

Table of Content

Acknowledgements	5
1. Summary	6
2. Background	23
3. Policy monitoring of REACH through indicators	25
3.1 REACH: Structure, objectives and new elements	25
3.2 REACH, risk reduction and a REACH indicator system	25
3.3 Demands for a system of REACH-related indicators	27
3.4 The Baseline Study Indicator System.....	28
3.4.1 Methodological background of the proposed system	29
3.4.2 The framework of the Baseline Study Indicator System	30
4. Risk & quality indicator system.....	34
4.1 Basic concept	34
4.1.1 Impact areas.....	35
4.1.2 Exposure assessment	35
4.1.3 Toxicity assessment	36
4.1.4 Risk characterisation ratio and nominal Risk Score	37
4.1.5 Quality Scores	37
4.1.5.1 Quality Score (toxicity assessment)	37
4.1.5.2 Quality Score (exposure assessment)	37
4.1.6 Nominal Risk Score modifiers	38
4.1.6.1 Population risk modifier	38
4.1.6.2 Severity modifier.....	39
4.1.7 Interpretation of results.....	39
4.1.7.1 Aggregation level.....	39
4.1.7.2 Expected changes over time (profile level)	40
4.1.7.3 Accountability (REACH-related changes vs. other causes)	42
4.1.8 Data sources	42
4.1.9 Substance selection	43
4.1.9.1 Number of substances and production volume classes	43
4.1.9.2 Groups of substances within the reference set	43
4.1.9.3 Analysis whether the selected substances can be used as reference substances ...	46
4.1.9.4 Documentation of the results of the selection process.....	48
4.1.9.5 Additional reference substances	48
4.1.9.6 Handling of changes in the production volumes of substances	48
4.1.9.7 Confidentiality	49
4.2 Impact area: workers	49
4.2.1 Production and use profiles	49
4.2.2 Exposure assessment	50
4.2.2.1 Exposure assessment based on measured data	50
4.2.2.2 Exposure assessment based on modelling.....	50
4.2.3 Toxicity assessment	51
4.2.3.1 Occupational Exposure Limits (OEL)	51
4.2.3.2 OEL derivation based on risk phrases	51
4.2.3.3 OEL derivation based on experimental data	51
4.2.3.4 Reference point for carcinogens	52
4.2.3.5 OEL derivation based on QSAR.....	52
4.2.4 Quality Scores	52
4.2.4.1 Quality Score (exposure).....	52
4.2.4.2 Quality Score (toxicity)	52
4.2.5 Result modifiers.....	52
4.2.5.1 Population risk modifier	52
4.2.5.2 Severity modifier.....	53

4.3 Impact area: consumers (direct)	53
4.3.1 Exposure assessment	53
4.3.1.1 Data gathering	53
4.3.1.2 General rationale for the derivation of the exposure score	53
4.3.1.3 Remarks	55
4.3.2 Toxicity assessment	56
4.3.2.1 Data gathering	56
4.3.2.2 General rationale for the derivation of the toxicity score	56
4.3.3 Quality Scores	57
4.3.3.1 Quality Score (exposure)	57
4.3.3.2 Quality Score (toxicity)	57
4.3.4 Result modifiers	58
4.4 Impact area: environment	58
4.4.1 Exposure assessment	58
4.4.1.1 Physico-chemical and fate data	59
4.4.1.2 Substance use pattern data	59
4.4.2 Toxicity assessment	60
4.4.3 Quality Scores	60
4.4.3.1 Quality Score (exposure)	60
4.4.3.2 Quality Score (toxicity)	61
4.4.4 Result modifiers	61
4.4.4.1 Population risk modifier	61
4.4.4.2 Severity modifier	62
4.5 Impact area: humans via the environment	62
4.5.1 Exposure assessment	63
4.5.2 Quality Scores	64
4.5.2.1 Quality Score (exposure)	64
4.5.2.2 Quality Score (toxicity)	65
4.5.3 Collection of data	66
5. Administrative and supplementary indicators	67
5.1 Administrative indicators	67
5.1.1 Indicators on progress in registration	67
5.1.2 Progress in evaluation	68
5.1.3 Progress in authorisation and restriction	68
5.2 Supplemental indicators	69
5.2.1 Changes in quality of safety data sheets	69
5.2.2 Toxic chemicals in households	70
5.2.3 Production of toxic chemicals	71
5.2.4 Transboundary transport of toxic chemicals	72
5.2.5 Occupational skin diseases	72
5.2.6 Changes in use patterns in Scandinavia	73
5.2.7 Availability of hazard data	74
5.2.8 Changes in classification and labelling	74
5.2.9 Availability of use and exposure data	75
5.2.10 Registration of new chemicals	76
5.2.11 Animal testing: use of QSAR, read-across and waiving options	76
5.3 Links to related activities outside of the REACH Baseline Study	81
5.3.1 Monitoring of the objective "Increasing transparency and consumer awareness"	81
5.3.2 Monitoring endocrine disrupting chemicals	81
5.3.3 Monitoring persistent and bioaccumulative chemicals	82
5.3.4 Monitoring the substitution of substances	82
6. Snapshot 2007	82
6.1 Risk and Quality Indicator System	82
6.1.1 Impact area: workers	83
6.1.1.1 Summary level	83
6.1.1.2 Profile level	85
6.1.1.3 Analysis level	89

6.1.2 Impact area: consumers.....	92
6.1.2.1 Summary Level	92
6.1.2.2 Profile level.....	93
6.1.2.3 Analysis level.....	96
6.1.3 Impact area: Environment	98
6.1.3.1 Summary level.....	98
6.1.3.2 Profile level.....	100
6.1.3.3 Analysis level.....	102
6.1.4 Impact area: humans via the environment	104
6.1.4.1 Summary level.....	104
6.1.4.2 Profile level.....	106
6.1.4.3 Analysis level.....	108
6.1.5 Discussion	110
 6.2 Supplemental indicators	111
6.2.1 Production of toxic chemicals.....	111
6.2.2 Cross-border transport of toxic chemicals.....	112
6.2.3 Changes in use patterns in Scandinavia	112
6.2.4 Registration of new chemicals.....	113
 7. Documentation; database(s) for indicators.....	114
 8. Discussion and further recommendations	116
 9. Glossary and abbreviations.....	117
 10. References	119
 11. Appendices.....	121