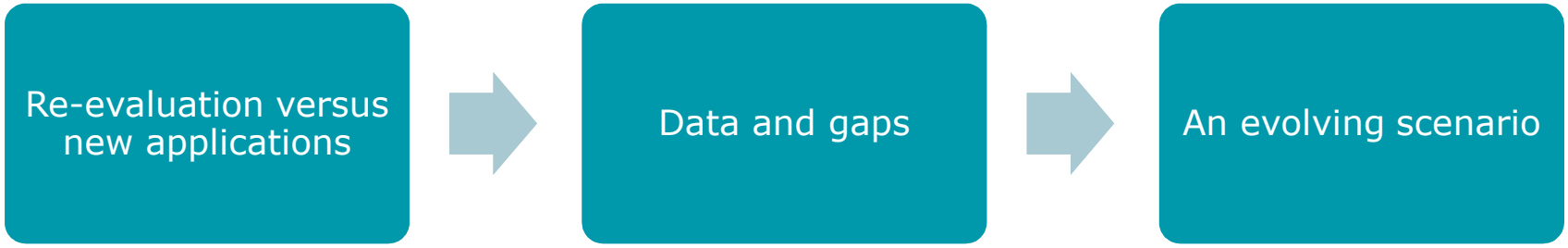
Guiding principles in the safety assessment of food additives

Parma, 24 November 2017

David Gott
Chair of the Working Groups Applications

efsa
European Food Safety Authority

OUTLINE

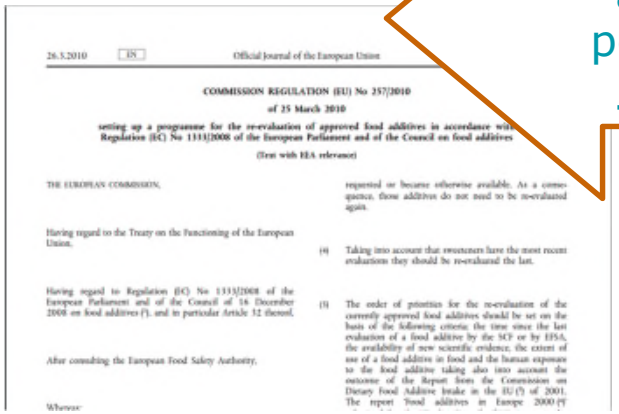

Re-evaluation versus new applications
Data and gaps
An evolving scenario

Re-evaluation vs new applications

RE-EVALUATION VS NEW APPLICATIONS

Re-evaluation programme

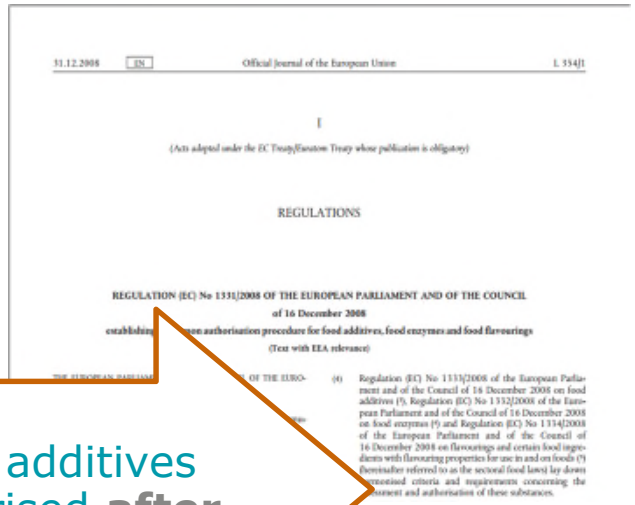
Reg. 257/2010



COMMISSION REGULATION (EU) No 257/2010
of 25 March 2010
setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives
(Text with EEA relevance)

Food additives already permitted **before**

Food additives authorised **after**



REGULATIONS

REGULATION (EC) No 1331/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
establishing a common authorisation procedure for food additives, food enzymes and food flavourings
(Text with EEA relevance)

Common authorisation procedure

Reg. 1331/2008

20 Jan 2009

RE-EVALUATION VS NEW APPLICATIONS

Re-evaluation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SCIENTIFIC OPINION

Statement on a conceptual framework for the risk assess
food additives re-evaluated under Commission Regulatio
257/2010[1]

EFSA Panel on Food additives and Nutrient Sources added to Food (ANS)[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific statement presenting a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010. This framework will be used in the evaluation made by the Panel, but the expert judgement of the scientific background, on a case-by-case basis, remains essential to reach a final conclusion. The outcome of the re-evaluation of food additives taking into account all available information is presented in the document, as well as the exposure assessment scenarios to be carried out by the Panel considering the use levels set in the legislation and the availability of adequate usage or analytical data.

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KEY WORDS

Commission Regulation (EU) No 257/2010, food additives, re-evaluation, risk assessment

Food additives already permitted **before**

Food additives authorised **after**


efsa
EFSA Journal 2012;10(7):2760

SCIENTIFIC OPINION

Guidance for submission for food additive evaluations[1]

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

This Scientific Opinion, published on 16 August 2012, replaces the earlier version published on 18 July 2012.[4]

ABSTRACT

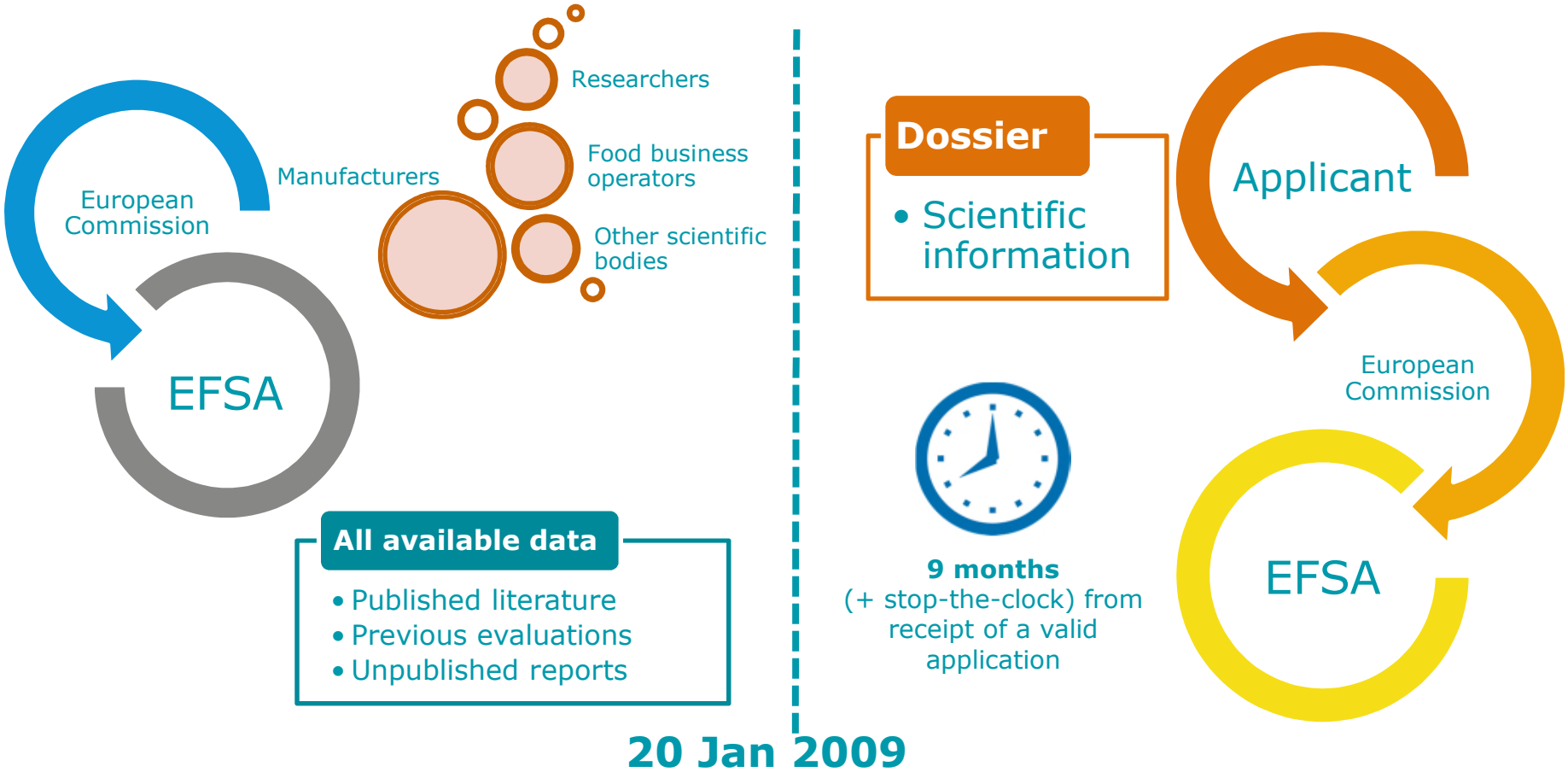
This guidance document refers to the applications for authorisation of a new food additive or to a modification of an already authorised food additive, combining in a single document the description of the data requirements and their context, and also a description of the risk assessment paradigm applied. The document is arranged in four main sections: chemistry and specifications, existing authorisations and evaluations, proposed uses and exposure assessment, and toxicological studies. Assessment of the exposure to food additives is based on information known, or anticipated human exposure to the proposed additive or toxicologically relevant constituents of the additive from food, and any other potential dietary sources. For the toxicological studies, this guidance proposes a tiered approach which balances data requirements against the risk, taking into consideration animal welfare by adopting animal testing strategies in line with the 3-Rs (replacement, reduction, refinement). This tiered approach for toxicological studies consists of 3 tiers, for which the testing strategy and triggers are described. According to this tiered approach, a minimal dataset has been developed under Tier 1, while Tier 2 testing, generating more extensive information which are absorbed and/or demonstrate (geno)toxicity in Tier 1 tests. Tier 3 is a case-by-case basis taking into consideration all the available data, to elucidate the mechanism of findings in Tier 2 tests. This guidance document replaces the Opinion of the Scientific Committee for Food published in 2001.

...tion, Tiered approach, Risk assessment, Toxicological studies.

New applications

20 Jan 2009

RE-EVALUATION VS NEW APPLICATIONS



Data and gaps

SCIENTIFIC ASSESSMENT

In the re-evaluation of food additives the available pieces of the jigsaw are put together

There may be missing pieces, but can we still understand the picture?

SCIENTIFIC ASSESSMENT

Technical part

- Identity of the substance
- Specifications
- Analytical results
- Manufacturing process
- Methods of analysis in food
- Stability and fate in food

Questions

- What is the food additive?
- Are we talking about the same substance that it was assessed at the time of the initial authorisation?
- What are residuals/by products resulting from manufacturing process/storage/interaction with food?

HAZARD IDENTIFICATION

SCIENTIFIC ASSESSMENT

Biological and toxicological data

- ADME (absorption, metabolism, distribution, excretion)
- Genotoxicity (in vitro, in vivo)
- General toxicity (short-term, sub-chronic, chronic, carcinogenicity)
- Reproductive toxicity
- Immunotoxicity
- Other studies

Questions

- What happen to the additive once it is ingested with the diet? Is it absorbed? To what is it metabolised?
- Are adverse effects identified from the available studies?
- If yes: can a dose response be identified?
- If no: true lack of effect or lack of data?
- Are the data availabile still reliable to today's standards?

HAZARD CHARACTERISATION

SCIENTIFIC ASSESSMENT

Dietary exposure

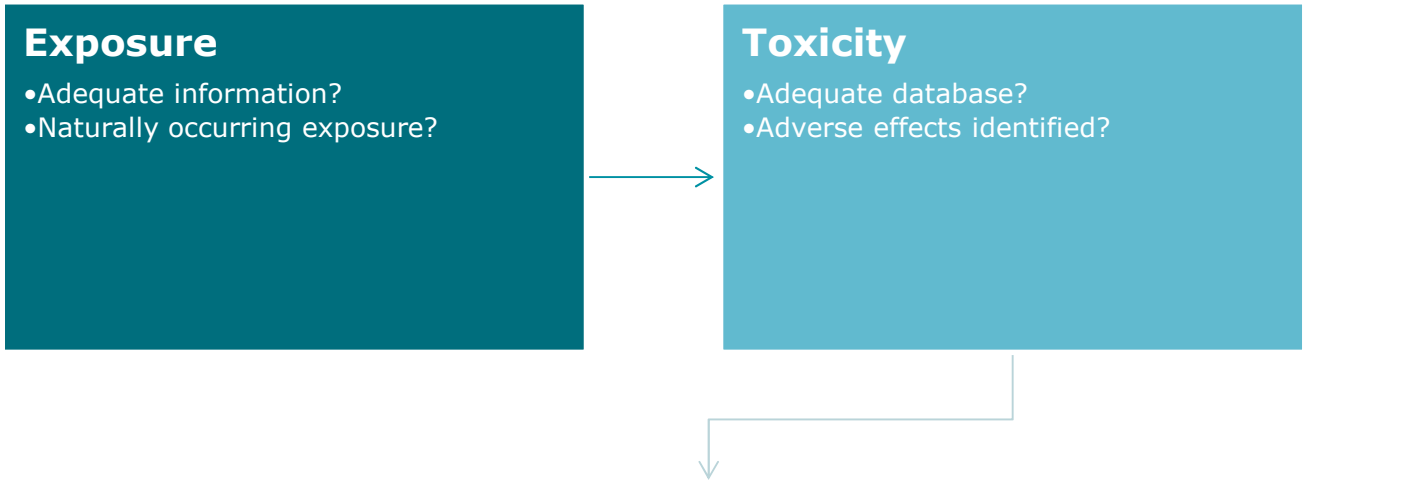
- Maximum permitted levels given in the legislation
- Typical uses and use levels
- Analytical data
- Other sources of exposure

Questions

- How much is the daily intake of the food additive in the EU population?
- Are there groups of the populaton that are exposed to it more than others?
- Is the additive really used in all the food categories in which it is authorised?
- Which food categories contribute most to the exposure?

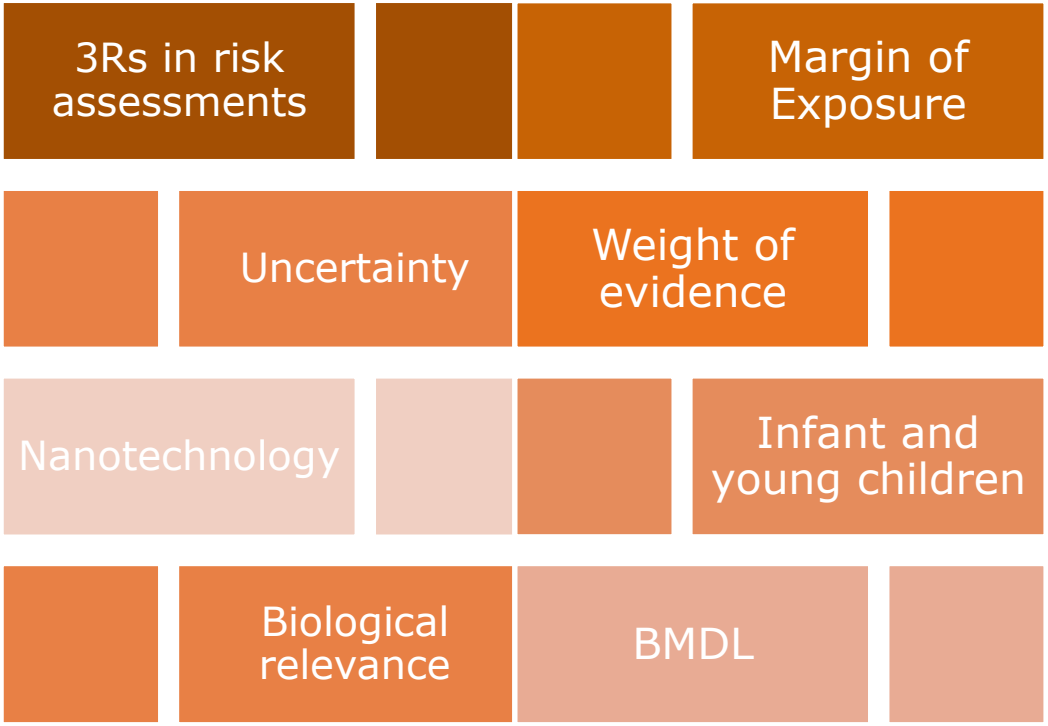
EXPOSURE ASSESSMENT

CONCEPTUAL FRAMEWORK FOR RE-EVALUATION



An evolving scenario

HORIZONTAL ISSUES



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