

Linking exposure models to regulatory driven frameworks

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Introduction

HAZARD



EXPOSURE



RISK

An essential element in risk assessment of chemicals is the **exposure assessment**. Exposure assessment can be performed by measuring or by modeling. If done by modeling, select an appropriate model for your purpose.

AIM: To put the 4FUN tool (MERLIN-EXPO) into perspective and to identify strengths, weaknesses, opportunities and threats. The 4FUN tool is a library of exposure models, coupling environmental multimedia and pharmacokinetic models. It is designed to be transparent and its fundamental structure and logic are easily understandable.

Which model to use for which regulatory framework?

Different steps were taken to develop a **transparent and objective framework** for exposure model comparison:

- Development of a hierarchically structured list of criteria for the evaluation of the characteristics of exposure tools
- Division of the criteria into two categories: **framework related criteria** (e.g. environmental compartments, processes, etc.) and **general model criteria** (user friendliness, sensitivity & uncertainty analysis, etc.)
- Analysis of criteria relations and importance by an **expert panel** with the use of dedicated questionnaires
- Framework related criteria received a score based on their applicability and importance in a certain type of framework (REACH regulation, Biocidal Product Regulation, environmental oriented directives (e.g. WFD) and site specific impact assessment)
- Assessment of a given exposure model according to the proposed criteria
- Calculation of a final framework specific and a general score with the application of an aggregation methodology that uses Multi-Criteria Decision Analysis (MCDA) techniques

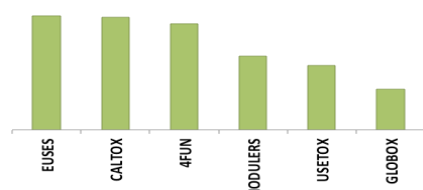
REGULATION OF CHEMICALS

REACH/biocides

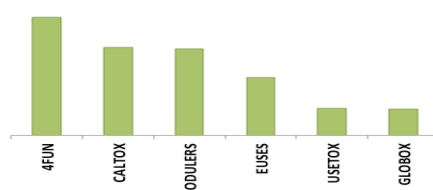
Site specific assessment

Environmental oriented directives
(e.g. WFD)

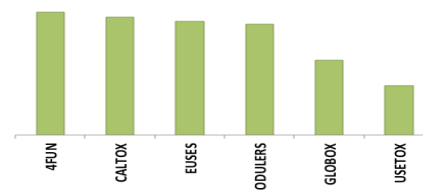
1. Evaluation of six multimedia exposure models with framework related criteria



CALTOX/4FUN are comparable to the EUSES tool which is accepted for exposure assessment under REACH/biocides

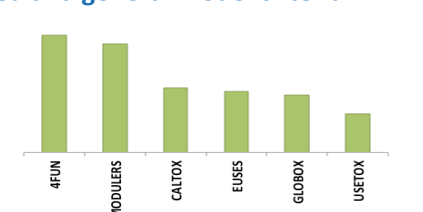
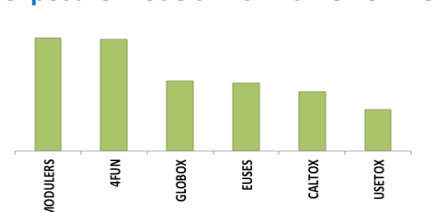
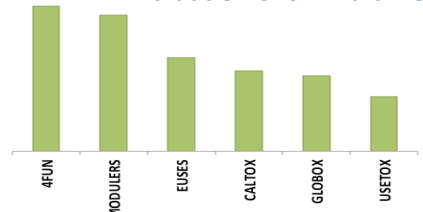


4FUN is best situated for site specific assessment due to its flexibility



USETox scores lower due to lower specificity, GLOBOX does not contain human exposure assessment and therefore scores lower

2. Evaluation of six multimedia exposure models with framework related and general model criteria



Taking general model requirements into consideration changes the ranking. **The 4FUN tool (MERLIN-EXPO) in general scores high due to its flexibility and transparency.** Nonetheless, specific aspects of the tool (**most notably regulatory specifics**) which score low should also be taken into account.

More information on website 4FUN: <http://4funproject.eu/en/home/>

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