Technical Stakeholder Event: Re-evaluation of authorised food additives- focus on sweeteners

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A move forward evidence-based risk assessments: developing protocols for the re-evaluation for sweeteners

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Trusted science for safe food

efsa
European Food Safety Authority

Scientific assessments

- EFSA contributes to the safety of the EU food chain by providing scientific advice on food and feed safety

- The assessment process includes collection, appraisal and analysis of existing evidence

- EFSA core values when carrying out such assessments are **impartiality**, excellence, **transparency and openness** and responsiveness.

Transparency and openness requires structure

A NARRATIVE APPROACH

The protocol is a part of a bigger picture

- PROmoting METHods for Evidence Use in Scientific assessments (**PROMETHEUS**) is an EFSA initiative designed to foster these principles.

SCIENTIFIC REPORT

EFSA Journal

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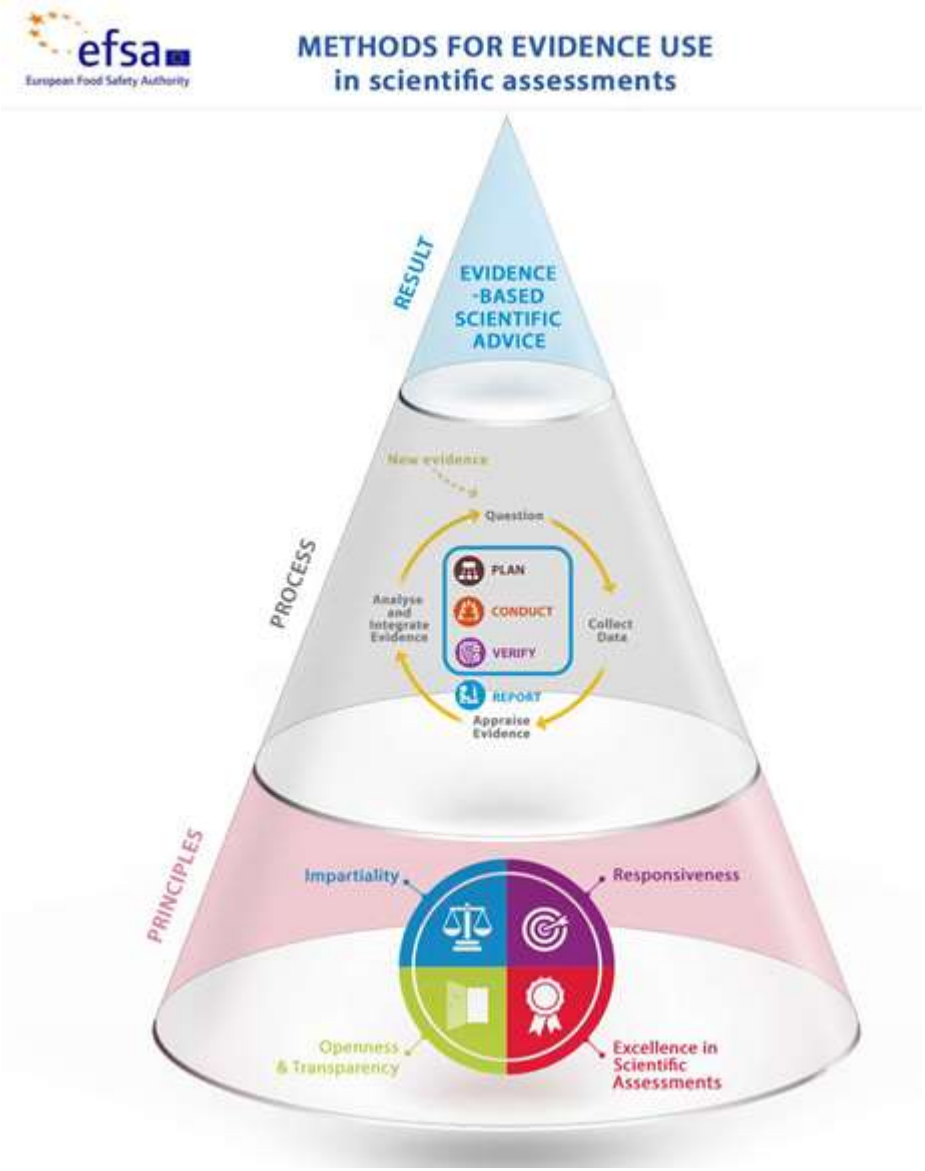
Principles and process for dealing with data and evidence in scientific assessments

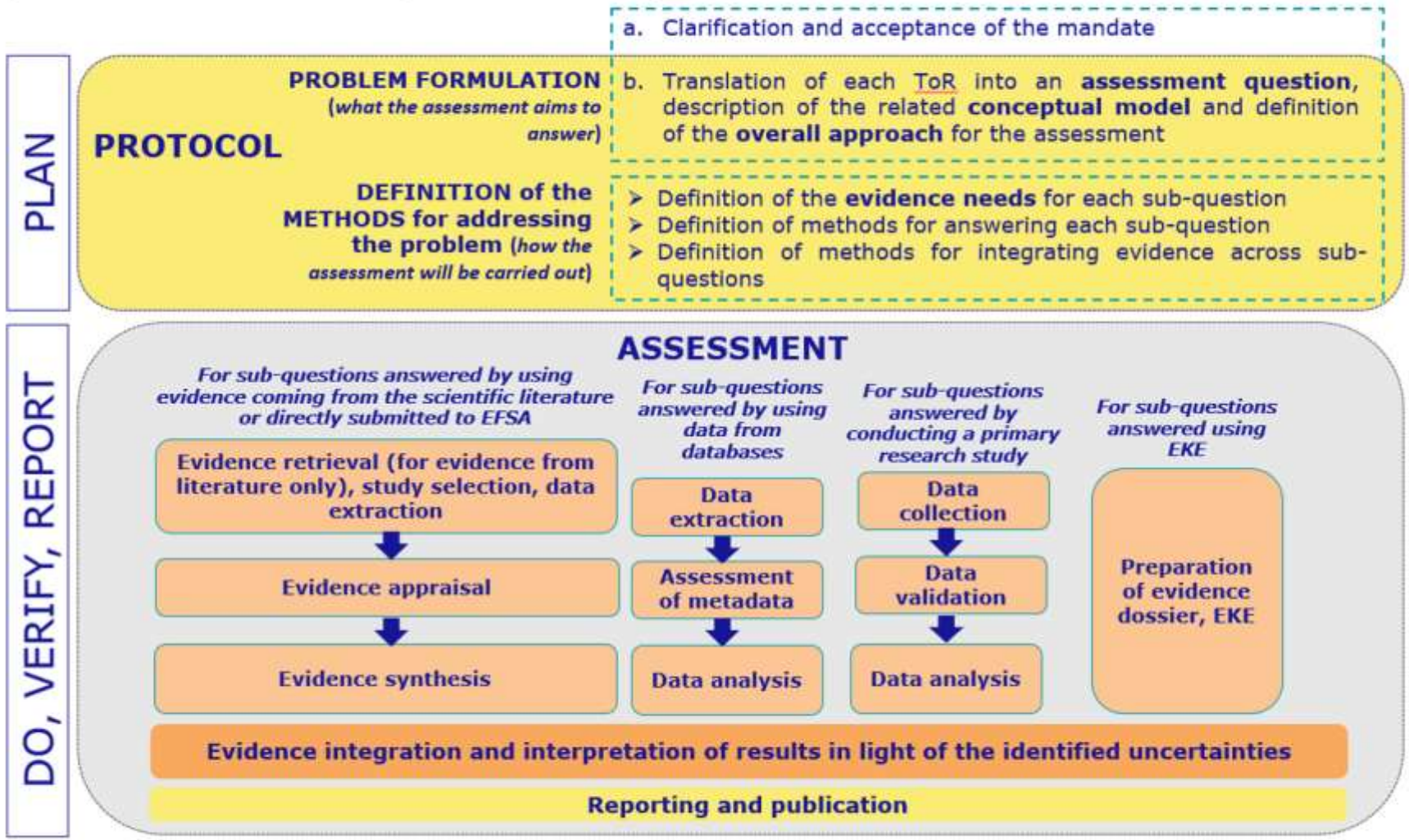
European Food Safety Authority (EFSA)

Abstract

In the context of further developing the excellence of its scientific assessments, enhancing their transparency and openness and in line with the trend in the scientific community, EFSA started the PROMETHEUS project (Promoting Methods for evidence use in scientific assessments) (2014–2016), which aims at further improving EFSA's methods for "dealing with data and evidence" (i.e. for collecting/extracting, validating/appraising, analysing and integrating data and evidence) and increasing their consistency. The project envisages two scientific reports: the present document, which illustrates the principles and process for evidence use, and a second one, which will contain an analysis of the methods for dealing with evidence applied by the Authority and an impact analysis of the implementation of the PROMETHEUS process in EFSA. Methodological aspects related to the



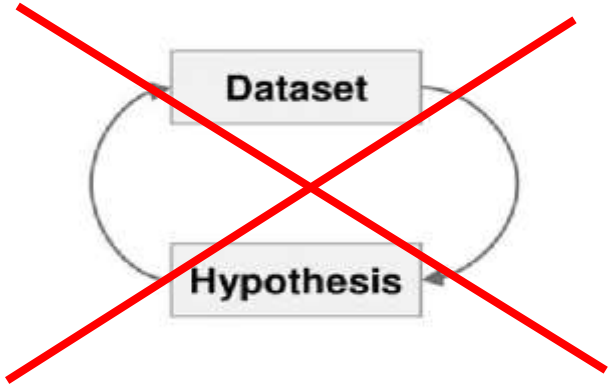
It has its logical place and function within the assessment process



Protocol = planning before doing

Advantages for the work process

- It ensures transparency and openness
- It acts as a guard against arbitrary decision making during the assessment process.
- It protects against cognitive biases, as outcomes are unknown when methods are defined
- It makes HARKing “Hypothesing After the Results are Known” more difficult
- “Asking questions at the design stage saves headaches at the analysis stage”



Advantages for stakholders

- Sharing and submitting the protocol for public consultation prior to initiating the assessment makes it more likely the work addresses the requestors´ needs

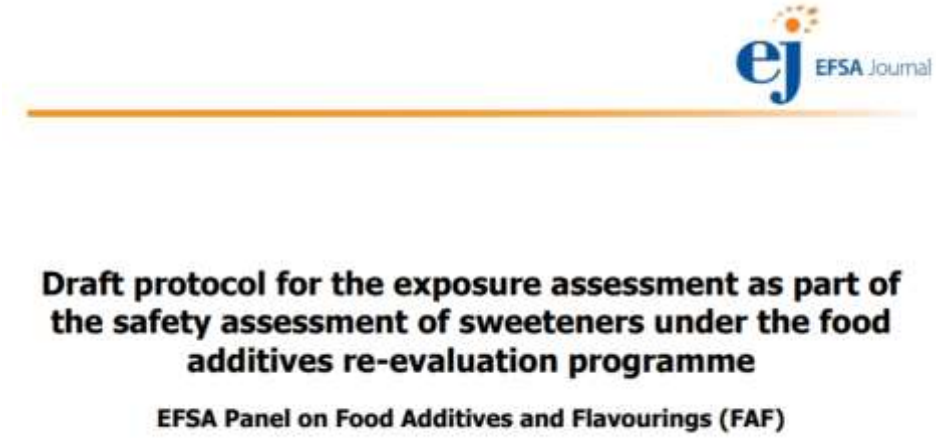
- It allows relevant stakeholders and others to assess what will be done and provide input (for consideration)

- Both for the requestor and stakeholders there should be fewer elements for surprise

Two protocols were developed

- Draft protocol for the assessment of hazard identification and characterisation of sweeteners

- A separate protocol for exposure



Challenges

- A large group of different substances
- Data density varies substantially
- Describing what method will be applied in detail in such a case is challenging

E Number	Food additive(s)		Substance
E 420	Sorbitols	E 420 (i) E 420(ii)	Sorbitol Sorbitol syrup
E 421	Mannitols	E 421(i) E 421(ii)	Mannitol by hydrogenation Mannitol manufactured by fermentation
E 950	Acesulfame K		
E 951[(a)]	Aspartame[(a)]		
E 952	Cyclamates	E 952(i) E 952(ii) E 952(iii)	Cyclamic acid Sodium cyclamate Calcium cyclamate
E 953	Isomalt		
E 954	Saccharin and its Na, K and Ca salts	E 954(i) E 954(ii) E 954(iii) E 954(iv)	Saccharin Sodium saccharin Calcium saccharin Potassium saccharin
E 955	Sucralose		
E 957	Thaumatin		
E 959	Neohesperidine dihydrochalcone		
E 961	Neotame		
E 962	Salt of aspartame-acesulfame		
E 965	Maltitols	E 965(i) E 965(ii)	Maltitol Maltitol syrup
E 966	Lactitol		
E 967	Xylitol		
E 968	Erythritol		

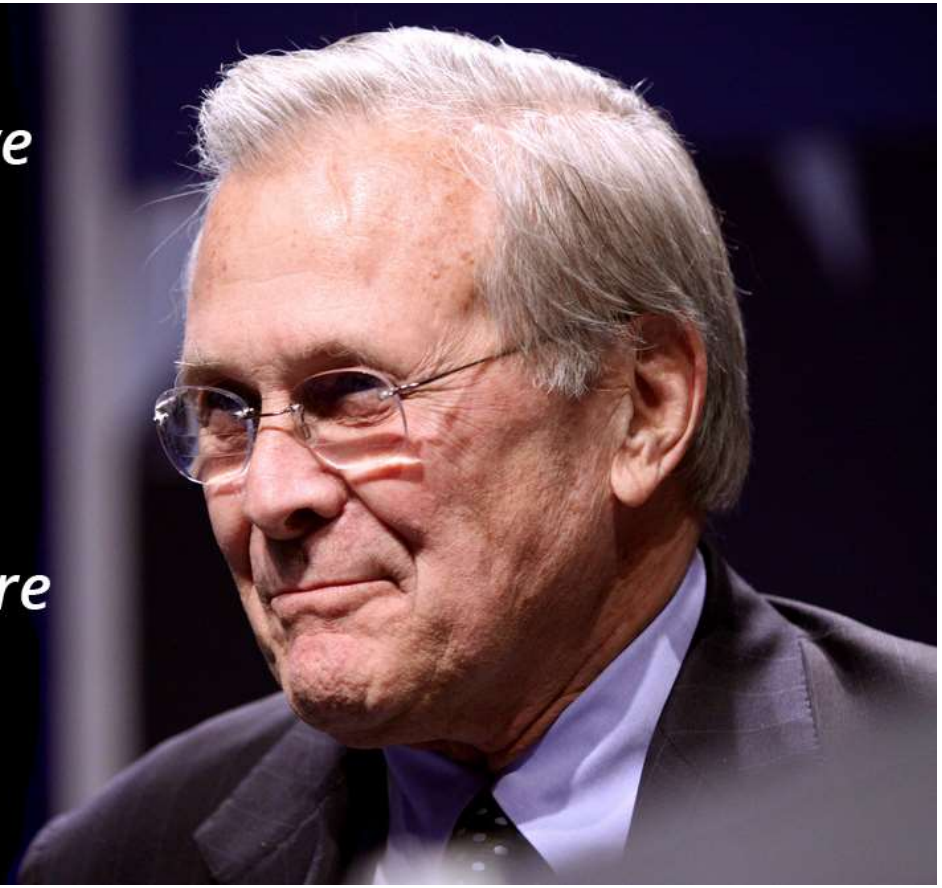
Not everything can be planned for

There are known knowns; there are things we know that we know.

There are known unknowns; that is to say, there are things that we now know we don't know.

But there are also unknown unknowns – there are things we do not know we don't know.

-Donald Rumsfeld



A protocol does not mean being inflexible

- There should always be room for adapting and responding to new reality

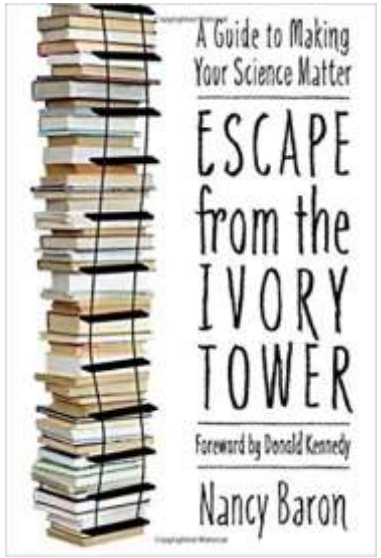
- …but any such changes need to be documented and justified

Important to avoid and be aware of

- A protocol provides structure, but that on its own is not sufficient

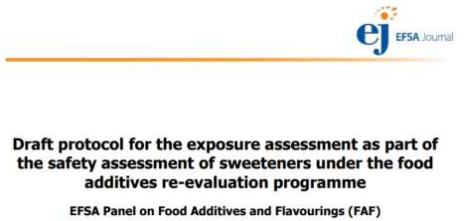
- **A protocol does also not guarantee a more valid output**.

- **It just makes right or wrong decisions more transparent**



You can newer take expertise out of the equation

- The two published protocols define what will be done in a transparent way.



- For that to be successfully implemented you need a group of experts

Experts

Name	Role	Declaration of Interest
CASTLE Laurence	Member	DoI
CREBELLI Riccardo	Member	DoI
FRUTOS FERNANDEZ Maria Jose	Member	DoI
FURST Peter	Member	DoI
GUNDERT-REMY Ursula	Member	DoI
HALLDORSSON Thorhallur Ingi	Member	DoI
HUSOY Trine	Member	DoI
LEBLANC Jean-Charles	Member	DoI
LINDTNER Oliver	Member	DoI
SHAH Romina	Member	DoI
YOUNES Maged	Chair	DoI

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