

High-level statements

Stephan Wörseck

Switch to the voting system now regarding the project name

A name of a project is important for the communication.
Are there any other ideas?

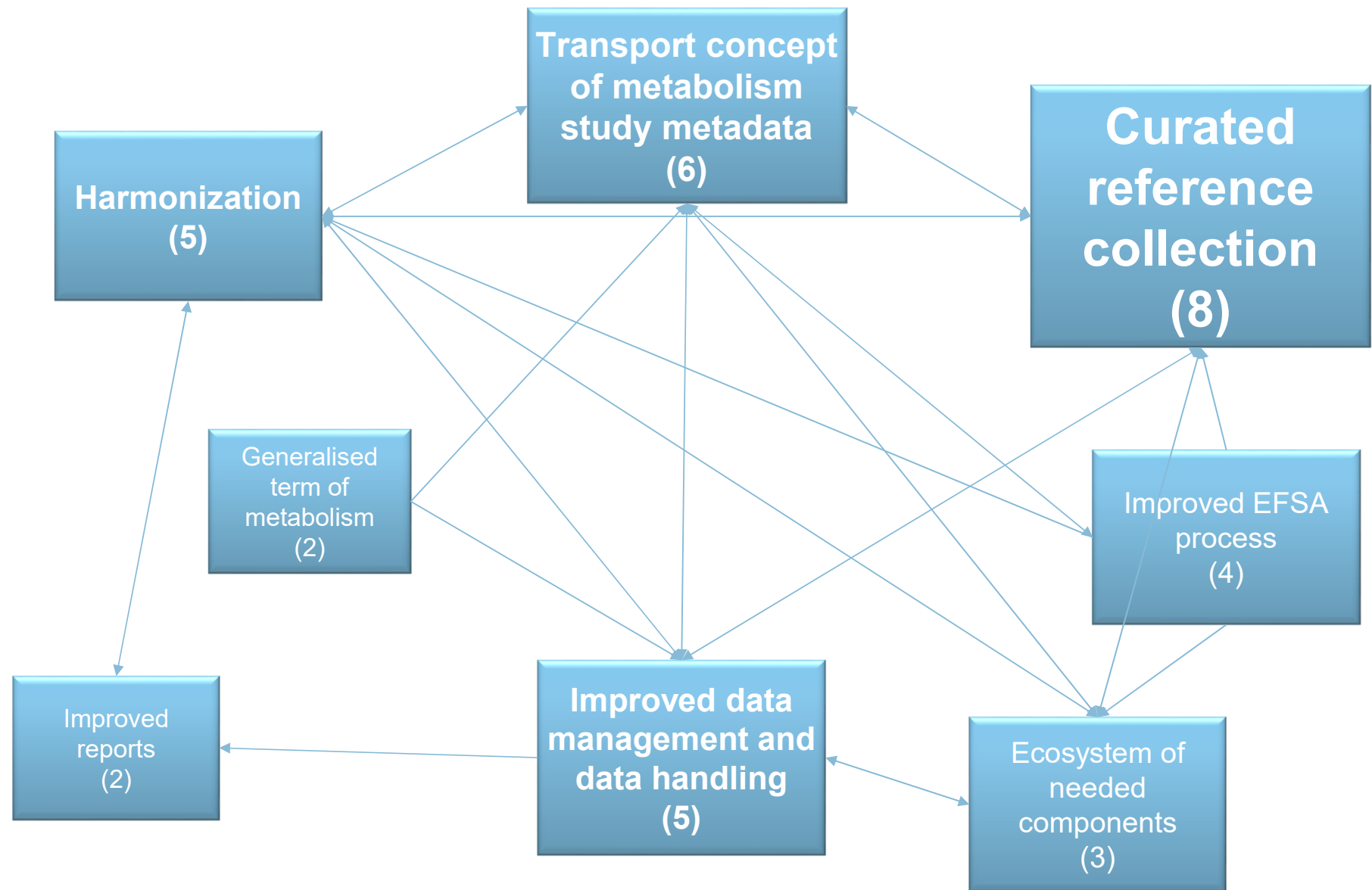
Which name do you prefer when it comes to an updated/improved MetaPath?

(multiple choice)

- MetaPath
- MetaPath II
- *i* MetaPath or MetaPath i (improved MetaPath)
- *e* MetaPath (extended MetaPath)
- *g* MetaPath (generalized MetaPath or global MetaPath)
- OECD MetaPath (comparable to OECD Toolbox)
- MetabolAS (**M**etabolism **A**ssessment **S**ystem)



High-level statements could be classified regarding the context



High-level statements could be classified regarding the type

Starting with	Meaning	Objective	Count of high level statements
O	Opinion	Assessment of the current state or of proposals by BfR	18
P	Proposal	BfR recommendations for further development	16
R	user R equirement	Objective requirement for further development but independent of the viewer	1

BfR received NO comments regarding the high-level statements in the commenting phase.

Interpretation:

The BfR has summarized the current situation correctly and has made generally acceptable proposals for the improvement.

Summary of high-level statements

Solid basis to start a substantial improvement process

because of the high degree of overlap of the user requirements of applicants and authorities.

“Generic” concept of the term metabolism

was not contradicted in the commenting phase.

There is a need for a MetabolAS ecosystem

The governance concept should be open for all metabolism studies independent of the legal context (pesticides, biocides, chemicals).

Summary of high-level statements

There is a need for an appropriate transport concept of metabolism study metadata

The preferred technical transport mechanism for “Aggregated Raw Data” from metabolism studies is the “**OECD Attachment Type**”.

There is a need for a curated reference collection of metabolism study metadata

to avoid further tests on vertebrate animals as well as reducing uncertainty in human exposure assessments without lowering the level of protection.

IUCLID is not suitable to serve as the database management system for the curated reference collection of metabolism study metadata.

Summary of high-level statements

There is a need for improved data management and data handling

The time has come to move the valuable concept and information contained in “MetaPath” to a new technological level.

Proposal to make a radical technological change !

There is a need for improved reports

The quality and the reusability of formatted text blocks will become the indicator of user acceptance.

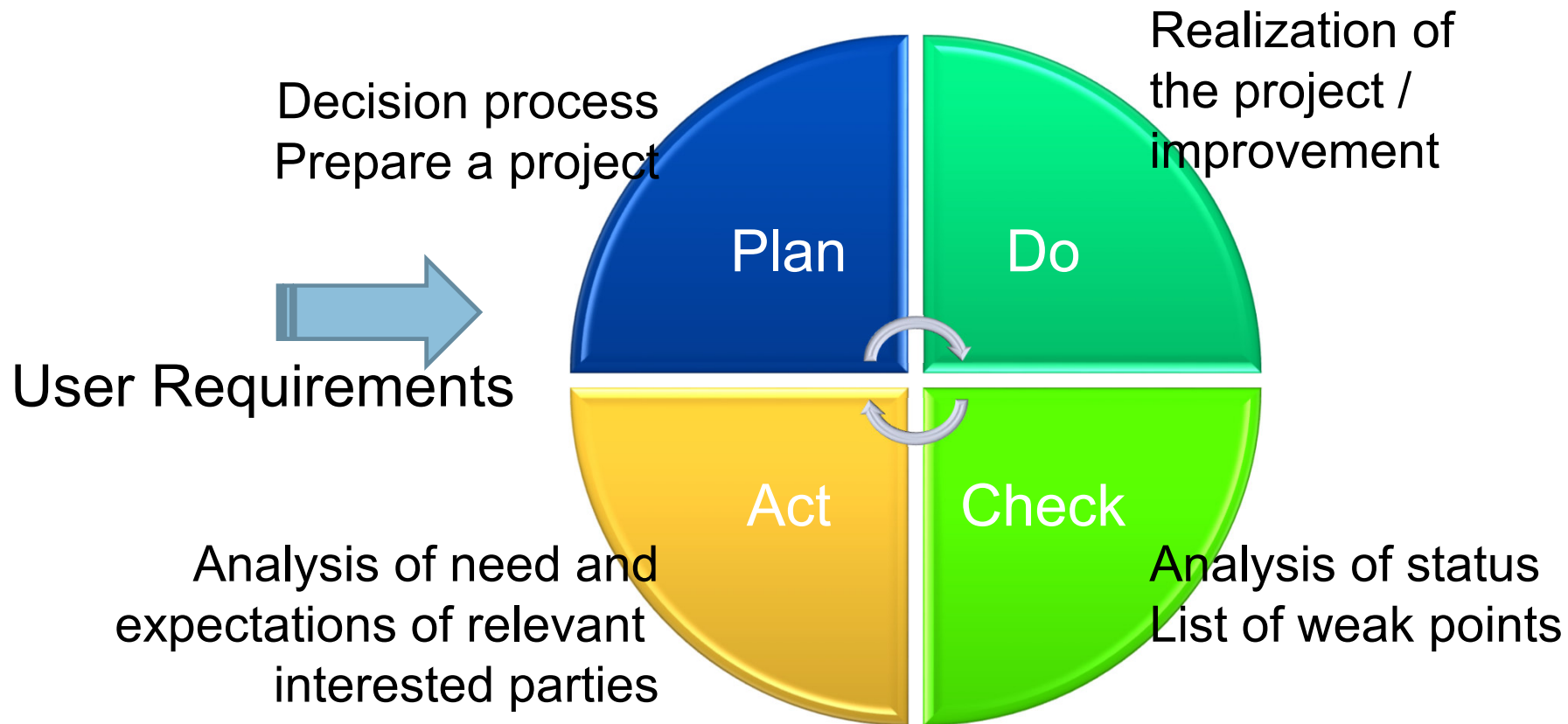
There is a need for an improved authority process

The role of the XML files in the process must be fundamentally changed. In future, the XML files are to be only considered as temporary transport containers.

The improved authority process should guarantee the principle:

“One substance – one assessment”

Be open for improvements according the PDCA Cycle of ISO 9001 “Quality management systems”



Now the EFSA has to take the role of leading the process!

Before making decisions, always put traditional practices up to the test.

Meet fact-based, not political, decisions!

If radical changes are needed, they should be initiated.

Thank you for your attention

Stephan Worseck

German Federal Institute for Risk Assessment

Max-Dohrn-Straße 8-10 • 10589 Berlin, GERMANY

Phone +49 30 - 184 12 - 0 • Fax +49 30 - 184 12 – 99 0 99

bfr@bfr.bund.de • www.bfr.bund.de/en