Conceptual Design of the HARMLESS Decision Support System

Eugene van Someren[1], Neeraj Shandilya[1], Remy Franken[1], Tanja Krone[1], Robin van Stokkum[1], Blanca Suarez-Merino[2], Véronique Adam[2], Beatrice Salieri[2], Wendel Wohlleben[3], Gino Kalkman[1], Mark van Barneveld[1], Ioannis Tolios[4], Carina Rubingh[1], Shaji Krishnan[1], Wouter Fransman[1], Susan Dekkers[1]

[1] RAPID, Unit Healthy Living, TNO, Netherlands, [2] TEMAS Solutions GmbH, Switzerland, [3] BASF SE, Germany, [4] Data Science, Unit ICT, TNO, Netherlands

HARMLESS Project and DSS Introduction

- Potential users of Safe and Sustainable-by-Design (SSbD) approaches suffer from **the sheer vastness and variety** of existing knowledge, testing methods and tools.
- We **aim to guide them** in making important decisions throughout their entire design process on safety and sustainability of **advanced nanomaterials and HARNs**.
- To this end, the **HARMLESS project** is developing a **user-friendly intelligent SSbD Decision Support System** (DSS) as an online IT tool.

Here, we present our **functional design of the HARMLESS DSS:**

- based on previous **experience and stakeholder analysis**
- bringing a novel multi-faceted **Safe Innovation Approach** (SIA)
- creating a tool-box of **New Approach Methodologies** (NAMs) …
- … converted into **FAIR data, knowledge and models**
- brought together into a **unified HARMLESS framework**
- made available as a **online user-friendly Safe and Sustainable-by-Design Decision Support System**

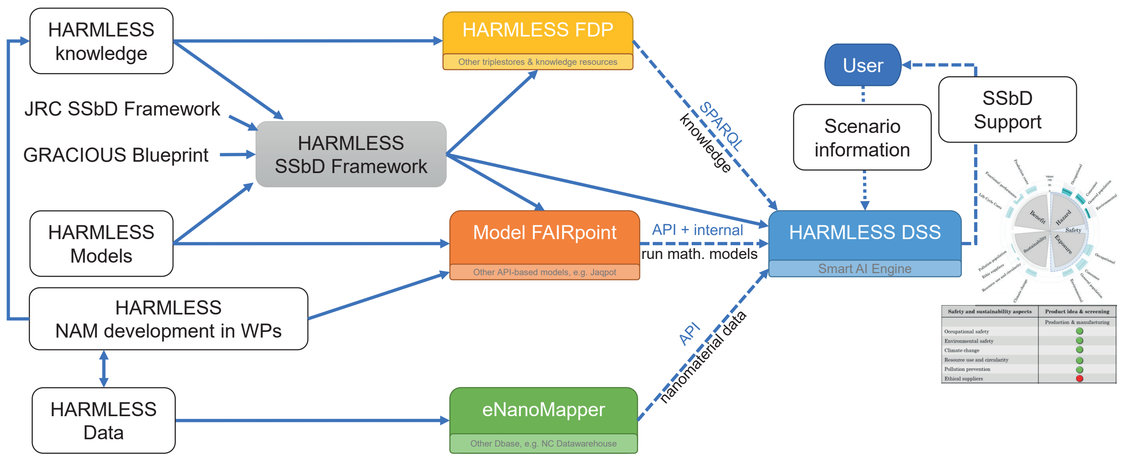
The conceptual design of the HARMLESS DSS contains

1) an **IT-architecture**,
2) a **data and model integration approach** and
3) a **decision support framework**

This conceptual design functions as **a technical blue-print** for the actual implementation of the HARMLESS DSS.

Modular IT-Architecture and Workflow

- The IT-architecture describes **a modular and FAIR approach**
- All data, knowledge and models are captured (in standardized fashion) in **stand-alone, but interconnected & exchangeable components**, i.e.
  1. **eNanoMapper** as **a database** to store all nanomaterial & experimental **data**
  2. a new official **FAIR Data Point** and **GraphDb Triplestore** to capture all **knowledge and decision rules** in Resource Description Framework (RDF)
  3. a novel **Model FAIRpoint** with runnable **algorithms**
  4. a new smart interactive **Decision Support System interface**



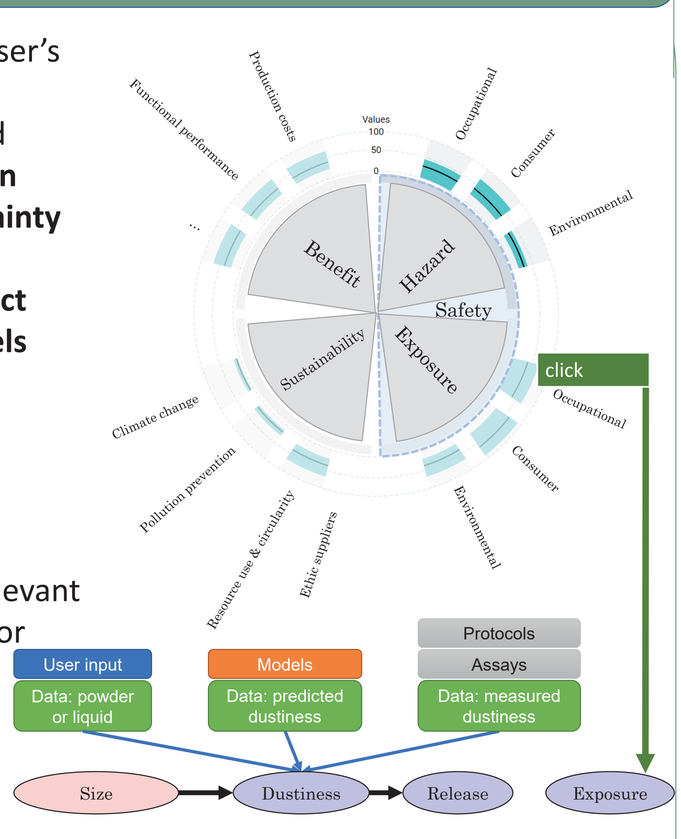
Being **modular and FAIR**, the **DSS interface** connects to the **HARMLESS components**, but **can also connect to external components** (e.g. NanoCommons Data Warehouse, SBD4Nano Semantic landscape, Jaqpot, ...)

And likewise, other **nanosafety IT-systems** can in turn connect to and exploit each of the **individual stand-alone HARMLESS components**.

Decision Support by Interactive Visualization

Relevant information about the user's safety situation is presented in an

- user-adaptable ontology-based interactive **circular visualization**
- showing **the value and uncertainty** for each high-level criterium
- the user is **guided** how to **collect** more **data** and run more **models** thereby **selectively reducing uncertainty**
- **Decision rules** will construct **SSbD advices** adapted to the user's current situation
- **Knowledge pages** collect all relevant information for each SSbD factor
  - up- & down-stream factors
  - relevant models & assays
  - data availability
  - text mining

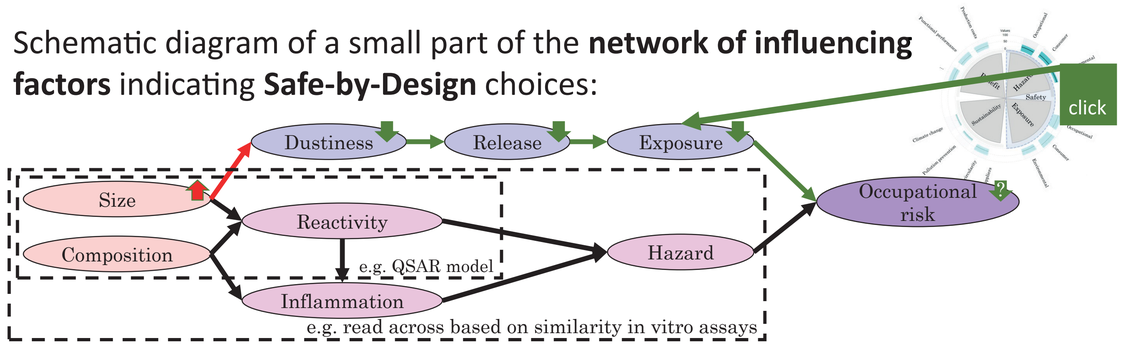


- **Status & Stage-gate progression** is presented by **stage-dependent decision criteria** indicating both **data sufficiency** as well as **safety itself**
  - Criteria are captured in **decision rule** logic

Safety and sustainability aspects	Product idea & screening
	Production & manufacturing
Occupational safety	
Environmental safety	
Climate change	
Resource use and circularity	
Pollution prevention	
Ethical suppliers	
	Use
Consumer safety	
Environmental safety	
Climate change	
Resource use and circularity	
Pollution prevention	
Benefits	
	End of life
Occupational safety	
Environmental safety	
Climate change	
Resource use and circularity	
Pollution prevention	

Data and Model Integration Approach

Schematic diagram of a small part of the **network of influencing factors** indicating **Safe-by-Design** choices:



- **Knowledge pages** for each node create an **interactive SSbD encyclopedia**
- **Runnable Models** allow to calculate factor values
- a **Bayesian Network model** will be used as an underlying integrative modelling framework
  - Allowing the **fusion of knowledge (RDF), data and models**
    - **Semantic knowledge (RDF)** can create the underlying network
    - Heterogenous data can be used to determine **probability function**
    - **Existing models** can be fused with the Bayesian model
  - Allowing to calculate values including their **uncertainty distribution**
  - Allowing **a tiered-approach** as not all inputs need to be known
- **a Business Rule Engine** will allow decision rules to
  - formulate **adaptive SSbD advice** texts (on each page/moment in the DSS)
    - How to improve insight in current status (which data/models)
    - How to improve design and process (which changes)
  - **Stage-dependent decision criteria** (traffic lights)

Decision Support Process

The decision support process is based on a well-established concept of **Risk Informed Decision Making** adopted by NASA & US NRC, based on the fusion of deterministic and probabilistic risk assessment. This allows decision making based on the probability density functions coming out of the Bayesian Network

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