.1	General	8
5.1.1	Introduction	8
5.1.2	The use of data sets	8
5.1.3	Use of default values and assumptions	9
5.1.4	Evaluating data quality	10
5.2	Develop physical/chemical properties profile	10
5.3	Develop hazard profile	11
5.3.1	Introduction	11
5.3.2	Testing issues	11
5.3.3	Use of "bridging information"	12
5.3.4	The process of creating the hazard profile	13
5.4	Develop exposure profile	14
5.4.1	Introduction	14
5.4.2	The process of developing the exposure profile	15
6	Evaluate risks	20
6.1	General	20
6.2	The risk evaluation process	21
7	Assess risk management options	22
8	Decide, document and act	24
8.1	General	24
8.2	Assemble a cross-functional decision-making review team	25
8.3	Review information	25
8.4	Consider business, legal, and stakeholder issues	26
8.5	Determine who is responsible for implementing recommended actions	26
8.6	Based on these inputs, decide whether and how to proceed	26
8.7	Determine additional data needs and initiate data collection, as necessary	26

8.8	Establish and implement appropriate risk management, monitoring, compliance, and communication processes	26
9	Review and adapt	28
9.1	General	28
9.2	As needed reviews	28
9.3	Regular reviews	28
9.4	Adapting risk management and collecting additional information, as appropriate	29
9.5	Documenting and communicating any new decisions and actions	29
	Annex A (informative) Data set of physical and chemical properties	31
	Annex B (informative) Tiered testing approach to health hazard data	34
	Annex C (informative) Health hazard data set (alternative approach)	36
	Annex D (informative) Environmental hazard data set	40
	Annex E (informative) Environmental fate data set	42
	Annex F (informative) Output worksheet	45
	Annex G (informative) Sources and references for data sets	57
	Bibliography	58