Data availability and the outcome of risk assessment

Claude Lambré, Vice-Chair of the ANS Panel

Stakeholder Workshop, Brussels, 28th April 2014
The Risk Assessment Paradigm (1)

HAZARD IDENTIFICATION

EXPOSURE ASSESSMENT

HAZARD CHARACTERISATION

RISK CHARACTERISATION

Relates exposure to health-based guidance value (e.g. ADI)
• **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.
• **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.
• **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 remain below the ADI.
• 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).
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.
**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.
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

<table>
<thead>
<tr>
<th>Food additives</th>
<th>Legal deadline (c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most of the gums (e.g. acacia gum, locust bean gum, xanthan gum)</td>
<td>2016</td>
</tr>
<tr>
<td>E 440(i,ii) pectins</td>
<td>2016</td>
</tr>
<tr>
<td>E470a sodium, potassium and calcium salts of fatty acids</td>
<td>2016</td>
</tr>
<tr>
<td>E460i microcrystalline cellulose</td>
<td>2016</td>
</tr>
<tr>
<td>E 331 potassium citrate</td>
<td>2018</td>
</tr>
<tr>
<td>E 500 sodium carbonate</td>
<td>2018</td>
</tr>
<tr>
<td>E 508 potassium chloride</td>
<td>2018</td>
</tr>
<tr>
<td>E 524 sodium hydroxide</td>
<td>2018</td>
</tr>
</tbody>
</table>

(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

Adequate information on exposure?

NO

Adequate toxicity database?

NO

Not possible to assess the safety in the absence of data

YES

Adverse effect(s) reported?

YES

Allocate an ADI - additional exposure data required to conclude on safety of uses and use levels

NO

Low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals (no need for a numerical ADI)*

* indicative total exposure value might be considered
Preliminary outcome of re-evaluation

Adequate information on exposure?
  YES
  Adequate toxicity database?
    YES
    Adverse effect(s) reported?
      NO
      No safety concern at the reported uses and use levels, no need for a numerical ADI
      NO
      Derive an ADI
        ADI > daily intake
        No safety concern at the reported uses and use levels
        ADI < daily intake
        Not possible to conclude that the current uses and use levels are safe
    NO
    Is the food additive and/or its breakdown products/metabolites identical to a compound which is a normal constituent in the body and/or is a regular component of the diet?
      NO
      Conclusion based on the comparison between naturally occurring exposure and the exposure arising from the use of the food additive
      YES
      Not possible to conclude on the safety due to the lack of adequate hazard characterisation
Thank you for your attention