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English version

## Standard documentation of chemical exposure models

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# Contents

Page

European foreword .....	4
Introduction.....	6
1 Scope.....	7
2 Terms, definitions and abbreviations .....	7
2.1 Terms and definitions .....	7
2.2 Abbreviations .....	13
3 Requirements for the documentation of exposure models .....	14
3.1 General principles .....	14
3.2 Model purpose .....	14
3.3 Model components .....	15
3.4 Model mode and type.....	16
3.5 Model applicability .....	16
3.6 Model evaluation .....	16
4 Communication .....	17
4.1 General .....	17
4.2 Level 1 documentation: Basic knowledge.....	17
4.3 Level 2 documentation: Process knowledge .....	18
4.4 Level 3 documentation: Input data .....	19
4.5 Level 4 documentation: Mathematical knowledge.....	20
4.6 Level 5: Model evaluation.....	20
Annex A (informative) Main components of exposure models through environmental pathways.....	21
A.1 General principles .....	21
A.2 MERLIN-Expo tool example.....	23
Annex B (informative) Sample documentation of the "River" model .....	25
B.1 Introduction.....	25
B.2 Level 1 documentation: Basic knowledge.....	25
B.2.1 Model purpose .....	25
B.2.2 Model components.....	25
B.2.3 Model mode.....	39
B.2.4 Model applicability .....	39
B.3 Level 2 documentation: Process knowledge .....	39
B.3.1 Process n°1: Deposition of particulate contaminants to bed sediment.....	39
B.3.2 Process n°2.....	40
B.4 Level 3 documentation: Input data .....	41
B.4.1 Parameter n°1: Settling velocity of particles $W_s$ .....	41
B.4.2 Parameter n°2 .....	43
B.5 Level 4 documentation: Mathematical knowledge.....	43
B.5.1 State variable n°1: Deposition flux of particles $F_d$ .....	43
B.5.2 State variable n°2 .....	43
Annex C (informative) Sample documentation of the "Advanced REACH Tool" (ART) .....	44
C.1 Introduction.....	44
C.2 Level 1 documentation: Basic knowledge.....	44
C.2.1 Model Purpose.....	44
C.2.2 Model components.....	44
C.2.3 Model mode.....	46
C.2.4 Model applicability .....	47
C.3 Level 2 documentation: Process knowledge .....	47
C.3.1 Process n°1: Emission.....	47
C.3.2 Process n°2: Transmission .....	48
C.3.3 Process n°3: Immission.....	49
C.4 Level 3 documentation: Input data .....	49
C.4.1 Forcing variable n°1: Substance emission potential.....	49
C.4.2 Forcing variable n°2: Activity emission potential.....	51

<b>C.5</b>	<b>Level 4 documentation: Mathematical knowledge.....</b>	<b>51</b>
<b>Annex D</b>	<b>(informative) Sample documentation of the "Evaporation" model .....</b>	<b>53</b>
<b>D.1</b>	<b>Introduction.....</b>	<b>53</b>
<b>D.2</b>	<b>Level 1 documentation: Basic knowledge.....</b>	<b>53</b>
<b>D.2.1</b>	<b>Model Purpose.....</b>	<b>53</b>
<b>D.2.2</b>	<b>Model components.....</b>	<b>53</b>
<b>D.2.3</b>	<b>Model mode.....</b>	<b>55</b>
<b>D.2.4</b>	<b>Model applicability .....</b>	<b>56</b>
	<b>List of Tables .....</b>	<b>57</b>
	<b>List of Figures.....</b>	<b>58</b>
	<b>Bibliography.....</b>	<b>59</b>

## European foreword

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties on 2015-07-08, the constitution of which was supported by CEN following the public call for participation made on 2014-05-26.

This CEN Workshop Agreement "Standard documentation of chemical exposure models" was developed in accordance with CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – The way to rapid agreement" and with the relevant provisions of CEN/CENELEC Internal Regulations – Part 2.

A list of the individuals and organizations which supported the technical consensus represented by the CEN Workshop Agreement is available to purchasers from the CEN-CENELEC Management Centre. These organizations were drawn from the following economic sectors: chemical industry, environmental technology and research institutes, construction, public authorities and academia.

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The final text of CWA "Standard documentation of chemical exposure models" was submitted to CEN for publication on 2015-08-14. It was developed and approved by:

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It is possible that some elements of CWA "Standard documentation of chemical exposure models" may be subject to patent rights. The CEN-CENELEC policy on patent rights is set out in CEN-CENELEC Guide 8 "Guidelines for Implementation of the Common IPR Policy on Patents (and other statutory intellectual property rights based on inventions)". CEN shall not be held responsible for identifying any or all such patent rights.

The final review/endorsement round for this CWA was started on 2015-04-16 and was successfully closed on 2015-06-16. The final text of this CWA was submitted to CEN for publication on 2015-08-13.

The Workshop participants have made every effort to ensure the reliability and accuracy of the technical and non-technical content of CWA "Standard documentation of chemical exposure models", but this does not guarantee, either explicitly or implicitly, its correctness.

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Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.

## Introduction

Today models are intensively used to predict the outcomes of a process or the fate of the chemicals in the environment, living organisms and humans based on scientific and empirical observation, and they are helpful in overcoming existing data gaps. However, information available about particular model applicability domain, limitations and evaluation can be fragmented and inconsistent.

This document aims to provide a framework for model description which will facilitate the use and comparability of models, as well as their potential coupling. It addresses the minimum requirement for amount and type of information to be provided for documenting exposure models. The standardized structure is expected to promote appropriate model application, and also be in support to informed decision making.

The intention is to cover the description of a wide range of models, simple or complex, such as environmental models, multimedia models, exposure models and toxicokinetic models. Annex A gives an overview of the main components of exposure models through environmental pathways. Annexes B, C and D give an example of the documentation of an environmental exposure model, an occupational exposure model and a consumer exposure model, respectively. The target audiences include model developers, model users, policy makers who work with models and others.

The basis of this document has been provided by a research report [1] written in the course of the EU-funded FP7 project 4FUN (<http://4funproject.eu/>), Grant Agreement Nr. 308440.

## 1 Scope

This CEN Workshop Agreement (CWA) establishes terms and definitions for exposure models and their elements, specifies minimum requirements for the amount and type of information to be documented on exposure models, and proposes a structure for communicating the documentation to different users.

This document is applicable to the documentation of a wide range of exposure models (quantitative and non quantitative), including

- environmental models describing the fate of chemicals in different media such as soil, air or water;
- environmental models describing the chain of chemicals from the environment to humans, in particular via food (e.g. plants and animals), drinking water and other pathways, and
- human exposure models (occupational, consumers) including toxicokinetic models but excluding toxicodynamic models.

The documentation of the coupling of different exposure models that were developed independently and that can cause consistency issues is not the focus of this CWA. However, this CWA is applicable to models (or sub-models) originally designed to be consistently coupled.

Excluded from the scope of this document are issues of

- model coding and translation into software,
- hazard assessment and risk assessment,
- source characterization, and
- legislation dependent aspects of exposure assessment such as tiered approaches and exposure assessment reporting.

## 2 Terms, definitions and abbreviations

### 2.1 Terms and definitions

Terms used in this documents that are not assumed to be generally understood are defined in this section. Terms are presented in alphabetical order. Synonyms, if any, are stated below the defined term. The definitions are specific to the use of the terms in this document and are not meant to be of general validity. Definitions are formulated in a single sentence so as to replace the term where it occurs in the text. Further explanations needed beyond the single sentence are given below the definitions as notes or examples. Sources of the definitions are provided where applicable.

For the purposes of the present document, the following terms and definitions apply.

#### 2.1.1

##### **accuracy**

closeness of a measured or computed value to its "true" value, where the "true" value is obtained with perfect information

[SOURCE: US EPA (2009)]

Note 1 to entry: Due to the natural heterogeneity and stochasticity [2.1.36] of many exposure systems, the "true" value generally derives from spatial [2.1.34] and temporal [2.1.37] aggregation.

#### 2.1.2

##### **algorithm**

precise rule or set of rules expressed as mathematical equation(s) to characterise an exposure [2.1.11] model [2.1.20]