

## TABLE OF CONTENTS

FOREWORD .....	vi
<b>PART 1: GUIDANCE DOCUMENT ON CHARACTERIZING AND COMMUNICATING UNCERTAINTY IN EXPOSURE ASSESSMENT</b>	
ACKNOWLEDGEMENTS .....	viii
MEMBERS OF THE WHO/IPCS WORKING GROUP ON UNCERTAINTY IN EXPOSURE ASSESSMENT .....	ix
LIST OF ACRONYMS AND ABBREVIATIONS .....	xi
EXECUTIVE SUMMARY .....	xii
1. INTRODUCTION .....	1
1.1 Why uncertainty analysis? .....	2
1.2 Consideration of uncertainty in the harmonization of risk assessment methods .....	3
1.3 Scope and objectives .....	3
2. CONTEXT, CONCEPTS AND DEFINITIONS .....	5
2.1 Historical context and background .....	5
2.2 Rationale for characterizing uncertainty in exposure assessment .....	6
2.2.1 Assessment objectives .....	6
2.2.2 Defining the conceptual exposure model .....	7
2.2.3 Building an exposure model and assessment .....	8
2.3 Planning for uncertainty analysis in exposure assessment .....	9
2.3.1 Balancing the uncertainties of exposure and hazard .....	10
2.3.2 Variability versus uncertainty .....	11
2.3.3 Sensitivity analysis .....	13
3. SOURCES OF UNCERTAINTY .....	15
3.1 Approaches and steps in exposure assessment .....	15
3.2 Nature of uncertainty sources .....	16
3.2.1 Scenario uncertainty .....	17
3.2.2 Model uncertainty .....	18
3.2.3 Parameter uncertainty .....	23
4. TIERED APPROACH TO UNCERTAINTY ANALYSIS .....	30
4.1 Regulatory background .....	30
4.2 Determination of the tiered level .....	31
4.2.1 Tier 0 (screening) uncertainty analysis .....	31
4.2.2 Tier 1 (qualitative) uncertainty analysis .....	32
4.2.3 Tier 2 (deterministic) uncertainty analysis .....	33
4.2.4 Tier 3 (probabilistic) uncertainty analysis .....	33

4.3 Summary of the tiered approach.....	36
<b>5. UNCERTAINTY CHARACTERIZATION METHODS, INTERPRETATION AND USE.....</b>	<b>38</b>
5.1 Qualitative uncertainty characterization.....	38
5.1.1 Rationale and objective.....	38
5.1.2 Methodology for qualitative uncertainty characterization.....	39
5.1.3 Conclusion.....	46
5.2 Quantitative uncertainty characterization.....	46
5.2.1 Intervals and probability bounds.....	47
5.2.2 Fuzzy methods.....	48
5.2.3 Probabilistic methods.....	49
5.2.4 Sensitivity analysis.....	58
5.3 Data and resource requirements.....	60
5.4 Interpretation of results.....	61
5.5 Use of uncertainty analysis in evaluation and validation.....	64
5.6 Summary of uncertainty characterization methods.....	65
<b>6. COMMUNICATION.....</b>	<b>67</b>
6.1 Introduction and historical background.....	67
6.2 The position of exposure and uncertainty assessment in the risk communication process.....	69
6.2.1 Uncertainty in exposure assessment as a prognostic technique.....	69
6.2.2 From scenario definition to uncertainty analysis: communication with the risk managers.....	70
6.2.3 Anticipating the demands of the audiences.....	73
6.2.4 Requirements for accepted exposure assessment.....	74
6.3 Proposals for the presentation/visualization of uncertainty.....	74
6.3.1 Presentation of numerical results.....	75
6.3.2 Communication of quantified uncertainties.....	76
6.3.3 Communication of unquantified uncertainties.....	80
6.4 Avoiding typical conflicts in risk communication.....	81
6.5 Conclusions.....	83
<b>7. CONCLUSIONS.....</b>	<b>84</b>
<b>8. REFERENCES.....</b>	<b>85</b>
<b>GLOSSARY OF TERMS.....</b>	<b>97</b>
<b>ANNEX 1: CASE-STUDY—QUALITATIVE UNCERTAINTY ANALYSIS.....</b>	<b>105</b>
A1.1 Introduction.....	105
A1.2 Objective.....	105
A1.3 Sources of uncertainty.....	105
A1.4 Selected tier.....	106
A1.5 Characterization and evaluation of uncertainty.....	106
A1.6 Communication.....	108

A1.6.1 Communication with other scientists.....	108
A1.6.2 Communication with risk managers .....	109
A1.6.3 Communication with the public.....	109
Appendix 1: Background for case-study.....	111
<b>ANNEX 2: CASE-STUDY—QUANTITATIVE UNCERTAINTY ANALYSIS.....</b>	<b>119</b>
A2.1 Introduction.....	119
A2.2 Methods used in the case-study .....	119
A2.2.1 Conceptual model: the context, the question and scenario development .....	120
A2.2.2 Modelling approach .....	121
A2.2.3 Constructing input distributions.....	121
A2.2.4 Variance propagation methods.....	122
A2.3 Case-study: PBLx exposure from fish ingestion.....	123
A2.3.1 Elements of the exposure assessment: context and question .....	124
A2.3.2 Scenario definition .....	124
A2.3.3 Model selection .....	124
A2.3.4 Parameter values and data.....	125
A2.3.5 Worst-case scenario .....	128
A2.3.6 Variance propagation .....	128
A2.3.7 Variance propagation with uncertainty and variability combined.....	129
A2.3.8 Variance propagation with uncertainty and variability separated.....	134
A2.4 Summary of the case-study .....	138

## **PART 2: HALLMARKS OF DATA QUALITY IN CHEMICAL EXPOSURE ASSESSMENT**

---

PREPARATION OF THE DOCUMENT .....	140
1. INTRODUCTION .....	143
2. WHAT DO WE MEAN BY “DATA” IN EXPOSURE ASSESSMENT? .....	145
3. TOWARDS A BROADER DEFINITION OF QUALITY IN EXPOSURE ASSESSMENT: HALLMARKS OF DATA QUALITY .....	147
3.1 Appropriateness .....	149
3.2 Accuracy .....	150
3.3 Integrity.....	151
3.4 Transparency.....	153
4. FROM EXPOSURE DATA QUALITY TO THE QUALITY OF EXPOSURE ASSESSMENTS.....	155
5. CONCLUSIONS.....	157
6. REFERENCES .....	158