4FUN

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1 Introduction

The assessment of risks to human health from chemicals is of major concern for policy and industry and ultimately benefits all citizens. In this process, exposure assessment is generally considered to be the weakest point, as currently available tools show major flaws:

- lack of integrated approach for assessment of combined stressors (i.e. a number of potential pollutants);
- widespread use of “worst-case” scenarios leading to over-conservative results;
- lack of uncertainty/sensitivity tools that allow identifying the important exposure drivers.

To overcome these drawbacks, the FP6 project 2-FUN produced prototype software containing a library of models for exposure assessment, coupling environmental multimedia and pharmacokinetic models. The objective of the 4FUN project is to further improve and standardise the 2-FUN tool and guarantee its long term technical and economic viability.

The models classically used for exposure assessment (and health risk assessment in general) involve a large set of entities, variables, numerical schemes and potential outputs, and are by nature difficult to communicate in a comprehensive, unambiguous and accessible way. Furthermore, no standard exists at international level to classify the information requested for qualifying such large models, and no documentation protocol exists to structure its communication. However, state-of-the-art in exposure modelling has shown that bad communication in assumptions, theory, structure and/or parameterisation can lead to lack of confidence, errors and poor reproducibility among different users.

This report seeks to overcome such drawbacks of large and complex exposure models by proposing a standard documentation framework which facilitates an unambiguous and tiered appropriation by end-users. The scope of the report and the proposed framework includes the theoretical model and its data and computations, but not its translation into computer code, and also not the user manual for the software tool. The associated research has been conducted in close collaboration with the European Committee for Standardisation (CEN) and its national member Austrian Standards, as developments in standardisation of large models are likely of interest beyond the 2-FUN tool, and could be extended to other complex modelling systems used in risk assessments.

2 Executive summary

The standard documentation framework presented in this report has been derived from a review of literature and of sample documentations of other large exposure models. From this, a list of items has been distilled (see “low level structure” in Table 1) that must be covered by a standard documentation framework, which have been clustered around topics (see “high level structure” in Table 1). The list of items and topics was then applied to the documentation of the EUSES multimedia model (see *Appendix B: Testing the documentation framework on existing multimedia models: EUSES*) and further refined based on the experience.

Table 1 Standard documentation framework for large exposure models

High level structure	Low level structure	Description
Model purpose	Goal	General statement of the model outputs of concern, the stressors and the degree of model accuracy and precision needed. Explanations of why you need to build a complex model
	Decisions or regulatory framework	Explanations of what you are going to do with your model. Identify the (regulatory) framework to be supported (e.g. REACH, PPP, screening assessment, etc.)
Model context/ applicability	Spatial scale/ resolution	The spatial conditions (extent and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated. Boundaries or domain, specify the area or volume (spatial boundary) to which a model application will apply: Local, Regional, continental, or global scale
	Temporal scale/ resolution	The temporal conditions (extent and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated. Boundaries or domain specify the time period (temporal boundary) to which a model application will apply
	User community	
	Required inputs	
	Output of interest	To ensure transparency in the output being predicted by a given model, since a given endpoint could be determined by different experimental protocols and under different experimental conditions. Give units of measurement
	System limitations	Boundary conditions of the system
	Exposure pathways	The course a chemical takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, the transport/exposure medium (such as air) or media (in cases of intermedia transport, such as water to air) are also included
	Exposure routes	The way a chemical or physical agent comes in contact with an organism, i.e., inhalation, ingestion, dermal contact. Describe the possible exposure routes of the model
	Fate, exposure and effect	If fate, exposure and effect analyses are included or not
	Chemical	Outline the chemical range of substances that can be analysed with the model (e.g.

	considered	organic pollutants and/or inorganic pollutants, etc.). If mixture toxicity is included in the model, define the approach used to assess this. Define the origin of background concentrations, if used
	Media considered	An environmental or human compartment assumed to contain a given quantity of the chemical. Quantity of the chemical in the media is governed by inputs/outputs from/to other media and by transformation processes (e.g. degradation): Air, water (fresh, ground, sea, and etc), soil, sediment, vegetables, animals, etc and include a graphic representation of the conceptual compartments
	Human population	Define which part of the population is targeted with the model (worker, general population, division in subgroups, etc.)
	Environmental processes	Describe the prevailing environmental processes per compartment (e.g. for soil: leaching, run-off, etc.)
	Human processes	State the human processes taking place in the human body (e.g. accumulation, excretion, distribution)
Model component	Initialisation	Initial conditions assumed, i.e., what are the initial values of the state variables, is initialization always the same or changing among simulations?
	Overview input data	Environmental conditions which change over time and space, i.e., precipitation, management (e.g. harvesting regimes)
	State variable	The dependent variables calculated within a model, which are also often the performance indicators of the models that change over the simulation
	Forcing/ driving variable	An external or exogenous (from outside the model framework) factor that influences the state variables calculated within the model. Such variables include, for example, climatic or environmental conditions (temperature, wind flow, oceanic circulation, etc.)
	Parameters	Terms in the model that are fixed during a model run or simulation but can be changed in different runs as a method for conducting sensitivity analysis or to achieve calibration goals. List the input parameters and their units necessary to perform a simulation. State which kind of point value is required (e.g. mode, mean, etc.). State which probability distributions can be applied for input values. Indicate if QSARs are applied for which parameter in which part of the model
	Constants	A fixed value (e.g., the gravitational force) representing known physical, biological, or ecological activities. List the constants, their value and origin (reference)
	Model structure/ framework	The system of governing equations, parameterization, and data structures that make up the mathematical model. The model framework is a formal mathematical specification of the concepts and procedures of the conceptual model consisting of generalized algorithms. Detailed explanation of all the sub-models representing the processes listed above in ‘Process overview and scales’, including the parameterization of the model. All model equations and rules should be presented
Model type	Simulation vs. optimization	Statement of the model type; simulation vs. optimization
	Steady-state versus dynamic	Statement of the model type; static (steady-state) (A model providing the behaviour of the state variables assumed to be in immediate equilibrium with all the other interacting state variables or a model providing the long-term or time-averaged behaviour of the state variables) vs. dynamic (A model providing the time-varying behaviour of the state variables)
	Deterministic vs. stochastic	Statement of the model type; deterministic (a model that provides a solution for the state variables rather than a set of probabilistic outcomes. Because this type of model does not explicitly simulate the effects of data uncertainty or variability, changes in model outputs are solely due to changes in model components or in the boundary conditions or initial conditions) vs. stochastic (a model that includes uncertainty and variability (see definition) in model parameters. This variability is a function of changing environmental conditions, spatial and temporal aggregation within the model framework, and random variability. The solution obtained by the model or output is therefore a function of model components and random variability)

	Lumped vs. distributed	Statement of the model type: Solving a set of ordinary differential equations or solving partial differential equations
	Analytical or numerical model	Analytical (a model that can be solved mathematically in terms of analytical functions. For example, some models that are based on relatively simple differential equations can be solved analytically by combinations of polynomials, exponential, trigonometric, or other familiar functions) or numerical model (a model that represents the development of a solution by incremental steps through the model domain. Simulations are often used to obtain solutions for models that are too complex to be solved analytically. For most situations, where a differential equation is being approximated, the simulation model will use finite time step (or spatial step) to “simulate” changes in state variables over time (or space))
	Mode (of a model)	The manner in which a model operates. Models can be designed to represent phenomena in different modes. Prognostic (or predictive) models are designed to forecast outcomes and future events, while diagnostic models work “backwards” to assess causes and precursor conditions
	Screening model	A type of model designed to provide a “conservative” or risk-averse answer. Screening models can be used with limited information and are conservative, and in some cases they can be used in lieu of refined models, even when time or resources are not limited
Model evaluation	Model coding verification	Examination of the algorithms and numerical technique in the computer code to ascertain that they truly represent the conceptual model and that there are no inherent numerical problems with obtaining a solution
	Input data	The accuracy, variability, and precision of input data. The source of parameter default values, as well as PDFs, should be indicated in the SDP, with an explanation of the process of parameter estimation (e.g. expert elicitation, extrapolation, statistical treatment of environmental data)
	Model calibration	If applicable, the general explanation about model calibration
	Model framework/ structure uncertainty	The uncertainty in the underlying science and algorithms of a model. Model framework uncertainty is the result of incomplete scientific data or lack of knowledge about the factors that control the behavior of the system being modeled. Model framework uncertainty can also be the result of simplifications necessary to translate the conceptual model into mathematical terms
	Model predictivity	The predictivity of a model, determined by using an appropriate test set. There is no absolute measure of predictivity that is suitable for all purposes, since predictivity can vary according to the statistical methods and parameters used in the assessment. • Indication is test set is independent from training set (if relevant) • Provide details on full test set • Representativeness of test set
	Uncertainty analyses	Investigation of the effects of lack of knowledge or potential errors on the model (e.g, the “uncertainty” associated with parameter values). When combined with sensitivity analysis (see definition), uncertainty analysis allows a model user to be more informed about the confidence that can be placed in model results. Uncertainty analysis can be qualitative or quantitative
	Sensitivity analysis	The computation of the effect of changes in input values or assumptions (including boundaries and model functional form) on the outputs (Morgan and Henrion 1990); the study of how uncertainty in a model output can be systematically apportioned to different sources of uncertainty in the model input (Saltelli et al. 2000a). By investigating the “relative sensitivity” of model parameters, a user can become knowledgeable of the relative importance of parameters in the model

To tailor the communication to the needs of different users, 3-4 levels are proposed as the 4FUN standard documentation protocol (SDP):

Level 1 – Basic Knowledge

Provides a general overview for end-users who trust model developers on scientific, numerical and mathematical issues

Level 2 – Process Knowledge

Targeted towards end-users, who want to have a clear understanding of the scientific background and foundations of the model

Level 3 – Numerical knowledge

Targeted towards end-users, who want to have a clear vision of all the parameter values included in the model, to better capture the assumptions related to the parameterization of the model

Level 4 – Mathematical knowledge

For end-user who wants to deeply understand the equations that translate the processes described at level 2

Alternatively, level 4 can be included in level 2, resulting in a 3 level structure. Level 1 would be targeted at the user trying to figure out if the model fits his/her purpose. The medium level would be targeted advanced users of the model, and level 3 would be more specifically for the user that needs to carry out a parametric sensitivity analysis.

The proposed 4FUN standard documentation protocol is illustrated in detail in Chapter 7, by applying it to the 4FUN freshwater model.

Furthermore, the 4FUN Consortium should consider gaining additional benefits from standardisation. The following options are identified in this report that can be implemented within the existing budget of 4FUN if considered useful and requested by the Consortium

- Using available European or International Standards covering the analysis of various media as a source for trusted and continuously updated parameters as well on accepted scientific models and measurement methods for the 4FUN library (see *Appendix A: Analysis Standards covering various media*).
- Establishing formal links to the relevant Technical Committee at CEN and ISO to monitor ongoing standardisation developments at a nominal cost, while retaining the option to actively participate should proposals on relevant new standards emerge (see 8.2 Contributing to the development of a standard).
- Consider developing this report into a CEN workshop agreement, thereby shaping a standard framework representing consensus and expertise beyond 4FUN with potentially important and strategic long-term benefits

3 Large exposure models and the 4FUN model

3.1 Introduction

The evaluation of health risks raised by chemical releases into the environment is of major concern of regulatory bodies, policy makers, industries, and the public. The integrated study of contaminant release, transport, fate, exposure, dose, and response is the basis for the environmental health risk assessment paradigm (Figure 1).

Multimedia models (MM models) such as CalTOX (McKone, 1993a), EUSES (Vermeire et al.,1997), RAIDAR (Arnot et al., 2006), TRIM.FaTE (US EPA, 2005) are used to evaluate the fate of chemicals in the environment and also the human exposure to chemicals. Physiologically based pharmacokinetic (PBPK) models are used to predict the internal effective concentrations in the target internal tissues where toxic effects arise. Coupling such PBPK models with the MM models allows a comprehensive evaluation of environmental health risks, in line with the paradigm described in the table below.

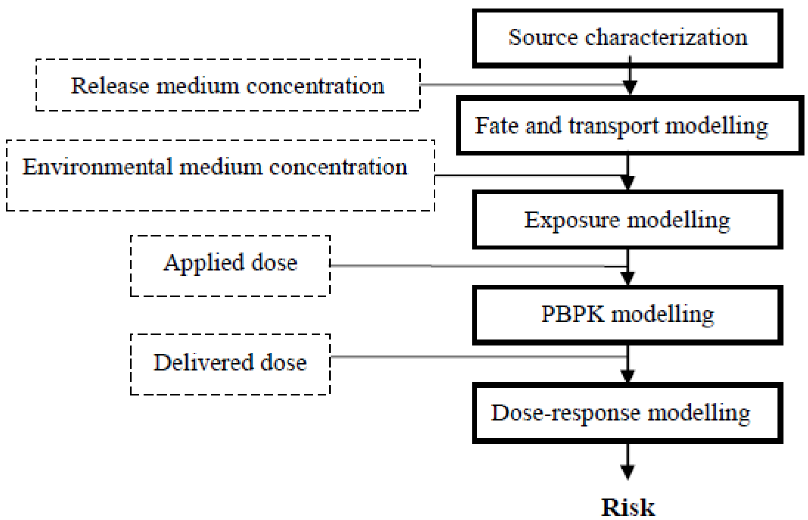


Figure 1 Integrated environmental health risk assessment paradigm (Ramaswami et al., 2005)

A large exposure model integrating MM and PBPK models was developed and demonstrated in the European project (FP6) named "2-FUN" (Full-chain and uncertainty approaches for assessing health risks in future environmental scenarios). Presently the 4FUN project was launched with the purposes to improve and standardize the model (hereafter, the 4-FUN model).

The objectives of this chapter are to give a general description of main components of MM and PBPK models, and to present the specificity of the 4FUN model.

3.2 Description of main components of MM/PBPK models

Many MM and PBPK models are set up in compartment or box formats where the environment or the human anatomy is divided into a number of volumes or boxes, which are fixed in space and are usually treated as being homogeneous, i.e. well-mixed, in chemical composition. Such models are generally composed of mass balance equations which account for the production, loss, and accumulation of the contaminant within a specified control volume. Transport phenomena and physical, chemical, and biological transformations are represented within the framework of this fundamental concept. In some of these models the mass balance principle is expressed mathematically as a time-dependent differential equation:

$$\frac{dM}{dt} = \frac{dCV}{dt} = M_{in}(C,t) - Mout(C,t) + S(C,t) \pm Rxn(C,t)$$

where M is the mass of the contaminant within the control volume, V is its volume, C (=M/V) is the concentration, t is time, M_{in} and M_{out} are the transport rates across the boundaries of the control volume from and to the surrounding environment, respectively, S is the source emission rate, and Rxn is the rate of internal reactions that may either produce or consume the contaminant. Figure 2 illustrates the mass-balance principle within a well-defined control volume.

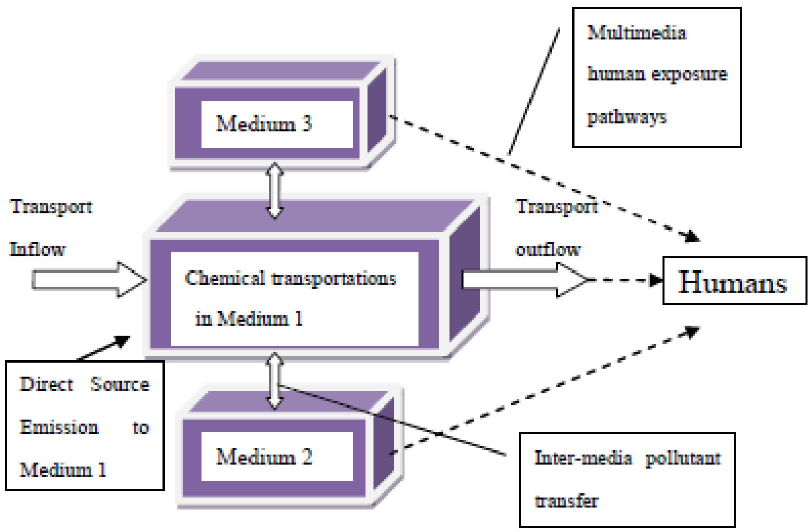


Figure 2 Illustration of mass balance principle for multimedia models (Ramaswami et al., 2005)

MM models calculate the distribution of pollutants in multiple environmental media, i.e., air, water, soil, vegetation by considering inter-media pollutant transfers. Combined with the information about human behaviours such as dietary habit, time spent outside/inside, and types of activities, the multimedia models can provide an estimation of the daily chemical intake by inhalation, ingestion, and dermal intake by the population of interest.

Once the exposure scenario is identified, the dose-response assessment is typically achieved by comparing exposure outputs (e.g., the daily intake) to the reference doses estimated from toxicological data. Currently, risk assessment methodologies involve integrative dose-response models that link the external dose (e.g., environmental concentration) to the adverse effects. However, the use of such simple dose-response models does not reflect the current understanding of the mode of action of a chemical and does not facilitate extrapolations to other scenarios (species, exposure routes, etc). Thus the determination of internal effective concentrations, i.e., in the target tissues where toxic effects arise, is required to characterize accurately the link between an external exposure and the internal dosimetry that may be associated with the observed effects (Andersen and Dennison 2002).

PBPK models have been developed to predict the internal effective concentrations in the target internal tissues where toxic effects arise. PBPK models are quantitative descriptions of the absorption, distribution, metabolism and excretion (ADME) of chemicals in biota based on interrelationships among key physiological, biochemical and physicochemical determinants of these processes (WHO 2010). Moreover, these models are well-suited for integrating available information on age- or gender-dependent changes and then evaluating the influence of these changes on the internal dosimetry (Clewell et al. 2004; Beaudouin et al. 2010). A dose-response model is then applied to link the effective concentration to the adverse effects. Figure 3 illustrates the structure of an inhalation PBPK model for a volatile organic chemical.

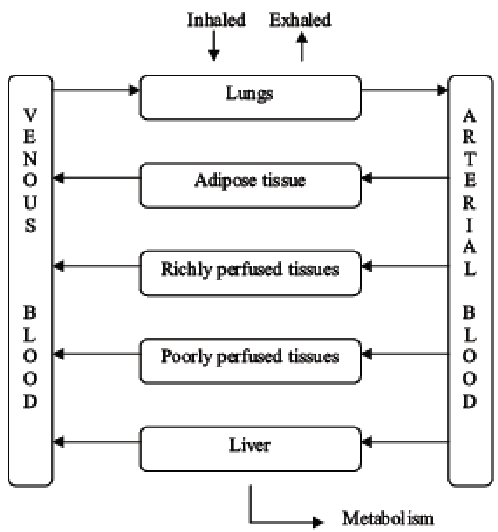


Figure 3 Illustration of the structure of an inhalation PBPK model for a volatile organic chemical (WHO, 2010)

3.3 Specificity of 4FUN model

The 4FUN model currently comprises 24 sub-models[1]. One half of them deal with organic substances (organic sub-models) and the other half with inorganic substances (metal sub-models). The model considers 1 medium for the human body and the following 11 environmental media; air, fresh water, soil, plant (root, potato, leaf, grain, grass, and fruit), fish, cow, and each sub-model corresponds to one medium. The human medium is dealt with by PBPK sub-models. Combining the PBPK sub-models with the environmental sub-models, the 4FUN model is capable of estimating the concentrations of pollutants in the environmental media, the external exposure dose via ingestion and inhalation, and the internal effective concentrations in human tissues and organs. An overall diagram of the 4FUN tool is presented in Figure 5.

The platform system of the 4FUN model stores all the sub-models in a library. From the library, model users can flexibly select and connect the sub-models depending on exposure scenarios designed by the users. The effective graphical interfaces of the platform system can facilitate a comprehensive identification and visualization of the exposure pathways and of the roles of different sub-models in terms of their transfer relationships (see Figure 4).

[1] Some new sub-models could be added through the 4FUN project.

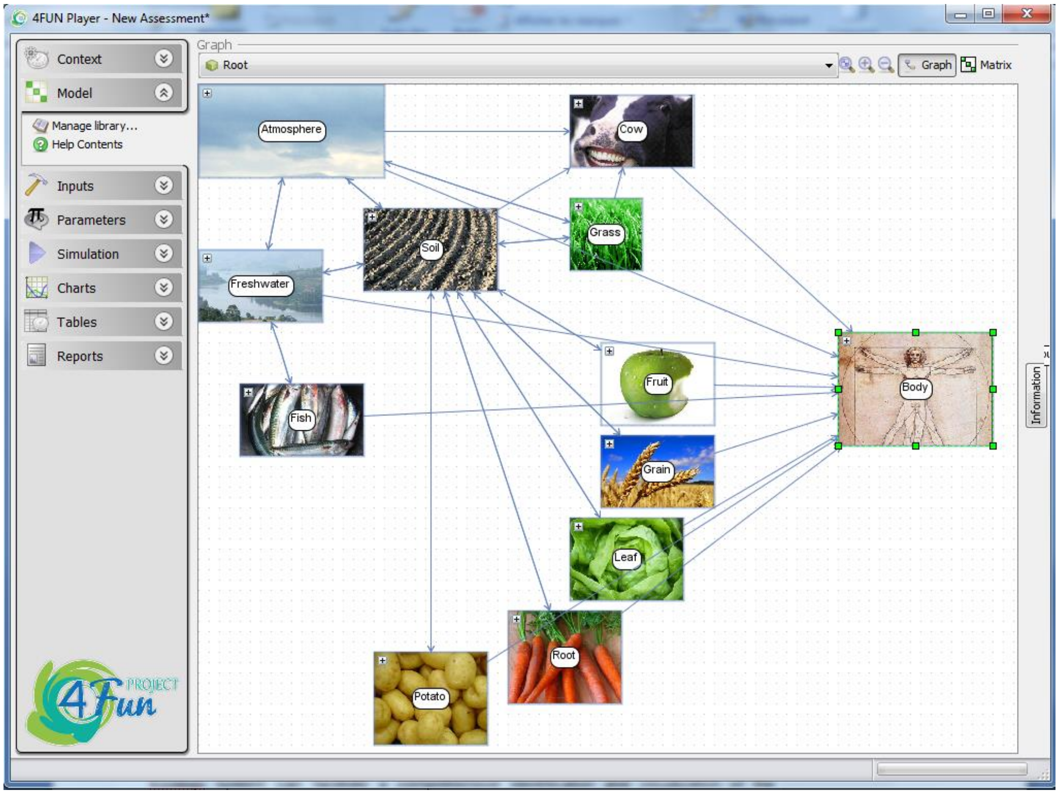


Figure 4 Visualization of the 4FUN model in the platform system

Other prominent features of the 4FUN model are summarized as follows:

- A dynamic model;
- Performing deterministic or probabilistic simulations;
- Performing Monte Carlo or Latin Hypercube sampling for probabilistic simulations;
- Availability of many types of probability density functions applied to input parameters;
- Availability of a wide range of methods for sensitivity and uncertainly analyses, such as Pearson, Spearman, EASI correlation coefficients, regression coefficients, the Morris method, and other methods;
- Capability to conduct lifetime risk assessments for different population groups (general population, children at different ages, pregnant women).

3.4 Summary

The 4FUN model is a large, complex, and integrated tool. The model is capable of conducting a full-chain lifetime risk assessment for different population groups by estimating chemical concentrations in the environment, external exposure doses, and internal effective concentrations. The user-friendly platform system facilitates the usage of the model.

From perspectives of potential model users, what will be needed next is a comprehensive document which describes the 4FUN model in a well-structured and transparent manner. A standard format for describing such a large model is proposed in this deliverable. The complete documentation of the 4FUN model based on the standard format is expected to make model users deeply understand the model and to prevent them from misusing it.

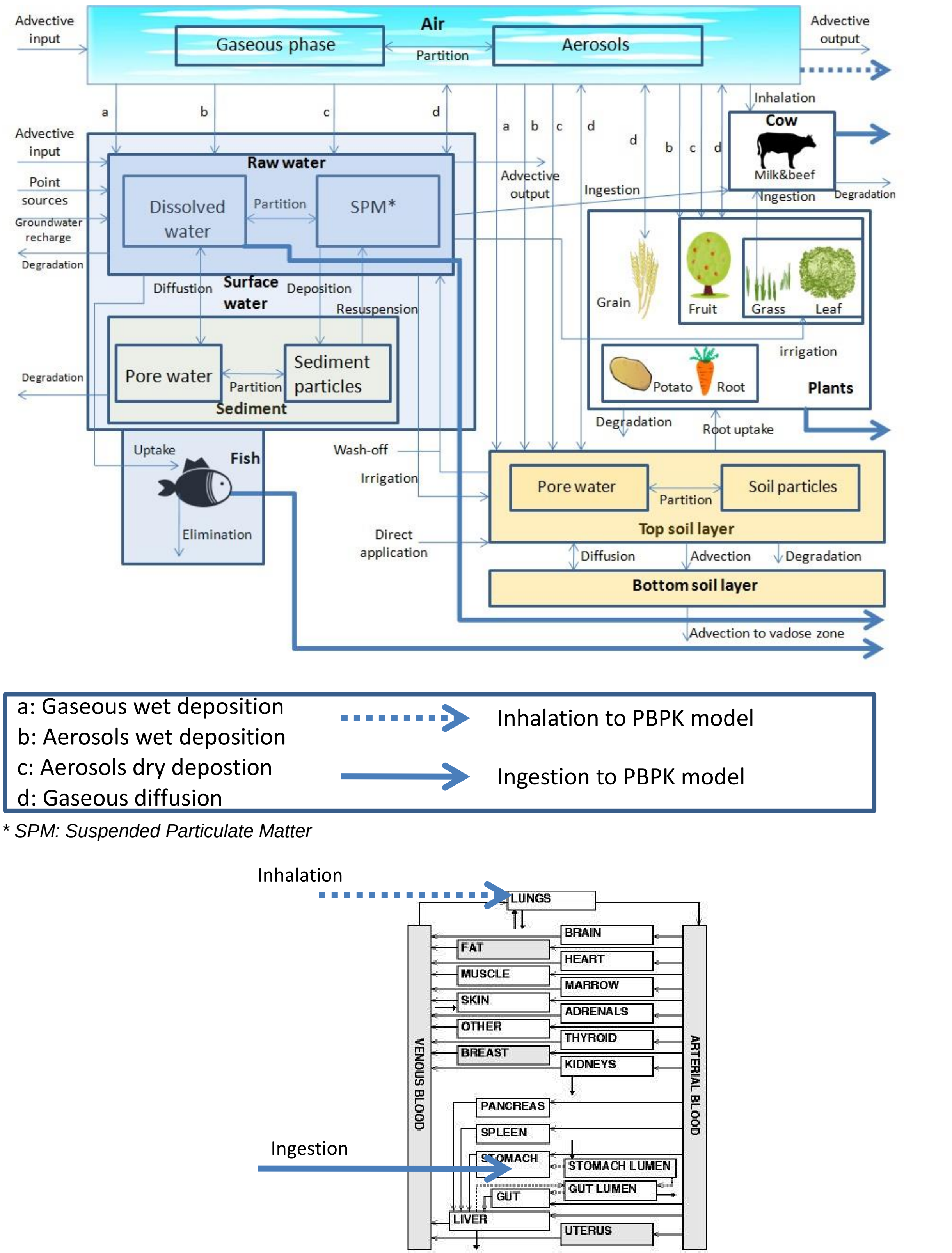


Figure 5 Overall diagram of the 4FUN model used for organic substances - environmental organic sub-models (above) and PBPK sub-model (below)

4 Standardized frameworks for large exposure models

4.1 Introduction

A standardized framework for large exposure models should describe all the aspects of such a model in a structural, transparent, and reader-friendly manner. Some proposals to form the frameworks for describing computational models have already been made by several scientific groups in different domains. In this section, essences of those proposals are summarized in order to find out all the features that are indispensable to describe a large exposure model and to give ideas to form an optimal structure of a standardized documentation model.

4.2 US EPA (2009) – Guidance on the development, evaluation and application of environmental models

US EPA (2009) presents recommendations for the effective development, evaluation, and use of environmental models in environmental decision making. In the document, the recommendations are categorized into three basic steps: Model development, model evaluation, and model application. This document lists the three steps in the following table (see Table 2).

Table 2 Basic steps in the process of modelling for environmental decision making (US EPA 2009)

Step		Modeling Issues
Problem identification and specification: to determine the right decision-relevant questions and establish modelling objectives	Definition of model pur pose	• Goal • Decisions to be supported • Predictions to be made
	Specification of modelling context	• Scale (spatial and temporal) • Application domain • User community • Required inputs • Desired output • Evaluation criteria
Model development: to develop the conceptual model that reflects the underlying science of the processes being modelled, and develop the mathematical representation of that science and encode these mathematical expressions in a computer program	Conceptual model formulation	• Assumptions (dynamic, static, stochastic, deterministic) • State variables represented • Level of process detail necessary • Scientific foundations
	Computational model development	• Algorithms • Mathematical/computational methods • Inputs • Hardware platforms and software infrastructure • User interface • Calibration/parameter determination • Documentation
Model evaluation: to test that the model expressions have been encoded correctly into the computer program and test the model outputs by comparing them with empirical data	Model testing and revision	• Theoretical corroboration • Model components verification • Corroboration (independent data) • Sensitivity analysis • Uncertainty analysis • Robustness determination • Comparison to evaluation criteria set during formulation

Model application: running the model and analyzing its outputs to inform a decision	Model use	• Analysis of scenarios • Predictions evaluation • Regulations assessment • Policy analysis and evaluation • Model post-auditing

Over the content of Table 2 above, the first two parts, ‘Problem identification and specification’ and ‘Model development’, can be more relevant for our goals which are to find out an optimal template to describe models, because those parts point out fundamental aspects that can be essential to be described for any type of computational model. US EPA (2009) further categorizes these parts into three main steps: (1) problem specification and conceptual model development, (2) mathematical model development, and (3) parameterization of model. In the document, several points are remarked within each main step from (1) to (3). These points are summarized according to our goal in the following Tables.

Table 3 Problem specification and conceptual model development

Points	**Descriptions**
Modelling objectives	Statement of the model outputs of concern, the stressors, appropriate temporal and spatial scales, and the degree of model accuracy and precision needed
The type of model	Statement of the model type; empirical vs. mechanistic, static vs. dynamic, simulation vs. optimization, deterministic vs. stochastic, and lumped vs. distributed
The scope of model	Spatial, temporal and process details - are they simple or complex (model complexity)?
Determination of data criteria	Development of data quality objectives (DQOs[2]) and specification of the acceptable range of uncertainty
Determination of the model’s domain of applicability	Identification of the environmental domain to be modelled and then specifying the processes and conditions within that domain, including the transport and transformation processes relevant to the policy/management/research objectives, the important time and space scales inherent in transport and transformation processes within that domain in comparison to the time and space scales of the problem objectives, and any peculiar conditions of the domain that will affect model selection or new model construction
Development of the conceptual model	Description of the most important behaviours of the system, object, or process relevant to the problem of interest: the clarification of each element of the conceptual model and the science behind each element (e.g., laboratory experiments, mechanistic evidence, empirical data supporting the hypothesis, peer-reviewed literature) in mathematical form, when possible

Table 4 Mathematical model development

Points	**Descriptions**
Mathematical specification	Mathematical specification of the concepts, procedures, and behaviours underlying the system, object, or process relevant to the problem of

[2] The DQO Process is a seven-step planning approach to develop sampling designs for data collection activities that support decision making. This process uses systematic planning and statistical hypothesis testing to differentiate between two or more clearly defined alternatives (US EPA 2000a).

	interest, and the description of scientific justification of the model; i.e., if sound science (including peer-reviewed theory and equations) supports the underlying hypothesis?
Model coding and verification	Several tips to minimize programming errors

Table 5 Parameterization of model

Points	**Descriptions**
Input data	The accuracy, variability, and precision of input data
Model calibration	The general explanation about model calibration

Strenghts and usefulness

- The US EPA document reviewed here covers the majority of aspects related to a MM model and a standard documentation framework
- It presents a comprehensive approach to analyse the relevance and reliability of a MM model
- It provides a detailed overview of issues to consider when developing complex environmental models

Weaknesses

- Strictly speaking, the document does not propose a structured framework for documentation since all the information seems to be delivered at the same level.
- It misses some aspects (model developer, software related features, operating system, etc.) related to the general model information
- It is sometimes too general to describe a multimedia model (more detail on different aspects of the models are necessary)

4.3 Grimm and Railsback (2005), Grimm et al (2006) and Grimm et al (2010) - The “Overview, Design concepts, and Details (ODD)” framework

Grimm and Railsback (2005) initially proposed the basic idea of a standard protocol for explaining simulation models used in the ecological field; those models describe autonomous individual organisms (individual-based models, IBM) or agents (agent-based models, ABM). The basic idea was revised by Grimm et al (2006) and subsequently by Grimm et al (2010). Due to the complexity of IBMs in their structures, their published descriptions are generally hard to read, incomplete, ambiguous, and therefore less accessible. The standard protocol was then proposed to make reading and understanding IBMs easier for readers. The protocol consists of three blocks (Overview, Design concepts, and Details), which are subdivided into seven elements: Purpose; state variables and scales; process overview and scheduling; design concepts; initialization; input; and sub-models. The proposed standard protocol was developed and tested by 28 modellers who cover a wide range of fields with ecology. According to the revision proposed by Grimm et al (2010), the ODD protocol is summarized in the following Table 6.

Table 6 Summary of the ODD concept

Main categories	Sub-categories	Descriptions
Overview	Purpose	Explanations of why you need build a complex model Explanations of what you are going to do with your model
	Entities, state variables, and scales	The structure of a model by hierarchical levels of entities (individual – territory – population – environment) The full set of state variables (low-level variables), i.e., individuals (age, sex, social rank, and etc) or habitat units (location, soil type, and etc) The temporal and spatial scales
	Process overview and scheduling	A verbal & conceptual description of each process and its effects defined in a model (a concise overview) The scheduling of the model processes, i.e., the orders in which the state variables are updated (winter mortality-eviction-inheritance-dispersal-re-colonization…….) by using flow charts
Design concepts	Design concepts	Basic principles, emergence, adaptation, objectives, learning, sensing interaction, stochasticity, collectives, and observation
Details	Initialisation	Initial conditions assumed, i.e., what are the initial values of the state variables, is initialization always the same or changing among simulation?
	Input data	Environmental conditions which change over time and space, i.e., precipitation, management (e.g. harvesting regimes)
	Sub-models	Detailed explanation of all the sub-models representing the processes listed above in 'Process overview and scales', including the parameterization of the model. Two versions of the detailed model description are proposed: 1. The model equations and rules and one or more tables presenting the model parameters and their dimensions; 2. This version has the same structure as the first version but each equation and parameter is verbally explained in full detail, i.e., what specific assumptions are underlying the equations and rules?, how were parameter values chosen?, How were sub-models tested and calibrated?

Strenghts and usefulness

- The ODD framework specifically focuses on documentation rather than the development of models

- It was tested on actual models in the field of ecological modelling
- The information is structured enabling the user to have the appropriate level of information at the right tier
- Flow charts are proposed for a better understanding of the dependency between variables
- The ODD concept can then be partly used for constructing a basic format of a standard documentation protocol (SDP)

Weaknesses

- The protocol was developed to be applied in the ecological field, which contains a lot of aspects not relevant for multimedia models.
- Model evaluation and application is not covered in the ODD protocol.

4.4 CEMN (Canadian Environmental Modelling Network) (2005) – Development and application of models of chemical fate (Modelling guidance document)

The CEMN report (2005) was written to support the novice model-user in understanding when, why, and how to use models of chemical fate in the environment. The document consists of four main parts that describe (1) Canadian regulatory background, (2) environmental fate models in general, (3) CEMN models, and (4) aspects of interpreting model results. Over those parts, a topic which may be useful to enrich the content of a SDP was found in part (2). In the part (2), the categorization of models by levels of model complexity is illustrated from the simpler models which are easiest to understand and have fewest data requirements, to the complex models which become more challenging to understand and require a lot of input data. The categorization of models is summarized in the following Table 7.

Table 7 Summary of levels of complexity in multimedia models

Levels	Assumptions
I	Models merely show the relative equilibrium partitioning of a conserved (i.e. non-reacting) chemical in a multimedia setting. They assume equilibrium and steady-state to apply in the closed system.
II	Models include degrading reactions and advective loss but assume all media are at equilibrium, so only one fugacity[3] and one mass balance equation applies. They assume equilibrium and steady-state to apply in an open system with inputs and outputs. Mode-of-entry is irrelevant because the chemical immediately establishes equilibrium upon introduction to the system.
III	Models assume steady-state, i.e., conditions are constant with time but compartments are not at equilibrium and different fugacities apply to each medium. Rates of inter-media transport are calculated. Mode-of-entry information is needed.
VI	Models are dynamic. They are most often used to determine how long it will take for concentrations to change as a result of changing rates of emissions.

In the context of the CEMN report (2005), this categorization is discussed along with fugacity-based multimedia models which were developed by the CEMN. However, concerning that the concept of fugacity is a surrogate for and is proportional to concentration, those fugacity-based models are identical to concentration-based models such as 2-FUN tool, in terms of the mass-balance concept. Therefore, the way of categorizing models present in the table could

[3] Fugacity is a surrogate for concentration. It is a criterion of equilibrium and is essentially partial pressure (measure in Pa) and is assumed to be proportional to concentration.

be also applied to concentration-based models in order to indicate the complexity of a model that we use.

Strenghts and usefulness

- Indication of relative complexity of a model according to the definition provided by CEMN report (Level I – IV) is now commonly used among the MM model users/developers

Weaknesses

- The guidance document does not give a stepwise overview of the steps needed to describe a procedure for a model protocol. It describes the processes and pathways in details
- The categorization of models by Level I – IV may not be so useful for general model users who are not familiar with MM models

4.5 OECD (2007) - Guidance document on the validation of quantitative structure-activity relationship (QSAR) models

OECD (2007) presents detailed guidance that explains and illustrates the application of the validation principles to different types of QSAR models, based on agreed OECD principles of QSAR validations. QSAR models are conceptually different from MM models; briefly speaking, they are based on regression analysis between compounds molecular descriptors and a defined endpoint (e.g. toxicological or ecotoxicological endpoints, substance-specific fate parameters such as Henry's law constant, soil organic carbon/water partition coefficient (Koc), octanol/water partition coefficient (Kow), Bioaccumulation factor for fish (BAF for fish), and etc). It is then not possible to directly apply rules defined for the description of QSAR models for MM models, but it appeared useful to analyse the OECD specifications recommended for the documentation of such models. According to the OECD principles, a QSAR model should be associated with the following information: (1) a defined endpoint, (2) an unambiguous algorithm, (3) a defined domain of applicability, (4) appropriate measures of goodness-of-fit, robustness and predictivity, and (5) a mechanistic interpretation, if possible. The following Table 8 and Table 9 present a summary of explanatory notes for OECD principles of QSAR validation and a check list of the interpretation and application of the OECD principles.

Table 8 Summary of explanatory notes for OECD principles of QSAR validations

Principles	**Descriptions**
A defined endpoint[4]	The principle is intended to ensure transparency in the endpoint being predicted by a given model, since a given endpoint could be determined by different experimental protocols and under different experimental conditions. Ideally, QSAR models should be developed from homogeneous training set of data[5] generated by a single protocol. However, this is rare in practice, and data generated by different protocols are often combined.
An unambiguous algorithm	The principle is intended to ensure transparency in the description of the model algorithm, e.g. algorithms of multiple

[4] Endpoints refer to any physicochemical, biological or environmental effects that can be measured and therefore modeled, e.g. vapour pressure, Kow, biodegradation, bioaccumulation, acute fish toxicity, skin irritation and etc.

[5] If endpoint data are available for a sufficient number of chemicals, the data set is often divided into a training set of data, used to derive the model through the application of a statistical method, and a test set of data, containing chemicals not used in the derivation of the model but used to evaluate the model

	linear regression (MLR) , principal component analysis (PCA), principal component regression (PCR), and etc.
A defined domain of applicability	This principle states the need to establish the scope and limitations of a model based on the structural, physicochemical and response information in the model training set. The importance of the principle lies in the fact that a given model can only be expected to give reliable predictions for chemicals that are similar to those used to develop the model. Predictions that fall outside the applicability domain (AD) represent extrapolations, and are less likely to be reliable. When applying a QSAR model, it is important to know whether its AD is known, and whether it is being used inside or outside of this boundary.
Appropriate measures of goodness-of-fit, robustness and predictivity	This principle states the need to provide two types of information: (1) the internal performance of a model (as represented by goodness-of-fit and robustness), determined by using a training set; and (2) the predictivity of a model, determined by using an appropriate test set. There is no absolute measure of predictivity that is suitable for all purposes, since predictivity can vary according to the statistical methods and parameters used in the assessment.
A mechanistic interpretation	The principle is intended to ensure that there is an assessment of the mechanistic associations between molecular descriptors used in a model and the endpoint being predicted, and that any association is documented.

Table 9 Check list of the interpretation and application of the OECD principles (extracted from OECD (2007))

Principle	**Considerations** Is the following information available for the model?	Yes/No/NA
1) **Defined endpoint**		
1,1	A clear definition of the scientific purpose of the model (*i.e*. does it make predictions of a clearly defined physicochemical, biological or environmental endpoint)?	
1,2	The potential of the model to address (or partially address) a clearly defined regulatory need (*i.e*. does it make predictions of a specific endpoint associated with a specific test method or test guideline)?	
1,3	Important experimental conditions that affect the measurement and therefore the prediction (*e.g*. sex, species, temperature, exposure period, protocol)?	
1,4	The units of measurement of the endpoint?	
2) **Defined algorithm**		
2,1	In the case of a SAR, an explicit description of the substructure, including an explicit identification of its substituents?	
2,2	In the case of a QSAR, an explicit definition of the equation, including definitions of all descriptors?	

3) **Defined domain of applicability**		
3,1	In the case of a SAR, a description of any limits on its applicability (*e.g*. inclusion and/or exclusion rules regarding the chemical classes to which the substructure is applicable)?	
3,2	In the case of a SAR, rules describing the modulatory effects of the substructure's molecular environment?	
3,3	In the case of a QSAR, inclusion and/or exclusion rules that define the following variable ranges for which the QSAR is applicable (*i.e*. makes reliable estimates): a) descriptor variables? b) response variables?	
3,4	A (graphical) expression of how the descriptor values of the chemicals in the training set are distributed in relation to the endpoint values predicted by the model?	
4A) **Internal performance**		
4,1	Full details of the training set given, including details of: a) number of training structures b) chemical names c) structural formulae d) CAS numbers e) data for all descriptor variables f) data for all response variables g) an indication of the quality of the training data?	
4,2	a) An indication whether the data used to the develop the model were based upon the processing of raw data (*e.g*. the averaging of replicate values) b) If yes to a), are the raw data provided? c) If yes to a), is the data processing method described?	
4,3	An explanation of the approach used to select the descriptors, including: a) the approach used to select the initial set of descriptors b) the initial number of descriptors considered c) the approach used to select a smaller, final set of descriptors from a larger, initial set d) the final number of descriptors included in the model ?	
4,4	a) A specification of the statistical method(s) used to develop the model (including details of any software packages used) b) If yes to a), an indication whether the model has been independently confirmed (*i.e.* that the independent application of the described statistical method to the training set results in the same model)?	
4,5	Basic statistics for the goodness-of-fit of the model to its training set (*e.g*. r2 values and standard error of the estimate in the case of regression models)?	
4,6	a) An indication whether cross-validation or resampling was performed b) If yes to a), are cross-validated statistics provided, and by which method? c) If yes to a), is the resampling method described?	
4,7	An assessment of the internal performance of the model in relation to the quality of the training set, and/or the known variability in the response?	
4B) **Predictivity**		
4,8	An indication whether the model has been validated by using a test set that is	

	independent of the training set?	
4,9	If an external validation has been performed (yes to 4.8), full details of the test set, including details of: a) number of test structures b) chemical names c) structural formulae d) CAS numbers e) data for all descriptor variables f) data for all response variables g) an indication of the quality of the test data?	
4,10	If an external validation has been performed (yes to 4.8): a) an explanation of the approach used to select the test structures, including a specification of how the applicability domain of the model is represented by the test set ? b) was the external set *sufficiently large and representative* of the training data set? c) a specification of the statistical method(s) used to assess the predictive performance of the model (including details of any software packages used) d) a statistical analysis of the predictive performance of the model (*e.g*. including sensitivity, specificity, and positive and negative predictivities for classification models) e) an evaluation of the predictive performance of the model that takes into account the quality of the training and test sets, and/or the known variability in the response f) a comparison of the predictive performance of the model against previously-defined quantitative performance criteria?	
5) **Mechanistic interpretation**		
5,1	In the case of a SAR, a description of the molecular events that underlie the properties of molecules containing the substructure (*e.g*. a description of how substructural features could act as nucleophiles or electrophiles, or form part or all of a receptor-binding region)?	
5,2	In the case of a QSAR, a physicochemical interpretation of the descriptors that is consistent with a known mechanism of (biological) action?	
5,3	Literature references that support the (purported) mechanistic basis?	
5,4	An indication whether the mechanistic basis of the model was determined *a priori* (*i.e*. before modelling, by ensuring that the initial set of training structures and/or descriptors were selected to fit a pre-defined mechanism of action) or *a posteriori* (*i.e*. after the modelling, by interpretation of the final set of training structures and/or descriptors) ?	

<u>Strenghts and usefulness</u>

- The OECD document reported here covers the majority of aspects related to a standard documentation framework. Moreover, it is already an internationally accepted standard
- It corresponds to a very precise way to document the development and verification of a model.
- The validation protocols of QSAR methods could be partly used to evaluate the equations in a MM model if those equations were derived empirically

<u>Weaknesses</u>

- It does not deal with multimedia models but other type of models
- Such approach is not applicable to all MM models
- The evaluation of equations in a MM model may be out of scope of a Standard Documentation Protocol

4.6 Bilitewski et al (2013) – Global risk-based management of chemical activities II, risk-based assessment and management strategies

A chapter of Bilitewski et al (2013) describes nine MM models and evaluates them by predefined principal characteristics. Those nine models consist of six models used to assess the chemical fate in environmental compartments (Qwasi, ChemCAN, CHEMGL, GREAT-ER, SimpleBox, BETR) and of three models used to assess it in both environmental and human compartments (CalTOX, ExtraFood, 2-FUN Tool). The principal characteristics listed above depict some basic aspects of MM models of which model-users should be informed, and thus some of the aspects can be incorporated into the SDP of a MM model. The following Table 10 shows principal characteristics discussed in Bilitewski et al (2013).

Table 10 Principal characteristics of multimedia models

Principal characteristics	**Descriptions**
Impact categories (model outputs)	Eco-toxicity impacts and/or human toxicity impact
Exposure routes	Ingestion, inhalation, dermal contact
Fate, exposure and effect	If fate, exposure and effect analyses are included or not
Chemical considered	Organic pollutants and/or inorganic pollutants
Media considered	Air, water (fresh, ground, sea, and etc), soil, sediment, vegetables, animals, and etc
Spatial variation	Regional, continental, or global scale
Source code availability	
Model availability	Commercial model or free model
Dynamic or steady-state	
Availability for sensitivity and uncertainty analyses	
Population category	If the differences in man/woman and adult/child are considered or not

As an example, Table 11 of principal characteristics depicting the CalTOX is presented below.

Table 11 Principal characteristics of the CalTOX

Principal characteristics	**Descriptions**
Impact categories (model outputs)	Human toxicity
Exposure routes	Ingestion, inhalation, dermal contact
Fate, exposure and effect	Fate, exposure and effect are considered

Chemical considered	Organic and inorganic compounds
Media considered	Air, water, sediments, three soil layers, vegetation (two sub-compartments)
Spatial variation	Not considered
Source code availability	Yes, as Excel spreadsheet
Model availability	Freely available
Dynamic or steady-state	Dynamic
Availability for sensitivity and uncertainty analyses	Yes
Population category	Not considered

Strenghts and usefulness

- The tables proposed by Bilitewski et al (2013) provide a good high level overview.
- The principal characteristics could be partly used to describe a MM model.

Weaknesses

- It does not provide a framework.
- The description for each principal characteristics is poor.
- It does not consider the model approach (deterministic/probabilistic, etc.), software related information, model application.

4.7 Summary of a literature study on currently existing multimedia models

A literature study on currently existing multimedia models was performed in the framework of the SWOT analysis of the 4FUN project (Bilitewski, 2009a,b; Fryer et al., 2006; Fryer et al., 2004; Furtaw et al., 2001; Huijbregts et al., 2005; Maddalena et al., 1995; Park et al., 2006; Pistocchi et al., 2010; Rong-Rong et al., 2012; US EPA, 1999; WHO, 2005)

From this literature study, essential keypoints of aspects/compartments necessary to build and report large multimedia exposure models were identified. The identified keypoints are based on the list of criteria following four lines of evidence (reliability, relevance, user-friendliness and uncertainty), which are presented in Table 12. The list of criteria following the relevance line of evidence is based on the requirements of three regulatory frameworks, REACH, PPP and Biocide regulations/directives.

Table 12 Identified keypoints for documentation of multimedia models

STEP	KEYPOINTS	DESCRIPTION
General model information	Model developer	Define the identity and contact details of the model developer.
	Helpdesk	Indicate if there is an external helpdesk
	Communication with other software	E.g. import/export from excel
	Operating systems	E.g. Windows, Mac, etc.
	References	Quote the references used to describe the model

Model context	Model approach	Probabilistic/deterministic, empirical/mechanistic, simulation/optimization, lumped/distributed
	Model range	Define the boundary conditions
	Model complexity	Define the degree of complexity (based on fugacity level)
	Temporal resolution	Describe the static/dynamic approach
	Spatial resolution	Define the spatial resolution of the model (e.g. local, regional, etc.)
	QSAR	Define and describe which QSARs are applied in which part of the model
Model development	Population	Define which part of the population is targeted with the model (worker, general population, division in subgroups, etc.)
	Exposure routes	Described the possible exposure routes of the model (e.g. ingestion, inhalation, dermal absorption)
	Compartments	Give an overview of all compartments studied and include a graphic representation of the conceptual model
	Environmental processes	Describe the prevailing environmental processes per compartment (e.g. for soil: leaching, run-off, etc.)
	Human processes	State the human processes taking place in the human body (e.g. accumulation, excretion, distribution)
	Exposure time range	Identify whether the model covers acute and/or chronic exposure
	Equations and statements	Define the equations and statements per compartment
	Chemical substance	Outline the chemical range of substances that can be analysed with the model (e.g. metals, organics, etc.) If mixture toxicity is included in the model, define the approach used to assess this. Define the origin of background concentrations, if used.
	Input parameters	List the input parameters and their units necessary to perform a simulation State which kind of point value is required (e.g. mode, mean, etc.) State which probability distributions can be applied for input values.
	Default parameters	List the default parameters, their value and origin (reference)
	Risk management measures	Define the use of risk management measures if applicable
Model evaluation	Model validation	Indicate the validation process performed for the selected applications of the model
	Error messages	List the main error messages which might be occurring
	Process time	Provide suggestions on how to speed up the simulation
	Uncertainty	Explain how to display predicted exposure profiles and uncertainties
	Probabilistic approach	Define the different probabilistic approaches possible and their applicability domain

	Sensitivity analysis	Described the sensitivity analysis to determine key inputs and parameters
Output	Results accessibility	Define how to obtain intermediate results
	Reporting	State the functions to build a report
	Graphs/tables	Define how to build a graphical and tabular output
Model application	Model framework/purpose	Identify the (regulatory) framework (e.g. REACH, PPP, screening assessment, etc.)
	Scenario analysis	Describe how to run the model with several conditions, assumptions or mathematical approaches

In scientific literature, most attention is paid to the model development aspect of the multimedia model. In model development all routes and exposure pathways are discussed in detail in most papers. Nonetheless, other aspects such as model context, model application and model evaluation are very important in the documentation of multimedia models as these can largely influence the interpretation, applicability and uncertainty of the results obtained from the model for a certain application. The general information and output is important for the traceability and the user-friendliness of a model.

Strenghts and usefulness

- The literature study identifies concrete key points of aspects and compartments applicable to a large number of MM models
- It covers a series of scientific publications and is therefore “broadly” applied in practice
- Additional important points compared to the previous documents are treated here, especially concerning how to use the model easily (elements concerning friendliness)
- Key elements to be described in a SDP are comprehensive and well identified. The table in this section can be a good model for the content of a SDP

Weaknesses

- It was originally developed for the purpose of a SWOT analysis and not for a standard documentation framework
- Some points are more suitable for a user manual than for a standard framework

5 International Standards on large exposure models

5.1 Introduction

Standards are agreed definitions or specifications of units, methods, products, processes or services. They provide people or organisations with a basis for mutual understanding and exchange, and are used as tools to facilitate communication, measurement, commerce and manufacturing. Standards are everywhere in a developed and modern economy, - they make life easier and safer for businesses and consumers. Standards are useful for optimizing performance, ensuring the health and safety of consumers and workers, protecting the environment and enabling companies to comply with relevant laws and regulations. Most people are aware of Standards for building materials, paper size (such as A4), optical media (such as DVD), mobile telephones (such as GSM), connecting cables (such as USB and HDMI), or for bank transactions (such as SWIFT or BIC codes), to name but a few examples.

There are many thousand Standards spanning all sectors of the economy. The can be categorised into four major types:

- Fundamental Standards which concern terminology, conventions, sings and symbols
- Test methods and analysis Standards which measure characteristics such as chemical composition physical properties
- Specification Standards which define the characteristics of a product or a service and their performance thresholds such as fitness for use, interface and interoperability, health and safety or environmental protection
- Organisation Standards which describe the functions and relationships of a company as well as elements such as quality management and assurance, environmental management, risk management, maintenance, system management, etc

International Standards are approved by recognized International Standardization Bodies (such as ISO, IEC and ITU) and have been through a process of public enquiry followed by a vote of approval by member countries and final ratification. They are reviewed periodically and either confirmed for a further period or revised in the light of changes in regulations or technical capabilities. Standards are voluntary and not legally binding regulations. However, Standards can be referenced by law and thereby made binding. They are also often referenced in public procurement contracts and they are a preferred basis for a technical expertise requested by a judge or an arbitration panel. Finally, they can also be used as a basis for certification schemes determining if a product or service meets certain standards and resulting in a certification mark or label displayed on the product or in connection with the service.

European Standards are Standards adopted by CEN, CENELEC and/or ETSI, and have an approval process and quasi-legal characteristics similar to International Standards as described above. They are made available in English, French and German and are valid throughout the entire European single market consisting of 500 mio inhabitants and 30 countries. The content of a European Standard does not conflict with the content of another European Standard and all conflicting national standards are withdrawn. European Standards have played an important role in creating the single market by reducing technical barriers to trade. The so called “New Approach” defined in a European Council Resolution in 1985, introduced, among other things, a clear separation of responsibilities between the EU legislator and the European standards bodies in the legal framework allowing for the free movement of goods. Specifically, EU directives or EU regulations define the "essential requirements", e.g., protection of health and safety, which goods must meet when they are placed on the market. The European standardisation bodies have the task of drawing up the corresponding technical specifications meeting the essential requirements of the directives, compliance with which provides a presumption of conformity with the essential requirements. Such specifications that have been mandated by the EU are referred to as "Harmonised Standards". [6]

In the field of **research and development**, European and International Standards can play an important role in bridging the gap between innovation and the market by

- reducing overall costs to get to market (no need to reinvent the wheel);
- enabling interoperability between new and existing products, services and processes;
- providing access to large scale markets;
- building confidence among consumers/users on new products/services;
- disseminating research results

The following sections of this chapter will identify and review International Standards and related documents that are applicable to a standard documentation framework for large exposure models. These documents are dispersed among several technical fields and their associated Technical Committees (TC's), as summarized in Table 13 below. These CEN and ISO TCs together have produced over 1000 documents currently in force, which were scanned for relevance with respect to the documentation of large exposure models (see *Appendix A*). They consist mostly of 2 types of documents, those relating to specific media such as water, soil, air or the work environment, and those covering aspects of organisation and methodology.

Table 13 ISO and CEN TC's relevant for standard documentation frameworks of large exposure models

TC's providing Standards on specific media

- Water
  CEN/TC 164 "Water supply"
  CEN/TC 230 "Water analysis"
- Air
  CEN/TC 264 "Air quality"
- Soil
  CEN/TC 260 "Fertilizers and liming materials"
  CEN/TC 223 "Soil improvers and growing media"
  CEN/TC 345 "Characterization of soils"
- Waste
  CEN/TC 292 "Characterization of waste"
  CEN/TC 308 "Characterization of sludges"
  CEN/TC 400 "Horizontal standards in the fields of sludge, biowaste and soil"
- Work environment
  CEN/TC 137 "Assessment of workplace exposure to chemical and biological agents"
- Foodstuffs
  CEN/TC 275 "Food analysis – Horizontal methods"
- Construction materials
  CEN/TC 351 "Construction products – Assessment of release of dangerous substances

TC's providing Standards on organisation/methodology

- ISO/TC 069 "Application of statistical methods"
- ISO/TC 176 "Quality management and quality assurance"
- ISO/TC 207 "Environmental management"

[6] http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/new-approach_en.htm

Most of the Standards on specific media describe aspects of standardised procedures for sampling, testing or analysis (see *Appendix A*), i.e. an experimental approach to determine the resulting amount of a certain chemical in given media or the human body. Modelling as an alternative to experimental testing is of relatively recent origin, and not yet widely established to be at a developed stage of technical capability, which is a precondition for a Standard to emerge. Thus, Standards on modelling in the context of large exposure models are only just about to evolve. Only 2 of the many documents on specific media reviewed mention multimedia modelling, specifically. Both of them are of recent origin (2012). Both of them are a kind of a pre-Standard and not (yet) an International or European Standard.[7]

A further 2 documents were found that appear useful for the development of a documentation framework of a multimedia model from a general methodological/ process point of view. These 4 documents (listed in Table 14) will be reviewed individually in the remainder of this chapter.

Table 14 International Standards and related documents applicable to the development of standard documentation frameworks of large exposure models

- **ISO/TS 14033:2012-03-15** Environmental management—Quantitative environmental information—Guidelines and examples (ISO/TC 207)
- **CEN/TR 16364:2012-06** Influence of materials on water intended for human consumption - Influence due to migration - Prediction of migration from organic materials using mathematical modelling (CEN TC 230)
- **ISO 9001:2009-08-15** Quality management systems – Requirements (ISO/TC 176)
- **ISO/TR 13425:2006-03-01** Guidelines for the selection of statistical methods in standardization and specification (ISO/TC 069)

5.2 ISO/TS 14033 Environmental management - Quantitative environmental information - Guidelines and examples

The purpose of this Technical Specification (TS) is to help break down the complexity of environmental data handling into manageable and understandable elements. The TS addresses issues related to defining, collecting, processing, interpreting and presenting quantitative environmental information. It provides guidelines on how to establish accuracy, verifiability and reliability for the intended use. It utilizes proven and well-established approaches for the preparation of information adapted to the specific needs of environmental management. It is applicable to all organizations, regardless of their size, type, location, structure, activities, products, level of development and whether or not they have an environmental management system in place or not.

[7] An International Standard is labelled with EN (CEN Standard) or ISO (ISO Standard), followed by the number of the Standard, such as EN 23456 or ISO 23456. A Technical Specification (TS) or a Technical Report (TR) are standardisation documents that may later on evolve into a Standard, as soon as there is consensus on a developed stage of technical capability. A Technical Specification is a normative document reviewed at least every three years to decide either to confirm the technical specification for a further three years, revise the technical specification, process it further to become an International Standard or withdraw the technical specification. After six years, a technical specification must be either converted into an International Standard or be withdrawn. A Technical Report (TR) is an informative document that provides information on the technical content of standardisation work established. It may be prepared when it is considered advisable to provide additional information to the CEN national members, the European Commission, other governmental agencies or outside bodies.

The following fundamental principles have guided the drafting of ISO/TS 14033 to ensure that resulting quantitative environmental information provides a true and fair account:

Relevance: Ensure that selected data sources, system boundaries, measurement methods and assessment methods meet the requirements of the interested parties and/or the application

Credibility: Provide quantitative environmental information that is truthful, accurate and not misleading to interested parties

Consistency: Develop compatible, coherent and not self-contradictory quantitative environmental data and information using recognized and reproducible methods and indicators, which respect related integrity constraints

Comparability: Ensure that the quantitative environmental information is generated, selected and provided in a consistent way, with consistent measurement units, thereby allowing for comparisons

Transparency: Make the processes, procedures, methods, data sources and assumptions for providing and generating quantitative information available to all interested parties. This is in order to ensure a proper interpretation of the results and to give explicit reasons for any extrapolations, simplifications or modelling performed, taking into account confidentiality of information, if required. In addition, any volatility or uncertainty is disclosed

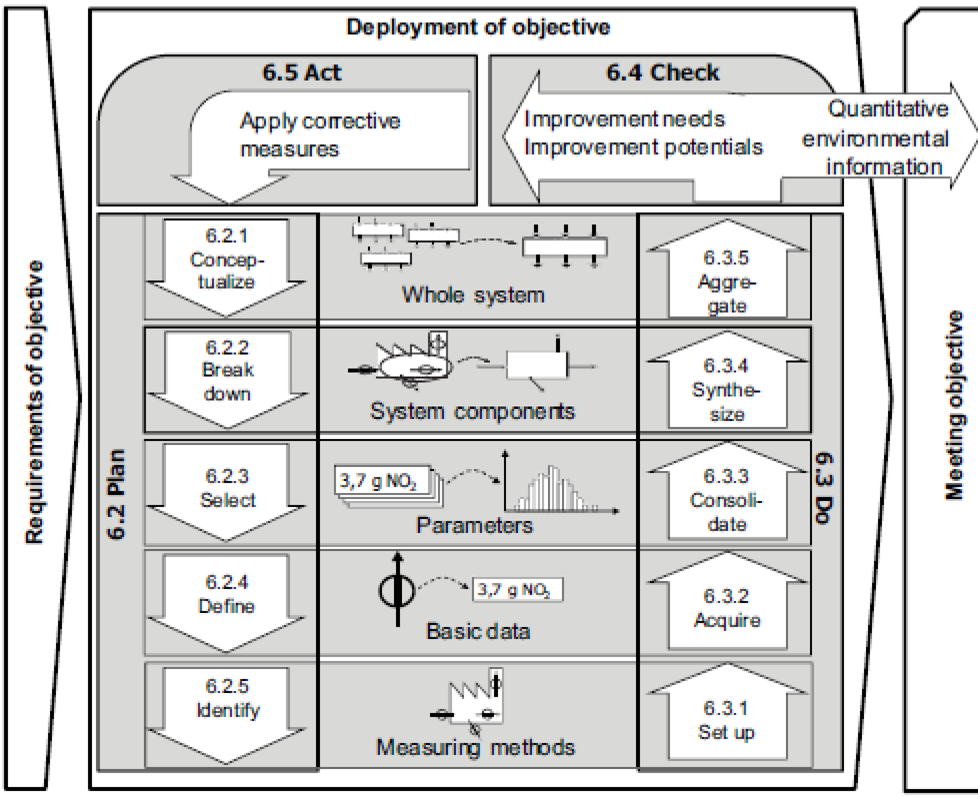
Completeness: Reflect all significant quantitative environmental information for the intended use, in such a way that no other relevant information needs to be added

Accuracy: Minimize uncertainties as far as practicable and eliminate tendencies towards a particular perspective or bias

Appropriateness: Make quantitative environmental information relevant and fully understandable to interested parties, by using formats, language and media that meet their expectations and needs

The guidelines given in ISO/TS 14033 are based on the methodology known as Plan-Do-Check-Act (PDCA), as summarized in Figure 6 below. This methodology takes a process view and stipulates that the requirement of each specific application or study is the basis for the specification of how data and information should be acquired and provided.

Figure 6 Guidelines for acquiring and providing quantitative environmental information in accordance with the Plan-Do-Check-Act methodology[8]



The focus of the guidelines lies in tasks that belong to Plan and Do. Each task of Plan corresponds to a task in Do. This covers the handling of specific issues down through the planning and data acquisition, up to the provision of the quantitative environmental information, if necessary in the form of a continual improvement. The TS addresses the general issue of data quality by providing clear guidelines on how to acquire and provide quantitative environmental information in a structured way.

The guidelines given in ISO/TS 14033 are applicable to many different types of projects and studies involving the handling of large quantities of environmental data. They are thus quite broad and also contain many details and examples with respect to aspects not necessarily relevant for the documentation of large exposure models. Below is a short summary of the content of the ISO/TS 14033 that appears applicable specifically to the documentation of large exposure models. While the ISO/TS 14033 does not directly provide a documentation framework for large exposure models, it does specify what data and information needs to be available for a given study or project to meet the fundamental principles stated above when handling complex environmental data sets. As such, it defines the aspirations for the content of a documentation framework. The five tasks are a possible way to structure the information to be given in a standard documentation of a large exposure model. They describe the necessary information on 5 levels of information that have distinct requirements.

[8] The numbers in the figure refer to the respective clauses and subclauses in the ISO/TS 14033

1. **Whole system**:

The whole system corresponds to the large exposure model for impact assessment that is a combination of system components that have been combined to reflect the purpose of the given study. On this level, the objective of the information and its intended use, the object on which information is provided, the system boundaries, the interested parties and target audience and requirements for the general quality of the information should be documented.

2. **System components**:

The system components are the models for the different media types/dose response models that are linked into the combined model by defined relationships or pathways. The system components are characterized each by different parameters. The parameters of a system component that have different origins may not have a clear relationship with each other which must therefore be defined coherently. The relationship can be defined on the basis of mechanistic or other physical or chemical relationships, synchronization of timeline, logic, or other relevant causalities. The significance of lacking data/estimates on system components must be identified, and if significant, it must be associated with an uncertainty measure. When the purpose of the study or project is to compare system components, it is essential that the individual system components are functionally comparable.

3. **Parameters**:

Parameters are identified quantifiable entities of a system component that are represented by quantified data. The consolidation of the quantified data into a parameter must be defined. If data processing differs from plan, the deviation is explained together with an estimation, evaluation or analysis of its significance. Significances are estimated iteratively, starting with a qualitative analysis that subsequently can lead to a thorough statistical analysis of uncertainty. When a comparison application is carried out, it is important that the environmental significance of the individual parameters is comparable to those of the systems intended for comparison.

4. **Basic data**:

Basic data is the data needed to quantify each parameter selected. Besides the description of the basic data, the scale of precision and statistical representativeness of the basic data must be described. When a comparison application is carried out, it is essential that comparable basic data are equally defined for any of the systems intended for comparisons.

Table 15 Examples on basic data

Object	Physical property	Scale of precision
General urban area	Mass per m^2 of dust fall	Based on distribution models. A flat average within the 90th percentile
Drainage pipe from waste landfill	Throughput of liquid per second	To be measured at one minute each day between 11:59 and 12:00 every day and averaged into yearly throughput
Forest area	Number of woody stemmed plants greater than 2 m in height per unit area	Manually counted within □10 cm using benchmark stick at randomly selected and statistically significant number of samples of size 100 m □ 100 m areas within the forest area

Geographical data	Position, altitude and area	GPS and altimeter logging
Emission data	Concentration of pollutant	Precision of laboratory analytical method
Demographic data	Share of different demographic populations	Statistical sample interviews

5. Measuring methods:
Methods should be suitable regarding the definition of the basic data and may be based on available standards, literature and/or expert advice. Part of the definition of the measuring method is the data quality assurance associated with the measuring method (eg establishing baselines, calibration or validation of equipment and verification of data collected). Disturbances in measurement and estimations of the significance of these disturbances are expressed in terms of uncertainty. For primary data sources there are several key parameters to consider besides the choice of methodology depending on the data to acquire, such as location of the measurement; choice of entity to sample; or sample frequency. For secondary data sources (eg data from literature, databases or from consulting experts) the key question is to choose those that are sufficiently representative for the intended use: This can be assessed based on the credibility of the data source, the relevance of the data and the sufficiency of the data for the purpose. For comparison applications, it is essential that the measurement methods provide comparable results for the systems intended for comparison.

5.3 CEN/TR 16364 Influence of materials on water intended for human consumption - Influence due to migration - Prediction of migration from organic materials using mathematical modelling

The purpose of the TR is to stimulate the use of modelling techniques in CEN member states such that sufficient experience is generated to enable the value of such modelling to be assessed in relation to complementing or substituting the conventional approach. Normally, in member states the estimation of such migration is performed by standardised procedures based on laboratory testing and analysis (see EN12873-1 and -2, appendix xx). Migration modelling is an alternative to this type of experimental testing. The modelling approach is considered attractive in some instances, because in principle it is quicker and more flexible than the conventional testing approach, in that different exposure conditions can be readily investigated, and it should also be cheaper.

The report points out that in the US modelling of migration has been used since several years as an additional tool in support of regulatory decisions. Also, the European Union has introduced such diffusion modelling by means of EU Directive 2001/62/EC (the 6th amendment of Directive 90/128/EEC), consolidated in Directive 2002/72/EC as a compliance and quality assurance tool for plastic materials intended to come in contact with foodstuff. The European project SMT-CT98-7513, Evaluation of Migration Models in Support of Directive 90/128/EEC, successfully demonstrated the practical value of such diffusion models.

Various parameters and data are needed to feed the diffusion model, and various assumptions need to be valid. Also, a personal computer set-up capable of running an appropriate validated software tool is required. The diffusion model as described can be used in a manner that simulates the conditions applied in the conventional analytical approach used in member states. Depending on how the various data inputs are obtained, or used, the diffusion model can also be used to estimate a worst-case value of migration.

The assumptions and required information as they are detailed in the TR are summarized below, together with the recommended report on the result.

Assumptions

- the migration process of the substance within organic materials shall obey the law of diffusion (Fick's Second Law);
- the migrant is an uncharged, organic substance;
- the mass of the substance in the system is conserved, i.e. no substance is consumed or built up;
- the initial concentration of the substance in the material shall be homogeneous, i.e. it does not vary significantly and is constant, i.e. is non-degradable by chemical reaction; this applies to each layer in the case of multilayer products;
- the material thickness shall be uniform (i.e. it does not vary significantly);
- the volume of the organic material and the water is finite;
- there shall be no boundary resistance for the transfer of the substance between the organic material and water;
- the uptake of the substance by the water shall be fast, i.e. the water is a high diffusivity medium or well-mixed liquid;
- the interaction between the organic material and water shall be negligible such that no swelling of organic material by uptake of water occurs during the migration process.

Data inputs

- Diffusion coefficient of the substance. It may be obtained from tables, or determined by experiment, or estimated by a validated scientific estimation procedure, or assumed to be a worst-case value;
- Partition coefficient of the substance. The partition coefficient is a parameter dependant on the relative solubility of the substance in relation to the organic material and the water. It may be obtained from tables, or determined by experiment, or estimated by a validated scientific estimation procedure;
- Temperature of the system;
- Geometry of the material. The surface area of the material and the amount of test water in contact with the material shall be known. In the case of organic materials in the form of sheets or piping these values are readily calculable. More complex product forms may require assumptions and approximations to be made. These should be noted in the report;
- Material thickness. Evidence is needed, or an assumption shall be made, that the thickness does not vary significantly;
- Initial concentration of the substance in the material. It may be obtained by: determination (analysis of the substances in the organic material – the feasibility of this will depend on the specific substance/material combination), or based on the amount added during the production of the material; this applies readily to additives but not, of course, monomers and other reactive starting substances;
- Chemical identity of the substance and its relative molecular weight in g/mol;
- Specific gravity of the material;
- Simulation of contact of organic material with test water, e.g. duration of the contact of the sample of organic material with water during in s, and number of migration test cycles.

Report

The report should include if relevant a full description of:

- the organic material under test;
- the modelling software used;
- the values of all the inputs and their source or derivation;
- concentration of the substance in the material;
- the specific gravity of the material;

- thickness of the material;
- chemical identity (not commercial trade names) of the substances;
- molecular weight of the substance;
- diffusion coefficient of the substances in the organic material (if applicable the estimation procedure and relevant parameters used);
- partition coefficient of the substances between the organic material and water (if applicable the estimation procedure and relevant parameters used);
- the report shall provide full details of the simulated migration test;
- the temperature of the migration test;
- duration and number of migration periods;
- the ratio of the surface area of the material to the volume of test water.
- Any deviation from the procedures described in this report shall be reported.

In the annex of the CEN/TR 16364, criteria for assessing the correctness of calculation of migration by software tools (validation) are given. The validation of software tools is outside the scope of this report, is however mentioned at this point as the information may be useful for other deliverables of 4FUN.

CEN/TR 16364 does not provide a standard framework for the documentation of large exposure models. However it gives concrete examples for the amount and quality of information that needs to be available on large exposure models for their results to be considered equivalent in quality to the results of the standardised conventional approach.

5.4 ISO/TR 13425 Guidelines for the selection of statistical methods in standardization and specification

Statistical methods have numerous practical applications and many of them are used in large exposure models. The effectiveness of the statistical method depends firstly on the suitability of the chosen method for the intended purpose, and secondly on the application. Incorrect choice or poor application can lead to improper deductions and therefore to crucial errors and inappropriate decisions. This is one of the reasons why ISO has produced a whole range of International Standards for the application of statistical methods. The ISO/TR 13425 contains a descriptive catalogue of the available International Standards and Guides, to assist the reader in selecting those most suitable for his purpose, according to his needs. Figure 7 below gives an overview of the available range of standards.

A detailed look at available standardised statistical methods is beyond the scope of this report. Nevertheless, some ISO statistical standards may be useful for other deliverables of 4FUN, which is why an overview of the entire available range is given. With respect to the framework for large exposure models, specifically, the ISO 3534 is pointed out, providing standardised definitions of statistical terms and of terms used in the theory of probability and of applied statistics, which might be useful to rely on to ensure clear and consistent definitions as a basis for a framework.

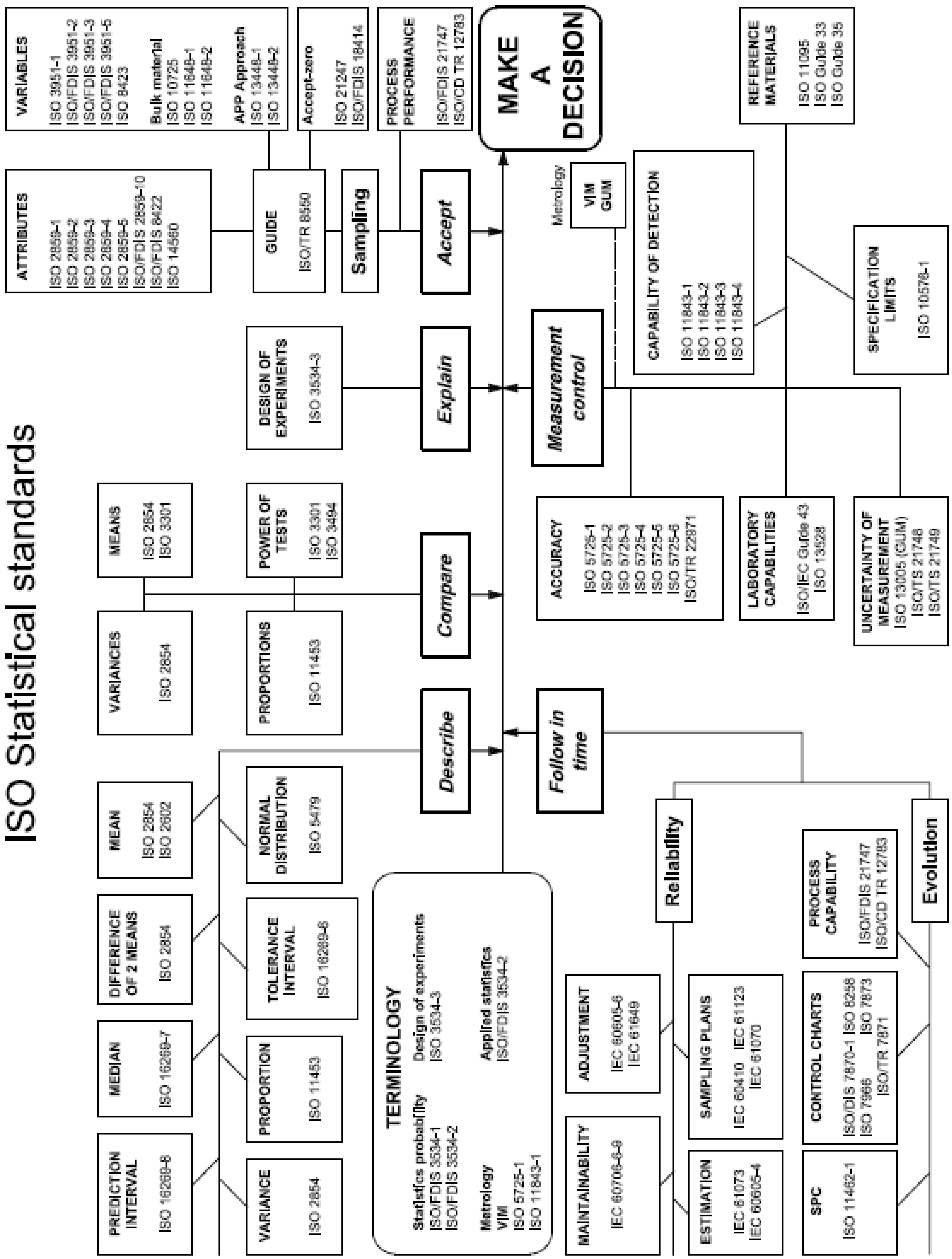


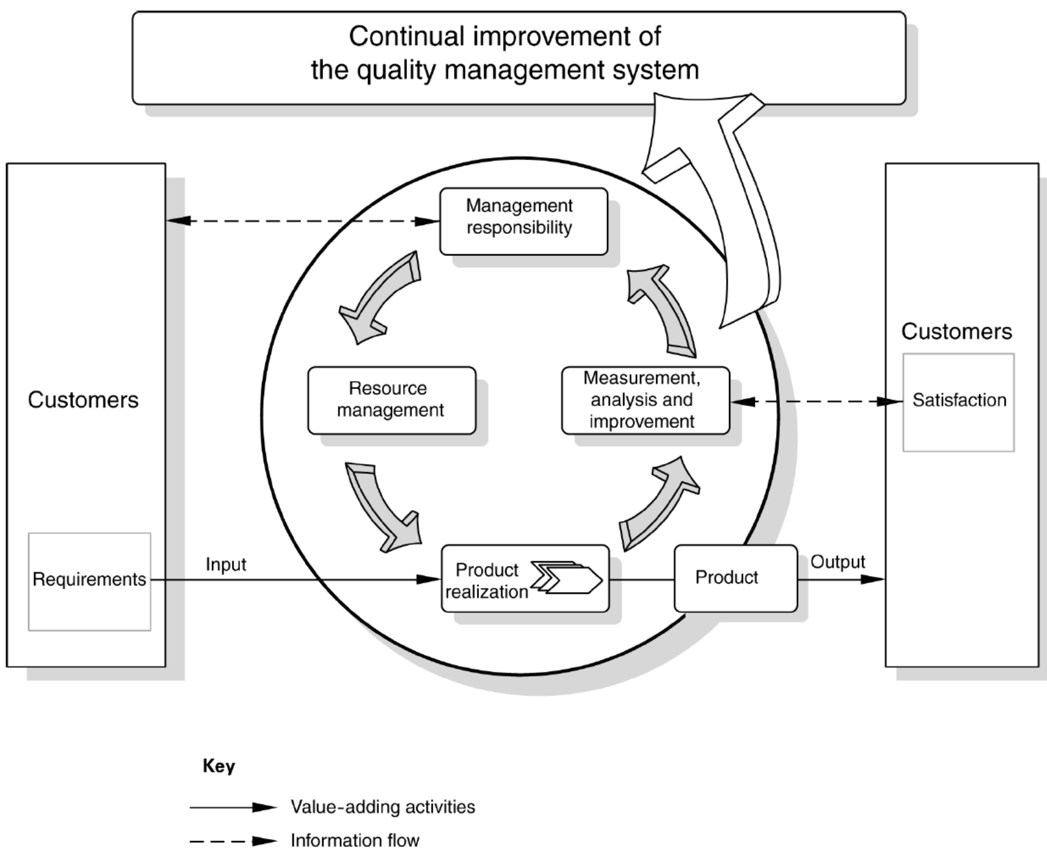
Figure 7 ISO Statistical Standards

5.5 ISO 9001 Quality management systems - Requirements

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide a product that meets customer and applicable statutory and regulatory requirements, such as is the case with the 4FUN product. The ISO 9001 is implemented by over one million companies and organizations in over 170 countries, and its implementation can be certified.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach". An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction. Figure 8 below gives an overview of the process-based quality management system of ISO 9001.

Figure 8 Model of a process-based quality management system



With respect to 4FUN, ISO 9001 can provide linkages of the documentation framework to a living and learning organisation and ensure continuous improvement of the framework driven by customer satisfaction. In other words, ISO 9001 spells out in more detail the first and the last process phases (requirements of objectives/meeting objectives), while ISO/TS 14033 focuses on the middle process phase (deployment of objectives). In particular the process of interacting with customers, feeding into changes in the product realisation and the continuous measurement and analysis of output as described in ISO 9001 appear most relevant to maintain a high quality documentation of the 4FUN product on an ongoing basis. The relevant clauses of ISO 9001 are summarized below.

- **General requirements**. The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall

  a) determine the processes needed for the quality management system and their application throughout the organization
  b) determine the sequence and interaction of these processes,
  c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
  d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
  e) monitor, measure where applicable, and analyse these processes, and
  f) implement actions necessary to achieve planned results and continual improvement of these processes.

- **Documentation requirements**. The quality management system documentation shall include

  a) documented statements of a quality policy and quality objectives,
  b) a quality manual,
  c) documented procedures and records required by this International Standard, and
  d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

- **Planning of product realization.** In planning product realization, the organization shall determine the following, as appropriate:

  a) quality objectives and requirements for the product;
  b) the need to establish processes and documents, and to provide resources specific to the product;
  c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
  d) records needed to provide evidence that the realization processes and resulting product meet requirements

- **Determination of requirements related to the product.** The organization shall determine

  a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
  b) requirements not stated by the customer but necessary for specified or intended use, where known,
  c) statutory and regulatory requirements applicable to the product, and
  d) any additional requirements considered necessary by the organization.

- **Review of requirements related to the product**. The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved, and
c) the organization has the ability to meet the defined requirements.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

- **Customer communication.** The organization shall determine and implement effective arrangements for communicating with customers in relation to

  a) product information,
  b) enquiries, contracts or order handling, including amendments, and
  c) customer feedback, including customer complaints.

- **Measurement, analysis and improvement**. The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

  a) to demonstrate conformity to product requirements,
  b) to ensure conformity of the quality management system, and
  c) to continually improve the effectiveness of the quality management system.

  This shall include determination of applicable methods, and the extent of their use.

5.6 Summary and recommendation

While no single International or European Standard exists that provides a standard framework for large exposure models, it appears likely that such a standard will emerge in the years to come. First precursors have already emerged (ISO/TS 14033 and CEN/TR 16364).

The ISO/TS 14033 is directly applicable to large exposure models. However, it is too broad and abstract, providing guiding principles and a process to develop a framework rather than a concrete and detailed framework itself. The CEN/TR 16364 provides a concrete standardized modelling procedure relying on a software too and states the required documentation, however, it is applicable only to a very small area, the migration of organic substances into water. The ISO/TR 13425 gives an overview of statistical methods in standardization and specification. It may be useful for a consistent and clear statistics terminology and some guidance in areas important to large exposure models (for example how to deal with uncertainty), but that is not a framework either. The ISO 9000 covers how to ensure continuous improvement, quality control and customer focus of an existing documentation framework, but it doesn't say how to create one in the first place.

Most available standards relate to the conventional approach of testing and analysing, the established alternative approach to modelling (see *Appendix A:* p.80). However, it is pointed out, that these numerous standards covering the "conventional approach" can provide a very valuable source of tested, accepted and continuously updated parameters as well on accepted scientific models and measurement methods which could be used by the 4FUN library.

6 Summary of aspirations for the documentation of the 4FUN model

From all the standardization frameworks reviewed in this report an overview of the major model aspects discussed was made in order to identify commonalities between the existing frameworks (Table 16). From this overview, a harmonized high-level structure was proposed in the most right column of Table 16.

As a next step, starting from the proposed high-level structure in Table 16, and the most relevant existing frameworks, a preliminary standard documentation model was developed on a lower level with increased specificity concerning the different components necessary to obtain a standard documentation protocol.

This protocol was then applied to an existing multimedia model, namely EUSES. The European Union System for the Evaluation of Substances (EUSES) is a decision-support instrument which enables government authorities, research institutes and chemical companies to carry out rapid and efficient assessments of the general risks posed by chemical substances. EUSES is intended mainly for initial and refined risk assessments rather than for comprehensive assessments. EUSES is comparable to the 4-FUN model what concerns the environmental and human health exposure assessment but does not contain a PPBK model. The documentation is quite fragmented over different publications/booklets. The regional model is described in the RIVM report no. 719101029 and the local model in the RIVM report no. 601900005/2004. More publications are used to describe EUSES.

The evaluation of the available documentation of EUSES is presented in *Appendix B: Testing the documentation framework on existing multimedia models: EUSES*.

From this exercise it could be concluded that certain parts of the proposed standardisation documentation protocol are obsolete or irrelevant, while other parts need to be rephrased.

Aspects that were identified to be redundant or too difficult to be determined:

- Exposure point: not relevant
- Detailed information on the model equations: too complex
- Empirical vs. mechanistic: multimedia models are in general always mechanistic
- Model coding including source code availability, communication with other software and operating systems: not relevant
- Model coding verification and model framework/structure uncertainty where moved to Model evaluation
- Model use might be more appropriate in a User Manual

This exercise lead to a proposed low level structure presented in Table 17.

Table 16 Proposed high level structure based commonalities between the existing standardization frameworks

US EPA	ODD Framework	CEMN	OECD QSAR	Bilitewski	SWOT analysis	ISO/TS 14033 Env management	CEN/TR 16364 Migration model	Definitions 4FUN model	Proposed high level structure standard
Definition of model purpose	Overview – purpose	Regulatory applicability	Defined endpoint	Model outputs	Output	•Relevance	Not applicable		**Model purpose**
Specification of model context	• Overview: entities, variables & scales • Overview - Process • Details – Initialization • Details – Input data • Details- Submodels		Defined domain of applicability	All principal characteristics except otherwise listed	Model context Model development		• Assumptions	Model limitations	**Model context/ applicability**
Conceptual		Environmental process and pathways	Unambiguous algorithm			•Transparency of processes, procedures, methods,…	• Data inputs • Procedure	Model components	**Model components**
Computational model development	• Design concepts	Fugacity concept	Mechanistic interpretation		Model approach			Model typology	**Model type**
				Source code availability	General		• Software	Coding	**Model coding**
Model evaluation: testing and revision			Appropriate measures of goodness-of-fit, robustness and predictivity	Sensitivity and uncertainty analysis	Model evaluation	•Credibility •Accuracy	• Validation of the numerical algorithm and software tools	Parameterization and uncertainty	**Model evaluation**
Model application: model use		Interpreting model results			Model application	•Consistency •Comparability •Completeness •Appropriateness	• Report		**Model use**

Table 17 Proposed low level structure for the standard documentation protocol

High level structure	Low level structure	Description	Sources
Model purpose	Goal	General statement of the model outputs of concern, the stressors and the degree of model accuracy and precision needed. Explanations of why you need to build a complex model	US EPA (2009) and ODD
	Decisions or regulatory framework	Explanations of what you are going to do with your model, Identify the (regulatory) framework to be supported (e.g. REACH, PPP, screening assessment, etc.)	US EPA (2009), ODD, CEMN, SWOT, 4FUN
Model context/applicability	Spatial scale/resolution	The spatial conditions (extent and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated. Boundaries or domain, specify the area or volume (spatial boundary) to which a model application will apply: Local, regional, continental, or global scale	US EPA (2009), Bilitewski, SWOT, 4FUN
	Temporal scale/resolution	The temporal conditions (extent and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated. Boundaries or domain specify the time period (temporal boundary) to which a model application will apply.	US EPA (2009), SWOT, 4FUN
	User community		US EPA (2009)
	Required inputs		US EPA (2009)
	Output of interest	To ensure transparency in the output being predicted by a given model, since a given endpoint could be determined by different experimental protocols and under different experimental conditions. Give units of measurement.	US EPA (2009), OECD QSAR
	System limitations	Boundary conditions of the system	
	Exposure pathways	The course a chemical takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, the transport/exposure medium (such as air) or media (in cases of intermedia transport, such as water to air) are also included.	4FUN
	Exposure routes	The way a chemical or physical agent comes in contact with an organism, i.e., inhalation, ingestion, dermal contact. Describe the possible exposure routes of the model.	Bilitewski, SWOT, 4FUN
	Fate, exposure and effect	If fate, exposure and effect analyses are included or not	Bilitewski
	Chemical considered	Outline the chemical range of substances that can be analysed with the model (e.g. Organic pollutants	Bilitewski,

		and/or inorganic pollutants, etc.). If mixture toxicity is included in the model, define the approach used to assess this. Define the origin of background concentrations, if used.	SWOT
	Media considered	An environmental or human compartment assumed to contain a given quantity of the chemical. Quantity of the chemical in the media is governed by inputs/outputs from/to other media and by transformation processes (e.g. degradation): Air, water (fresh, ground, sea, and etc), soil, sediment, vegetables, animals, and etc and include a graphic representation of the conceptual compartments	Bilitewski, SWOT, 4FUN
	Human population	Define which part of the population is targeted with the model (worker, general population, division in subgroups, etc.)	Bilitewski, SWOT
	Environmental processes	Describe the prevailing environmental processes per compartment (e.g. for soil: leaching, run-off, etc.)	SWOT
	Human processes	State the human processes taking place in the human body (e.g. accumulation, excretion, distribution)	SWOT
Model component	Initialisation	Initial conditions assumed, i.e., what are the initial values of the state variables, is initialization always the same or changing among simulation?	ODD
	Overview input data	Environmental conditions which change over time and space, i.e., precipitation, management (e.g. harvesting regimes)	ODD
	State variable	The dependent variables calculated within a model, which are also often the performance indicators of the models that change over the simulation.	4FUN
	Forcing/driving variable	An external or exogenous (from outside the model framework) factor that influences the state variables calculated within the model. Such variables include, for example, climatic or environmental conditions (temperature, wind flow, oceanic circulation, etc.).	4FUN
	Parameters	Terms in the model that are fixed during a model run or simulation but can be changed in different runs as a method for conducting sensitivity analysis or to achieve calibration goals. List the input parameters and their units necessary to perform a simulation. State which kind of point value is required (e.g. mode, mean, etc.). State which probability distributions can be applied for input values. Indicate if QSARs are applied for which parameter in which part of the model.	SWOT, 4FUN
	Constants	A fixed value (e.g., the gravitational force) representing known physical, biological, or ecological activities. List the constants, their value and origin (reference)	SWOT, 4FUN
	Model structure/ framework	The system of governing equations, parameterization, and data structures that make up the mathematical model. The model framework is a formal mathematical specification of the concepts and procedures of the conceptual model consisting of generalized algorithms. Detailed explanation of all the sub-models representing the processes listed above in ‘Process overview and scales’, including the parameterization of the model. All model equations and rules should be presented.	ODD, SWOT, 4FUN
Model type	Simulation vs. optimization	Statement of the model type; simulation vs. optimization,	US EPA (2009), SWOT

	Steady-state versus dynamic	Statement of the model type; static (steady-state) (a model providing the behaviour of the state variables assumed to be in immediate equilibrium with all the other interacting state variables or a model providing the long-term or time-averaged behaviour of the state variables) vs. dynamic (a model providing the time-varying behaviour of the state variables)	US EPA (2009), Bilitewski, SWOT, 4FUN
	Deterministic vs. stochastic	Statement of the model type; deterministic (Aamodel that provides a solution for the state variables rather than a set of probabilistic outcomes. Because this type of model does not explicitly simulate the effects of data uncertainty or variability, changes in model outputs are solely due to changes in model components or in the boundary conditions or initial conditions) vs. stochastic (a model that includes uncertainty and variability (see definition) in model parameters. This variability is a function of changing environmental conditions, spatial and temporal aggregation within the model framework, and random variability. The solution obtained by the model or output is therefore a function of model components and random variability.	US EPA (2009), OECD QSAR, SWOT, 4FUN
	Lumped vs. distributed	Statement of the model type: solving a set of ordinary differential equations or solving partial differential equations	US EPA (2009) and OECD QSAR
	Analytical or numerical model	Analytical (a model that can be solved mathematically in terms of analytical functions. For example, some models that are based on relatively simple differential equations can be solved analytically by combinations of polynomials, exponential, trigonometric, or other familiar functions) or numerical model (a model that represents the development of a solution by incremental steps through the model domain. Simulations are often used to obtain solutions for models that are too complex to be solved analytically. For most situations, where a differential equation is being approximated, the simulation model will use finite time step (or spatial step) to “simulate” changes in state variables over time (or space))	4FUN
	Mode (of a model)	The manner in which a model operates. Models can be designed to represent phenomena in different modes. Prognostic (or predictive) models are designed to forecast outcomes and future events, while diagnostic models work “backwards” to assess causes and precursor conditions	4FUN
	Screening model	A type of model designed to provide a “conservative” or risk-averse answer. Screening models can be used with limited information and are conservative, and in some cases they can be used in lieu of refined models, even when time or resources are not limited	4FUN
Model evaluation	Model coding verification	Examination of the algorithms and numerical technique in the computer code to ascertain that they truly represent the conceptual model and that there are no inherent numerical problems with obtaining a solution	US EPA (2009), 4FUN
	Input data	The accuracy, variability, and precision of input data. The source of parameter default values, as well as PDFs, should be indicated in the SDP, with an explanation of the process of parameter estimation (e.g. expert elicitation, extrapolation, statistical treatment of environmental data)	US EPA (2009), 4FUN
	Model calibration	If applicable, the general explanation about model calibration	US EPA (2009),

			4FUN
	Model framework/ structure uncertainty	The uncertainty in the underlying science and algorithms of a model. Model framework uncertainty is the result of incomplete scientific data or lack of knowledge about the factors that control the behavior of the system being modeled. Model framework uncertainty can also be the result of simplifications necessary to translate the conceptual model into mathematical terms.	4FUN
	Model predictivity	The predictivity of a model, determined by using an appropriate test set. There is no absolute measure of predictivity that is suitable for all purposes, since predictivity can vary according to the statistical methods and parameters used in the assessment. • Indication if test set is independent from training set (if relevant) • Provide details on full test set • Representativeness of test set	OECD QSAR, SWOT
	Uncertainty analyses	Investigation of the effects of lack of knowledge or potential errors on the model (e.g, the “uncertainty” associated with parameter values). When combined with sensitivity analysis (see definition), uncertainty analysis allows a model user to be more informed about the confidence that can be placed in model results. Uncertainty analysis can be qualitative or quantitative.	Bilitewski, SWOT, 4FUN
	Sensitivity analysis	The computation of the effect of changes in input values or assumptions (including boundaries and model functional form) on the outputs (Morgan and Henrion 1990); the study of how uncertainty in a model output can be systematically apportioned to different sources of uncertainty in the model input (Saltelli et al. 2000a). By investigating the “relative sensitivity” of model parameters, a user can become knowledgeable of the relative importance of parameters in the model	Bilitewski, SWOT, 4FUN

7 The 4FUN standard documentation protocol (SDP)

7.1 Specifications

The literature review that is presented in Chapter 4-6 allows to precise the specifications that are expected for a standard documentation protocol (SDP):

- the documentation must include all the information that is needed for evaluating and using the model in a transparent, easy and flexible way. The literature review allows to establish a checklist containing all the issues that must be covered by the SDP (seeTable 17);
- it is recommended to define a tiered documentation protocol (e.g. ODD protocol), with several target audiences. 'Basic' end-users may use the model without being aware of all its scientific foundations and mathematical elements. It is however essential to provide them with a clear understanding of the applicability domain of the model in order to avoid any misuse, and to provide an overview of the main model components and their interactions. On the other hand, it is essential to provide to expert end-users detailed information to allow a transparent evaluation regarding scientific foundations and assumptions, numerical issues and mathematical methods. In summary, the SDP must adopt a hierarchical structure with clearly defined target audiences;
- the SDP must be designed for a wide range of multimedia models (MM), whatever their features (e.g. steady-state vs dynamic, etc) and objectives (e.g. environmental vs human exposure assessment vs fate models). The general structure of the SDP must then be independent of the specificity of each MM model.

7.2 The 4FUN SDP

Based on the standard documentation framework proposed in Table 17 above, a part of the 4FUN model (freshwater sub-model) is described in this section. It should be noted that the proposed SDP was slightly modified for adjusting to the specific features which the 4FUN freshwater sub-model has. The 4FUN SDP is based on a hierarchical structure:

Level 1 – Basic knowledge

The 1st level of the structure (called 'basic knowledge' level) is targeted towards basic end-users, defined as end-users who trust model developers on scientific, numerical and mathematical issues. They need to have a global overview of the model structure, but don't intend to evaluate model assumptions. The responsibility of the model developer is however to clearly define what the end-users can expect from the model and its applicability domain. The main objective is here to avoid any misuse. It seems also important to provide to the end-users an overview of the main components of the model to explain the process allowing to convert inputs to final outputs. The 'basic knowledge' level is then subdivided in the following sub-levels:

Sub-level 1.1 - Model purpose

The objective of this sub-level is to provide a brief overview of:

- the goal of the model, with an indication of the main outputs that the end-user is able to calculate and of the main environmental systems that are represented in the model.
- the main potential decision(s) that can be taken from the model outputs and the main regulatory framework(s) it could be useful for. This list is indicative but can help a basic end-user to know if his specific issue corresponds to the potentiality of the model.

Sub-level 1.2 - Model applicability

It is essential to clearly indicate the applicability domain for which the model can give reliable and relevant results. The main limitations in the application of MM models generally regards temporal, spatial, chemical and/or kinetic issues. For this reason, the following issues will be discussed more in detail:

- Spatial scale and resolution. The model can be applicable for a given range of dimensions (area and/or volumes, near-field vs global scale); it can be limited to spatial boundaries (e.g. interface freshwater/brackish waters) or it can require a minimum spatial resolution.

  Example: if a model is one-dimensional, it is not reliable to represent near-field concentrations where non-mixing conditions are not respected.

- Temporal scale and resolution. Similarly to spatial issues, some processes can be relevantly described at a minimum temporal resolution because they know abrupt changes in time (e.g. temporal resolution governed by day vs night variability, seasonal variability, etc).

  Example: if a process is governed by floods events, the model is not reliable at a monthly or annual temporal resolution

- Chemical considered. The model can be limited to a given family of chemicals only, either because of process and/or parametric issues.

  Example: the fate of neutral organic chemicals in biological media is governed by simple passive diffusion across lipid membranes, justifying the use of hydrophobicity descriptors. Ionic chemicals can be only partly governed by lipophilic interactions, and be dominated by ionic interactions. Models can then be limited to a specific range of chemicals.

- Steady-state vs dynamic conditions. Some models are based on steady-state assumptions, i.e. they assume that the behavior of variables is in immediate equilibrium with all the other interacting variables. In this case, it is not relevant to study some scenario where chemicals show kinetic evolutions in the system.

  Example: just upstream of a point release, or in near-field after an accidental evant (short term release), equilibrium conditions can be not respected .

Sub-level 1.3 - Model components

The overall structure of the model with its elemental components is presented at this sub-level in order to given to the reader a transparent overview of the transformation process from inputs to outputs. A better knowledge of the model components allows also to capture the treatment of the inputs that each end-user has to define for his own scenario (in particular, the forcing variables).

- Media considered. The media are defined as the environmental or human compartments assumed to contain a given quantity of the chemical. It is essential to present soon in the SDP a comprehensive list of the media considered in the model because the reader who is aware of them have access to the main potential regulatory outputs provided by the model (i.e. chemical concentrations in environmental and/or human compartments). As some media can eventually include several 'sub-media', it is recommended to present a picture to illustrate the overlaps between them.

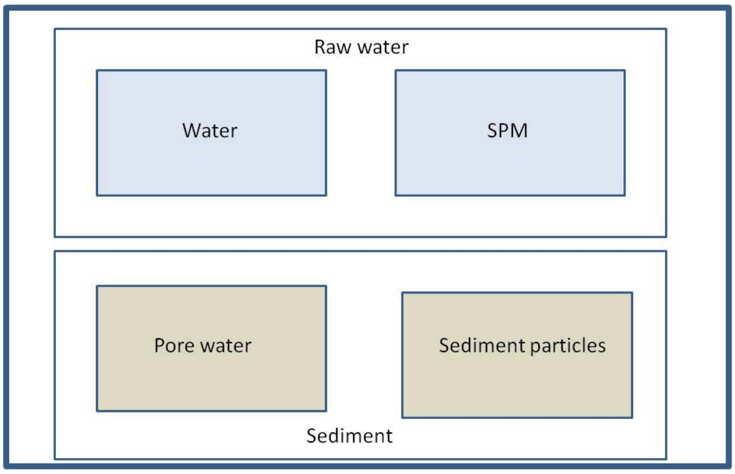


Figure 9 Illustration of freshwater model with several media

- Loadings. Loadings are defined as releases/input rates of the chemical of interest to the receiving system(s). It is essential to present soon in the SDP a comprehensive list of the loadings considered in the model because they correspond to inputs that the end user should specify for defining his scenario. As loadings can enter the system through several media, it is recommended to present a picture to illustrate the interactions between loadings and media. The picture below allows to identify that the loadings enter the freshwater system into the “raw water” medium and not into the “sediment” medium.

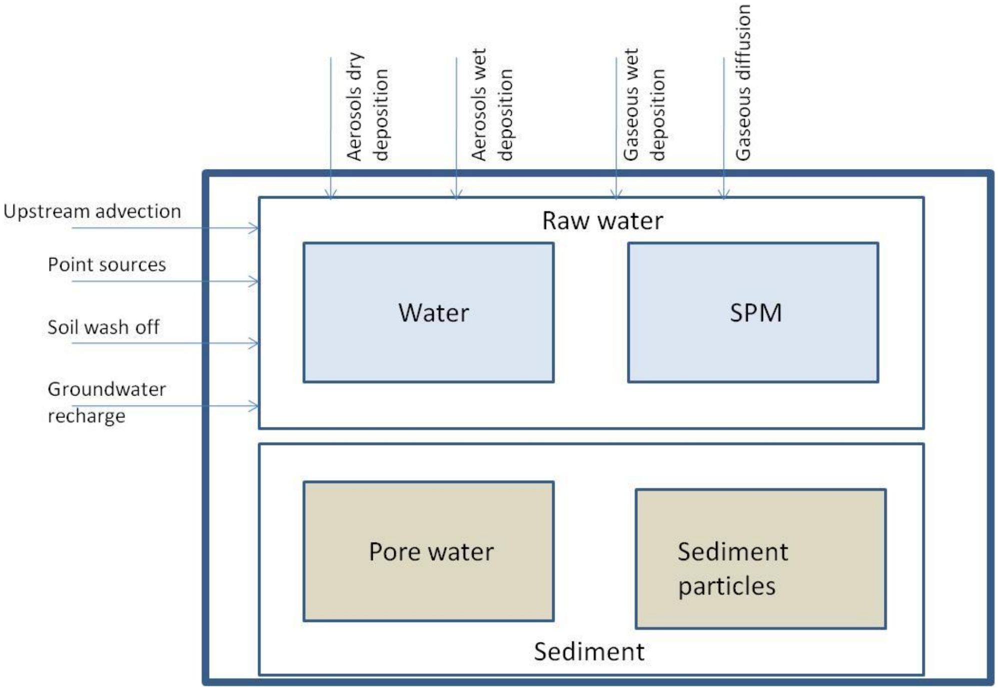


Figure 10 Illustration of loadings of freshwater model

- Losses. Losses are defined as output rates of the chemical of interest from the receiving system(s). As losses can leave the system through several media, it is recommended to present a picture to illustrate the interactions between losses and media. The picture below allows to identify that one loss (downstream advection) leaves the system from the “raw water” medium, while the other (degradation) regards both the “raw water” and the “sediment” media.

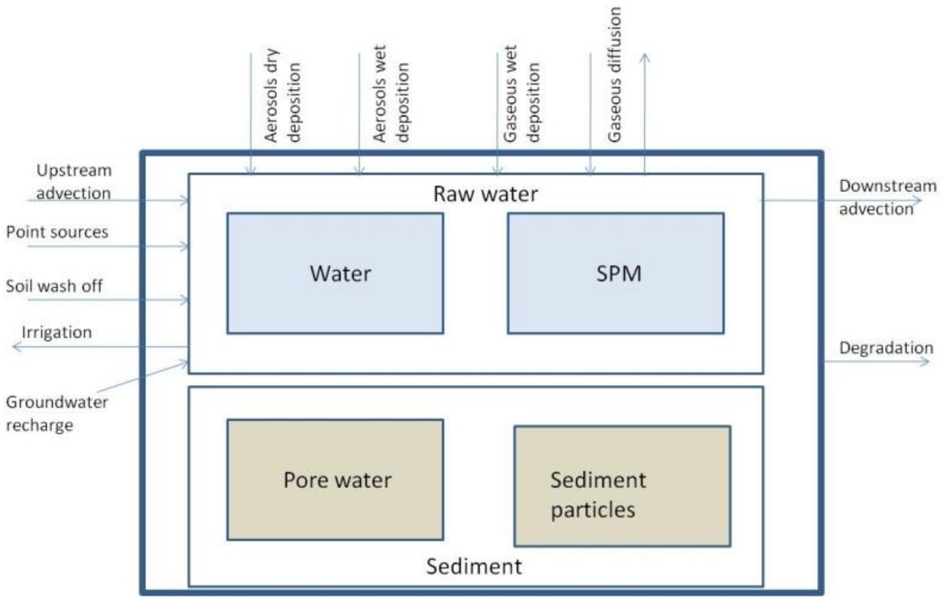


Figure 11 Illustration of losses of freshwater model

- Exchanges between model media. Exchanges between model media are defined as transfers of the chemical(s) of interest between two media of the system. The exchanges between media are the core concept of the model which is precisely designed for calculating the redistribution of a chemical in several compartments of a given system. It is then essential to present a comprehensive list of the exchanges actually taken into account in the model. To improve transparency, it is recommended to present a picture to illustrate the interactions between media. The picture below provides a transparent overview of the relationships between the media themselves and between the media of the "external" world.

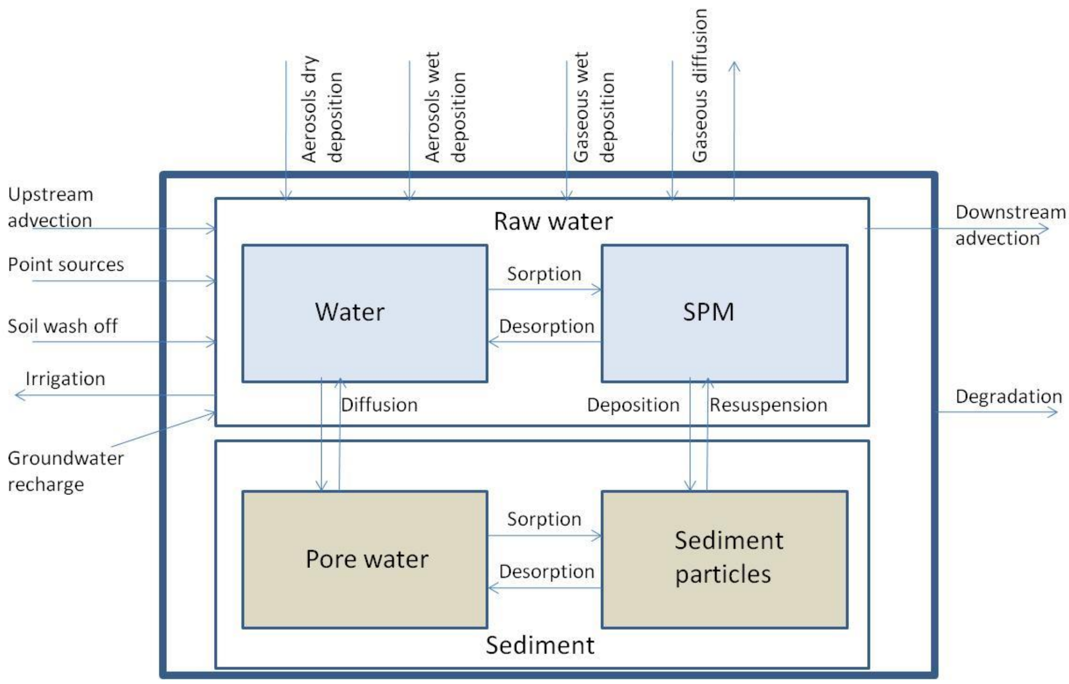


Figure 12 Illustration of exchanges of freshwater model

- Potential coupled models. Some inputs can be defined by the end-user as raw datasets (i.e. time series of chemical loading) or can be generated by other models that can be coupled to the documented model. Similarly, some losses can be directed to a ‘sink’ or can be used as inputs for coupled systems. It is recommended to present a picture to illustrate which kind of loadings/losses can be generated/used by coupled models. The picture below for example shows that the loadings entering the freshwater model can be generated by an upstream model called “atmospheric-org” model.

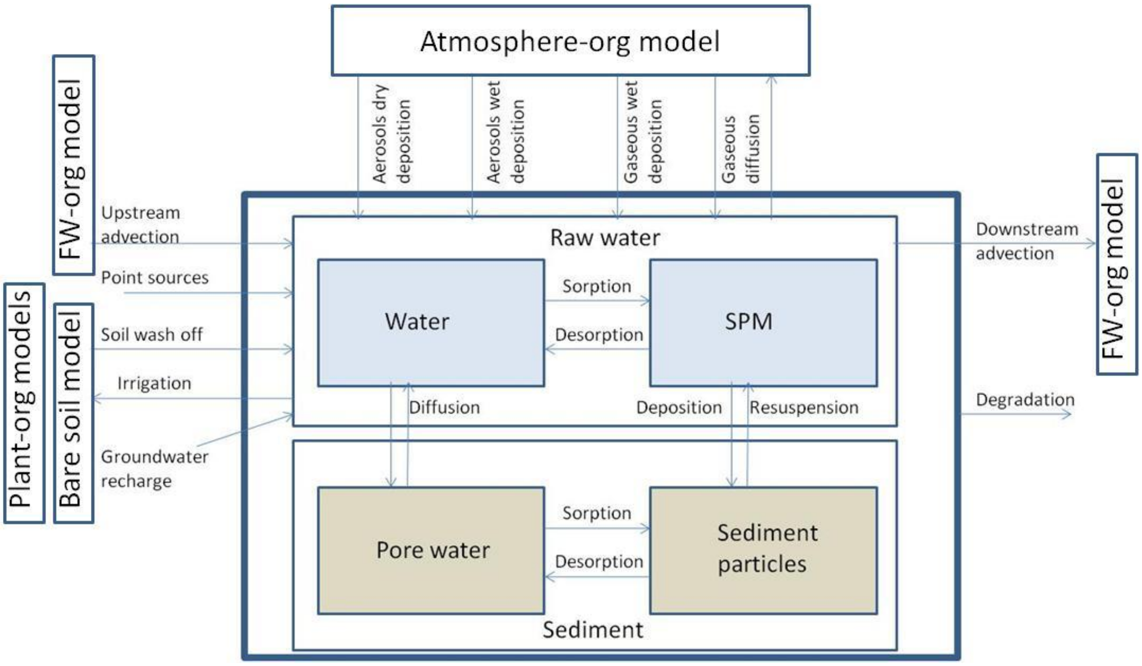
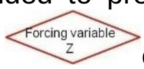


Figure 13 Illustration of freshwater model coupled to atmospheric-org model

- Forcing variables. Forcing variables are defined as all the external or exogenous (from outside the model framework) time series that influence the calculation of model outputs. Forcing variables include in particular loadings that can show variability in time (e.g. pesticide discharge(s) in the system, wet deposition of atmospheric pollution governed by rain, etc). They can also include e.g. meteorological, agronomical, biological factors that show a temporal variability. Instead, factors that are fixed during a simulation are classified in the parameter component (see below). Concretely, forcing variables have to be defined by the end user according to his specific scenario and it is then essential to present a comprehensive list of them at the 1st level of the SDP. Forcing variables are generally related to a given loading or process and it is recommended to present a picture to illustrate their role in the model (a specific symbol, e.g. 

can be introduced to systematically represent the forcing variables in the pictures). It has to be noted also that some forcing variables can be generated by the coupled models previously defined. In this case, they can be visualized by another color in the picture. The figure below illustrates the forcing variables of the freshwater model in addition to the loadings, losses and exchanges identified in the previous step

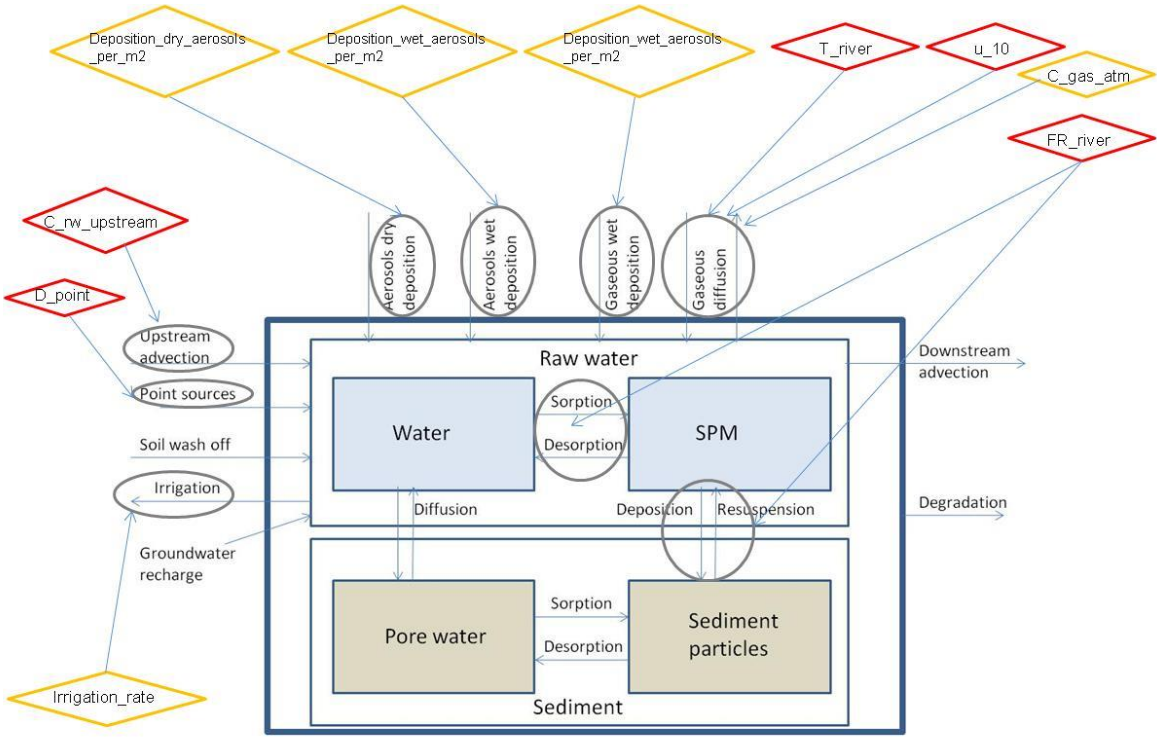


Figure 14 Illustration of forcing variables of freshwater model

- Parameters (scenario-specific and default). Parameters are defined as all the factors that are fixed for a given simulation (under the deterministic mode). Among the parameters, some of them are by definition specific to the scenario defined by the end-user (e.g. river depth, land use coverage, vegetables production in the investigated region, etc). These parameters must be easily identified by the reader because these are those he must change in priority case by case. Other parameters can be informed by default generic values, even if site-specific data can improve their relevance. It is recommended to present the parameters in the form of a table, with indication of the relationship between parameters and state variables (i.e. identification of model components the parameters are used for), as shown in the example below.

Name	Abbreviation and unit	Purpose	Used for calculating the following state variable(s)
Water-organic carbon partition coefficient	log10_K_oc (unitless - expressed in log10)	The exchanges of contaminants between Water and Suspended Particulate Matter (SPM), or between Pore water and particles in sediment, are assumed to be at equilibrium and represented by a Partition coefficient at equilibrium Kd_SPM and Kd_sed (see § 3.8). The K_oc parameter allows calculating these latter state variables.	1) Distribution coefficient at the interface 'river Water'-SPM (Kd_SPM) 2) Distribution coefficient of the pollutant at the interface sediment pore water-sediment particles (Kd_sed)
Fraction of organic matter in sediment	y_OC_sed (unitless)	The exchanges of contaminants between Pore water and particles in sediment are assumed to be at equilibrium and represented by a Partition coefficient at equilibrium Kd_sed (see § 3.8). The y_OC_sed parameter allows calculating this latter state variable.	1) Distribution coefficient of the pollutant at the interface sediment pore water-sediment particles (Kd_sed)

Table 18 Example of presentation of parameters of fresh water model

- State variables. State variables are defined as all the dependent variables calculated within the model. Some state variables are fixed during a model run or simulation because they are calculated only from parameters. Some others are time-dependent because they are calculated from parameters, but also from time-dependent forcing variables. We distinguish “intermediate state variables” and “regulatory state variables”. The first ones are generally not used by decision-makers for regulatory purposes but can be used as performance indicators of the model that change over the simulation. The second ones can be used by decision-makers for regulatory purposes. As the calculation process eventually involves many other model components (i.e. parameters, forcing variables and/or other state variables), it is recommended to present a picture to illustrate the conceptual relationship between state variables and other components. At this stage, specific symbols, e.g. 

can be defined to clearly distinguish parameters, state variables and forcing variables. For example, in the 4FUN freshwater model, a state variable called “resuspension flux of particles” and noted “F_r” must be calculated to estimate the transfer of contaminated particles from sediment to water column. The following figure shows how the state variable is calculated. It can be observed that F_r directly interacts with 5 other components of the model (number of arrows that arrives on the F_r box). Among these 5 components, three of them are parameters and two of them are other state variables that are themselves calculated from other components including one forcing variable.

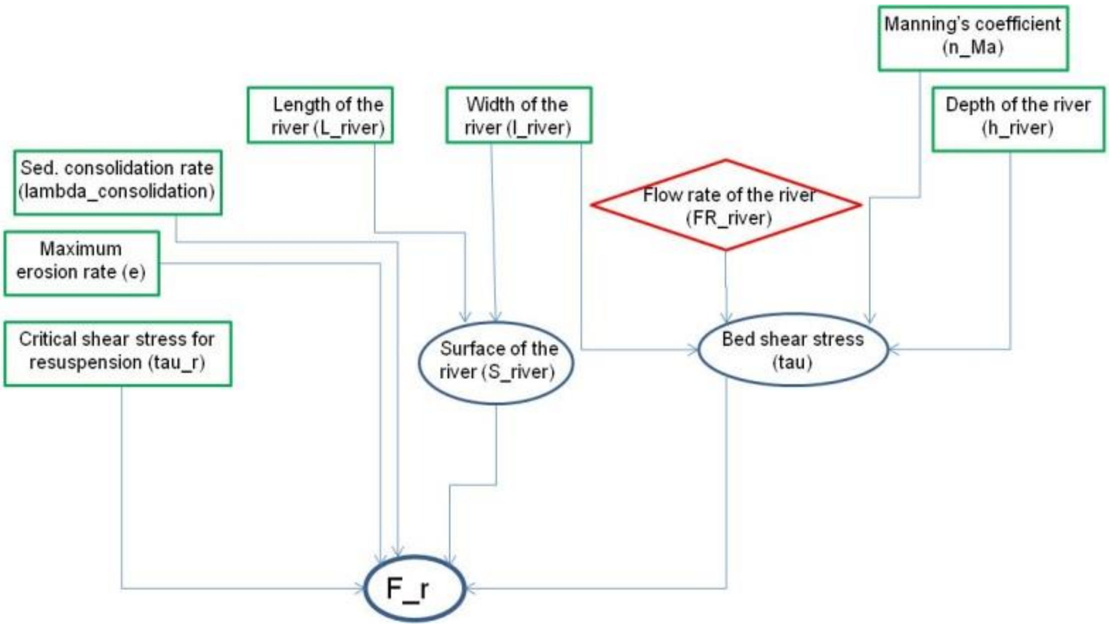


Figure 15 Illustration of state variables of fresh water model and their relationship with other model components

A synthetic overview of all the relationships between model components can be proposed for regulatory state variables (end of the calculation chain). The following figure represents the complete overview of the 4FUN freshwater model.

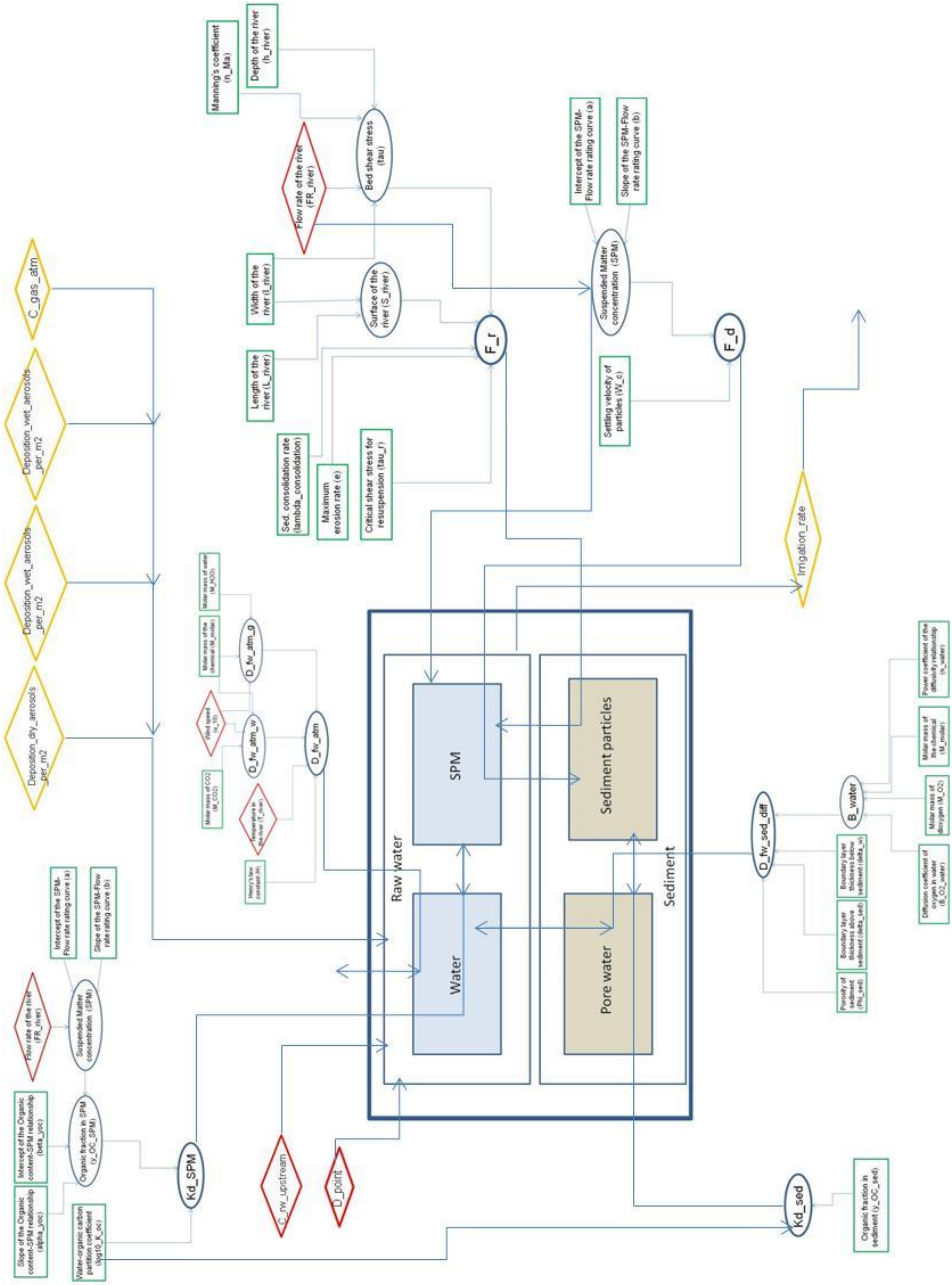


Figure 16 Overview of 4FUN freshwater model components

Level 2 – Process knowledge

The 2nd level of the structure (called 'Process knowledge' level) is targeted towards end-user, who wants to have a clear vision of the scientific background and foundations of the model. Such end-users trust model developers on numerical and mathematical issues but want to better capture the scientific assumptions on which the model is built. Knowing the scientific modeling assumptions can indeed help to avoid any abusive use. It is also important to present to the reader the other alternative assumptions that were not selected in the model but that are available in the literature. The 'Process knowledge' level is then subdivided in the following sub-levels:

Sub-level 2.1 – Process n°1

At each sub-level, a given process (i.e. calculation chain for simulating a state variable) is described in a comprehensive way.

- Motivation. In this section, it is highlighted: why it is important to incorporate the given process in the global model; to what extend the given process can govern the calculation of one or more state variables and influence the estimation of regulatory state variables, etc.

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account. The motivation for considering this process can be explained as follows:

  'Exchange of contaminants between the water column and the bottom sediment is generally considered as an important pathway because: (i) bottom sediments represent the habitat compartment for benthic organisms, especially those playing the essential role of decomposition in freshwater communities; (ii) the residence time of contaminants in freshwater streams is strongly affected by deposits in sedimentation zones; (iii) sediments can act as a temporary or long-term sink for pollutants; (iv) the uptake of contaminants by some aquatic organisms (e.g., benthic fish) can be partly governed by the accumulation and distribution of pollutants in sediments. Exchange of contaminants between the water column and sediments can especially result from deposition of contaminated particles.'

- Selected model and assumptions. For describing the process under review, a mathematical model is selected. This latter is by nature based on scientific assumptions that must be clearly explained in this section. It is proposed at this stage to avoid complex mathematical description, but to rather use a verbal description of scientific background and assumptions that justify that a given model is selected for representing the process. Important literature sources can also be given.

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account. The model selected for representing this process and its assumptions can be explained as follows:

  'Modelling of the deposition of fine cohesive particles (and associated contaminants) is based on the assumption that the gravitational settling velocity of particles (governed by their density and granulometry) plays the dominant role. It is then assumed that the Deposition flux of particles (state variable F_d) is proportional to the SPM concentration and that the proportionality factor is the Settling velocity parameter (W_c)'

- Model type. The model selected for calculating a given state variable can: (i) be based on empirical vs mechanistic assumptions; (ii) be based steady-state vs dynamic assumptions; (iii) be calculated by analytical or numerical schemes (all the definitions are given in the Table). A synthetic information related to these model types is proposed in this section.

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account. The model selected for representing this process belongs to the following types:

Empirical [ ]	*vs mechanistic [X]*
Steady-state [ ]	*vs dynamic [X]*
Analytical [X]	*vs numerical [ ]*

- Alternatives and limits. Other models and assumptions are eventually possible for describing the process under review. It is important to provide to the reader this material and to verbally describe the alternatives which were not selected in the model.

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account. The alternative models and assumptions which were not selected for representing this process can be described as follows:

'Many alternative models are based on steady-state assumptions, considering that permanent deposition and resuspension occur simultaneously and can be described by constant rates. This approach leads to a permanent net deposition, without any net resuspension period (i.e. Deposition-Resuspension=constant positive value). Such a steady-state assumption is not realistic for many rivers submitted to seasonal variations in the flow rate leading to temporal cycles of net deposition/resuspension (floods). Besides, to compensate the continuous accumulation of sediments resulting from a constant positive net deposition, models generally include a burial process, old sediments being considered as inactive and assimilated to a sink compartment. The model is then highly dependent of the choice of the active sediment depth and of the burial rate. Thus, it appeared that the simplicity of the steady-state approach needs to be compensated by the addition of a process not easily parameterised (i.e. the 'burial' process).

Mechanistic dynamic models based on physical assumptions developed in sedimentology were developed and appear to be more realistic. Two conflicting paradigms were however proposed for mechanistically representing deposition and resuspension of cohesive sediments: (i) the 'exclusive' paradigm suggests that deposition and resuspension do not occur at the same time; (ii) the 'simultaneous' paradigm allows deposition and resuspension to occur at the same time. These two paradigms were discussed by Ha and Maa (2009) and Winterwerp (2006), who presented contradictory conclusions. In our work, we considered the approach proposed by Winterwerp (2006) (i.e. the simultaneous paradigm that assumes that deposition is not limited by the bed shear stress) because: (i) it was shown to fit well with field data, while the exclusive paradigm was essentially validated under laboratory conditions; (ii) it requires less parameters (no critical shear stress for deposition); (iii) a comparative sensitive analysis showed that the 'model uncertainty' is not critical compared to the parametric uncertainty (Ciffroy et al, submitted).'

<u>Sub-level 1.2 – Process n°2</u>.

Repeat the same description as for process n°1 - Etc

<u>...</u>

<u>Level 3 – Numerical knowledge</u>

The 3rd level of the structure (called 'Numerical knowledge' level) is targeted towards end-users who want to have a clear vision of all the parameter values included in the model. Such end-users trust model developers on mathematical issues but want to better capture the assumptions related to the parameterization of the model. Knowing the scientific assumptions and databases that allows to propose default parameter values and probability

Density functions (PDFs) can indeed help to conduct uncertainty and sensitivity analysis. The 'Numerical knowledge' level is then subdivided in the following sub-levels:

<u>Sub-level 3.1 – Parameter n°1</u>.

At each sub-level, a given parameter is described in a comprehensive way.

- <u>Definition.</u> In this section, the definition of the parameter is given.

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account and is modeled by a parameter called 'Settling velocity'. Its definition can be given as follows:

  'Settling is the process by which particles settle to the bottom of a liquid and form sediment. There are two main forces enacting upon any particle that is considered individually in water: gravity, and a drag force that is due to the motion of the particle through water. Gravity is not affected by the particle's velocity, whereas the drag force is a function of the particle velocity. For a particle at rest no drag force will exhibited, which causes the particle to accelerate due to the applied force. When the particle accelerates, the drag force acts in the direction opposite to the particle's motion, retarding further acceleration. As the particle increases in velocity the drag force and the applied force will approximately equate, causing no further change in the particle's velocity. This velocity is known as the settling velocity of the particle.'

- <u>Factors influencing the parameter value.</u> A checklist of the main parameters potentially influencing the parameter value is given here. This qualitative (or quantitative) information can help the end-user to adapt the parameter value according to his context or to undertake measurements of influencing variables (e.g. pH, meteorological conditions, etc).

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account and is modeled by a parameter called 'Settling velocity'. The factors that influence the parameter value are listed as follows:

  'The settling velocity of the particle is affected by many parameters, i.e. anything that will alter the particle's drag. Hence the terminal velocity is most notably dependent upon particle size, the shape (roundness and sphericity) and density of the particle, as well as to the viscosity and density of the fluid. Particles which interact with chemicals are also cohesive and thus form aggregates (mud flocs) characterized by size and settling velocity potentially quite different of the individual particles.'

- Role in the model. Even if the linkage between each parameter and the other components of the model are already given at sub-level 1.3, it is reminded here to facilitate the understanding of the parameter value .

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account and is modeled by a parameter called 'Settling velocity'. Its role in the model is described as follows:

  'In the FW-org model, the W_c parameter is used to calculate the state variable 'Deposition flux of particles (F_d)'

- Database used for parameter estimation. The parameter default value and the PDF are generally derived from the statistical analysis of a database that can be taken from the literature or built ad hoc. It is essential to present the source of this database (with literature references and eventually a comprehensive presentation in Appendix).

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account and is modeled by a parameter called 'Settling velocity'. The database used for parameter estimation is described as follows:

  'A database containing W_c values obtained by different experimental methods was built (see Appendix). Several experimental methods are possible for estimating W_c values, e.g. use of sediment traps (Kozerski, 2002); measurements of vertical gradients of SPM and application of the Rouse profile (Ciffroy et al, 2000), flume experiments (Blom and Aalderink, 1998; Lau and Droppo, 2000; Krishnappan et Marsalek, 2002), long-term monitoring of SPM concentrations in a river (Luck, 2001)). All these methods were indifferently used here without considering any hierarchy among them'

- Estimation type. Several estimation approaches are possible for calculating a default value and a PDF. These approaches are presented in detail in the table below. It is important to have a synthetic overview of the main methods followed for treating the database presented above.

  Example: in the 4FUN freshwater model, the deposition of contaminated particles onto sediment is taken into account and is modeled by a parameter called 'Settling velocity'. The estimation type is described as follows:

  Calibration [ ]

  Extrapolation [ ]

  Expert elicitation [ ]

  Bayesian approach [X]

  QSAR or read-across [ ]

  Mechanistic model [X]

  Perfect information [ ]

- Parameter estimation description. The detailed process for parameter estimation (i.e. an explanation of the estimation type(s) listed above) is described. The content of the description is considered case by case according to the statistical treatment applied and/or the nature of expert elicitation.
- Default values and Probability Density Function (PDF). The default value and the PDF resulting from the data process described above are given in this section.

Sub-level 3.2 – Parameter n°2

Same process… - Etc

Level 4 – Mathematical knowledge

The 4th level of the structure (called '"mathematical knowledge" level) is targeted towards end-user who wants to deeply understand the equations that translate the process described at level 2. At this stage, the reader has already a comprehensive knowledge of all the components of the model and of the scientific background. The understanding of the mathematical model becomes then easier. The "mathematical knowledge" level is then subdivided in the following sub-levels:

Sub-level 4.1 – State variable n°1

By definition, a state variable is calculated from other components of the model (parameters, forcing variables and/or other state variables). The flow chart (already presented at sub-level 1.3) where these components can easily be identified can be reminded here.

Sub-level 4.2 – State variable n°2

Idem - Etc

Sub-level 4.n – Mass balance model for media n°1

Multimedia models are generally based on mass balance equations that allow to calculate the quantity of the contaminant in each media, taking into account the loadings, losses and transformation processes. The flow chart (already presented at sub-level 1.3) where the loading and losses are presented can be reminded here.

Table 19 Summary of 4FUN standard documentation protocol (freshwater model)

Target	Issue	Information	Content
Basic knowledge	Model purpose	Goal	General statement of the model outputs of concern, the stressors, the media and exchanges considered. Explanations of why you need to build a complex model
		Potential decision and regulatory framework(s)	Explanations of what you are going to do with your model, Identify the (regulatory) framework to be supported (e.g. REACH, PPP, WFD, screening assessment, etc.)
	Model applicability	Spatial scale and resolution	The spatial conditions (scale and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated (boundaries, domain, area or volume to which a model application will apply: Local, regional, continental, or global scale)
		Temporal scale and resolution	The temporal conditions (scale and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated (boundaries, domain, time period to which a model application will apply)
		Chemical considered	The chemicals or chemical families and practical constraints under which environmental data and processes were defined during the model development. Chemical range of substances that can be analysed with the model (e.g. organic pollutants and/or inorganic pollutants, etc.). If mixture toxicity is included in the model, define the approach used to assess this. Define the origin of background concentrations, if used.
		Steady-state vs dynamic processes	Statement of the model type (steady-state vs. dynamic – see definitions in the core text) and implications for the conditions over which it should be evaluated (e.g. accidental release, kinetic issues)
	Model components	Media considered	Comprehensive list environmental or human compartments assumed to contain a given quantity of the chemical
		Loadings	Comprehensive list of releases/input rates of the chemical of interest to the receiving system
		Losses	Comprehensive list of output rates of the chemical of interest from the receiving system
		Exchanges between model media	Comprehensive list of transfers of the chemical(s) of interest between two media of the system
		Potential coupled models	Models that can generate loadings to the investigated system (here the Freshwater system) or receive losses from the latter

		Forcing variables	External or exogenous (from outside the model framework) factor that influences the state variables calculated within the model. Such variables include, for example, climatic or environmental conditions (temperature, wind flow, etc.)
		Scenario-specific parameters	Term in the model that is fixed during a model run or simulation but can be changed in different runs as a method for conducting sensitivity analysis or to achieve calibration goals. Scenario-specific parameters must be adapted case by case for being adapted to the given scenario (e.g. depth of a river, surface of land occupied by forest, etc)
		Default parameters	Term in the model that is fixed during a model run or simulation but can be changed in different runs as a method for conducting sensitivity analysis or to achieve calibration goals. Default parameters can be used in absence of site-specific data.
		Intermediate state variable	Dependent variable calculated within the model. Some State variables are fixed during a model run or simulation because they are calculated only from parameters. Some others are time-dependent because they are calculated from parameters, but also from time-dependent forcing variables. We distinguish 'intermediate state variables' and 'regulatory state variables'. The first ones are generally not used by decision-makers for regulatory purposes but can be used as performance indicators of the model that change over the simulation. The second ones can be used by decision-makers for regulatory purposes.
		Regulatory state variable	See above
Process knowledge	Process n°1	Motivation	Statement and importance of the process in the general model. Linkage between the process and state variables Scenarii for which the process is of particular relevance.
		Selected model and assumption(s)	Verbal description of scientific background and foundations that justify that a given model is selected for representing the process. Main literature sources. Mechanistic and/or empirical underlying assumptions.
		Model type	Statement of the model type, in particular indicate: Empirical vs Mechanistic, i.e. An empirical model is a model whose structure is determined by the observed relationship among experimental data. These models can be used to develop relationships that are useful for forecasting and describing trends in behavior, but they are not necessarily mechanistically relevant; A mechanistic model is a model whose structure explicitly represents an understanding of physical, chemical, and/or biological processes. Mechanistic models quantitatively describe the relationship between some phenomenon and underlying first principles of cause. Hence, in theory, they are useful for inferring solutions outside the domain in which the initial data were collected and used to parameterize the mechanisms. Steady-state (or static) vs dynamic, i.e. A steady-state model is a model providing the behavior

			of the state variables assumed to be in immediate equilibrium with all the other interacting state variables OR a model providing the long-term or time-averaged behavior of the state variables; A dynamic model is a model providing the time-varying behavior of the state variables. Analytical vs Numerical, i.e. An analytical model is a model that can be solved mathematically in terms of analytical functions. For example, some models that are based on relatively simple differential equations can be solved analytically by combinations of polynomials, exponential, trigonometric, or other familiar functions; A numerical model is a model that represents the development of a solution by incremental steps through the model domain. Simulations are often used to obtain solutions for models that are too complex to be solved analytically. For most situations, where a differential equation is being approximated, the simulation model will use finite time step (or spatial step) to "simulate" changes in state variables over time (or space).
		Alternatives and limits	Other potential model able to represent the process. Strengths and weaknesses of the selected model in comparison to these alternative models
	Process n°2	Motivation	Idem
		….	etc
Numerical knowledge	Initialization of concentration in Media		Initial conditions assumed, i.e., what are the initial values of the concentration in each media? Is initialization always the same or changing among simulation?
	Parameter n°1	Definition	What is the physical/chemical/biological meaning of the parameter? If the parameter is empirical and has no mechanistic meaning, it must be indicated
		Factors influencing parameter value	Checklist of environmental factors that can potentially influence the value of the parameter (e.g. pH, temperature, meteorological conditions, etc)
		Role in the model	Identification of the state variable(s) the parameter is used for
		Database used for parameter estimation	Brief description of the in-house or referenced database (source and number of data) used for parameter estimation. The complete database can eventually be attached in appendix.
		Estimation type	Statement of the parameter estimation approach, in particular indicate if the parameter was estimated by: Calibration: process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible fit to the observed data (e.g. regression analysis of empirical relationships; fitting a distribution from a dataset); Extrapolation: process that uses assumptions about fundamental causes underlying the observed phenomena in order to project beyond the range of the data; Expert elicitation: Expert elicitation can be used to characterize uncertainty and fill data gaps where traditional scientific research is not feasible or data are not yet available. Typically, the necessary quantities are obtained through structured interview(s) and/or

			questionnaire(s). Procedural steps can be used to minimize the effects of heuristics and bias in expert judgments; Bayesian approach: Bayesian approaches can be adapted to build PDFs when prior knowledge is available and when only a limited set of data can be collected for a subcategory of the database. Generally speaking, the method used here aimed at calculating the full posterior distribution knowing a prior distribution; QSAR or read-across model: QSAR models and read-across can be used in order to extrapolate data from one chemical to another. Read-across is based on experimental data and expert judgment, while QSAR models propose a regression-based relationship between the values of relevant descriptors and the parameter value. Read-across requires the assessment of chemical similarity. Mechanistic model: process of adjusting model parameter from a mechanistic model (e.g. relying the parameter to environmental factors; Perfect information: state of information where in which there is no uncertainty. The current and future values for all parameters are known with certainty.
		Parameter estimation description	Complete description of the estimation process, giving details on the estimation type(s) indicated above
		Default values and Probability Density Function (PDF)	Give here the final result of the estimation process, i.e. a default value and/or a PDF
Mathematical knowledge	Mathematical models for state variables	State variable n°1	Indicate here the parameters/forcing variables/other state variables necessary for calculating the targeted state variable (eventually under the form of a flow chart) Give the mathematical formulation
		State variable n°2	Idem
		…	…
	Mass balance models	Media n°1	Set of differential equations allowing to calculate the mass balance in media n°1 taking into account loadings, losses and exchanges processes
		Media n°2	Idem
		…	…

7.3 Alternative SDPs

The information that is absolutely needed for a comprehensive understanding of the model is listed in the 4FUN SDP previously described in detail. The hierarchical structure of the information can however follow another framework. For example, the following alternative proposal can be preferred:

(i) Level 1: the basic knowledge (allowing a reader to get an overview of the model and to know whether it can meet its needs) could cover the parts until the presentation of exchanges between model media (including sections “model purpose”, “model applicability” and a part of “model components”) and include a list of state variables.

(ii) Level 2: the Process knowledge and the mathematical knowledge could be merged as the process-mathematical knowledge

(iii) Level 3: the numerical knowledge

The following table presents the alternative structure.

These different alternatives will be discussed in the frame of the 4FUN consortium to choose the most adapted to the models included in our library. Some adaptations are then expected when the SDP will be applied to concrete description of models.

Table 20 Alternative 4FUN standard documentation protocol (freshwater model)

Target	Issue	Information	Content
Basic knowledge	Model purpose	Goal	General statement of the model outputs of concern, the stressors, the media and exchanges considered. Explanations of why you need to build a complex model
		Potential decision and regulatory framework(s)	Explanations of what you are going to do with your model, Identify the (regulatory) framework to be supported (e.g. REACH, PPP, WFD, screening assessment, etc.)
	Model applicability	Spatial scale and resolution	The spatial conditions (scale and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated (boundaries, domain, area or volume to which a model application will apply: Local, Regional, continental, or global scale)
		Temporal scale and resolution	The temporal conditions (scale and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated (boundaries, domain, time period to which a model application will apply)
		Chemical considered	The chemicals or chemical families and practical constraints under which environmental data and processes were defined during the model development. Chemical range of substances that can be analysed with the model (e.g. Organic pollutants and/or inorganic pollutants, etc.). If mixture toxicity is included in the model, define the approach used to assess this. Define the origin of background concentrations, if used.
		Steady-state vs dynamic processes	Statement of the model type (steady-state vs. dynamic – see definitions in the core text) and implications for the conditions over which it should be evaluated (e.g. accidental release, kinetic issues)
	Model components	Media considered	Comprehensive list environmental or human compartments assumed to contain a given quantity of the chemical
		Loadings	Comprehensive list of releases/input rates of the chemical of interest to the receiving system
		Losses	Comprehensive list of output rates of the chemical of interest from the receiving system
		Exchanges between model media	Comprehensive list of transfers of the chemical(s) of interest between two media of the system
		Intermediate state variable (only the list)	Dependent variable calculated within the model. Some State variables are fixed during a model run or simulation because they are calculated only from parameters. Some others are time-dependent because they are calculated from parameters, but also from time-dependent forcing variables. We distinguish 'Intermediate State variables' and 'Regulatory State variables'. The first ones are generally not used by decision-makers for regulatory purposes but can be used as performance indicators of the model that change over the simulation. The second ones can be used by decision-makers for regulatory purposes.

		Regulatory state variable (only the list)	See above
Process-mathematical knowledge		Forcing variables	External or exogenous (from outside the model framework) factor that influences the state variables calculated within the model. Such variables include, for example, climatic or environmental conditions (temperature, wind flow, etc.)
		Parameter	Term in the model that is fixed during a model run or simulation but can be changed in different runs as a method for conducting sensitivity analysis or to achieve calibration goals
	Mathematical models for state variables	State variable n°1	Indicate here the parameters/forcing variables/other state variables necessary for calculating the targeted state variable (eventually under the form of a flow chart) Give the mathematical formulae
		State variable n°2	Idem
		…	…
	Mass balance models	Media n°1	Set of differential equations allowing to calculate the mass balance in media n°1 taking into account loadings, losses and exchanges processes
		Media n°2	Idem
		…	…
	Process n°1	Motivation	Statement and importance of the process in the general model. Linkage between the process and state variables Scenarii for which the process is of particular relevance.
		Selected model and assumption(s)	Verbal description of scientific background and foundations that justify that a given model is selected for representing the process. Main literature sources. Mechanistic and/or empirical underlying assumptions.
		Model type	Statement of the model type, in particular indicate: Empirical vs mechanistic, i.e. An empirical model is a model whose structure is determined by the observed relationship among experimental data. These models can be used to develop relationships that are useful for forecasting and describing trends in behavior, but they are not necessarily mechanistically relevant; A mechanistic model is a model whose structure explicitly represents an understanding of physical, chemical, and/or biological processes. Mechanistic models quantitatively describe the relationship between some phenomenon and underlying first principles of cause. Hence, in theory, they are useful for inferring solutions outside the domain in which the initial data were collected and used to parameterize the mechanisms. Steady-state (or static) vs dynamic, i.e. A steady-state model is a model providing the behavior of the state variables assumed to be in immediate equilibrium with all the other interacting state variables OR a model providing the long-term or time-averaged behavior of the state variables; A dynamic model is a model providing the time-varying behavior of the state variables. Analytical vs numerical, i.e. An analytical model is a model that can be solved mathematically in terms of analytical functions. For example,

			some models that are based on relatively simple differential equations can be solved analytically by combinations of polynomials, exponential, trigonometric, or other familiar functions; A numerical model is a model that represents the development of a solution by incremental steps through the model domain. Simulations are often used to obtain solutions for models that are too complex to be solved analytically. For most situations, where a differential equation is being approximated, the simulation model will use finite time step (or spatial step) to “simulate” changes in state variables over time (or space).
		Alternatives and limits	Other potential model able to represent the process. Strengths and weaknesses of the selected model in comparison to these alternative models
	Process n°2	Motivation	Idem
		….	etc
Numerical knowledge	Initialization of concentrations in media		Initial conditions assumed, i.e., what are the initial values of the concentration in each media? Is initialization always the same or changing among simulation?
	Parameter n°1	Definition	What is the physical/chemical/biological meaning of the parameter? If the parameter is empirical and has no mechanistic meaning, it must be indicated
		Factors influencing parameter value	Checklist of environmental factors that can potentially influence the value of the parameter (e.g. pH, temperature, meteorological conditions, etc)
		Role in the model	Identification of the state variable(s) the parameter is used for
		Database used for parameter estimation	Brief description of the in-house or referenced database (source and number of data) used for parameter estimation. The complete database can eventually be attached as appendix.
		Estimation type	Statement of the parameter estimation approach, in particular indicate if the parameter was estimated by: Calibration: process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible fit to the observed data (e.g. regression analysis of empirical relationships; fitting a distribution from a dataset); Extrapolation: process that uses assumptions about fundamental causes underlying the observed phenomena in order to project beyond the range of the data; Expert elicitation: Expert elicitation can be used to characterize uncertainty and fill data gaps where traditional scientific research is not feasible or data are not yet available. Typically, the necessary quantities are obtained through structured interview(s) and/or questionnaire(s). Procedural steps can be used to minimize the effects of heuristics and bias in expert judgments; Bayesian approach: Bayesian approaches can be adapted to build PDFs when prior knowledge is available and when only a limited set of data can be collected for a subcategory of the database. Generally speaking, the method used here aimed at calculating the full posterior distribution knowing a prior distribution; QSAR or read-across model: QSAR models and read-across can be used in order to extrapolate data from one chemical to another. Read-across is based on experimental data and expert judgment, while QSAR models propose a regression-based

			relationship between the values of relevant descriptors and the parameter value. Read-across requires the assessment of chemical similarity. Mechanistic model: process of adjusting model parameter from a mechanistic model (e.g. relying the parameter to environmental factors; Perfect information: state of information where in which there is no uncertainty. The current and future values for all parameters are known with certainty.
		Parameter estimation description	Complete description of the estimation process, giving details on the estimation type(s) indicated above
		Default values and Probability Density Function (PDF)	Give here the final result of the estimation process, i.e. a default value and/or a PDF

8 Beyond 4FUN

8.1 Introduction

There are several possibilities to leverage standardisation for the benefit of a newly developed service or product. One possibility is to simply use the International Standards that there already are (see Chapter 5), thereby benefitting from reduced costs to get to market (no need to reinvent the wheel). Another possibility is to get actively involved in the process of standardisation, either by contributing to the development of a standard, or by developing an own standard. These possibilities will be presented in the remainder of this chapter. As pointed out under Section 5.1 above, standards referring to large exposure models are just about to emerge, with a first pre-standard published by ISO in 2012 (ISO/TS 14033), and a report recommending wider usage of the modelling approach published by CEN also in 2012 (CEN/TR 16364). Thus, there may exist a window of opportunity at this point in time to gain a strategic advantage through getting actively involved in standardisation.

8.2 Contributing to the development of a standard

To contribute to the development of a standard means to actively participate in the work of a Technical Committee (TC). To do so, some form of membership or right of access to the TC is required, which differs slightly between CEN and ISO.

Participation in a CEN/TC via liaison status

The members of CEN are the National Standardisation Bodies (NSBs) of the 33 European countries, including all EU and EFTA member countries as well as Crotia, the former Yugoslav Republic of Macedonia and Turkey. The members of CEN/TCs in turn are experts sent as national delegates from the NSBs, representing the views of their respective home country and its technical committees. An International/European organisation (incl a EU funded research project such as 4FUN) however can obtain the right to directly participate in the work of a CEN/TC by applying for liaison status. A liaison status is an observer status that comes with the right of full participation in the TC but without the right to vote. An organisation in liaison may for example send an observer to meetings of the TC, obtains automatically all working documents and internal communications of the TC, may comment on draft standards and may propose specific text, may join drafting and working groups of the TC, and may also propose new work items. The lack of the right to vote should not be seen as resulting in a second-class participation. The statutes of CEN foresee that TCs must try to achieve consensus among all stakeholders whenever possible, and the votes are distributed among member countries such that a single vote often makes little difference when it comes to a vote.

When applying for liaison status, the application is first evaluated by CEN for conformity with the CEN rules and regulations, based on the statutes and the list of members of the applying organisation, along with a letter from the organisation outlining the relevance and intent of the liaison. Once CEN has vetted the application, it proceeds to a vote of approval in the CEN/TC concerned. If all goes well, that process will take around 4-5 months. .

The cost of participation via liaison status amounts to an annual nominal fee of around 500 EUR plus the travel and time expenses of the observer, usually amounting to about twice 2 days per year to participate in the meetings, plus he time required to review and comment on the draft standard(s) of interest.

Benefits of a liaison status include

- Information on content and direction of evolving standards long before they become public knowledge

- Possibility to shape evolving standards by proposing text and by commenting on text proposed by others and by promoting specific solutions to the TC
- Network of experts and stakeholders from countries across Europe, including from public administrations, research centres and universities, industry associations and consumer interests

Participation in a ISO/TC via a national delegation

All CEN members (NSBs) are also members of ISO, which is the worldwide standardisation organisation. A direct participation of 4FUN in an ISO/TC is however not possible as opposed to a CEN/TC, because in ISO liaison status is not open to EU funded research projects. However, 4FUN can participate in an ISO/TC indirectly, by delegating an expert to a national technical committee formally associated to the ISO/TC, a so-called national mirror committee (NMC). The NMC in turn can nominate up to three national delegates to the ISO/TC. National delegates to an ISO/TC receive a copy of all internal communications and documents of the ISO/TC, they discuss the standards being drafted by their ISO/TC and provide comments on them, they may participate in the ISO/TC meetings and the meetings of its working groups, they may provide text proposals or proposals for new standards, and may vote on decision of the ISO/TC. Thus, a national delegate to ISO has much the same rights as an observer to CEN, the main difference being the right to vote. When voting, the national delegation must take into account any instructions on the national position received from the NMC. The right to vote at ISO should not be overvalued as the principle is to seek the broadest possible consensus among all stakeholders is paramount also in ISO, and the votes of individual countries amount to small fractions of a required quorum.

To be accepted as expert to a NMC, the secretary of the NMC in a country of choice should be contacted and provided with a curriculum of the expert and the background of the application, which will be forwarded to the technical committee for consideration. Next the committee will have to vote on accepting the new member. That process may take 2-3 months.

The cost of participation in ISO via a NMC is roughly the same as the cost of a liaison (eg cost of travel plus the time of the expert to participate plus any fees charged by the NSB for participation in its NMC). The fees charged by NSBs vary from country to country. At ASI for example, the cost currently amounts to a onetime registration fee per expert of around 500 EUR.

The benefits to a national delegate of a NMC is similar to the benefits of an observer outlined under liaison status above.

Process to develop a standard

The process of creating a European Standard (EN) may take anywhere from less than a year (for straight adoption of another international document such as for example an ISO publication) to around 3 years (creation entirely from scratch without any pre-existing suitable work).

When seeking to create a new standard, it is always first established whether there are published International Standards or other suitable published documents (copyright issues resolved) in the field, which would be acceptable as a European Standard. If there is a suitable document, it will be assessed through the so-called „Questionnaire Procedure“, whereby the document is sent to the members of the CEN/TC, asking if there is sufficient interest in European harmonization, and if the document is suitable for progressing directly to a formal vote as a European Standard, or if the document needs reworking of varying degrees to reflect European regulations and needs. The normal time limit to respond to a Primary Questionnaire is three months.

Once work on a standard has been initiated within a CEN/TC based on a Questionnaire Procedure or directly initiated by the relevant TC or proposed by a NSB, successive working drafts are circulated to the members of the CEN/TC for comments. When consensus has been reached, the text is distributed to the CEN NSBs for public comment (so called “CEN Enquiry"), usually lasting 5 months. If the result of the Public Enquiry shows sufficient agreement on the content of the draft, the text is finalised and submitted to a formal vote by CEN members. The time to vote usually is 2 months. The decision is taken by weighted majority, the votes being weighed by the relative size of the country. If the CEN Enquiry does not show sufficient agreement, a second Enquiry is possible. If in the formal vote the required consensus is not achieved, it may still be possible to publish the draft as a Technical Specification. If the standardisation project is not completed within the foreseen target dates (normally 3 years with the possibility to extend for 9 months for an entirely new standard), the project is stopped.

A Technical Specification (TS) is a document adopted by CEN for which there is the future possibility of agreement on a European Standard, but for which there is doubt on whether consensus has already been achieved or the subject matter is still under technical development. It has been approved by weighted majority vote in the relevant TC, but it need not have been subject to Public Enquiry. A TS is not permitted to conflict with an EN, but conflicting national standards are allowed to exist. A TS is reviewed every 3 years at the latest, at which point it is decided to either proceed to Public Enquiry and publishing as an EN, to prolong for another 3 years, or to withdraw the TS. TSs are established with a view to serving, for instance, the purpose of publishing aspects of a subject which may support the development and progress of the European market; giving guidance to the market on or by specifications and related test methods; or providing specifications in experimental circumstances and/or evolving technologies.

The process to create an International Standard (ISO) is much similar to the process of creating a European Standard, but varies in some small aspects.

Relation of ISO and CEN (Vienna Agreement)

What is the difference between an ISO standard and a CEN standard and an ISO/TC and a CEN/TC and how do they relate?

International Standards have primacy, eg the adoption of existing ISO Standards without change is considered the preferred solution for all countries worldwide if not prevented by different local regulations or policy priorities. However, the requirement of adoption of an ISO Standard is not legally binding and thus still voluntary. A European Standard (EN) is directly valid in all countries of the single European market and conflicting standards must be withdrawn.

ISO and CEN cooperate based on the Vienna Agreement, which has the objective to eliminate duplication of work and potentially conflicting standards. Under the agreement, ISO and CEN cooperate through exchange of information and through exchange of representatives to each other’s TCs when there are common interests (eg when there are TCs with overlapping areas of standardization). Both organisations consider adopting publications that already pre-exist from the other organisation before starting work on standards in new areas. A mechanism is foreseen by which CEN and ISO jointly develop new standards with either CEN or ISO taking the lead in drafting a new standard, and resulting standards are simultaneously presented to both organisations for approval. Approximately 30% of CEN standards are developed under the mechanism of lead by one organisation with parallel approval at both organisations. A Standard that has been adopted by both organisations carries the letters of both organisations before their number, eg EN ISO xxxxx.

Recommendation

It is recommended to 4FUN Consortium to designate a 4FUN partner to join ISO/TC 207 “Environmental Management” via a national delegation, as well as to request liaison status to CEN/TC 230 “Water analysis”, with the same or another partner being designated to act as observer on behalf of 4FUN. This will allow 4 FUN to monitor emerging standardisation developments at a very small cost, e.g. a one-off nominal registration fee to a national mirror committee, plus 1-2 hours per months to review ongoing work of the TCs by electronic means. This has the additional advantage that 4FUN will have the option to participate actively in the work of the respective TC if and when relevant standardization work emerges. ASI can arrange and support the necessary formalities required for the delegate/liaison status.

8.3 Developing an own Standard through a CEN Workshop Agreement

There exists a type of a CEN publication that allows a group of interested parties such as for example a research consortium and/or any organisation or company from Europe or outside of Europe, to develop their own standard in 6-18 months, the so called CEN Workshop Agreement (CWA). The CWA is a process that aims at bridging the gap between industrial or research consortia that produce de facto standards or technical specifications, and the formal European standardization process. It provides a platform for stakeholders in a specific area to come together, while ensuring the principles of transparency, openness, coherence and consensus, to develop a harmonised European technical document. CWAs are particularly suited to dealing with experimental topics, often in connection with the output from research and innovation projects. Concretely, this report could serve as a draft/basis for a CWA document to be developed, inviting other interested parties to contribute their view and experience to develop a consensus document, which will be made publicly available as a CEN document.

To prepare a CWA, a Business Plan needs to be drawn up, describing the scope, objectives, outline of content, participants and stakeholders, workshop organisational structure and processes, time schedule and agreed contributions of the participants to support the development of the proposed document, and the funding of the CEN workshop resources such as the Secretariat and other logistical support. Once the request for a CWA has been reviewed by CEN, the Business Plan of the CWA is posted on the CEN Web site for 60 days for comments and the date of the kick-off meeting is announced. At the kick-off meeting, the workshop participants confirm and finalize the business plan (by consensus) along with the appointments of Secretariat and the Chairmanship. Following this, the workshop participants develop the CWA, which is considered approved as soon as there is consensus. The draft CWA may also be made available for comments to the CEN national members or to a wider public enquiry via the CEN web site for a minimum 60-day-period, - this is recommended but not mandatory.

When consensus is reached among the Workshop participants, the CWA is considered to be approved and the CEN national members will announce the CWA at national level and may also consider making it available at national level. The CWA is valid for 3 years or until its transformation into another CEN publication, such as a TS or EN, or its reapproval be the former workshop participants for another 3 years or its withdrawal. Revision of a CWA after 3 years is also possible. The CWA is owned by CEN as a publication. Conflicting national normative documents may continue to exist, but a CWA may not conflict with an EN.

Costs amount to the man days budgeted by the consortium for the man days of the experts seconded to the CWA and for the Secretariat to complete the document as outlined in the Business Plan. These should be available in the existing 4FUN budget.

Benefits include

- Testing of project outcomes with a wider community of stakeholders in Europe
- Dissemination of research results, making the results well known and possibly a reference
- Integration of new technologies into complex, innovative systems and solutions, assisting in ensuring interoperability
- Possibility to make CWA the basis for a future European Standard
- Building confidence among consumers/users on new products/services

8.4 Summary and recommendation

While no International or European Standard exists that provides a standard framework for large exposure models, it appears likely that such standards will emerge in the years to come. Mutlimedia modelling becomes increasingly established, first precursor standards have already emerged (ISO/TS 14033 and CEN/TR 16364), and the field of large exposure modelling is inherently in need of standardisation to ensure interoperability and conformity with EU regulations as well as consumer confidence.

It is therefore advantageous to 4FUN to establish formal links to standardization. A liaison (CEN) or delegate status (ISO) to the relevant TCs should be established to keep track of the evolving standardisation landscape with respect to large multimedia models. This amounts to an insurance policy not to miss crucial developments at very little cost, while retaining the option to get actively involved as soon as relevant work emerges.

4 FUN should also consider using this report as a draft for a CWA, developing a standard framework that represents a broader consensus and expertise beyond the consortium, relying on the established rules and infrastructure of CEN to do so. The cost for ASI to write the required business plan and establish and run the workshop is available in the 4FUN budget.

9 Frequently used terms and definitions (US EPA)

Family of terminology	Term	Definition
Terminology related to model components	**Class**	A set of objects that share a common structure and behavior. The structure of a class is determined by the class variables, which represent the state of an object of that class; the behavior is given by the set of methods associated with the class
	Module	An independent or self-contained component of a model, which is used in combination with other components and forms part of one or more larger programs
	Medium	An environmental or human compartment assumed to contain a given quantity of the chemical. Quantity of the chemical in the media is governed by inputs/outputs from/to other media and by transformation processes (e.g. degradation)
	Constant	A fixed value (e.g., the gravitational force) representing known physical, biological, or ecological activities
	Forcing/driving variable	An external or exogenous (from outside the model framework) factor that influences the state variables calculated within the model. Such variables include, for example, climatic or environmental conditions (temperature, wind flow, oceanic circulation, etc.)
	Loading	The rate of release of a constituent of interest to a particular receiving medium
	State variables	The dependent variables calculated within a model, which are also often the performance indicators of the models that change over the simulation
	Parameters	Terms in the model that are fixed during a model run or simulation but can be changed in different runs as a method for conducting sensitivity analysis or to achieve calibration goals
Terminology related to model limitations	**Applicability and utility**	Extent to which the information provided by the model is relevant for the intended use defined by the model end-user (e.g. regulators)
	Application niche	The set of conditions under which the use of a model is scientifically defensible. The identification of application niche is a key step during model development. Peer review should include an evaluation of application niche. An explicit statement of application niche helps decision makers understand the limitations of the scientific basis of the model
	Application niche uncertainty	Uncertainty as to the appropriateness of a model for use under a specific set of conditions
	Graded approach	The process of basing the level of application of managerial controls to an item or work on the intended use of results and degree of confidence needed in the results
	Mode (of a model)	The manner in which a model operates. Models can be designed to represent phenomena in different modes. Prognostic (or predictive) models are designed to forecast outcomes and future events, while diagnostic models work “backwards” to assess causes and precursor conditions
	Boundaries OR domain (spatial and temporal)	The spatial and temporal conditions (extent and resolution) and practical constraints under which environmental data and processes were defined during the model development and over which it should be evaluated. Boundaries or Domain specify the area or volume (spatial boundary) and the time period (temporal boundary) to which a model application will apply
	Boundary or domain conditions	Sets of values for state variables and their rates along problem domain boundaries, sufficient to determine the state of the system within the problem domain
	Exposure pathway	The course a chemical takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, the transport/exposure medium (such as air) or media (in cases of intermedia transport, such as water to air) are also included

	Exposure point	A geographical location of potential contact between an organism and a chemical or physical agent
	Exposure route.	The way a chemical or physical agent comes in contact with an organism, i.e., inhalation, ingestion, dermal contact
Terminology related to model typology	**Conceptual basis**	An underlying scientific foundation of model algorithms or governing equations. The conceptual basis for a model is either empirical (based on statistical relationships between observations) or mechanistic (process-based) or a combination. See definitions for “empirical model” and “mechanistic model”
	Conceptual model	A hypothesis regarding the important factors that govern the behavior of an object or process of interest. This can be an interpretation or working description of the characteristics and dynamics of a physical system
	Model framework	The system of governing equations, parameterization, and data structures that make up the mathematical model. The model framework is a formal mathematical specification of the concepts and procedures of the conceptual model consisting of generalized algorithms (computer code/software) for different site- or problem-specific simulations
	Model framework uncertainty	The uncertainty in the underlying science and algorithms of a model. Model framework uncertainty is the result of incomplete scientific data or lack of knowledge about the factors that control the behavior of the system being modeled. Model framework uncertainty can also be the result of simplifications necessary to translate the conceptual model into mathematical terms
	Algorithm	A precise rule (or set of rules) for solving some problem
	Computational models	Models that use measurable variables, numerical inputs, and mathematical relationships to produce quantitative outputs
	Analytical model	A model that can be solved mathematically in terms of analytical functions. For example, some models that are based on relatively simple differential equations can be solved analytically by combinations of polynomials, exponential, trigonometric, or other familiar functions
	Numerical model	A model that represents the development of a solution by incremental steps through the model domain. Simulations are often used to obtain solutions for models that are too complex to be solved analytically. For most situations, where a differential equation is being approximated, the simulation model will use finite time step (or spatial step) to “simulate” changes in state variables over time (or space)
	Empirical model	A model whose structure is determined by the observed relationship among experimental data. These models can be used to develop relationships that are useful for forecasting and describing trends in behavior, but they are not necessarily mechanistically relevant
	Mechanistic model	A model whose structure explicitly represents an understanding of physical, chemical, and/or biological processes. Mechanistic models quantitatively describe the relationship between some phenomenon and underlying first principles of cause. Hence, in theory, they are useful for inferring solutions outside the domain in which the initial data were collected and used to parameterize the mechanisms
	Steady-state model	A model providing the behavior of the state variables assumed to be in immediate equilibrium with all the other interacting state variables OR A model providing the long-term or time-averaged behavior of the state variables
	Dynamic model	A model providing the time-varying behavior of the state variables
	Deterministic model	A model that provides a solution for the state variables rather than a set of probabilistic outcomes. Because this type of model does not explicitly simulate the effects of data uncertainty or variability, changes in model outputs are solely due to changes in model components or in the boundary conditions or initial conditions
	Stochastic model	A model that includes uncertainty and variability (see definition) in model parameters. This variability is a function of changing environmental conditions, spatial and temporal aggregation within the model framework, and random variability. The solution obtained by the model or output is therefore a function of model components and

		random variability
	Screening model	A type of model designed to provide a “conservative” or risk-averse answer. Screening models can be used with limited information and are conservative, and in some cases they can be used in lieu of refined models, even when time or resources are not limited
	Statistical model	A model built using observations within a probabilistic framework. Statistical models include simple linear or multivariate regression models obtained by fitting observational data to a mathematical function
	Function	A mathematical relationship between variables
Terminology related to parameterization and uncertainty	**Uncertainty**	The term used in this document to describe lack of knowledge about models, parameters, constants, data, and beliefs. There are many sources of uncertainty, including the science underlying a model, uncertainty in model parameters and input data, observation error, and code uncertainty. Additional study and collecting more information allows error that stems from uncertainty to be minimized/reduced (or eliminated). In contrast, variability (see definition) is irreducible but can be better characterized or represented with further study
	Uncertainty analysis	Investigation of the effects of lack of knowledge or potential errors on the model (e.g, the “uncertainty” associated with parameter values). When combined with sensitivity analysis (see definition), uncertainty analysis allows a model user to be more informed about the confidence that can be placed in model results
	Parametric uncertainty analysis	Investigation of the effects the “uncertainty” associated with parameter values). Uncertainty analysis can be combined with sensitivity analysis that allows a model user to identify the main parameters responsible for model parametric uncertainty
	Calibration or Parameter estimation	The process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible fit to the observed data
	Expert elicitation	A systematic process for quantifying, typically in probabilistic terms, expert judgments about uncertain quantities. Expert elicitation can be used to characterize uncertainty and fill data gaps where traditional scientific research is not feasible or data are not yet available. Typically, the necessary quantities are obtained through structured interviews and/or questionnaires. Procedural steps can be used to minimize the effects of heuristics and bias in expert judgments
	Extrapolation	Extrapolation is a process that uses assumptions about fundamental causes underlying the observed phenomena in order to project beyond the range of the data. In general, extrapolation is not considered a reliable process for prediction; however, there are situations where it may be necessary and useful
	Perfect information	The state of information where in which there is no uncertainty. The current and future values for all parameters are known with certainty. The state of perfect information includes knowledge about the values of parameters with natural variability
	Probability density function	Mathematical, graphical, or tabular expression of the relative likelihoods with which an unknown or variable quantity may take various values. The sum (or integral) of all likelihoods equals 1 for discrete (continous) random variables (Cullen and Frey 1999). These distributions arise from the fundamental properties of the quantities we are attempting to represent. For example, quantities formed from adding many uncertain parameters tend to be normally distributed, and quantities formed from multiplying uncertain quantities tend to be lognormal
	Default value	Typical value for the investigated parameter. Default values should be scientifically justified and, where possible, be based on existing data. To compensate for the absence of data, the risk assessor may have to refer to default values to be able to perform the assessment
	Worst-case value	Value for the investigated parameter that generates output estimates "on the safe side" of the risk, i.e. that maximizes the exposure risk
	Intrinsic variation (or variability)	Observed differences attributable to true heterogeneity or diversity. Variability is the result of natural random processes and is usually not reducible by further measurement or study (although it can be better characterized)

	Reducible uncertainty	Uncertainty in models that can be minimized or even eliminated with further study and additional data
	Stochasticity	Fluctuations in ecological processes that are due to natural variability and inherent randomness
	Data incompleteness (or ignorance)	Uncertainty that is caused by measurement errors, analytical imprecision, and limited sample sizes during the collection and treatment of data. Data incompleteness, in contrast to variability (see definition), is the component of total uncertainty that is “reducible” through further study
	Data inconsistency	Uncertainty that is caused by conflicting information or data
	Response surface	A theoretical multi-dimensional “surface” that describes the response of a model to changes in its parameter values. A response surface is also known as a sensitivity surface
	Sensitivity	The degree to which the model outputs are affected by changes in selected input parameters
	Sensitivity analysis	The computation of the effect of changes in input values or assumptions (including boundaries and model functional form) on the outputs (Morgan and Henrion 1990); the study of how uncertainty in a model output can be systematically apportioned to different sources of uncertainty in the model input (Saltelli et al. 2000a). By investigating the “relative sensitivity” of model parameters, a user can become knowledgeable of the relative importance of parameters in the model
	Qualitative uncertainty assessment	Some of the uncertainty in model predictions may arise from sources whose uncertainty cannot be quantified. Examples are uncertainties about the theory underlying the model, the manner in which that theory is mathematically expressed to represent the environmental components, and the theory being modeled. The subjective evaluations of experts may be needed to determine appropriate values for model parameters and inputs that cannot be directly observed or measured (e.g., air emissions estimates). Qualitative corroboration activities may involve the elicitation of expert judgment on the true behavior of the system and agreement with model-forecasted behavior
	Quantitative uncertainty assessment	The uncertainty in some sources — such as some model parameters and some input data — can be estimated through quantitative assessments involving statistical uncertainty and sensitivity analyses. In addition, comparisons can be made for the special purpose of quantitatively describing the differences to be expected between model estimates of current conditions and comparable field observations
Terminology related to coding	**Code (or program)**	Instructions, written in the syntax of a computer language, that provide the computer with a logical process. “Code” can also refer to a computer program or subset. The term “code” describes the fact that computer languages use a different vocabulary and syntax than algorithms that may be written in standard language
	Model coding	The process of translating the mathematical equations that constitute the model framework into a functioning computer program
	Code verification	Examination of the algorithms and numerical technique in the computer code to ascertain that they truly represent the conceptual model and that there are no inherent numerical problems with obtaining a solution
	Checks	Specific tests in a quality assurance plan that are used to evaluate whether the specifications (performance criteria) for the model developed at its onset have been met
	Debugging	The identification and removal of bugs from computer code. Bugs are errors in computer code that range from typos to misuse of concepts and equations
	Robustness	The capacity of a model to perform well across the full range of environmental conditions for which it was designed

10 References

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11 Appendices

11.1 Appendix A: Analysis Standards covering various media

CEN/TC 164 Water supply	*EN 12873-1:2003*	*Influence of materials on water intended for human consumption - Influence due to migration - Part 1: Test method for non-metallic and non-cementitious factory made products*
	EN 12873-2:2005	*Influence of materials on water intended for human consumption - Influence due to migration - Part 2: Test method for non-metallic and non-cementitious site-applied materials*
	EN 12873-3:2006	*Influence of materials on water intended for human consumption - Influence due to migration - Part 3: Test method for ion exchange and adsorbent resins*
	EN 12873-4:2006	*Influence of materials on water intended for human consumption - Influence due to migration - Part 4: Test method for water treatment membranes*
	EN 14944-1:2006	*Influence of cementitious products on water intended for human consumption - Test methods - Part 1: Influence of factory made cementitious products on organoleptic parameters*
	EN 14944-3:2007	*Influence of cementitious products on water intended for human consumption - Test methods - Part 3: Migration of substances from factory-made cementititous products*
	EN 15664-1:2008	*Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of metal release - Part 1: Design and operation*
	EN 15664-2:2010	*Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of metal release - Part 2: Test waters*
	EN 16056:2012	*Influence of metallic materials on water intended for human consumption - Method to evaluate the passive behaviour of stainless steels*
	EN 16057:2012	*Influence of metallic materials on water intended for human consumption - Determination of residual surface lead (Pb) - Extraction method*
	EN 16058:2012	*Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of surface coatings with nickel layers - Long-term test method*
CEN/TC 230 Water analysis	*CEN ISO/TR 15462:2009*	*Water quality - Selection of tests for biodegradability*
	CEN/TR 16151:2011	*Water quality - Guidance on the design of Multimetric Indices*
	EN 12260:2003	*Water quality - Determination of nitrogen - Determination of bound nitrogen (TNb), following oxidation to nitrogen oxides*
	EN 1233:1996	*Water quality - Determination of chromium - Atomic absorption spectrometric methods*
	EN 12673:1998	*Water quality - Gas chromatographic determination of some selected chlorophenols in water*
	EN 12918:1999	*Water quality - Determination of parathion, parathion-methyl and some other organophosphorus compounds in water by dichloromethane extraction and gas chromatographic analysis*

	EN 13946:2003	*Water quality - Guidance standard for the routine sampling and pretreatment of benthic diatoms from rivers*
	EN 14011:2003	*Water quality - Sampling of fish with electricity*
	EN 14184:2003	*Water quality - Guidance standard for the surveying of aquatic macrophytes in running waters*
	EN 14207:2003	*Water quality - Determination of epichlorohydrin*
	EN 14407:2004	*Water quality - Guidance standard for the identification, enumeration and interpretation of benthic diatom samples from running waters*
	EN 14486:2005	*Water quality - Detection of human enteroviruses by monolayer plaque assay*
	EN 14614:2004	*Water Quality - Guidance standard for assessing the hydromorphological features of rivers*
	EN 14757:2005	*Water quality - Sampling of fish with multi-mesh gillnets*
	EN 1484:1997	*Water analysis - Guidelines for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC)*
	EN 14962:2006	*Water quality - Guidance on the scope and selection of fish sampling methods*
	EN 14996:2006	*Water quality - Guidance on assuring the quality of biological and ecological assessments in the aquatic environment*
	EN 15110:2006	*Water quality - Guidance standard for the sampling of zooplankton from standing waters*
	EN 15196:2006	*Water quality - Guidance on sampling and processing of the pupal exuviae of Chironomidae (Order Diptera) for ecological assessment*
	EN 15204:2006	*Water quality - Guidance standard on the enumeration of phytoplankton using inverted microscopy (Utermöhl technique)*
	EN 15460:2007	*Water quality - Guidance standard for the surveying of macrophytes in lakes*
	EN 15708:2009	*Water quality - Guidance standard for the surveying, sampling and laboratory analysis of phytobenthos in shallow running water*
	EN 15843:2010	*Water quality - Guidance standard on determining the degree of modification of river hydromorphology*
	EN 15972:2011	*Water quality - Guidance on quantitative and qualitative investigations of marine phytoplankton*
	EN 16039:2011	*Water quality - Guidance standard on assessing the hydromorphological features of lakes*
	EN 16101:2012	*Water quality - Guidance standard on interlaboratory comparison studies for ecological assessment*
	EN 16150:2012	*Water quality - Guidance on pro-rata Multi-Habitat sampling of benthic macro-invertebrates from wadeable rivers*
	EN 16161:2012	*Water quality - Guidance on the use of in vivo absorption techniques for the estimation of chlorophyll-a concentration in marine and fresh water samples*
	EN 16164:2013	*Water quality - Guidance standard for designing and selecting taxonomic keys*
	EN 1622:2006	*Water quality - Determination of the threshold odour number (TON) and threshold flavour number (TFN)*
	EN 16260:2012	*Water quality - Visual seabed surveys using remotely operated and/or towed observation gear for collection of environmental data*
	EN 1899-	*Water quality - Determination of biochemical oxygen demand after*

	1:1998	*n days (BODn) - Part 1: Dilution and seeding method with allylthiourea addition*
	EN 1899-2:1998	*Water quality - Determination of biochemical oxygen demand after n days (BODn) - Part 2: Method for undiluted samples*
	EN 25663:1993	*Water quality - Determination of Kjeldahl nitrogen - Method after mineralization with selenium*
	EN 25813:1992	*Water quality - Determination of dissolved oxygen - Iodometric method*
	EN 26461-1:1993	*Water quality - Detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia) - Part 1: Method by enrichment in a liquid medium*
	EN 26461-2:1993	*Water quality - Detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia) - Part 2: Method by membrane filtration*
	EN 26777:1993	*Water quality - Determination of nitrite - Molecular absorption spectrometric method*
	EN 27888:1993	*Water quality - Determination of electrical conductivity*
	EN 872:2005	*Water quality - Determination of suspended solids - Method by filtration through glass fibre filters*
	EN 903:1993	*Water quality - Determination of anionic surfactants by measurement of the methylene blue index MBAS*
	EN ISO 10253:2006	*Water quality - Marine algal growth inhibition test with Skeletonema costatum and Phaeodactylum tricornutum*
	EN ISO 10301:1997	*Water quality - Determination of highly volatile halogenated hydrocarbons - Gas-chromatographic methods*
	EN ISO 10304-1:2009	*Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate*
	EN ISO 10304-1:2009/AC:2012	*Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate - Technical Corrigendum 1*
	EN ISO 10304-3:1997	*Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 3: Determination of chromate, iodide, sulfite, thiocyanate and thiosulfate*
	EN ISO 10304-4:1999	*Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 4: Determination of chlorate, chloride and chlorite in water with low contamination*
	EN ISO 10523:2012	*Water quality - Determination of pH*
	EN ISO 10634:1995	*Water quality - Guidance for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium*
	EN ISO 10695:2000	*Water quality - Determination of selected organic nitrogen and phosphorus compounds - Gas chromatographic methods*
	EN ISO 10705-1:2001	*Water quality - Detection and enumeration of bacteriophages - Part 1: Enumeration of F-specific RNA bacteriophages*
	EN ISO 10705-2:2001	*Water quality - Detection and enumeration of bacteriophages - Part 2: Enumeration of somatic coliphages*
	EN ISO 10707:1997	*Water quality - Evaluation in an aqueous medium of the "ultimate" aerobic biodegradability of organic compounds - Method by analysis of biochemical oxygen demand (closed bottle test)*
	EN ISO 10712:1995	*Water quality - Pseudomonas putida growth inhibition test (pseudomonas cell multiplication inhibition test)*

	EN ISO 10870:2012	*Water quality - Guidelines for the selection of sampling methods and devices for benthic macroinvertebrates in fresh waters (ISO 10870:2012)*
	EN ISO 11348-1:2008	*Water quality - Determination of the inhibitory effect of water samples on the light emission of Vibrio fischeri (Luminescent bacteria test) - Part 1: Method using freshly prepared bacteria*
	EN ISO 11348-2:2008	*Water quality - Determination of the inhibitory effect of water samples on the light emission of Vibrio fischeri (Luminescent bacteria test) - Part 2: Method using liquid-dried bacteria*
	EN ISO 11348-3:2008	*Water quality - Determination of the inhibitory effect of water samples on the light emission of Vibrio fischeri (Luminescent bacteria test) - Part 3: Method using freeze-dried bacteria*
	EN ISO 11369:1997	*Water quality - Determination of selected plant treatment agents - Method using high performance liquid chromatography with UV detection after solid-liquid extraction*
	EN ISO 11731-2:2008	*Water quality - Detection and enumeration of Legionella - Part 2: Direct membrane filtration method for waters with low bacterial counts*
	EN ISO 11732:2005	*Water quality - Determination of ammonium nitrogen - Method by flow analysis (CFA and FIA) and spectrometric detection*
	EN ISO 11733:2004	*Water quality - Determination of the elimination and biodegradability of organic compounds in an aqueous medium - Activated sludge simulation test*
	EN ISO 11734:1998	*Water quality - Evaluation of the "ultimate" anaerobic biodegradability of organic compounds in digested sludge - Method by measurement of the biogas production*
	EN ISO 11885:2009	*Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)*
	EN ISO 11905-1:1998	*Water quality - Determination of nitrogen - Part 1: Method using oxidative digestion with peroxodisulfate*
	EN ISO 11969:1996	*Water quality - Determination of arsenic - Atomic absorption spectrometric method (hydride technique)*
	EN ISO 12020:2000	*Water quality - Determination of aluminium - Atomic absorption spectrometric methods*
	EN ISO 12846:2012	*Water quality - Determination of mercury - Method using atomic absorption spectrometry (AAS) with and without enrichment*
	EN ISO 13395:1996	*Water quality - Determination of nitrite nitrogen and nitrate nitrogen and the sum of both by flow analysis (CFA and FIA) and spectrometric detection*
	EN ISO 14402:1999	*Water quality - Determination of phenol index by flow analysis (FIA and CFA)*
	EN ISO 14403-1:2012	*Water quality - Determination of total cyanide and free cyanide using flow analysis (FIA and CFA) - Part 1: Method using flow injection analysis (FIA)*
	EN ISO 14403-2:2012	*Water quality - Determination of total cyanide and free cyanide using flow analysis (FIA and CFA) - Part 2: Method using continuous flow analysis (CFA)*
	EN ISO 14593:2005	*Water quality - Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium - Method by analysis of inorganic carbon in sealed vessels (CO2 headspace test)*
	EN ISO 14911:1999	*Water quality - Determination of dissolved Li+, Na+, NH4+, K+, Mn2+, Ca2+, Mg2+, Sr2+ and Ba2+ using ion chromatography - Method for water and waste water*
	EN ISO 15061:2001	*Water quality - Determination of dissolved bromate - Method by liquid chromatography of ions*

	EN ISO 15088:2008	*Water quality - Determination of the acute toxicity of waste water to zebrafish eggs (Danio rerio)*
	EN ISO 15586:2003	*Water quality - Determination of trace elements using atomic absorption spectrometry with graphite furnace*
	EN ISO 15587-1:2002	*Water quality - Digestion for the determination of selected elements in water - Part 1: Aqua regia digestion*
	EN ISO 15587-2:2002	*Water quality - Digestion for the determination of selected elements in water - Part 2: Nitric acid digestion*
	EN ISO 15680:2003	*Water quality - Gas-chromatographic determination of a number of monocyclic aromatic hydrocarbons, naphthalene and several chlorinated compounds using purge-and-trap and thermal desorption*
	EN ISO 15681-1:2004	*Water quality - Determination of orthophosphate and total phosphorus contents by flow analysis (FIA and CFA) - Part 1: Method by flow injection analysis (FIA)*
	EN ISO 15681-2:2004	*Water quality - Determination of orthophosphate and total phosphorus contents by flow analysis (FIA and CFA) - Part 2: Method by continuous flow analysis (CFA)*
	EN ISO 15682:2001	*Water quality - Determination of chloride by flow analysis (CFA and FIA) and photometric or potentiometric detection*
	EN ISO 15839:2006	*Water quality - On-line sensors/analysing equipment for water - Specifications and performance tests*
	EN ISO 15913:2003	*Water quality - Determination of selected phenoxyalkanoic herbicides, including bentazones and hydroxybenzonitriles by gas chromatography and mass spectrometry after solid phase extraction and derivatization*
	EN ISO 16264:2004	*Water quality - Determination of soluble silicates by flow analysis (FIA and CFA) and photometric detection*
	EN ISO 16265:2012	*Water quality - Determination of the methylene blue active substances (MBAS) index - Method using continuous flow analysis (CFA)*
	EN ISO 16266:2008	*Water quality - Detection and enumeration of Pseudomonas aeruginosa - Method by membrane filtration*
	EN ISO 16588:2003	*Water quality - Determination of six complexing agents - Gas-chromatographic method*
	EN ISO 16588:2003/A1 :2005	*Water quality - Determination of six complexing agents - Gas-chromatographic method*
	EN ISO 16665:2005	*Water quality - Guidelines for quantitative sampling and sample processing of marine soft-bottom macrofauna*
	EN ISO 16712:2006	*Water quality - Determination of acute toxicity of marine or estuarine sediment to amphipods*
	EN ISO 17294-1:2006	*Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 1: General guidelines*
	EN ISO 17294-2:2004	*Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2: Determination of 62 elements*
	EN ISO 17353:2005	*Water quality - Determination of selected organotin compounds - Gas chromatographic method*
	EN ISO 17495:2003	*Water quality - Determination of selected nitrophenols - Method by solid-phase extraction and gas chromatography with mass spectrometric detection*
	EN ISO 17852:2008	*Water quality - Determination of mercury - Method using atomic fluorescence spectrometry*

	EN ISO 17993:2003	*Water quality - Determination of 15 polycyclic aromatic hydrocarbons (PAH) in water by HPLC with fluorescence detection after liquid-liquid extraction*
	EN ISO 17994:2004	*Water quality - Criteria for establishing equivalence between microbiological methods*
	EN ISO 18412:2006	*Water quality - Determination of chromium(VI) - Photometric method for weakly contaminated water*
	EN ISO 18856:2005	*Water quality - Determination of selected phthalates using gas chromatography/mass spectrometry*
	EN ISO 18857-1:2006	*Water quality - Determination of selected alkylphenols - Part 1: Method for non-filtered samples using liquid-liquid extraction and gas chromatography with mass selective detection*
	EN ISO 18857-2:2011	*Water quality - Determination of selected alkylphenols - Part 2: Gas chromatographic-mass spectrometric determination of alkylphenols, their ethoxylates and bisphenol A in non-filtered samples following solid-phase extraction and derivatisation*
	EN ISO 19458:2006	*Water quality - Sampling for microbiological analysis*
	EN ISO 19493:2007	*Water quality - Guidance on marine biological surveys of hard-substrate communities*
	EN ISO 20079:2006	*Water quality - Determination of the toxic effect of water constituents and waste water on duckweed (Lemna minor) - Duckweed growth inhibition test*
	EN ISO 21427-2:2009	*Water quality - Evaluation of genotoxicity by measurement of the induction of micronuclei - Part 2: Mixed population method using the cell line V79*
	EN ISO 21427-2:2009/AC:2009	*Water quality - Evaluation of genotoxicity by measurement of the induction of micronuclei - Part 2: Mixed population method using the cell line V79*
	EN ISO 22032:2009	*Water quality - Determination of selected polybrominated diphenyl ethers in sediment and sewage sludge - Method using extraction and gas chromatography/mass spectrometry*
	EN ISO 22478:2006	*Water quality - Determination of certain explosives and related compounds - Method using high-performance liquid chromatography (HPLC) with UV detection*
	EN ISO 23631:2006	*Water quality - Determination of dalapon, trichloroacetic acid and selected haloacetic acids - Method using gas chromatography (GC-ECD and/or GC-MS detection) after liquid-liquid extraction and derivatization*
	EN ISO 23631:2006/AC:2007	*Water quality - Determination of dalapon, trichloroacetic acid and selected haloacetic acids - Method using gas chromatography (GC-ECD and/or GC-MS detection) after liquid-liquid extraction and derivatization*
	EN ISO 23913:2009	*Water quality - Determination of chromium(VI) - Method using flow analysis (FIA and CFA) and spectrometric detection*
	EN ISO 5667-1:2006	*Water quality - Sampling - Part 1: Guidance on the design of sampling programmes and sampling techniques*
	EN ISO 5667-1:2006/AC:2007	*Water quality - Sampling - Part 1: Guidance on the design of sampling programmes and sampling techniques*
	EN ISO 5667-16:1998	*Water quality - Sampling - Part 16: Guidance on biotesting of samples*
	EN ISO 5667-19:2004	*Water quality - Sampling - Part 19: Guidance on sampling in marine sediments*

	EN ISO 5667-23:2011	*Water quality - Sampling - Part 23: Guidance on passive sampling in surface waters*
	EN ISO 5667-3:2012	*Water quality - Sampling - Part 3: Preservation and handling of water samples*
	EN ISO 5814:2012	*Water quality - Determination of dissolved oxygen - Electrochemical probe method*
	EN ISO 5961:1995	*Water quality - Determination of cadmium by atomic absorption spectrometry*
	EN ISO 6222:1999	*Water quality - Enumeration of culturable micro-organisms - Colony count by inoculation in a nutrient agar culture medium*
	EN ISO 6341:2012	*Water quality - Determination of the inhibition of the mobility of Daphnia magna Straus (Cladocera, Crustacea) - Acute toxicity test*
	EN ISO 6468:1996	*Water quality - Determination of certain organochlorine insecticides, polychlorinated biphenyls and chlorobenzenes - Gas chromatographic method after liquid-liquid extraction*
	EN ISO 6878:2004	*Water quality - Determination of phosphorus - Ammonium molybdate spectrometric method*
	EN ISO 7027:1999	*Water quality - Determination of turbidity*
	EN ISO 7346-1:1997	*Water quality - Determination of the acute lethal toxicity of substances to a freshwater fish (Brachydanio rerio Hamilton-Buchanan (Teleostei, Cyprinidae)) - Part 1: Static method*
	EN ISO 7346-2:1997	*Water quality - Determination of the acute lethal toxicity of substances to a freshwater fish (Brachydanio rerio Hamilton-Buchanan (Teleostei, Cyprinidae)) - Part 2: Semi-static method*
	EN ISO 7346-3:1997	*Water quality - Determination of the acute lethal toxicity of substances to a freshwater fish (Brachydanio rerio Hamilton-Buchanan (Teleostei, Cyprinidae)) - Part 3: Flow-through method*
	EN ISO 7393-1:2000	*Water quality - Determination of free chlorine and total chlorine - Part 1: Titrimetric method using N, N-diethyl-1,4-phenylenediamine*
	EN ISO 7393-2:2000	*Water quality - Determination of free chlorine and total chlorine - Part 2: Colorimetric method using N, N-diethyl-1, 4-phenylenediamine, for routine control purposes*
	EN ISO 7393-3:2000	*Water quality - Determination of free chlorine and total chlorine - Part 3: Iodometric titration method for the determination of total chlorine*
	EN ISO 7827:2012	*Water quality - Evaluation of the "ready", "ultimate" aerobic biodegradability of organic compounds in an aqueous medium - Method by analysis of dissolved organic carbon (DOC)*
	EN ISO 7887:2011	*Water quality - Examination and determination of colour*
	EN ISO 7899-1:1998	*Water quality - Detection and enumeration of intestinal enterococci in surface and wastewater - Part 1: Miniaturized method (Most Probable Number) by inoculation in liquid medium*
	EN ISO 7899-1:1998/AC:2000	*Water quality - Detection and enumeration of intestinal enterococci in surface and wastewater - Part 1: Miniaturized method (Most Probable Number) by inoculation in liquid medium*
	EN ISO 7899-2:2000	*Water quality - Detection and enumeration of intestinal enterococci - Part 2: Membrane filtration method*
	EN ISO 7980:2000	*Water quality - Determination of calcium and magnesium - Atomic absorption spectrometric method*
	EN ISO 8192:2007	*Water quality - Test for inhibition of oxygen consumption by activated sludge for carbonaceous and ammonium oxidation*

	EN ISO 8199:2007	*Water quality - General guidance on the enumeration of micro-organisms by culture*
	EN ISO 8467:1995	*Water quality - Determination of permanganate index*
	EN ISO 8689-1:2000	*Water quality - Biological classification of rivers - Part 1: Guidance on the interpretation of biological quality data from surveys of benthic macroinvertebrates*
	EN ISO 8689-2:2000	*Water quality - Biological classification of rivers - Part 2: Guidance on the presentation of biological quality data from surveys of benthic macroinvertebrates*
	EN ISO 8692:2012	*Water quality - Fresh water algal growth inhibition test with unicellular green algae*
	EN ISO 9308-1:2000	*Water quality - Detection and enumeration of Escherichia coli and coliform bacteria - Part 1: Membrane filtration method*
	EN ISO 9308-1:2000/AC:2008	*Water quality - Detection and enumeration of Escherichia coli and coliform bacteria - Part 1: Membrane filtration method*
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	EN ISO 12782-3:2012	Soil quality - Parameters for geochemical modelling of leaching and speciation of constituents in soils and materials - Part 3: Extraction of aluminium oxides and hydroxides with ammonium oxalate/oxalic acid (ISO 12782-3:2012)
	EN ISO 12782-4:2012	Soil quality - Parameters for geochemical modelling of leaching and speciation of constituents in soils and materials - Part 4: Extraction of humic substances from solid samples (ISO 12782-4:2012)
	EN ISO 12782-5:2012	Soil quality - Parameters for geochemical modelling of leaching and speciation of constituents in soils and materials - Part 5: Extraction of humic substances from aqueous samples (ISO 12782-5:2012)
	EN ISO 14240-1:2011	Soil quality - Determination of soil microbial biomass - Part 1: Substrate-induced respiration method (ISO 14240-1:1997)
	EN ISO 14240-2:2011	Soil quality - Determination of soil microbial biomass - Part 2: Fumigation-extraction method (ISO 14240-2:1997)
	EN ISO 14254:2011	Soil quality - Determination of exchangeable acidity in barium chloride extracts (ISO 14254:2001)
	EN ISO 15175:2011	Soil quality - Characterization of soil related to groundwater protection (ISO 15175:2004)
	EN ISO 15952:2011	Soil quality - Effects of pollutants on juvenile land snails (Helicidae) - Determination of the effects on growth by soil contamination (ISO 15952:2006)
	EN ISO 16072:2011	Soil quality - Laboratory methods for determination of microbial soil respiration (ISO 16072:2002)
	EN ISO 16133:2011	Soil quality - Guidance on the establishment and maintenance of monitoring programmes (ISO 16133:2004)
	EN ISO 16703:2011	Soil quality - Determination of content of hydrocarbon in the range C10 to C40 by gas chromatography (ISO 16703:2004)
	EN ISO 17402:2011	Soil quality - Requirements and guidance for the selection and application of methods for the assessment of bioavailability of contaminants in soil and soil materials (ISO 17402:2008)
	EN ISO 19258:2011	Soil quality - Guidance on the determination of background values (ISO 19258:2005)
	EN ISO 20963:2011	Soil quality - Effects of pollutants on insect larvae (Oxythyrea funesta) - Determination of acute toxicity (ISO 20963:2005)
	EN ISO 22030:2011	Soil quality - Biological methods - Chronic toxicity in higher plants (ISO 22030:2005)
	EN ISO 22155:2013	Soil quality - Gas chromatographic determination of volatile aromatic and halogenated hydrocarbons and selected ethers - Static headspace method (ISO 22155:2011)
	EN ISO 22892:2011	Soil quality - Guidelines for the identification of target compounds by gas chromatography and mass spectrometry (ISO 22892:2006)
	EN ISO 23470:2011	Soil quality - Determination of effective cation exchange capacity (CEC) and exchangeable cations using a hexamminecobalt trichloride solution (ISO 23470:2007)
	EN ISO 23611-1:2011	Soil quality - Sampling of soil invertebrates - Part 1: Hand-sorting and formalin extraction of earthworms (ISO 23611-1:2006)

	EN ISO 23611-2:2011	Soil quality - Sampling of soil invertebrates - Part 2: Sampling and extraction of micro-arthropods (Collembola and Acarina) (ISO 23611-2:2006)
	EN ISO 23611-3:2011	Soil quality - Sampling of soil invertebrates - Part 3: Sampling and soil extraction of enchytraeids (ISO 23611-3:2007)
	EN ISO 23611-4:2011	Soil quality - Sampling of soil invertebrates - Part 4: Sampling, extraction and identification of soil-inhabiting nematodes (ISO 23611-4:2007)
	EN ISO 23611-5:2013	Soil quality - Sampling of soil invertebrates - Part 5: Sampling and extraction of soil macro-invertebrates (ISO 23611-5:2011)
	EN ISO 23753-1:2011	Soil Quality - Determination of dehydrogenase activity in soil - Part 1: Method using triphenyltetrazolium chloride (TTC) (ISO 23753-1:2005)
	EN ISO 23753-2:2011	Soil Quality - Determination of dehydrogenase activity in soils - Part 2: Method using iodotetrazolium chloride (INT) (ISO 23753-2:2005)
	EN ISO 25177:2011	Soil quality - Field soil description (ISO 25177:2008)
CENTC 292 Characterisation of waste	CEN/TR 14589:2003	Characterization of waste - State of the art document - Chromium VI specification in solid matrices
	CEN/TR 15018:2005	Characterization of waste - Digestion of waste samples using alkali-fusion techniques
	CEN/TR 15310-1:2006	Characterization of waste - Sampling of waste materials - Part 1: Guidance on selection and application of criteria for sampling under various conditions
	CEN/TR 15310-2:2006	Characterization of waste - Sampling of waste materials - Part 2: Guidance on sampling techniques
	CEN/TR 15310-3:2006	Characterization of waste - Sampling of waste materials - Part 3: Guidance on procedures for sub-sampling in the field
	CEN/TR 15310-4:2006	Characterization of waste - Sampling of waste materials - Part 4: Guidance on procedures for sample packaging, storage, preservation, transport and delivery
	CEN/TR 15310-5:2006	Characterization of waste - Sampling of waste materials - Part 5: Guidance on the process of defining the sampling plan
	CEN/TR 16110:2010	Characterization of waste - Guidance on the use of ecotoxicity tests applied to waste
	CEN/TR 16130:2011	Characterization of waste - On-site verification
	CEN/TR 16176:2011	Characterization of waste - Screening methods for elemental composition by X-ray fluorescence spectrometry for on-site verification
	CEN/TR 16184:2011	Characterization of Waste - State-of-the-art document - Analysis of eluates
	CEN/TR 16363:2012	Characterization of waste - Kinetic testing for assessing acid generation potential of sulfidic waste from extractive industries
	CEN/TR 16365:2012	Characterization of waste - Sampling of waste from extractive industries
	CEN/TR 16376:2012	Characterization of waste - Overall guidance document for characterization of waste from the extractive industries
	CEN/TS 14405:2004	Characterization of waste - Leaching behaviour tests - Up-flow percolation test (under specified conditions)
	CEN/TS 14429:2005	Characterization of waste - Leaching behaviour tests - Influence of pH on leaching with initial acid/base addition
	CEN/TS 14997:2006	Characterization of waste - Leaching behaviour tests - Influence of pH on leaching with continuous pH-control
	CEN/TS 15364:2006	Characterization of waste - Leaching behaviour tests - Acid and base neutralization capacity test
	CEN/TS 15862:2012	Characterisation of waste - Compliance leaching test - One stage batch leaching test for monoliths at fixed liquid to surface area ratio (L/A) for test portions with fixed minimum dimensions
	CEN/TS 15863:2012	Characterisation of waste - Leaching behaviour test for basic characterisation - Dynamic monolithic leaching test with periodic leachant renewal, under fixed test conditions
	CEN/TS 15864:2012	Characterisation of waste - Leaching behaviour test for basic characterisation - Dynamic monolithic leaching test with continuous

		leachant renewal under conditions relevant for specified scenario(s)
	CEN/TS 16229:2011	Characterization of waste - Sampling and analysis of weak acid dissociable cyanide discharged into tailings ponds
	EN 12457-1:2002	Characterisation of waste - Leaching - Compliance test for leaching of granular waste materials and sludges - Part 1: One stage batch test at a liquid to solid ratio of 2 l/kg for materials with high solid content and with particle size below 4 mm (without or with size reduction)
	EN 12457-2:2002	Characterisation of waste - Leaching - Compliance test for leaching of granular waste materials and sludges - Part 2: One stage batch test at a liquid to solid ratio of 10 l/kg for materials with particle size below 4 mm (without or with size reduction)
	EN 12457-3:2002	Characterisation of waste - Leaching - Compliance test for leaching of granular waste materials and sludges - Part 3: Two stage batch test at a liquid to solid ratio of 2 l/kg and 8 l/kg for materials with high solid content and with particle size below 4 mm (without or with size reduction)
	EN 12457-4:2002	Characterisation of waste - Leaching - Compliance test for leaching of granular waste materials and sludges - Part 4: One stage batch test at a liquid to solid ratio of 10 l/kg for materials with particle size below 10 mm (without or with size reduction)
	EN 12920:2006+A 1:2008	Characterization of waste - Methodology for the determination of the leaching behaviour of waste under specified conditions
	EN 13137:2001	Characterization of waste - Determination of total organic carbon (TOC) in waste, sludges and sediments
	EN 13656:2002	Characterization of waste - Microwave assisted digestion with hydrofluoric (HF), nitric (HNO3) and hydrochloric (HCl) acid mixture for subsequent determination of elements
	EN 13657:2002	Characterization of waste - Digestion for subsequent determination of aqua regia soluble portion of elements
	EN 13965-1:2004	Characterization of waste - Terminology - Part 1: Material related terms and definitions
	EN 13965-2:2010	Characterization of waste - Terminology - Part 2: Management related terms and definitions
	EN 14039:2004	Characterization of waste - Determination of hydrocarbon content in the range of C10 to C40 by gas chromatography
	EN 14345:2004	Characterization of waste - Determination of hydrocarbon content by gravimetry
	EN 14346:2006	Characterization of waste - Calculation of dry matter by determination of dry residue or water content
	EN 14582:2007	Characterization of waste - Halogen and sulfur content - Oxygen combustion in closed systems and determination methods
	EN 14735:2005	Characterization of waste - Preparation of waste samples for ecotoxicity tests
	EN 14735:2005/AC :2006	Characterization of waste - Preparation of waste samples for ecotoxicity tests
	EN 14899:2005	Characterization of waste - Sampling of waste materials - Framework for the preparation and application of a Sampling Plan
	EN 15002:2006	Characterization of waste - Preparation of test portions from the laboratory sample
	EN 15169:2007	Characterization of waste - Determination of loss on ignition in waste, sludge and sediments
	EN 15192:2006	Characterisation of waste and soil - Determination of Chromium(VI) in solid material by alkaline digestion and ion chromatography with spectrophotometric detection
	EN 15216:2007	Characterization of waste - Determination of total dissolved solids (TDS) in water and eluates
	EN 15308:2008	Characterization of waste - Determination of selected polychlorinated biphenyls (PCB) in solid waste by using capillary gas chromatography with electron capture or mass spectrometric detection
	EN 15309:2007	Characterization of waste and soil - Determination of elemental composition by X-ray fluorescence
	EN 15527:2008	Characterization of waste - Determination of polycyclic aromatic hydrocarbons (PAH) in waste using gas chromatography mass

		spectrometry (GC/MS)
	EN 15875:2011	Characterization of waste - Static test for determination of acid potential and neutralisation potential of sulfidic waste
	EN 15875:2011/AC :2012	Characterization of waste - Static test for determination of acid potential and neutralisation potential of sulfidic waste
	EN 16123:2013	Characterization of waste - Guidance on selection and application of screening methods
	EN 16192:2011	Characterization of waste - Analysis of eluates
CEN TC 308 Characterization of sludges	CEN/TR 13097:2010	Characterization of sludges - Good practice for sludge utilisation in agriculture
	CEN/TR 13714:2010	Characterization of sludges - Sludge management in relation to use or disposal
	CEN/TR 13767:2004	Characterisation of sludges - Good practice for sludges incineration with and without grease and screenings
	CEN/TR 13768:2004	Characterisation of sludges - Good practice for combined incineration of sludges and household wastes
	CEN/TR 13983:2003	Characterizataion of sludges - Good practice for sludge utilisation in land reclamation
	CEN/TR 14742:2006	Characterization of sludges - Laboratory chemical conditioning procedure
	CEN/TR 15126:2005	Characterization of sludges - Good practice for landfilling of sludges and sludge treatment residues
	CEN/TR 15175:2006	Characterization of sludges - Protocol for organizing and conducting inter-laboratory tests of methods for chemical and microbiological analysis of sludges
	CEN/TR 15214-1:2006	Characterization of sludges - Detection and enumeration of Escherichia coli in sludges, soils, soil improvers, growing media and biowastes - Part 1: Membrane filtration method for quantification
	CEN/TR 15214-2:2006	Characterization of sludges - Detection and enumeration of Escherichia coli in sludges, soils, soil improvers, growing media and biowastes - Part 2: Miniaturised method (Most Probable Number) by inoculation in liquid medium
	CEN/TR 15214-3:2006	Characterization of sludges - Detection and enumeration of Escherichia coli in sludges, soils, soil improvers, growing media and biowastes - Part 3: Macromethod (Most Probable Number) in liquid medium
	CEN/TR 15215-1:2006	Characterization of sludges - Detection and enumeration of Salmonella spp. in sludges, soils, soil improvers, growing media and biowastes - Part 1: Membrane filtration method for quantitative resuscitation of sub-lethally stressed bacteria (to confirm efficacy of log drop treatment procedures)
	CEN/TR 15215-2:2006	Characterization of sludges - Detection and enumeration of Salmonella spp. in sludges, soils, soil improvers, growing media and biowastes - Part 2: Liquid enrichment method in selenite-cystine medium followed by Rapport-Vassiliadis for semi-quantitative Most Probable Number (MPN) determination
	CEN/TR 15215-3:2006	Characterization of sludges - Detection and enumeration of Salmonella spp. in sludges, soils, soil improvers, growing media and biowastes - Part 3: Presence/absence method by liquid enrichment in peptone-novobiocin medium followed by Rapport-Vassiliadis
	CEN/TR 15252:2006	Characterization of sludges - Protocol for validating methods for physical properties of sludges
	CEN/TR 15463:2007	Characterization of sludges - Physical consistency - Thixotropic behaviour and piling behaviour
	CEN/TR 15473:2007	Characterization of sludges - Good practice for sludges drying
	CEN/TR 15584:2007	Characterisation of sludges - Guide to risk assessment especially in relation to use and disposal of sludges

	CEN/TR 15809:2008	Characterization of sludges - Hygienic aspects - Treatments
	CR 13846:2000	Recommendations to preserve and extend sludge utilization and disposal routes
	EN 12176:1998	Characterization of sludge - Determination of pH-value
	EN 12832:1999	Characterization of sludges - Utilization and disposal of sludges - Vocabulary
	EN 12879:2000	Characterization of sludges - Determination of the loss on ignition of dry mass
	EN 12880:2000	Characterization of sludges - Determination of dry residue and water content
	EN 13342:2000	Characterization of sludges - Determination of Kjeldahl nitrogen
	EN 13346:2000	Characterization of sludges - Determination of trace elements and phosphorus - Aqua regia extraction methods
	EN 14671:2006	Characterization of sludges - Pre-treatment for the determination of extractable ammonia using 2 mol/l potassium chloride
	EN 14672:2005	Characterization of sludges - Determination of total phosphorus
	EN 14701-1:2006	Characterisation of sludges - Filtration properties - Part 1: Capillary suction time (CST)
	EN 14701-2:2006	Characterization of sludges - Filtration properties - Part 2: Determination of the specific resistance to filtration
	EN 14701-3:2006	Characterization of sludges - Filtration properties - Part 3: Determination of the compressibility
	EN 14701-4:2010	Characterization of sludges - Filtration properties - Part 4: Determination of the drainability of flocculated sludges
	EN 14702-1:2006	Characterisation of sludges - Settling properties - Part 1: Determination of settleability (Determination of the proportion of sludge volume and sludge volume index)
	EN 14702-2:2006	Characterisation of sludges - Settling properties - Part 2: Determination of thickenability
	EN 15170:2008	Characterization of sludges - Determination of calorific value
	EN ISO 16720:2007	Soil quality - Pretreatment of samples by freeze-drying for subsequent analysis (ISO 16720:2005)
	EN ISO 23161:2011	Soil quality - Determination of selected organotin compounds - Gas-chromatographic method (ISO 23161:2009)
	EN ISO 5667-13:2011	Water quality - Sampling - Part 13: Guidance on sampling of sludges (ISO 5667-13:2011)
	EN ISO 5667-15:2009	Water quality - Sampling - Part 15: Guidance on the preservation and handling of sludge and sediment samples (ISO 5667-15:2009)
CEN TC 400: Horizontal standards in the fields of sludge, biowaste and soil	CEN/TS 16170:2012	Sludge, treated biowaste and soil - Determination of elements using inductively coupled plasma optical emission spectrometry (ICP-OES)
	CEN/TS 16171:2012	Sludge, treated biowaste and soil - Determination of elements using inductively coupled plasma mass spectrometry (ICP-MS)
	CEN/TS 16172:2013	Sludge, treated biowaste and soil - Determination of elements using graphite furnace atomic absorption spectrometry (GF-AAS)
	CEN/TS 16175-1:2013	Sludge, treated biowaste and soil - Determination of mercury - Part 1: Cold-vapour atomic absorption spectrometry (CV-AAS)
	CEN/TS 16175-2:2013	Sludge, treated biowaste and soil - Determination of mercury - Part 2: Cold-vapour atomic fluorescence spectrometry (CV-AFS)
	CEN/TS 16177:2012	Sludge, treated biowaste and soil - Extraction for the determination of extractable ammonia, nitrate and nitrite
	CEN/TS 16178:2012	Sludge, treated biowaste and soil - Determination of pharmaceutical products
	CEN/TS 16182:2012	Sludge treated biowaste and soil - Determination of nonylphenols (NP) and nonylphenol-mono- and diethoxylates using gas chromatography with mass selective detection (GC-MS)

	CEN/TS 16183:2012	Sludge, treated biowaste and soil - Determination of selected phthalates using capillary gas chromatography with mass spectrometric detection (GC-MS)
	CEN/TS 16188:2012	Sludge, treated biowaste and soil - Determination of elements in aqua regia and nitric acid digests - Flame atomic absorption spectrometry method (FAAS)
	CEN/TS 16189:2012	Sludge, treated biowaste and soil - Determination of linear alkylbenzene sulfonates (LAS) by high-performance liquid chromatography (HPLC) with fluorescence detection (FLD) or mass selective detection (MS)
	CEN/TS 16190:2012	Sludge, treated biowaste and soil - Determination of dioxins and furans and dioxin-like polychlorinated biphenyls by gas chromatography with high resolution mass selective detection (HR GC-MS)
	EN 15933:2012	Sludge, treated biowaste and soil - Determination of pH
	EN 15934:2012	Sludge, treated biowaste, soil and waste - Calculation of dry matter fraction after determination of dry residue or water content
	EN 15935:2012	Sludge, treated biowaste, soil and waste - Determination of loss on ignition
	EN 15936:2012	Sludge, treated biowaste, soil and waste - Determination of total organic carbon (TOC) by dry combustion
	EN 16166:2012	Sludge, treated biowaste and soil - Determination of adsorbable organically bound halogens (AOX)
	EN 16167:2012	Sludge, treated biowaste and soil - Determination of polychlorinated biphenyls (PCB) by gas chromatography with mass selective detection (GC-MS) and gas chromatography with electron-capture detection (GC-ECD)
	EN 16168:2012	Sludge, treated biowaste and soil - Determination of total nitrogen using dry combustion method
	EN 16169:2012	Sludge, treated biowaste and soil - Determination of Kjeldahl nitrogen
	EN 16173:2012	Sludge, treated biowaste and soil - Digestion of nitric acid soluble fractions of elements
	EN 16174:2012	Sludge, treated biowaste and soil - Digestion of aqua regia soluble fractions of elements
	EN 16179:2012	Sludge, treated biowaste and soil - Guidance for sample pretreatment
CEN TC 137 Assessment of workplace exposure to chemical and biological agents	CEN/TR 15230:2005	Workplace atmospheres - Guidance for sampling of inhalable, thoracic and respirable aerosol fractions
	CEN/TR 15278:2006	Workplace exposure - Strategy for the evaluation of dermal exposure
	CEN/TR 15547:2007	Workplace atmospheres - Calculation of the health-related aerosol fraction concentration from the concentration measured by a sampler with known performance characteristics
	CEN/TR 16013-1:2010	Workplace exposure - Guide for the use of direct-reading instruments for aerosol monitoring - Part 1: Choice of monitor for specific applications
	CEN/TR 16013-2:2010	Workplace exposure - Guide for the use of direct-reading instruments for aerosol monitoring - Part 2: Evaluation of airborne particle concentrations using Optical Particle Counters
	CEN/TR 16013-3:2012	Workplace exposure - Guide for the use of direct-reading instruments for aerosol monitoring - Part 3: Evaluation of airborne particle concentrations using photometers
	CEN/TS 15279:2006	Workplace exposure - Measurement of dermal exposure - Principles and methods
	CR 13841:2000	Workplace atmospheres - Scientific basis to describe the influence of the reference period on the presentation of exposure data
	EN 1076:2009	Workplace exposure - Procedures for measuring gases and vapours using pumped samplers - Requirements and test methods

	EN 1231:1996	Workplace atmospheres - Short term detector tube measurement systems - Requirements and test methods
	EN 1232:1997	Workplace atmospheres - Pumps for personal sampling of chemical agents - Requirements and test methods
	EN 12919:1999	Workplace atmospheres - Pumps for the sampling of chemical agents with a volume flow rate of over 5 l/min - Requirements and test methods
	EN 13098:2000	Workplace atmosphere - Guidelines for measurement of airborne micro-organisms and endotoxin
	EN 13205:2001	Workplace atmospheres - Assessment of performance of instruments for measurement of airborne particle concentrations
	EN 13890:2009	Workplace exposure - Procedures for measuring metals and metalloids in airborne particles - Requirements and test methods
	EN 14031:2003	Workplace atmospheres - Determination of airborne endotoxins
	EN 14042:2003	Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents
	EN 14530:2004	Workplace atmospheres - Determination of diesel particulate matter - General requirements
	EN 14583:2004	Workplace atmospheres - Volumetric bioaerosol sampling devices - Requirements and test methods
	EN 15051:2006	Workplace atmospheres - Measurement of the dustiness of bulk materials - Requirements and reference test methods
	EN 1540:2011	Workplace exposure - Terminology
	EN 481:1993	Workplace atmospheres - Size fraction definitions for measurement of airborne particles
	EN 482:2012	Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents
	EN 689:1995	Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy
	EN 838:2010	Workplace exposure - Procedures for measuring gases and vapours using diffusive samplers - Requirements and test methods
	EN ISO 13138:2012	Air quality - Sampling conventions for airborne particle deposition in the human respiratory system (ISO 13138:2012)
	EN ISO 28439:2011	Workplace atmospheres - Characterization of ultrafine aerosols/nanoaerosols - Determination of the size distribution and number concentration using differential electrical mobility analysing systems (ISO 28439:2011)
CEN TC 275 Food analysis – Horizontal methods	CEN ISO/TS 10272-3:2010	Microbiology of food and animal feeding stuffs - Horizontal method for detection and enumeration of Campylobacter spp. - Part 3: Semi-quantitative method (ISO/TS 10272-3:2010)
	CEN ISO/TS 10272-3:2010/AC:2011	Microbiology of food and animal feeding stuffs - Horizontal method for detection and enumeration of Campylobacter spp. - Part 3: Semi-quantitative method - Technical Corrigendum 1 (ISO/TS 10272-3:2010/Cor 1:2011)
	CEN ISO/TS 11133-1:2009	Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory (ISO/TS 11133-1:2009)
	CEN ISO/TS 11133-2:2003	Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 2: Practical guidelines on performance testing of culture media (ISO/TS 11133-2:2003)
	CEN ISO/TS 11133-2:2003/A1:2011	Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 2: Practical guidelines on performance testing of culture media - Amendment 1: Test microorganisms for commonly used culture media (ISO/TS 11133-2:2003/AMD 1:2011)

	CEN ISO/TS 13136:2012	Microbiology of food and animal feed - Real-time polymerase chain reaction (PCR)-based method for the detection of food-borne pathogens - Horizontal method for the detection of Shiga toxin-producing Escherichia coli (STEC) and the determination of O157, O111, O26, O103 and O145 serogroups (ISO/TS 13136:2012)
	CEN ISO/TS 20836:2005	Microbiology of food and animal feeding stuffs - Polymerase chain reaction (PCR) for the detection of food-borne pathogens - Performance testing for thermal cyclers (ISO/TS 20836:2005)
	CEN ISO/TS 22117:2010	Microbiology of food and animal feeding stuffs - Specific requirements and guidance for proficiency testing by interlaboratory comparison (ISO/TS 22117:2010)
	CEN ISO/TS 6579-2:2012	Microbiology of food and animal feed - Horizontal method for the detection, enumeration and serotyping of Salmonella - Part 2: Enumeration by a miniaturized most probable number technique (ISO/TS 6579-2:2012)
	CEN/TR 15298:2006	Foodstuffs - Sample comminution for mycotoxins analysis - Comparison between dry milling and slurry mixing
	CEN/TR 15641:2007	Food analysis - Determination of pesticide residues by LC-MS/MS - Tandem mass spectrometric parameters
	CEN/TR 16059:2010	Food analysis - Performance criteria for single laboratory validated methods of analysis for the determination of mycotoxins
	CEN/TR 16338:2012	Foodstuffs - Detection of food allergens - Template for supplying information about immunological methods and molecular biological methods
	CEN/TS 14537:2003	Foodstuffs - Determination of neohesperidin-dihydrochalcon
	CEN/TS 15568:2006	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Sampling strategies
	CEN/TS 15606:2009	Foodstuffs - Determination of acesulfame-K, aspartame, neohesperidine-dihydrochalcone and saccharin - High performance liquid chromatographic method
	CEN/TS 15633-3:2012	Foodstuffs - Detection of food allergens by immunological methods - Part 3: Quantitative determination of hazelnut with an enzyme immunoassay using polyclonal antibodies and Lowry protein detection
	CEN/TS 15634-2:2012	Foodstuffs - Detection of food allergens by molecular biological methods - Part 2: Celery (Apium graveolens) - Qualitative determination of a specific DNA sequence in cooked sausages by real-time PCR
	CEN/TS 16187:2011	Foodstuffs - Determination of fumonisin B1 and fumonisin B2 in processed maize containing foods for infants and young children - HPLC method with immunoaffinity column cleanup and fluorescence detection after precolumn derivatization
	CEN/TS 16233-1:2011	Foodstuffs - HPLC method for the determination of xanthophylls in fish flesh - Part 1: Determination of astaxanthin and canthaxanthin
	CEN/TS 16233-2:2011	Foodstuffs - HPLC method for the determination of xanthophylls in fish flesh - Part 2: Identification of the enantiomer ratio of astaxanthin
	CR 13505:1999	Food analysis - Biotoxins - Criteria of analytical methods of mycotoxins
	EN 12014-1:1997	Foodstuffs - Determination of nitrate and/or nitrite content - Part 1: General considerations
	EN 12014-1:1997/A1:1999	Foodstuffs - Determination of nitrate and/or nitrite content - Part 1: General considerations

	EN 12014-2:1997	Foodstuffs - Determination of nitrate and/or nitrite content - Part 2: HPLC/IC method for the determination of nitrate content of vegetables and vegetable products
	EN 12014-3:2005	Foodstuffs - Determination of nitrate and/or nitrite content - Part 3: Spectrometric determination of nitrate and nitrite content of meat products after enzymatic reduction of nitrate to nitrite
	EN 12014-4:2005	Foodstuffs - Determination of nitrate and/or nitrite content - Part 4: Ion-exchange chromatographic (IC) method for the determination of nitrate and nitrite content of meat products
	EN 12014-5:1997	Foodstuffs - Determination of nitrate and/or nitrite content - Part 5: Enzymatic determination of nitrate content of vegetable-containing food for babies and infants
	EN 12014-7:1998	Foodstuffs - Determination of nitrate and/or nitrite content - Part 7: Continuous flow method for the determination of nitrate content of vegetables and vegetable products after Cadmium reduction
	EN 12393-1:2008	Foods of plant origin - Multiresidue methods for the gas chromatographic determination of pesticide residues - Part 1: General considerations
	EN 12393-2:2008	Foods of plant origin - Multiresidue methods for the gas chromatographic determination of pesticide residues - Part 2: Methods for extraction and cleanup
	EN 12393-3:2008	Foods of plant origin - Multiresidue methods for the gas chromatographic determination of pesticide residues - Part 3: Determination and confirmatory tests
	EN 12396-1:1998	Non-fatty foods - Determination of dithiocarbamate and thiuram disulfide residues - Part 1: Spectrometric method
	EN 12396-2:1998	Non-fatty foods - Determination of dithiocarbamate and thiuram disulfide residues - Part 2: Gas chromatographic method
	EN 12396-3:2000	Non-fatty foods - Determination of dithiocarbamate and thiuram disulfide residues - Part 3: UV spectrometric xanthogenate method
	EN 12821:2009	Foodstuffs - Determination of vitamin D by high performance liquid chromatography - Measurement of cholecalciferol (D3) or ergocalciferol (D2)
	EN 12822:2000	Foodstuffs - Determination of vitamin E by high performance liquid chromatography - Measurement of alpha-, beta-, gamma-, and delta-tocopherols
	EN 12823-1:2000	Foodstuffs - Determination of vitamin A by high performance liquid chromatography - Part 1: Measurements of all-trans-retinol and 13-cis-retinol
	EN 12823-2:2000	Foodstuffs - Determination of vitamin A by high performance liquid chromatography - Part 2: Measurements of Beta-carotene
	EN 12856:1999	Foodstuffs - Determination of acesulfame-K, aspartame and saccharin - High performance liquid chromatographic method
	EN 12857:1999	Foodstuffs - Determination of cyclamate - High performance liquid chromatographic method
	EN 13191-1:2000	Non-fatty food - Determination of bromide residues - Part 1: Determination of total bromide as inorganic bromide
	EN 13191-2:2000	Non-fatty food - Determination of bromide residues - Part 2: Determination of inorganic bromide
	EN 13585:2001	Foodstuffs - Determination of fumonisins B1 and B2 in maize - HPLC method with solid phase extraction clean-up
	EN 13708:2001	Foodstuffs - Detection of irradiated food containing crystalline sugar by ESR spectroscopy
	EN 13751:2009	Foodstuffs - Detection of irradiated food using photostimulated

		luminescence
	EN 1376:1996	Foodstuffs - Determination of saccharin in table top sweetener preparations - Spectrometric method
	EN 1376:1996/AC: 1996	Foodstuffs - Determination of saccharin in table top sweetener preparations - Spectrometric method
	EN 1377:1996	Foodstuffs - Determination of acesulfame K in table top sweetener preparations - Spectrometric method
	EN 1377:1996/AC: 1996	Foodstuffs - Determination of acesulfame K in table top sweetener preparations - Spectrometric method
	EN 1378:1996	Foodstuffs - Determination of aspartame in table top sweetener preparations - Method by high performance liquid chromatography
	EN 1378:1996/AC: 1996	Foodstuffs - Determination of aspartame in table top sweetener preparations - Method by high performance liquid chromatography
	EN 13783:2001	Foodstuffs - Detection of irradiated food using Direct Epifluorescent Filter Technique/Aerobic Plate Count (DEFT/APC) - Screening method
	EN 13784:2001	Foodstuffs - DNA Comet Assay for the detection of irradiated foodstuffs - Screening method
	EN 1379:1996	Foodstuffs - Determination of cyclamate and saccharin in liquid table top sweetener preparations - Method by high performance liquid chromatography
	EN 1379:1996/AC: 1996	Foodstuffs - Determination of cyclamate and saccharin in liquid table top sweetener preparations - Method by high performance liquid chromatography
	EN 13804:2002	Foodstuffs - Determination of trace elements - Performance criteria, general considerations and sample preparation
	EN 13805:2002	Foodstuffs - Determination of trace elements - Pressure digestion
	EN 13806:2002	Foodstuffs - Determination of trace elements - Determination of mercury by cold-vapour atomic absorption spectrometry (CVAAS) after pressure digestion
	EN 14082:2003	Foodstuffs - Determination of trace elements - Determination of lead, cadmium, zinc, copper, iron and chromium by atomic absorption spectrometry (AAS) after dry ashing
	EN 14083:2003	Foodstuffs - Determination of trace elements - Determination of lead, cadmium, chromium and molybdenum by graphite furnace atomic absorption spectrometry (GFAAS) after pressure digestion
	EN 14084:2003	Foodstuffs - Determination of trace elements - Determination of lead, cadmium, zinc, copper and iron by atomic absorption spectrometry (AAS) after microwave digestion
	EN 14122:2003	Foodstuffs - Determination of vitamin B1 by HPLC
	EN 14122:2003/AC :2005	Foodstuffs - Determination of vitamin B1 by HPLC
	EN 14123:2007	Foodstuffs - Determination of aflatoxin B1 and the sum of aflatoxin B1, B2, G1 and G2 in hazelnuts, peanuts, pistachios, figs, and paprika powder - High performance liquid chromatographic method with post-column derivatisation and immunoaffinity column cleanup
	EN 14131:2003	Foodstuffs - Determination of folate by microbiological assay
	EN 14132:2009	Foodstuffs - Determination of ochratoxin A in barley and roasted coffee - HPLC method with immunoaffinity column clean-up

	EN 14133:2009	Foodstuffs - Determination of ochratoxin A in wine and beer - HPLC method with immunoaffinity column clean-up
	EN 14148:2003	Foodstuffs - Determination of vitamin K1 by HPLC
	EN 14152:2003	Foodstuffs - Determination of vitamin B2 by HPLC
	EN 14152:2003/AC :2005	Foodstuffs - Determination of vitamin B2 by HPLC
	EN 14164:2008	Foodstuffs - Determination of vitamin B6 by HPLC
	EN 14166:2009	Foodstuffs - Determination of vitamin B6 by microbiological assay
	EN 14176:2003	Foodstuffs - Determination of domoic acid in mussels by HPLC
	EN 14177:2003	Foodstuffs - Determination of patulin in clear and cloudy apple juice and puree - HPLC method with liquid/liquid partition clean-up
	EN 14185-1:2003	Non-fatty food - Determination of N-methylcarbamate residues - Part 1: HPLC-method with SPE clean-up
	EN 14185-2:2006	Non fatty foods - Determination of N-methylcarbamate residues - Part 2: HPLC method with clean-up on a diatomaceous earth column
	EN 14332:2004	Foodstuffs - Determination of trace elements - Determination of arsenic in seafood by graphite furnace atomic absorption spectrometry (GFAAS) after microwave digestion
	EN 14333-1:2004	Non fatty foods - Determination of benzimidazole fungicides carbendazim, thiabendazole and benomyl (as carbendazim) - Part 1: HPLC method with solid phase extraction clean up
	EN 14333-2:2004	Non fatty foods - Determination of benzimidazole fungicides carbendazim, thiabendazole and benomyl (as carbendazim) - Part 2: HPLC method with gel permeation chromatography clean up
	EN 14333-3:2004	Non fatty foods - Determination of benzimidazole fungicides carbendazim, thiabendazole and benomyl (as carbendazim) - Part 3: HPLC method with liquid/liquid-partition clean up
	EN 14352:2004	Foodstuffs - Determination of fumonisin B1 and B2 in maize based foods - HPLC method with immunoaffinity column clean up
	EN 14526:2004	Foodstuffs - Determination of saxitoxin and dc-saxitoxin in mussels - HPLC method using pre-column derivatization with peroxide or periodate oxidation
	EN 14546:2005	Foodstuffs - Determination of trace elements - Determination of total arsenic by hydride generation atomic absorption spectrometry (HGAAS) after dry ashing
	EN 14569:2004	Foodstuffs - Microbiological screening for irradiated food using LAL/GNB procedures
	EN 14573:2004	Foodstuffs - Determination of 3-monochloropropane-1,2-diol by GC/MS
	EN 14627:2005	Foodstuffs - Determination of trace elements - Determination of total arsenic and selenium by hydride generation atomic absorption spectrometry (HGAAS) after pressure digestion
	EN 14663:2005	Foodstuffs - Determination of vitamin B6 (including its glycosylated forms) by HPLC
	EN 15054:2006	Non fatty foods - Determination of chlormequat and mepiquat - LC-MS method
	EN 15055:2006	Non fatty foods - Determination of chlormequat and mepiquat - LC-MS/MS method

	EN 15086:2006	Foodstuffs - Determination of isomalt, lactitol, maltitol, mannitol, sorbitol and xylitol in foodstuffs
	EN 15111:2007	Foodstuffs - Determination of trace elements - Determination of iodine by ICP-MS (inductively coupled plasma mass spectrometry)
	EN 1528-1:1996	Fatty food - Determination of pesticides and polychlorinated biphenyls (PCBs) - Part 1: General
	EN 1528-2:1996	Fatty food - Determination of pesticides and polychlorinated biphenyls (PCBs) - Part 2: Extraction of fat, pesticides and PCBs, and determination of fat content
	EN 1528-3:1996	Fatty food - Determination of pesticides and polychlorinated biphenyls (PCBs) - Part 3: Clean-up methods
	EN 1528-4:1996	Fatty food - Determination of pesticides and polychlorinated biphenyls (PCBs) - Determination, confirmatory tests, miscellaneous
	EN 15505:2008	Foodstuffs - Determination of trace elements - Determination of sodium and magnesium by flame atomic absorption spectrometry (AAS) after microwave digestion
	EN 15517:2008	Foodstuffs - Determination of trace elements - Determination of inorganic arsenic in seaweed by hydride generation atomic absorption spectrometry (HGAAS) after acid extraction
	EN 15607:2009	Foodstuffs - Determination of d-biotin by HPLC
	EN 15633-1:2009	Foodstuffs - Detection of food allergens by immunological methods - Part 1: General considerations
	EN 15634-1:2009	Foodstuffs - Detection of food allergens by molecular biological methods - Part 1: General considerations
	EN 15637:2008	Foods of plant origin - Determination of pesticide residues using LC-MS/MS following methanol extraction and clean-up using diatomaceous earth
	EN 15652:2009	Foodstuffs - Determination of niacin by HPLC
	EN 15662:2008	Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS-method
	EN 15763:2009	Foodstuffs - Determination of trace elements - Determination of arsenic, cadmium, mercury and lead in foodstuffs by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion
	EN 15764:2009	Foodstuffs - Determination of trace elements - Determination of tin by flame and graphite furnace atomic absorption spectrometry (FAAS and GFAAS) after pressure digestion
	EN 15765:2009	Foodstuffs - Determination of trace elements - Determination of tin by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion
	EN 15829:2010	Foodstuffs - Determination of ochratoxin A in currants, raisins, sultanas, mixed dried fruit and dried figs - HPLC method with immunoaffinity column cleanup and fluorescence detection
	EN 15835:2010	Foodstuffs - Determination of ochratoxin A in cereal based foods for infants and young children - HPLC method with immunoaffinity column cleanup and fluorescence detection
	EN 15842:2010	Foodstuffs - Detection of food allergens - General considerations and validation of methods
	EN 15850:2010	Foodstuffs - Determination of zearalenone in maize based baby food, barley flour, maize flour, polenta, wheat flour and cereal based foods for infants and young children - HPLC method with

		immunoaffinity column cleanup and fluorescence detection
	EN 15851:2010	Foodstuffs - Determination of aflatoxin B1 in cereal based foods for infants and young children - HPLC method with immunoaffinity column cleanup and fluorescence detection
	EN 15890:2010	Foodstuffs - Determination of patulin in fruit juice and fruit based purée for infants and young children - HPLC method with liquid/liquid partition cleanup and solid phase extraction and UV detection
	EN 15891:2010	Foodstuffs - Determination of deoxynivalenol in cereals, cereal products and cereal based foods for infants and young children - HPLC method with immunoaffinity column cleanup and UV detection
	EN 15911:2010	Foodstuffs - Simultaneous determination of nine sweeteners by high performance liquid chromatography and evaporative light scattering detection
	EN 16155:2012	Foodstuffs - Determination of sucralose - High performance liquid chromatographic method
	EN 16204:2012	Foodstuffs - Determination of lipophilic algal toxins (okadaic acid group toxins, yessotoxins, azaspiracids, pectenotoxins) in shellfish and shellfish products by LC-MS/MS
	EN 1784:2003	Foodstuffs - Detection of irradiated food containing fat - Gas chromatographic analysis of hydrocarbons
	EN 1785:2003	Foodstuffs - Detection of irradiated food containing fat - Gas chromatographic/mass spectrometric analysis of 2-alkylcyclobutanones
	EN 1786:1996	Foodstuffs - Detection of irradiated food containing bone - Method by ESR spectroscopy
	EN 1787:2000	Foodstuffs - Detection of irradiated food containing cellulose by ESR spectroscopy
	EN 1788:2001	Foodstuffs - Thermoluminescence detection of irradiated food from which silicate minerals can be isolated
	EN 1988-1:1998	Foodstuffs - Determination of sulfite - Part 1: Optimized Monier-Williams method
	EN 1988-2:1998	Foodstuffs - Determination of sulfite - Part 2: Enzymatic method
	EN ISO 10272-1:2006	Microbiology of food and animal feeding stuffs - Horizontal method for detection and enumeration of Campylobacter spp. - Part 1: Detection method (ISO 10272-1:2006)
	EN ISO 10273:2003	Microbiology of food and animal feedings stuffs - Horizontal method for the detection of presumptive pathogenic Yersinia enterocolitica (ISO 10273:2003)
	EN ISO 11290-1:1996	Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of Listeria monocytogenes - Part 1: Detection method (ISO 11290-1:1996)
	EN ISO 11290-1:1996/A1:2004	Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of Listeria monocytogenes - Part 1: Detection method - Amendment 1: Modification of the isolation media and the haemolysis test, and inclusion of precision data (ISO 11290-1:1996/AM1:2004)
	EN ISO 11290-2:1998	Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of Listeria monocytogenes - Part 2: Enumeration method (ISO 11290-2:1998)
	EN ISO 11290-2:1998/A1:2004	Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of Listeria monocytogenes - Part 2: Enumeration method - Amendment 1: Modification of the enumeration medium (ISO 11290-2:1998/AM1:2004)

	EN ISO 13720:2010	Meat and meat products - Enumeration of presumptive Pseudomonas spp. (ISO 13720:2010)
	EN ISO 15141-1:1998	Foodstuffs - Determination of ochratoxin A in cereals and cereal products - Part 1: High performance liquid chromatographic method with silica gel clean up (ISO 15141-1:1998)
	EN ISO 15141-2:1998	Foodstuffs - Determination of ochratoxin A in cereals and cereal products - Part 2: High performance liquid chromatographic method with bicarbonate clean up (ISO 15141-2:1998)
	EN ISO 16050:2011	Foodstuffs - Determination of aflatoxin B1, and the total content of aflatoxins B1, B2, G1 and G2 in cereals, nuts and derived products - High-performance liquid chromatographic method (ISO 16050:2003)
	EN ISO 16140:2003	Microbiology of food and animal feeding stuffs - Protocol for the validation of alternative methods (ISO 16140:2003)
	EN ISO 16140:2003/A1:2011	Microbiology of food and animal feeding stuffs - Protocol for the validation of alternative methods - Amendment 1 (ISO 16140:2003/AMD 1:2011)
	EN ISO 16654:2001	Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Escherichia coli O157 (ISO 16654:2001)
	EN ISO 20837:2006	Microbiology of food and animal feeding stuffs - Polymerase chain reaction (PCR) for the detection of food-borne pathogens - Requirements for sample preparation for qualitative detection (ISO 20837:2006)
	EN ISO 20838:2006	Microbiology of food and animal feeding stuffs - Polymerase chain reaction (PCR) for the detection of food-borne pathogens - Requirements for amplification and detection for qualitative methods (ISO 20838:2006)
	EN ISO 21567:2004	Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Shigella spp. (ISO 21567:2004)
	EN ISO 21569:2005	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Qualitative nucleic acid based methods (ISO 21569:2005)
	EN ISO 21570:2005	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Quantitative nucleic acid based methods (ISO 21570:2005)
	EN ISO 21570:2005/AC:2007	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Quantitative nucleic acid based methods (ISO 21570:2005/Cor.1:2006)
	EN ISO 21571:2005	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Nucleic acid extraction (ISO 21571:2005)
	EN ISO 21572:2013	Foodstuffs - Molecular biomarker analysis - Protein-based methods (ISO 21572:2013)
	EN ISO 21871:2006	Microbiology of food and animal feeding stuffs - Horizontal method for the determination of low numbers of presumptive Bacillus cereus - Most probable number technique and detection method (ISO 21871:2006)
	EN ISO 22118:2011	Microbiology of food and animal feeding stuffs - Polymerase chain reaction (PCR) for the detection and quantification of food-borne pathogens - Performance characteristics (ISO 22118:2011)
	EN ISO 22119:2011	Microbiology of food and animal feeding stuffs - Real-time polymerase chain reaction (PCR) for the detection of food-borne pathogens - General requirements and definitions (ISO 22119:2011)
	EN ISO 22174:2005	Microbiology of food and animal feeding stuffs - Polymerase chain reaction (PCR) for the detection of food-borne pathogens - General

		requirements and definitions (ISO 22174:2005)
	EN ISO 24276:2006	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions (ISO 24276:2006)
	EN ISO 6579:2002	Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp (ISO 6579:2002)
	EN ISO 6579:2002/A1: 2007	Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp. - Amendment 1: Annex D: Detection of Salmonella spp. in animal faeces and in environmental samples from the primary production stage (ISO 6579:2002/Amd 1:2007)
	EN ISO 6579:2002/AC: 2006	Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp (ISO 6579:2002/Cor.1:2004)
	EN ISO 6887-1:1999	Microbiology of food and animal feeding stuffs - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 1: General rules for the preparation of the initial suspension and decimal dilutions (ISO 6887-1:1999)
	EN ISO 6887-2:2003	Microbiology of food and animal feeding stuffs - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 2: Specific rules for the preparation of meat and meat products (ISO 6887-2:2003)
	EN ISO 6887-3:2003	Microbiology of food and animal feeding stuffs - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 3: Specific rules for for the preparation of fish and fishery products (ISO 6887-3:2003)
	EN ISO 6887-4:2003	Microbiology of food and animal feeding stuffs - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 4: Specific rules for the preparation of products other than milk and milk products, meat and meat products, and fish and fishery products (ISO 6887-4:2003)
	EN ISO 6887-4:2003/A1:2011	Microbiology of food and animal feeding stuffs - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 4: Specific rules for the preparation of products other than milk and milk products, meat and meat products, and fish and fishery products (ISO 6887-4:2003/Amd 1:2011)
	EN ISO 6887-4:2003/AC:2004	Microbiology of food and animal feeding stuffs - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 4: Specific rules for the preparation of products other than milk and milk products, meat and meat products, and fish and fishery products (ISO 6887-4:2003)
	EN ISO 6887-5:2010	Microbiology of food and animal feeding stuffs - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 5: Specific rules for the preparation of milk and milk products (ISO 6887-5:2010)
	EN ISO 6888-1:1999	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 1: Technique using Baird-Parker agar medium (ISO 6888-1:1999)
	EN ISO 6888-1:1999/A1:2003	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 1: Technique using Baird-Parker agar medium - Amendment 1: Inclusion of precision data (ISO 6888-1:1999/Amd 1:2003)
	EN ISO 6888-2:1999	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 2: Technique using rabbit plasma fibrinogen agar medium (ISO 6888-2:1999)

	EN ISO 6888-2:1999/A1:2003	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 2: Technique using rabbit plasma fibrinogen agar medium - Amendment 1: Inclusion of precision data (ISO 6888-2:1999/Amd 1:2003)
	EN ISO 6888-3:2003	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 3: Detection and MPN technique for low numbers (ISO 6888-3:2003)
	EN ISO 6888-3:2003/AC:2005	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 3: Detection and MPN technique for low numbers (ISO 6888-3:2003)
	EN ISO 7218:2007	Microbiology of food and animal feeding stuffs - General requirements and guidance for microbiological examinations (ISO 7218:2007)
	EN ISO 7932:2004	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of presumptive Bacillus cereus - Colony-count technique at 30 °C (ISO 7932:2004)
	EN ISO 7937:2004	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of Clostridium perfringens - Colony-count technique (ISO 7937:2004)
	ENV 14194:2002	Foodstuffs - Determination of saxitoxin and dc-saxitoxin in mussels - HPLC method using post column derivatisation
CEN TC 351 Construction materials	CEN/TR 15855:2009	Construction products - Assessment of release of dangerous substances - Barriers to trade
	CEN/TR 15858:2009	Construction products - Assessment of the release of regulated dangerous substances from construction products based on the WT, WFT/FT procedures
	CEN/TR 16045:2010	Construction Products - Assessment of release of dangerous substances - Content of regulated dangerous substances - Selection of analytical methods
	CEN/TR 16098:2010	Construction products: Assessment of release of dangerous substances - Concept of horizontal testing procedures in support of requirements under the CPD
	CEN/TR 16220:2011	Construction products - Assessment of release of dangerous substances - Complement to sampling
	CEN/TR 16410:2012	Construction products - Assessment of release of dangerous substances - Barriers to use - Extension to CEN/TR 15855 Barriers to trade

11.2 Appendix B: Testing the documentation framework on existing multimedia models: EUSES

1. Model purpose

1.1 Goal

The European Union System for the Evaluation of Substances (EUSES) is a decision-support instrument which enables government authorities, research institutes and chemical companies to carry out rapid and efficient assessments of the general risks posed by chemical substances. EUSES is intended mainly for initial and refined risk assessments rather than for comprehensive assessments. Besides the release estimation, only a few data on substance properties are needed to calculate PECs at Tier 1 (Table 1). The end-point of

EUSES is a quantitative comparison per substance of the results of the effects and the exposure assessment.

The system can be used to carry out tiered risk assessments of increasing complexity on the basis of increasing data requirements.

1.2 Decision or regulatory framework

The model was developed to perform risk assessment of substances under the REACH (EC 1907/2006) and the Biocidal Product Directive (BPD) (98/8/EC) (To be replaced by the Biodical Product Regulation (BPR) (EC 528/2012)

2. Model context/applicability

2.1 Spatial scale/resolution

A distinction can be made between three spatial scales. At the ‘personal scale’, individual consumers or workers are considered, exposed directly to individual substances and preparations, and to substances embedded in a solid matrix. The local scale considers the protection goals in the vicinity of one large point source of the substance. The regional scale assesses the risks to protection targets due to all releases in a larger region. A fourth spatial scale, the continental scale (defined as the sum of all EU member states), is added to serve as background for the regional system. EUSES 2.0 includes also three overlying global scales (moderate, tropic and arctic) as option.

2.2 Temporal scale/resolution

Exposure of consumers, non-professional users of biocides and workers can be judged as acute, sub-chronic or chronic, depending on the product and its use pattern.

Emissions at the regional and continental scale are regarded as diffuse and continuous, leading to steady-state environmental concentrations. These steady-state levels can be considered as estimates of long-term average exposure levels. They can therefore be compared to no-effect levels derived from long-term toxicity data.

2.3 User community

EUSES 2.0 is designed to support decision-making by risk managers in government agencies, scientific institutes and industry in the evaluation of new and existing chemical substances.

2.4 Required inputs

For exposure estimation, the following inputs are required:

Table 21 Required input parameters for exposure estimation

Parameters	**Units**
REGION IDENTIFICATION	
General name	-
SUBSTANCE IDENTIFICATION General name CAS no.	
PHYSICAL-CHEMICAL SUBSTANCE PROPERTIES Molecular weight Melting point Vapour pressure at the temperature of the data set Temperature at which vapour pressure was measured	 $g.mol^{-1}$ ^oC Pa ^oC

Water solubility at the temperature of the data set	$mg.L^{-1}$
Temperature at which solubility was measured	^oC
Octanol-water partition coefficient	-
Chemical class for Koc-QSAR	-
Organic carbon - water partition coefficient	$L.kg^{-1}$
DEGRADATION AND TRANSFORMATION RATES	
Characterization	
Biodegradability test result	-
Rate constant for degradation in STP	d^{-1}
Total rate constant for degradation in surface water at env. temp	d^{-1}
Total rate constant for degradation in marine water at env. temp	d^{-1}
Total rate constant for degradation in bulk sediment at env. temp	d^{-1}
Rate constant for degradation in air	d^{-1}
Total rate constant for degradation in bulk soil at env. temp	d^{-1}
EMISSIONS	
Tonnages	
Tonnage in EU	$tonnes.yr^{-1}$
Fraction of EU production volume in Region	-
Release fractions	
Fraction of tonnage released to air	-
Fraction of tonnage released to waste water	-
Fraction of tonnage released to surface water	-
Fraction of tonnage released to industrial soil	-
Fraction of tonnage released to agricultural soil	-
Emission days	
Fraction of the main local source	-
Number of emission days per year	$d.yr^{-1}$
Local release rates	
Local emission to air during episode	$kg.d^{-1}$
Local emission to wastewater during episode	$kg.d^{-1}$

Toxicological substance properties necessary to characterize the RCR (Risk Characterization Ratio) are not included in this list.

2.5 Output of interest

Table 22 Output parameters from the exposure module

Output	**Units**
PREDICTED CONCENTRATIONS	
PECs	
Regional PEC in surface water (total)	$mg_c.L^{-1}$
Regional PEC in sea water (total)	$mg_c.L^{-1}$
Regional PEC in air (total)	$mg_c.m^{-3}$

Regional PEC in agricultural soil (total)	$mg_c.kg_{wwt}^{-1}$
Regional PEC in natural soil (total)	$mg_c.kg_{wwt}^{-1}$
Regional PEC in industrial soil (total)	$mg_c.kg_{wwt}^{-1}$
Regional PEC in sediment (total)	$mg_c.kg_{wwt}^{-1}$
Regional PEC in sea water sediment (total)	$mg_c.kg_{wwt}^{-1}$
Annual average local PEC in air (total)	$mg_c.m^{-3}$
Local PEC in surface water during emission episode (dissolved)	$mg_c.L^{-1}$
Annual average local PEC in surface water (dissolved)	$mg_c.L^{-1}$
Local PEC in fresh water sediment during emission episode	$mg_c.kg_{wwt}^{-1}$
Local PEC in sea water during emission episode (dissolved)	$mg_c.L^{-1}$
Annual average local PEC in sea water (dissolved)	$mg_c.L^{-1}$
Local PEC in marine sediment during emission episode	$mg_c.kg_{wwt}^{-1}$
Local PEC in agricultural soil, averaged over 30 days	$mg_c.kg_{wwt}^{-1}$
Local PEC agricultural soil, averaged over 180 days	$mg_c.kg_{wwt}^{-1}$
Local PEC in grass land, averaged over 180 days	$mg.kg_{wwt}^{-1}$
SECONDARY POISONING	
Environment	
Conc. in fish for secondary poisoning in freshwater environment	$mg_c.kg_{wwt}^{-1}$
Conc. in fish for secondary poisoning in marine environment	$mg_c.kg_{wwt}^{-1}$
Conc. in fish-eating predator for marine toppredators	$mg_c.kg_{wwt}^{-1}$
Conc. in earthworms for secondary poisoning	$mg_c.kg_{wwt}^{-1}$
Humans	
Regional daily dose via inhalatory intake for humans	$mg_c.kg_{bw}^{-1}.d^{-1}$
Regional total daily intake for humans	$mg_c.kg_{bw}^{-1}.d^{-1}$
local daily dose via inhalatory intake for humans	$mg_c.kg_{bw}^{-1}.d^{-1}$
local total daily intake for humans	$mg_c.kg_{bw}^{-1}.d^{-1}$

Predicted non-effect concentrations and risk ratios are not included in this list.

2.6 System limitations

Limitations of EUSES:

Important boundary conditions for the system are:

- the chemical-risk policies as laid down by the European Commission;
- the datasets available for risk assessment purposes;
- the need for a harmonised, general scheme for rapid and easy-to-perform quantitative hazard and risk assessment at the initial and intermediate level for new and existing substances.

EUSES is not specifically designed for use in site-specific assessments.

The environmental risk assessment in EUSES is for an environment with standard conditions. To a certain extent, however, these environmental conditions can be adapted.

Model analysis, including validation, has been performed to a limited extent and further work is required.

It is recognised that certain process formulations are based on limited research and need to be improved; examples are the equations describing the transfer of substances from soil and feed to cattle.

Even with a perfect model, unreliable results can still be obtained if quality control of input data is neglected or performed in a very rough manner. EUSES does not present any guidance for this essential step. Nor does the system present any guidance for the derivation of no-effect or effect levels from experimental animal tests or human data.

Several hazards are not yet considered in EUSES: examples are global warming, ozone depletion, acidification, eutrophication, depletion of raw materials, effects on materials, calamities and hazardous waste.

2.7 Exposure pathways

Indirect exposure of humans via the environment may occur by consumption of food and drinking water, inhalation of air and ingestion of soil.

The release sources are air, soil, groundwater, surface water, crops, cattle, dairy products, meat, drinking water and fish.

2.8 Exposure routes

Exposure can be modelled through ingestion, inhalation and dermal contact.

2.9 Fate, exposure and effect analysis

Fate, exposure and effect analysis are included.

2.10 Chemical considered

EUSES can be used for organic and inorganic chemicals but appears to be less suitable for the assessment of chemicals outside the neutral organic compounds.

2.11 Media considered

The following media are considered in the EUSES model: atmosphere, surface water (fresh and marine water), sediment (fresh and marine environment), soil (natural, agricultural and industrial soil) and two vegetation compartments (natural and agricultural soil).

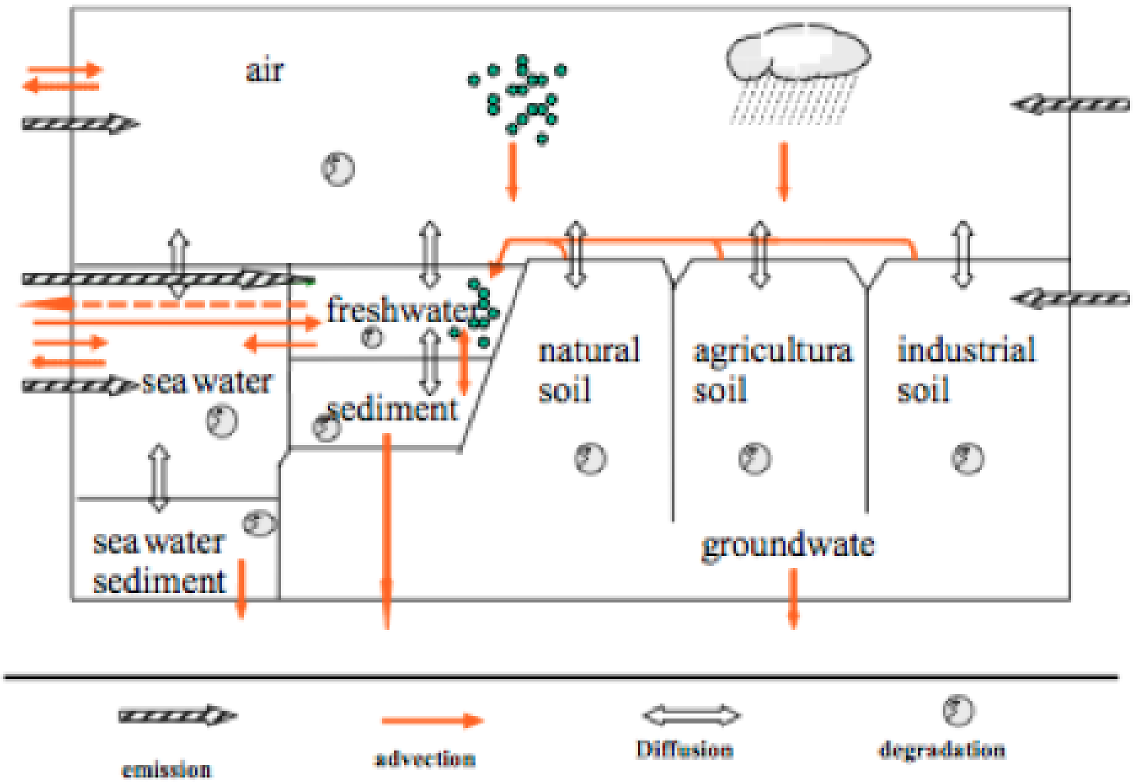

Figure 17 Schematic representation of the model for calculating the regional PEC

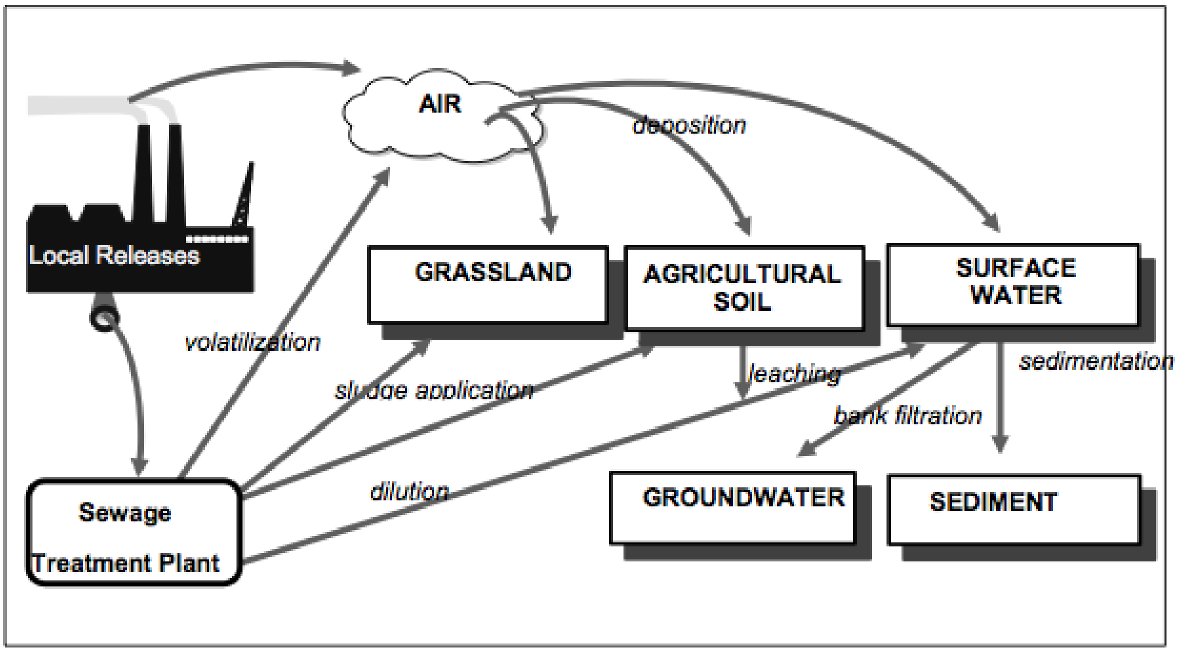

Figure 18 Schematic representation of the local distribution model (industrial setting)

A detailed description of the freshwater model is provided below.

Inputs to the freshwater compartment are emissions, import, run-off from soil to water, (wet and dry) atmospheric deposition, gas absorption from air and release from sediment to water. Outputs from the freshwater compartment are export, degradation, volatilization from water to air and uptake by sediment.

A graphic representation is not present in the Simple Box documentation.

Calculation of the **local** water concentration involves several sequential steps. It includes the calculation of the discharge concentration of a STP to a water body, dilution effects and removal from the aqueous medium by adsorption to suspended matter. Volatilisation, degradation and sedimentation are ignored because of the short distance between the point of effluent discharge and the exposure location.

In Figure 19 below the different fate processes in the water compartment are graphically represented.

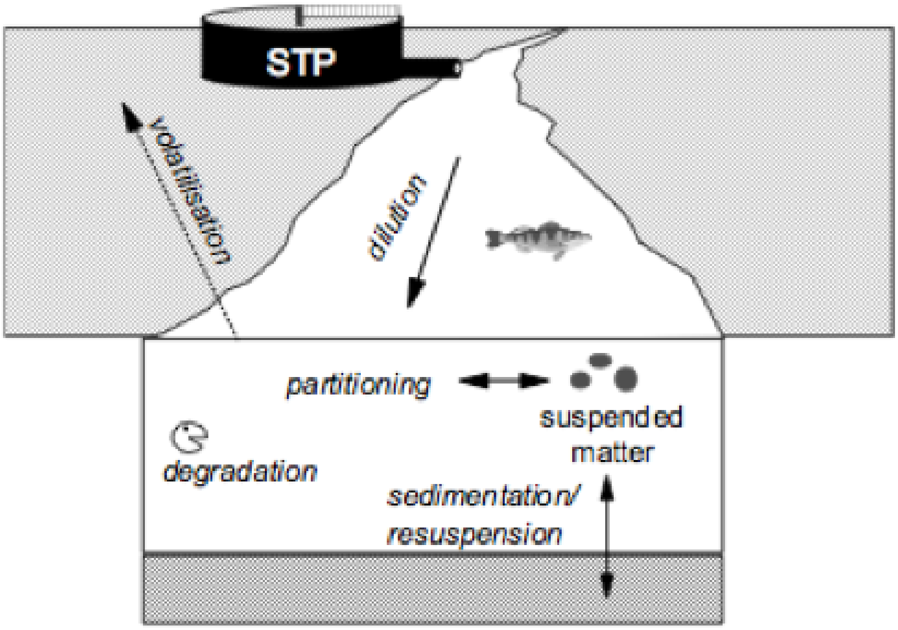

Figure 19 Fate processes in the surface water

2.12 Human population

The human population considered in EUSES is man exposed via environment, non-professional users of biocides, consumers and workers.

2.13 Environmental processes

The regional environmental processes taking place in the compartments are described in Table 23 below

Table 23 Environmental processes per compartment (regional)

Compartment	Environmental processes
Soil	Atmospheric wet & dry deposition, gas adsorption to soil, volatilization from soil, run-off, leaching and degradation
Air	Volatilization, gas absorption, degradation, wet/dry deposition
Water	Wet/dry deposition, run-off, gas absorption, sediment uptake, volatilization, degradation, sediment release
Sediment	Uptake by sediment, sedimentation, release to water, re-suspension, sediment burial, degradation
Vegetation	Deposition, gas absorption, plant death, plant removal, volatilization, degradation, transpiration from soil to vegetation

The local environmental processes taking places in the compartments are described in table 24

Table 24 Environmental processes per compartment (local)

Compartment	Environmental processes
Soil	Atmospheric wet & dry deposition, volatilization from soil, leaching and degradation, sludge application
Water	Diffusion from water to suspended matter, diffusion from suspended matter to water
Sediment	Diffusion from water to sediment, diffusion from sediment to water

2.14 Human processes

No human processes are taken into consideration.

3. Model component

3.1 Initialization

Default values are presented in section III of the RIVM report no. 601900005/2004. For example:

Table III-1 Defaults for the physico-chemical properties input

Parameter	Symbol	Unit	Value
Enthalpy of vaporisation	H_{0_VP}	$[J.mol^{-1}]$	5.10^4
Enthalpy of solution	H_{0_SOL}	$[J.mol^{-1}]$	1.10^4
Gas constant	R	$[Pa.m^3.mol^{-1}.K^{-1}]$	8.314^a
Environmental temperature	TEMP	[K]	
Freshwater environment (12 °C)			285
Marine environment (12 °C)			285^b

Table III-66 Default environmental characteristics for local, regional and continental scales

Parameter	**Symbol**	**Unit**	**Value**
General			
Density of solid phase	RHOsolid	[$kg_{solid}.m_{solid}^{-3}$]	2500
Density of water phase	RHOwater	[$kg_{water}.m_{water}^{-3}$]	1000
Density of air	RHOair	[$kg_{air}.m_{air}^{-3}$]	1.3
Environmental temperature Freshwater environment (12 °C) Marine environment (9 °C)	TEMP	[K]	 285 282
Constant of Junge equation	CONjunge	[Pa.m]	[a]
Specific surface area of aerosol particles	$SURF_{aer}$	[$m^2.m^{-3}$]	[a]
Gas constant	R	[$Pa.m^3.mol^{-1}.K^{-1}$]	8.314 [b]
Suspended matter			
Volume fraction of solids in susp. matter	$Fsolid_{susp}$	[$m_{solid}^3.m_{susp}^{-3}$]	0.1
Volume fraction of water in susp. matter	$Fwater_{susp}$	[$m_{water}^3.m_{susp}^{-3}$]	0.9
Weight fraction of organic carbon in susp. solids	Foc_{susp}	[$kg_{oc}.kg_{solid}^{-1}$]	0.1
Sediment			
Volume fraction of solids in sediment	$Fsolid_{sed}$	[$m_{solid}^3.m_{sed}^{-3}$]	0.2
Volume fraction of water in sediment	$Fwater_{sed}$	[$m_{water}^3.m_{sed}^{-3}$]	0.8
Weight fraction of organic carbon sediment solids	Foc_{sed}	[$kg_{oc}.kg_{solid}^{-1}$]	0.05
Soil			
Volume fraction of solids in soil	$Fsolid_{soil}$	[$m_{solid}^3.m_{soil}^{-3}$]	0.6
Volume fraction of water in soil	$Fwater_{soil}$	[$m_{water}^3.m_{soil}^{-3}$]	0.2
Volume fraction of air in soil	$Fair_{soil}$	[$m_{air}^3.m_{soil}^{-3}$]	0.2
Weight fraction of organic carbon in soil solids	Foc_{soil}	[$kg_{oc}.kg_{solid}^{-1}$]	0.02

The input data can be related to the Kow, have defaults that can be overwritten or are calculated from other parameters and can be overwritten.

3.2 Overview input data

No time/space dependent input data are present.

3.3 State variable

Model calculations of the system are specified in detail (Section III of the RIVM report no. 601900005/2004) and are divided in six main modules. Each module is described in detail and presents the resulting variables, which can be used in subsequent calculations (output).

3.4 Parameters

The parameters for each module are listed in Section III of the RIVM report 601900005/2004. The type of point value is in general not described, however, there are exceptions, e.g. for the flow rate, the 10th percentile is required. No probability distributions can be applied for input parameters. QSARs for Koc and BCFs are included in EUSES.

3.5 Constants

Constants are not listed separately but are provided in the different modules. E.g. Henry's Law constant.

3.6 Model structure/framework

Model equations are presented for each compartment on a local (RIVM report 60190005/2004) and a regional scale (RIVM report 719101029)

A detailed description of the freshwater model is provided below.

The mass balance equation for the water compartment on a **regional** scale is:

$$\begin{aligned} V_{water\,i[S]} \cdot \frac{dC_{water\,i[S]}}{dt} = &+ EMIS_{water\,i[S]} + IMP_{water\,i[S]} - EXP_{water\,i[S]} \\ &- V_{water\,i[S]} \cdot DEG_{water\,i[S]} \cdot C_{water\,i[S]} + DEP_{water\,i[S]} \cdot C_{air[S]} \\ &+ \sum RUN\text{-}OFF_{soil\,i[S]} \cdot C_{soil\,i[S]} - XCH_{water\,i\text{-}air[S]} \cdot C_{water\,i[S]} \\ &- XCH_{water\,i\text{-}sed\,i[S]} \cdot C_{water\,i[S]} + XCH_{air\text{-}water\,i[S]} \cdot C_{air[S]} \\ &+ XCH_{sed\,i\text{-}water\,i[S]} \cdot C_{sed\,i[S]} \end{aligned} \qquad 196$$

with

$V_{water\,i[S]}$:	volume of water compartment i at scale S [m_{water}^3] *(I)*
$C_{water\,i[S]}$:	concentration in water compartment i (dissolved) at scale S [$mol.m_{water}^{-3}$] *(S)*
t :	time [s] *(S)*
$EMIS_{water\,i[S]}$:	emission to water compartment i at scale S [$mol.s^{-1}$] *(I)*
$IMP_{water\,i[S]}$:	import mass flow into water compartment i at scale S [$mol.s^{-1}$] *(I)*
$EXP_{water\,i[S]}$:	export mass flow from water compartment i at scale S [$mol.s^{-1}$] *(I)*
$DEG_{water\,i[S]}$:	pseudo first order transformation rate constant in water i at scale S [s^{-1}] *(I)*
$DEP_{water\,i[S]}$:	transport coefficient for atmospheric deposition (wet and dry) to water i at scale S [$m_{air}^3.s^{-1}$] *(I)*
$RUN\text{-}OFF_{soil\,i[S]}$:	transport coefficient for run off from soil i to water i at scale S [$m_{soil}^3.s^{-1}$] *(I)*
$C_{soil\,i[S]}$:	concentration in soil i at scale S [$mol.m_{soil}^{-3}$] *(S)*
$XCH_{water\,i\text{-}air[S]}$:	transport coefficient for volatilization from water i at scale S [$m_{water}^3.s^{-1}$] *(I)*
$XCH_{water\,i\text{-}sed\,i[S]}$:	transport coefficient for uptake by sediment i at scale S [$m_{water}^3.s^{-1}$] *(I)*
$XCH_{air\text{-}water\,i[S]}$:	transport coefficient for gas absorption from air at scale S [$m_{air}^3.s^{-1}$] *(I)*
$C_{air[S]}$:	concentration in air at scale S [$mol.m_{air}^{-3}$] *(S)*
$XCH_{sed\,i\text{-}water\,i[S]}$:	transport coefficient for release from sediment i at scale S [$m_{sed}^3.s^{-1}$] *(I)*
$C_{sed\,i[S]}$:	concentration in sediment i at scale S [$mol.m_{sed}^{-3}$] *(S)*

The local concentration in water can be calculated as follow:

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}) \cdot DILUTION}$$

$Clocal_{eff}$	concentration of the substance in the STP effluent	[mg·l^{-1}]
Kp_{susp}	solids-water partitioning coefficient of suspended matter	[l·kg^{-1}]
$SUSP_{water}$	concentration of suspended matter in the river	[mg·l^{-1}]
DILUTION	dilution factor	[-]
$Clocal_{water}$	local concentration in surface water during release episode	[mg·l^{-1}]

4. Model type

EUSES is a steady-state, simulation, deterministic, distributed and analytical model.

4.1 Mode (of a model)

EUSES is a prognostic model.

4.2 Screening model

In line with most assessment procedures EUSES can be used to carry out tiered risk assessments of increasing complexity, requiring additional data. Using OECD terminology, EUSES can specifically be used in the initial, or screening, and intermediate, or refined, stages of assessment (OECD, 1989). With EUSES, substances can be assessed for their potential risks to man and the environment. On the basis of this screening, it can be decided if more data need to be generated and if a more refined (i.e. intermediate) assessment is necessary. When dealing with (large) numbers of chemicals, this screening can be used to set priorities for data gathering or refined assessments. EUSES can also be applied for intermediate or refined assessments by allowing the replacement of default values, estimated parameter values, or intermediate results by more accurately estimated values or by measured data. EUSES is not specifically designed for site-specific assessments, but adjustment of parameters may allow for insight into specific local or regional situations.

5. Model evaluation

5.1 Model coding verification

Not available

5.2 Input parameters

Not reported

5.3 Model calibration

Not applicable

A strict validation of systems like EUSES is not possible. The result of EUSES is a risk estimate: a PEC/PNEC quotient (quotient of the Predicted Environmental Concentration and the Predicted No-Effect Concentration for an endpoint) or a Margin Of Safety (MOS). These risk estimates are abstractions and cannot be determined in the real world. Nevertheless, an evaluation in a less strict manner should be performed to clarify the degree of confidence in the final results. Parts of the system (modules or models) can be validated numerically. Exposure concentrations can be measured but one has to realise that measured data are usually not representative for the situation described by EUSES for two reasons:

In the absence of specific data, several chemical-specific parameters are set to worst-case values (e.g. release rates, degradation rates) and the assessment is performed for a worst-case exposure scenario, the so-called “standard environment”. Measured field data will invariably be non-representative for this situation. The concept of a standard scenario clearly plays a crucial role in the assessment and its applicability and appropriateness should be considered in a model validation.

Validation of submodels of EUSES have been carried out and summarised by Jager et al., 1998. It was noted that validation activities for individual models are seldom directly applicable to EUSES, since this is a generic instrument, using a fixed, standard scenario.

Most variations in time and space are averaged out in EUSES.

5.4 Model framework/structure uncertainty

Uncertainty or uncertainty related studies performed on the EUSES model:

Matthies et al., 2004. Probabilistic uncertainty analyses of the European Union System for evaluation of susbtances multimedia regional distribution model. Environmental Toxicology and Chemistry, 23, 2494-2502.

Jager, T., 1998. RIVM report 679102047. Uncertainty analysis of EUSES: interviews with representatives from Member States and industry.

Jager et al., 1997. Uncertainty analysis of EUSES: Improving risk management by probabilistic risk assessment.

Jager et al.. 2001a. Opportunities for a probabilistic risk assessment of chemicals in the European Union. Chemosphere, 43, 257-64.

Jager et al., 2001b. Probabilistic environmental risk assessment for dibutylphthalate (DBP). Human ecological risk assessment, 7, 1681-1697.

Vermeire et al., 2001. A probabilistic human health risk assessment for environmental exposure to dibutylphthalate. Human ecological risk assessment,7, 1663-1679.

Lessmann, et al., 2005. Influence of distributional shape of substance parameters on exposure model output. Risk Analysis, 25, 1137-1145.

5.5 Model predictivity

No model predictivity test was performed.

5.6 Uncertainty analysis

See model framework/structure uncertainty.

5.7 Sensitivity analysis

See model framework/structure uncertainty.

6. Model use

6.1 Error messages

FATAL ERROR

Fatal errors occur if there is not enough memory to run the program. The effect of a fatal error is that the program aborts and an error message window is displayed.

General protection faults (GPFs) may be caused by program failure, other programs and/or wrong computer set-up parameters. A general protection fault generates the following message:

General Protection Fault at SSSS:AAAA

Please write down the (hexadecimal) number SSSS:AAAA. Contact the EUSES helpdesk for further assistance (tel: +(39) 332-785.866).

Terminate all applications after a fatal error or a general protection fault and leave Windows.

This is recommended, because these errors tend to cause problems in Windows and other Windows programs.

RANGE ERRORS

A range error message will appear if you enter a value that is less than the minimum or greater

than the maximum of a parameter. The given range is an

advised

range. You are always allowed

to enter a value outside this range.

The possible choices are:

1. Set to minimum Set the parameter to the minimum value.
2. Set to maximum Set the parameter to the maximum value.
3. Accept value Accept the value as entered. This option may be used in

certain cases to bypass specific model calculations.

4. Resume editing Enter a new value.

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ERROR MESSAGES

The window of the general EUSES error is shown in Figure 3-2. It contains a description of the

error and one or more possible solutions.

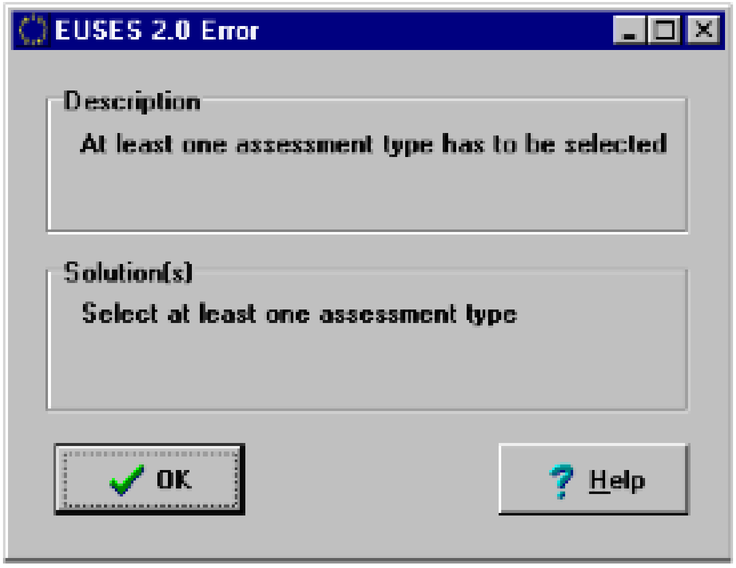

Figure 3-2 General EUSES error message

When you press <Enter> the error message will be cleared. The error messages are listed in alphabetical order.

More information can be found in the EUSES 2.1.1 User Manual p. 28-35.

6.2 <u>Process time</u>

Simulation time is short, no suggestions are made.

6.3 <u>Graphs/tables</u>

How to build a graphical and tabular output is not mentioned in the User Manual.

6.4 Scenario analysis

In the ECHA R16 Environmental exposure estimation guidance, different scenarios are described (i.e. different environmental release categories).