Standard Operating Procedure

Number: **023**

Name: **Method validation**

Title: Procedure for the validation of methods used on the EU Pollinator Hub

Category: Metadata

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Authors: Michael Rubinigg

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1 Document history

1.1 Current Release

1.1.1 Drafted

Submitted on 2023-06-17 by Michael Rubinigg, quality manager.

1.1.2 Reviewed

Reviewed on 2023-06-30 by Noa Simòn Delso, general manager.

1.1.3 Approved

Approved on 2024-02-07 by Michael Rubinigg, quality manager.

1.2 Change history

n.a.

2 Abbreviations

EU	European Union
EUPH	EU Pollinator Hub
n.a.	not available
SOP	Standard Operating Procedure

3 Introduction

The aim of the current SOP is to provide validation protocols for scripts containing analytical algorithms used in the EU Pollinator Hub.

4 Validity

4.1 Area

The of validity of this document is limited to the validation of methods used on the EU Pollinator Hub.

4.2 Time

The period of validity of this SOP begins on 2024-02-07 and ends with its revocation.

4.3 Related Documents

Document type	Number	Name
SOP	001	SOP instructions
SOP	004	Organisation chart
SOP	009	Methods

4.4 Related Tasks

Persons who have been assigned one of the following tasks, as defined in SOP-004, assume a responsibility within this SOP:

- Quality management
- Data analysis and statistics

5 Procedure

5.1 Validation of analytical algorithms used by the EU Pollinator Hub

5.1.1 Validation of scripts containing analytical algorithms used for data profiling

5.1.1.1 Development of a validation protocol

- The person responsible for data analysis and statistics, as defined by SOP-004, or a person appointed by him/her for this purpose, develops a validation protocol for newly developed scripts containing analytical algorithms used for the following purpose:
  - Unit conversion
  - Data profiling
  - Data analysis
- The Validation Protocol must contain the following information:
  - Description of the test item;
  - Description of the parameters to be measured;
  - Description of the parameters to be reported;
  - Description of the dataset used to test the analytical algorithm;
  - Description of the expected results obtained by the scripts to be validated;
  - Method(s) to be used to measure these parameters, according to SOP-009;
- The person responsible for quality management, as defined by SOP-004, approves the protocol, rejects it, or requests modifications.

5.1.1.2 Validation process

- The person responsible for data analysis and statistics, as defined by SOP-004, or a person appointed by him/her for this purpose, performs the method contained in the approved validation protocol.

5.1.1.3 Reporting

- The person responsible for data analysis and statistics, as defined by SOP-004, or a person appointed by him/her for this purpose, drafts a Validation Report (VR).
- A template file provided by the person responsible for quality management, shall be used for drafting the VR.
- A VR consists of a description of the test item and validation protocol (section 5.1.1.1), validation results (sections 5.1.1.2) and final decision (section 5.1.1.4).
- An incrementing report number is assigned to the report.

- The file name of the VR is composed as follows: ***VR_***[*report number*].

5.1.1.4 Final decision

- If, based on the results of the test, the person responsible for quality management, as defined by SOP-004, concludes that the results from validation are consistent with the expected results, it approves the change.
- If, based on the results of the test, the person responsible for quality management, as defined by SOP-004, concludes that the results from validation are not consistent with the expected results, it rejects the change.

5.1.1.5 Deployment to the production environment

- In case of approval of the validation, scripts may be deployed to production environment.

6 References

There are no sources in the current document.

7 Annexes

There are no annexes in the current document.