

# **Draft „Executive Summary“**

Tanja Schwerdtle

## The short chapter 3.2. “Executive Summary”

- This chapter is directly addressed to the originator of this report, to EFSA.
- EFSA has to organize the decision making process for the needed improvement process for the metabolism studies.
- A set of high-level decision's are needed. All relevant stakeholders should be included in this process.
- **It is recommended that no technical decisions are placed on this level.**
- After that, EFSA has to establish an adequate project structure.

It may be that a number of the following points are already identified in EFSA's follow-up presentation "Establish an adequate improvement process".

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### 3.2 Executive Summary

EFSA has to organize the decision making process for the needed improvement process. A set of high-level decision's are needed. All relevant stakeholders should be included in this process.

D 3.2-32: EFSA has to decide about the necessity, priority and time horizon to build up an ecosystem "Metabolism Assessment System" with the needed components regarding the information flow of metabolism studies.

→ Yes / No  
→ short-term / mid-term / long-term

D 3.2-33: EFSA has to decide which bugs should be fixed in "Metapath" and in the programs of the "DERMSS-Composer Family" to ensure the needed functionality in the meantime until the new "Metabolism Assessment System" could go into production.

→ Priority list

D 3.2-34: EFSA has to decide about the necessity, priority and time horizon to build up an international curated reference collection of metabolism studies as part of the "Metabolism Assessment System".

→ Yes / No  
→ short-term / mid-term / long-term

D 3.2-35: EFSA has to initiate a decision on OECD level about the governance body of the ecosystem "Metabolism Assessment System".

→ OECD as the governance body / governance body outside of the OECD

D 3.2-36: Decision whether IT components of the ecosystem could be part of an "Open Source Project" in which the interested parties contribute to the community.

→ Yes / No

D 3.2-37: If OECD takes on the role of the governance body, EFSA has to decide about their own role in this improvement process. EFSA should offer to start an improvement process on basis of the experiences and algorithms of "Metapath" but on a new technological level. The "Metabolism Assessment System" should be offered to the international community.

If OECD takes not the role of the governance body, EFSA has to organize the project "Metabolism Assessment System" in an adequate manner alone.

EFSA has to have a cost estimate carried out on the basis of this report and the political decisions taken. EFSA has to ensure an adequate funding in an adequate time frame.

→ Needed project funding is organized

After that, EFSA has to establish an adequate project structure.

## The list of needed decisions

### **D 3.2 32:**

EFSA has to decide about the necessity, priority and time horizon to build up an ecosystem “Metabolism Assessment System” with the needed components regarding the information flow of metabolism studies.

- Yes / No
- short-term / mid-term/ long-term

### **D 3.2 33:**

EFSA has to decide which bugs should be fixed in “MetaPath” and in the programs of the “DER/MSS-Composer Family” to ensure the needed functionality in the meantime until the new “Metabolism Assessment System” could go into production.

- Priority list

## The list of needed decisions

### D 3.2 37:

EFSA has to decide about the necessity, priority and time horizon to build up an international curated reference collection of metabolism studies as part of the “Metabolism Assessment System”.

- Yes / No
- short-term / mid-term/ long-term

### D 3.2 38:

EFSA has to initiate a decision on OECD level about the governance body of the ecosystem “Metabolism Assessment System”.

- OECD as the governance body /  
governance body outside of the OECD

### D 3.2 39:

Decision whether IT components of the ecosystem could be part of an “**Open Source Project**” in which the interested parties contribute to the community.

- Yes / No

## The list of needed decisions

### **D 3.2 40:**

If OECD takes on the role of the governance body, EFSA has to decide about their own role in this improvement process. EFSA should offer to start an improvement process on basis of the experiences and algorithms of “MetaPath” but on a new technological level. The “Metabolism Assessment System” should be offered to the international community.

If OECD takes not the role of the governance body, EFSA has to organize the project “Metabolism Assessment System” in an adequate manner alone.

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- Needed project funding is organized

# Which other high level decisions should be communicated to EFSA?

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- Yes / No
- short-term / mid-term/ long-term

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- Yes / No

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- If OECD takes not the role of the governance body, EFSA has to organize the project "Metabolism Assessment System" in an adequate manner alone.

EFSA has to have a cost estimate carried out on the basis of this report and the political decisions taken. EFSA has to ensure an adequate funding in an adequate time frame.

- Needed project funding is organized

After that, EFSA has to establish an adequate project structure.

# **Thank you for your attention**

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