European Food Safety Authority

Data availability and the outcome of risk assessment

Claude Lambré, Vice-Chair of the ANS Panel

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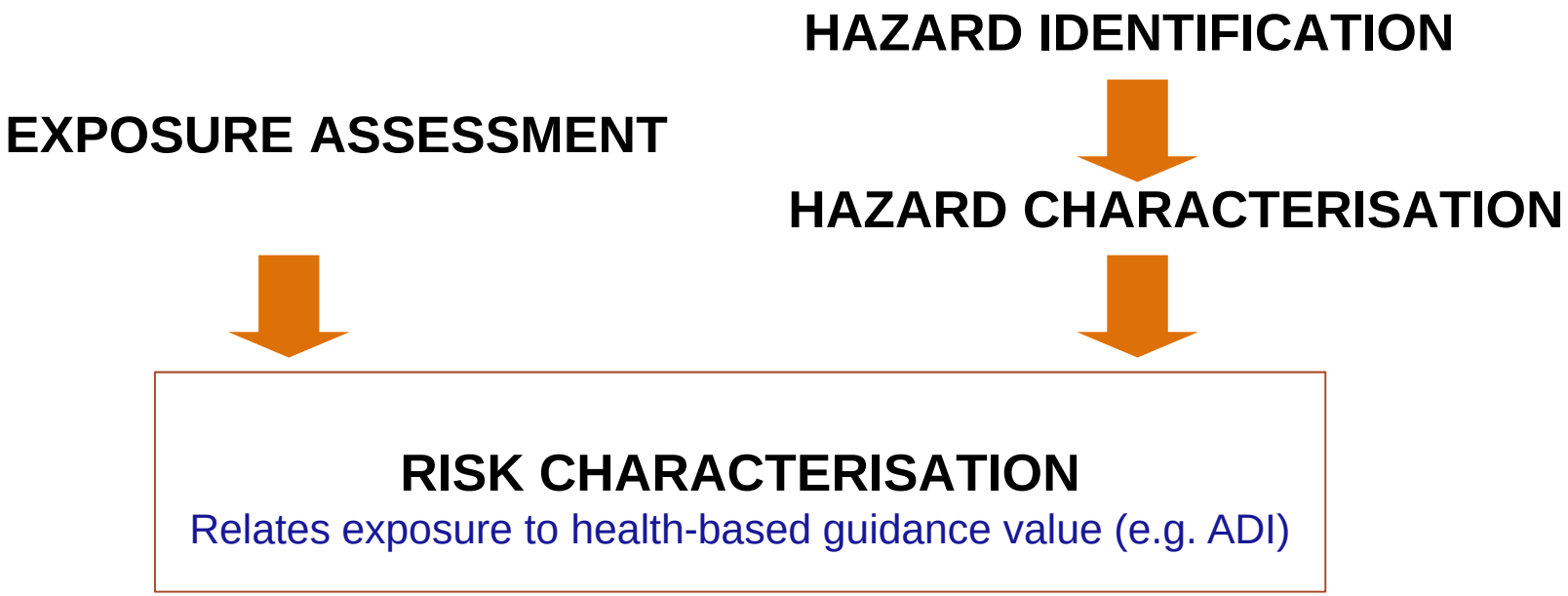
The Risk Assessment Paradigm (1)



The Risk Assessment Paradigm (2)

- ***Hazard identification and characterisation***

The chemical and technological assessment identifies the hazards, which are then further characterised via their biological and toxicological dose-response relationships.

In carrying out a risk assessment, the ANS Panel seeks to define a health-based guidance value, e.g. an Acceptable Daily Intake (ADI), applicable to the general population.

The ADI is defined for compounds for which a threshold mechanism of toxicity can be demonstrated based on the available data.

The Risk Assessment Paradigm (3)

- ***Exposure Assessment***

The qualitative and/or quantitative evaluation of the likely intake of a food additive by the European population.

The overall Risk Assessment of the food additive for potential human risk should be made in the context of its known or likely total human exposure in comparison with the ADI.

The Risk Assessment Paradigm (4)

- ***Outcome of the risk assessment***

The ADI is compared with the total human exposure estimate resulting from the use of the food additive at the proposed uses and use levels, and also includes exposure from other sources.

The daily intake must remains below the ADI

Background

- Since 2009 the ANS Panel is re-evaluating food additives (Regulation (EU) No 257/2010).
- EFSA makes one/more public open calls for scientific data (technical information, use and use levels, ADME data, toxicological data).
- In many cases, calls for data were unsuccessful: full risk assessment cannot be carried out with inadequate information on use (use and use levels) and limited biological data (often out-dated).

Background

That situation has strong consequences in the re-evaluation of those food additives, which:

- are authorised at *quantum satis* uses,
- were previously considered of low intrinsic toxicity (with an ADI “not specified”),
- were previously evaluated as of low toxicological concern as used in food.

Definitions

Quantum satis (QS) is defined in (Regulation (EC) No 1333/2008 on food additives).

It means that no maximum numerical level is specified and substances shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose, and provided the consumer is not misled

Definitions

ADI “not specified”: SCF Definition (1)

“ADI not specified” is a term used when, on the basis of available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and/or its present use or uses in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health. For this reason, the establishment of a numerical limit for the Acceptable Daily Intake is not considered necessary for these substances.

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ADI “not specified”: SCF Definition (2)

Any additive allocated as “ADI not specified” must be used according to good manufacturing practice, i.e.:

- It should be technological efficacious,
- It should be used at the lowest level necessary to achieve its technological effect,
- It should not conceal inferior quality or adulteration, and
- It should not create a nutritional imbalance.

Examples of food additives with QS uses

Food additives [(a) (b)]	**Legal deadline**[(c)]
Most of the gums (e.g. acacia gum, locust bean gum, xanthan gum)	2016
E 440(i,ii) pectins	2016
E470a sodium, potassium and calcium salts of fatty acids	2016
E460i microcrystalline cellulose	2016
E 331 potassium citrate	2018
E 500 sodium carbonate	2018
E 508 potassium chloride	2018
E 524 sodium hydroxide	2018

(a) Food additives included in the group of food additives "Group I" with a specific maximum level as *quantum satis* (Annex II of Regulation (EC) No 1333/2008)

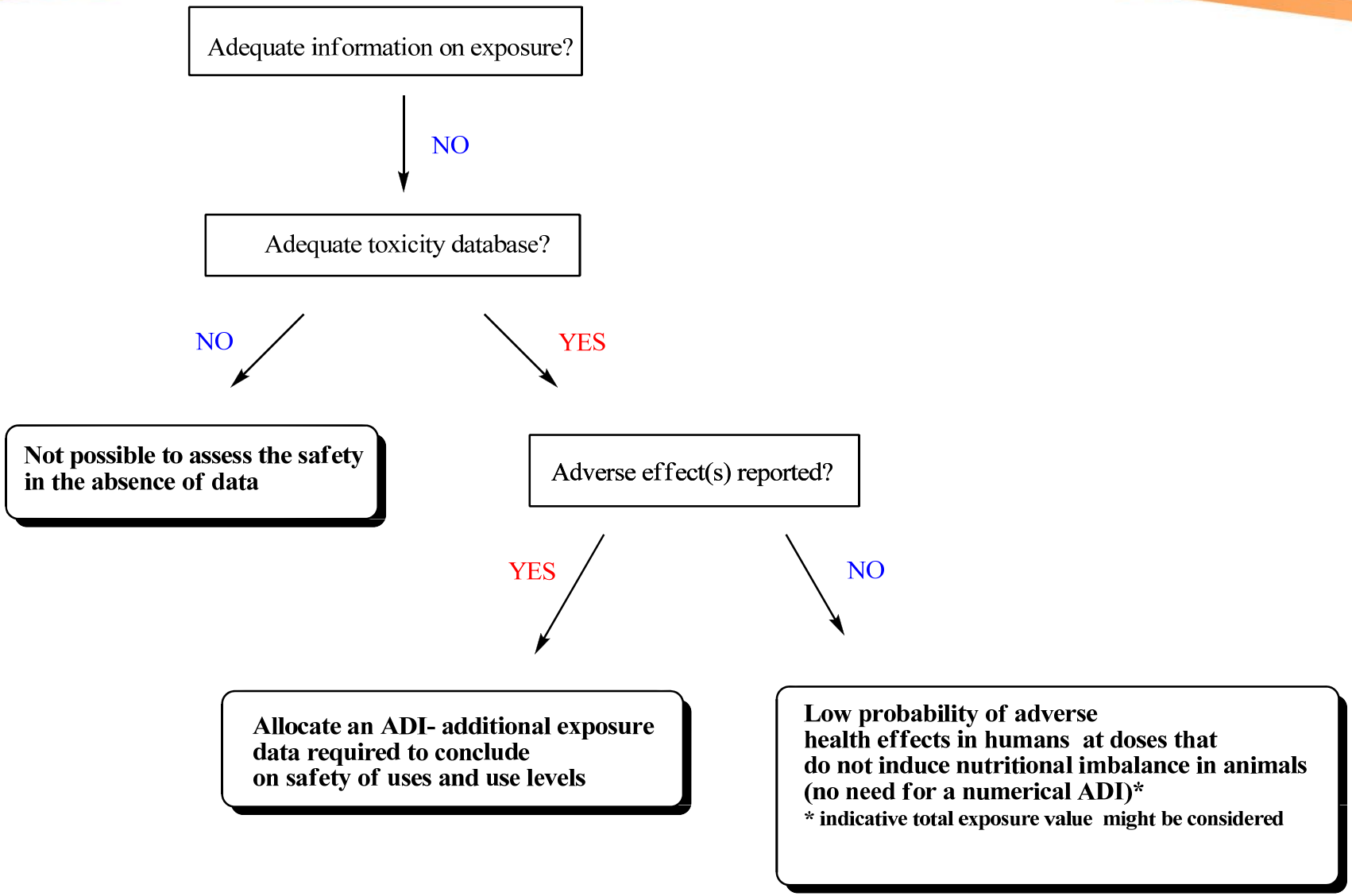
(b) Food additives previously evaluated by the SCF and for which an ADI "not specified" was established

(c) Regulation (EU) No 257/2010

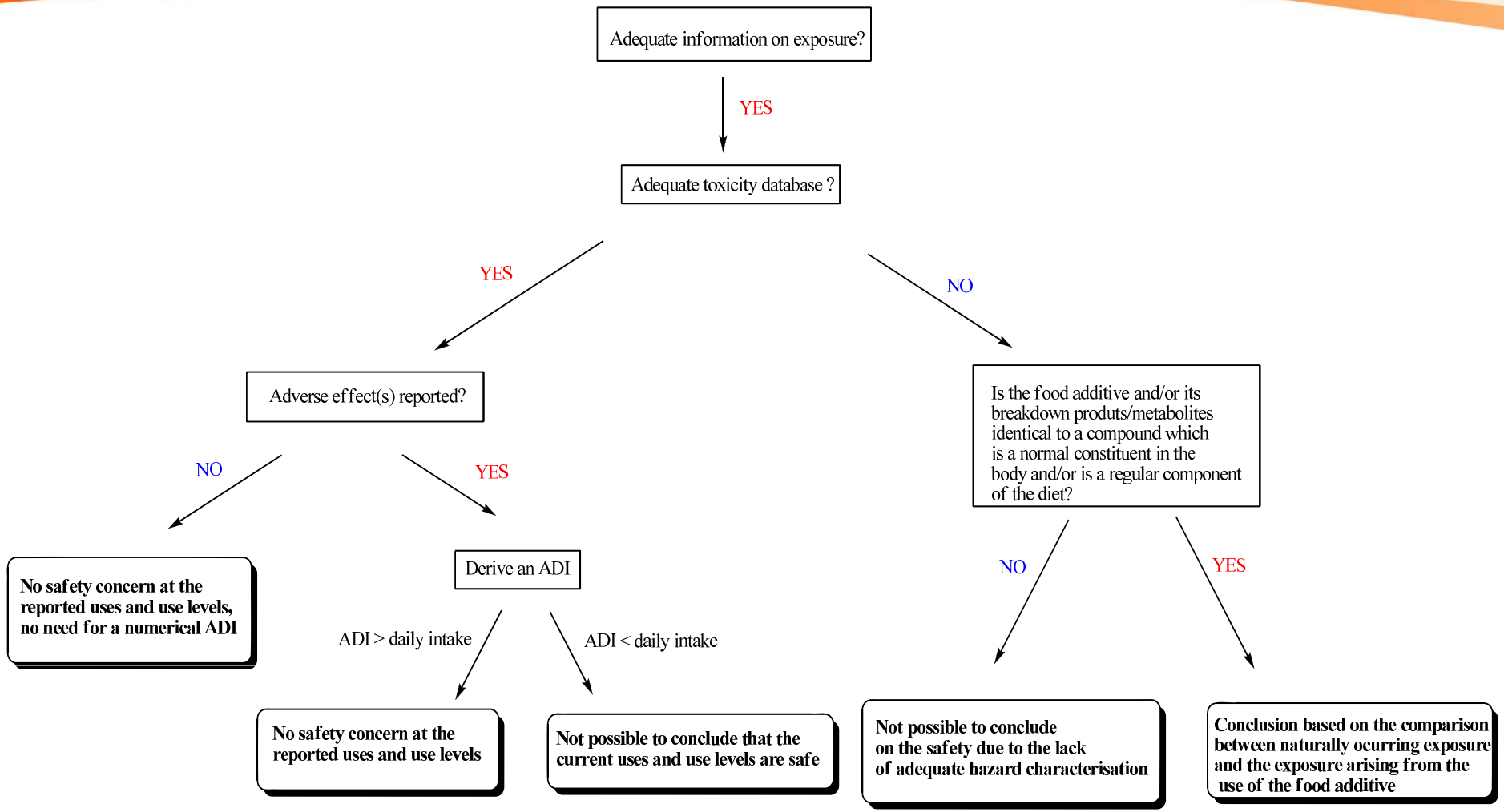
Purpose of the conceptual framework

- To define the general principles for determining the outcome of the re evaluation of certain food additives on the basis of available data, thus allowing the potential for sound outputs of "*abbreviated risk assessments*".
- To increase the transparency of the re-evaluations made by the EFSA ANS Panel.
- To ensure a consistent approach for certain food additives.

Preliminary outcome of re-evaluation



Preliminary outcome of re evaluation



Thank you for your attention