



PROMETHEUS

PROMoting METHods for Evidence Use in Scientific assessments

Management Board Meeting
11 October 2017

Background, rationale, objectives

OBJECTIVE 4 OF EFSA STRATEGY 2020

‘Prepare for future RA challenge’ and in particular:

1. Develop and implement harmonised methodologies and guidance documents for RA across the EU and internationally
2. Become a hub in methodologies, tools and guidance documents for RA

THE PROCESS for 'EVIDENCE USE'

Problem Formulation



In
consultation
with
mandate
requestor

Data collection
Evidence appraisal
Evidence integration
Interpretation of results

Publication

Uncertainty assessment
Weight of Evidence
Biological relevance

THE EFSA CONTEXT



EFSA questions and related evidence are **diverse**, e.g.:

- efficacy
- safety
- exposure
- prevalence/incidence
- full risk assessments

EFSA questions are answered by:

- primary data collections**
- reviews of existing data**
- expert knowledge elicitation**

Different actors involved: experts, staff, applicants, contractors

OBJECTIVES

EFSA PROMETHEUS project (2014-18)

PROmoting **METH**ods for **E**vidence **U**se in **S**cientific assessments

<http://www.efsa.europa.eu/en/methodology/evidence>

Data collection and analysis

Dealing with Evidence

To:

- improve further the methods for evidence use in EFSA scientific processes
- increase their consistency across the different EFSA areas

Original deadline: Oct 2016

Extension: Apr 2018, to allow further work on case-studies



DELIVERABLES

1st Deliverable



Jun 2015

Methodological framework

2nd Deliverable



Oct 2016

Analysis of EFSA needs to implement the framework

In consultation with and endorsed by the SC

The PROMETHEUS framework in a nutshell (deliverable 1)

PROMETHEUS

1. PLAN

Problem Formulation



Protocol Development

- methods for conducting the assessment
- the **extent to which apply extensive/systematic approaches**



2. CARRY OUT

Data collection
Evidence appraisal
Evidence integration
Interpretation of results

Uncertainty assessment
Weight of Evidence
Biological relevance

3. VERIFY

4. REPORT

Publication

1. Impartiality

2. Excellence in scientific

For all EFSA assessments:

- 3. not regulated
- 4. regulated
- outsourced

Case-studies testing the 4-step approach (2014-2019)

| Panel | Subject/Type | Status (12/09/2017) | Comment |
|------------|---|--|--|
| ANS | Isoflavones Non-dossier | Finished | / |
| BIOHAZ | Listex Dossier | Finished | Panel recommended to update GD |
| CONTAM | Dioxins Non-dossier | Ongoing (Jun 2018) | / |
| GMO | PMEM report (also for Uncertainty GD) Dossier | Finished (Protocol) On-going (GD - third quarter 2018 - tbc) | The Protocol included only the problem formulation part Panel proposed to stop and develop new GD |
| AHAW | Bluetongue Non-dossier | Finished | / |
| Pesticides | Glyphosate animal health Dossier + EC mandate | Ongoing (Nov 2017) | Targeted consultation on protocol |
| CEF | BPA Non-dossier | Ongoing (end 2018 - tbc) | Public consultation on protocol |
| NDA | Sodium (DRVs) Non-dossier | Ongoing (Mar 2019) | Public consultation on protocol |
| PLH | E. Lewisi Non-dossier | Finished | Panel is considering to integrate some of the PROMETHEUS elements in the GD |
| FEEDAP | Lancer (also for Uncertainty GD) Dossier (old) | Finished | Contributing to GD update |

- ❑ Diverse types of scientific assessment
- ❑ Impact of the 4-step approach assessed via a survey
- ❑ Benefits, issues, possible solutions related to implementation discussed in Internal Workshop on 9-10 Oct 2017

Way forward

IMPLEMENTATION OF 4-STEP APPROACH IN EFSA ASSESSMENTS

Next steps to be defined on the basis of:

- Experience in case-studies
- Impact assessment in case-studies
- Benefits, issues, solutions identified in Internal Workshop (Oct 9-10)

Projects triggered by PROMETHEUS

PROJECTS TRIGGERED BY PROMETHEUS

- 1. Evidence integration:** EFSA Colloquium in joint collaboration with Evidence Based Toxicology Collaboration (EBTC) (Lisbon, 25-26 Oct 2017)
- 2. Definition of quality and excellence for EFSA scientific assessments,** to lay down the basis for a quality management system for EFSA scientific processes
- 3. Methods for evidence appraisal** (under discussion)