Federation of European Specialty Food Ingredients Industries

Re-evaluation of food additives

EFSA Stakeholder Workshop – 28 April 2014

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- General observations on the re-evaluation of food additives
- 6 suggestions for a better procedure
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- **ELC at a glance**
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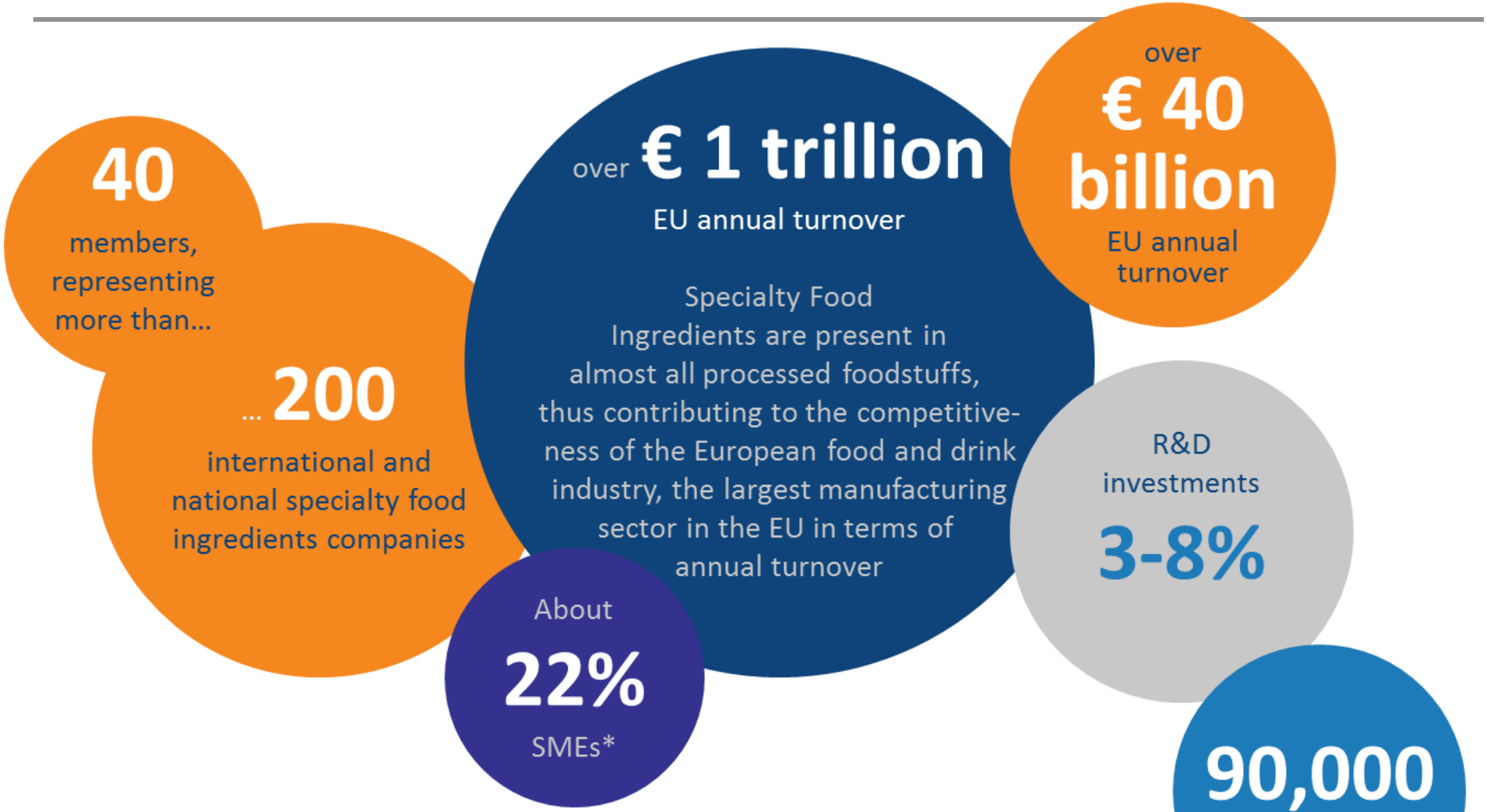
What are specialty food ingredients?

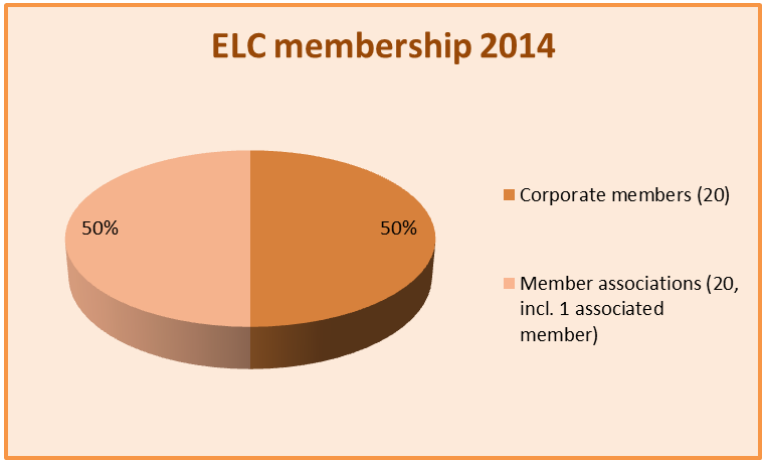
Specialty food ingredients typically **preserve, texture, emulsify, colour and improve the nutritional profile** of processed food.



* < 250 employees and TO < € 50 m.

These are guesstimates 2013, based on internal data gathering amongst our diverse membership (CEFIC is a member of ELC but is excluded from calculations due to unclear representation of industrial chemicals vs specialty food ingredients).

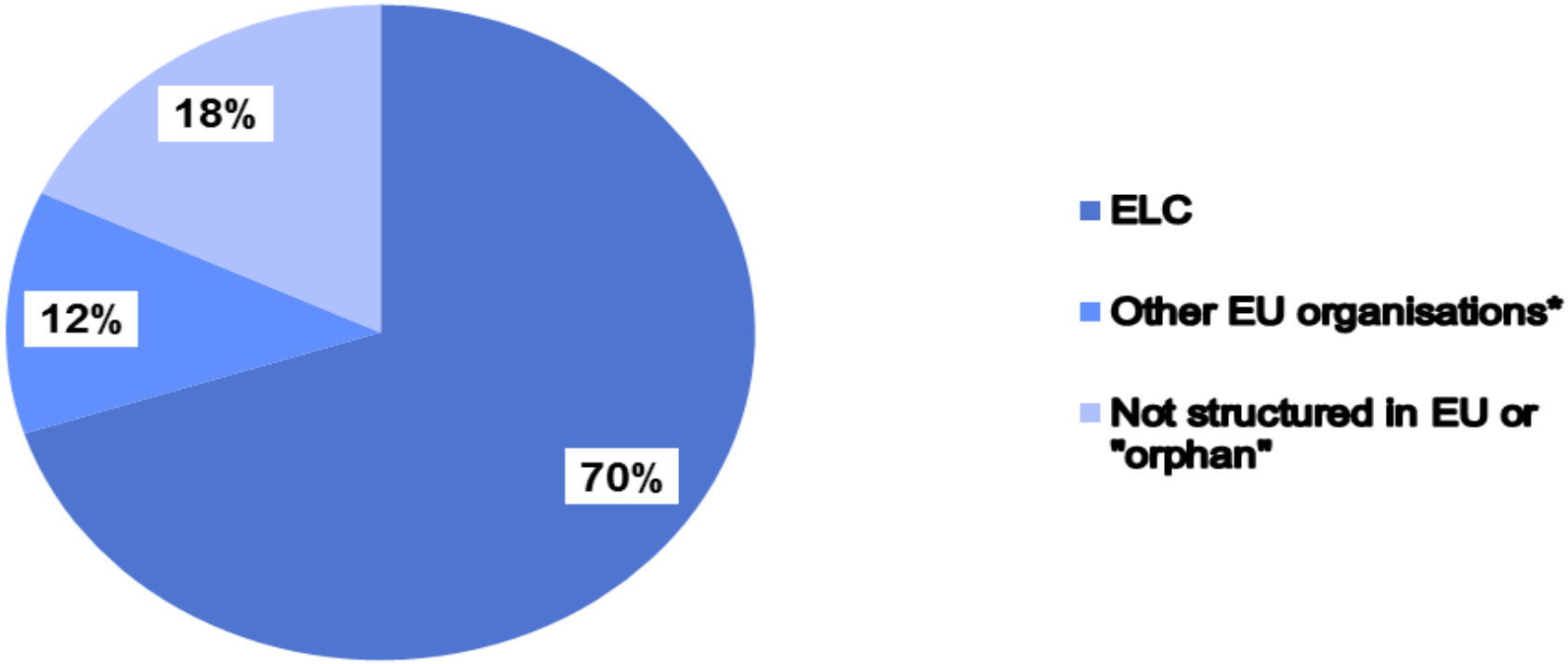
More than 200 EU companies represented either by direct membership or through a member association



ECU

INEC

Food additives representation (estimate)



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- ELC supports the re-evaluation as an essential tool to help (re-)build consumer trust in food additives

- However for all parties the re-evaluation exercise is far more challenging than expected at the time it was launched

- **Food additives are a collective asset**. If the re-evaluation does not turn into a successful exercise:
  - Significant reformulation of foods & drinks might be expected
  - This might nurture mistrust in food additives instead of building trust

- Efforts have been made to try and improve the procedure for data collection of usage levels of additives in food, and to subsequently implement approaches for more accurate (i.e. less conservative exposure assessment:
  - November 2011: EFSA technical meeting on exposure assessment of food additives
  - May 2013: EFSA training on usage levels data collection
  - November 2013: 1st meeting Discussion group on Food Chemical Occurrence Data
  - Upcoming revision of the Food Additives Intake Model

  Nevertheless improvement is still needed as regards the format and the short time granted for data collection.

- Yet exposure assessment is only one aspect of the re-evaluation procedure: **progress is needed on the other shortcomings of the procedure.**

Many problems arise from the under-estimation of the difficulty to gather data for food additives that are all granted **generic** authorisations (no well-identified data-holder):

- It cannot be a “press-the-button” process
- “Old” original study reports (papers) sometimes difficult to retrieve
  - No response to EFSA calls for data for all additives
  - Manufacturers in third countries not necessarily aware of calls for data
  - Manufacturers in the chemicals business may not always consider that it is worth the effort of submitting dossiers for a small food market

By its very nature the process to deal with generic information/no well-identified data holder is fundamentally different from the process to deal with an application for a new food additive.

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1. **To facilitate the coordination of responses by food additives producers by launching a call for interest prior to the call for data for a given additive and to publicly disclose the identity of interested respondents**

Expected improvement

- Reduction of the number of orphan additives
- Up-to-date list of relevant stakeholders for a given additive
- Better quality input
- Possibly reduced distortion of competition by limitation of free-riding
- Made for 1st time in March call for tox data ➔ **Standard for the future**

2. To develop a detailed guideline for industry on the re-evaluation procedure and its requirements, including standard calls for data

Expected improvement

- Preparation of better quality dossiers
- Subsequent reduction of EFSA repeated calls for a given additive
- Subsequent limitation of damages in public perception of its safety even though the opinion is not yet published

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3. To put in place a direct dialogue with the respondents (e.g. use of possibility of hearing experts in WG)

Expected improvement

- Better understanding of requests for clarification
- Opportunity to bring immediate responses whenever possible
- Subsequent efficiency & speediness of the process

4. To improve transparency towards respondents through feedback on the status of the evaluation of their additives

Expected improvement

- Better predictability for the additive manufacturer in terms of:
  - Annual allocation of resources, depending on progress on the programme
  - Coordination need (e.g. establishment of a consortium to fund a new study required by EFSA)

5. To put in place a longer "under embargo" period for draft opinions shared with respondents

Expected improvement

- To prevent the re-publication of the EFSA opinion in case of inaccuracy that may occur due to the intrinsically complex flow of information related to the generic status of food additives (lutein example)
- To avoid to food additive markets the detrimental confusion associated with the first opinion published

6. To develop criteria to determine how the data provided to EFSA is made available to third parties

Expected improvement

- To create a fair and consistent process for enabling access to data
- To protect legitimate rights of respondents to maintain their ownership on data submitted
- To allow respondents to anticipate the need to prepare for third party interests, should EFSA consider to publish their data

ELC welcomes the organisation of the workshop and has great expectations on subsequent progress towards a transparent, predictable and proportionate procedure.

Thank you for your attention

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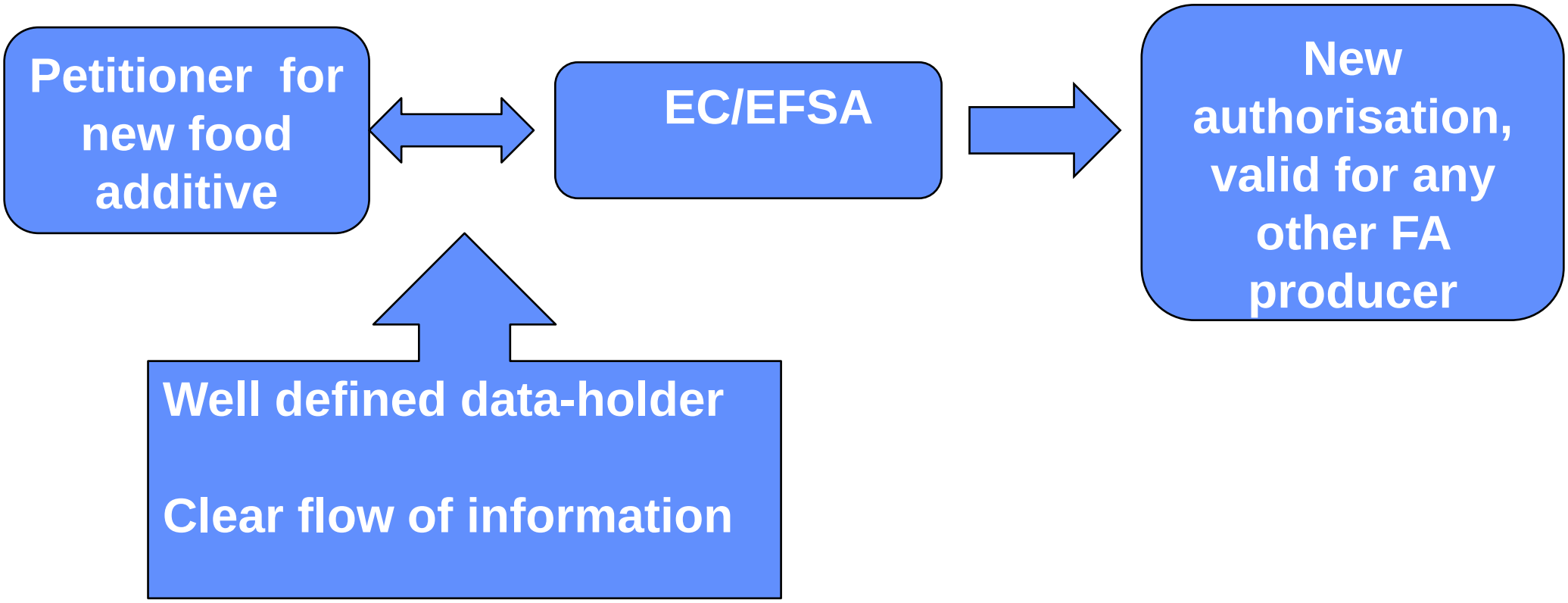
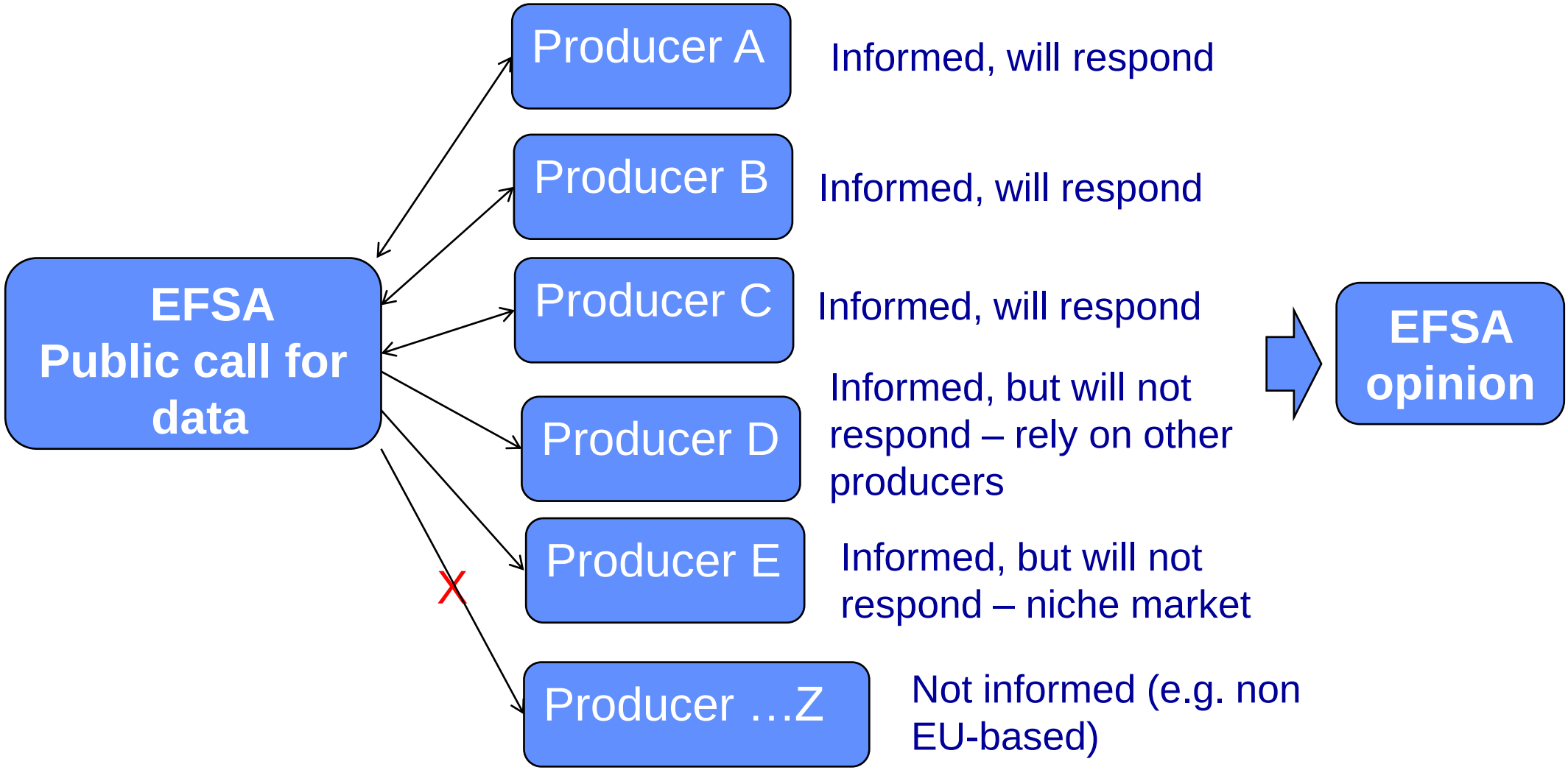
ANNEX

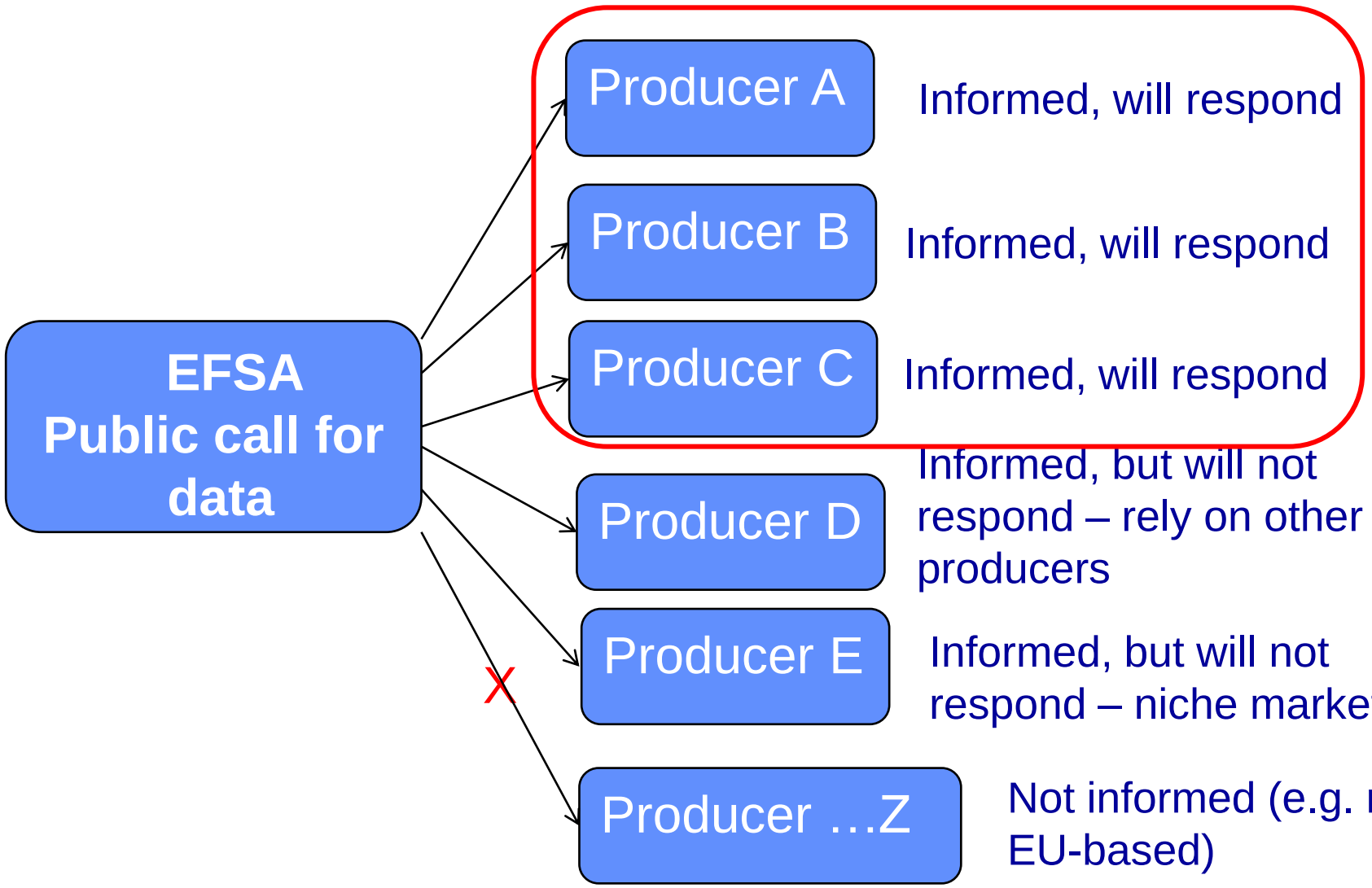
Application for new additive



Re-evaluation of a food additive



Re-evaluation of a food additive *(cont'd)*



. Difficult intra-industry coordination because no disclosure of identity of respondents.

. Little incentive (free-riding possible because no IP anymore).

Back

Fluctuant templates/requests from EFSA over time:

- From low level of information requested in first call in 2006 (colours) to high level of information requested in more recent calls

Call for scientific data on food colours to support re-evaluation of all food colo under the EU legislation

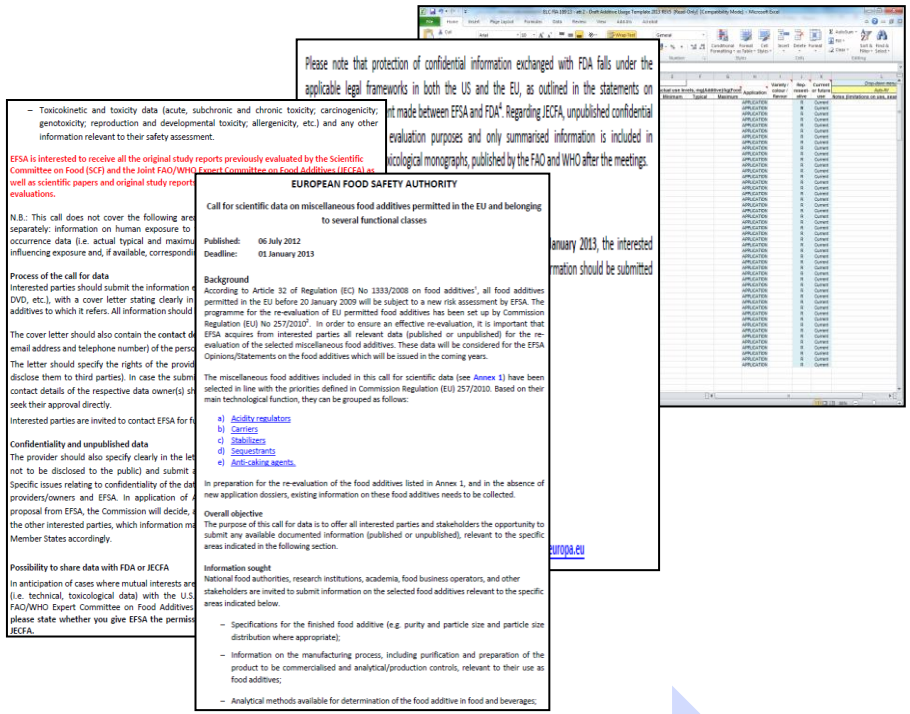
Deadline: 31 March 2007

Within the framework of the systematic re-evaluation of all food colours authorised under the EU legislation, the AFC Panel is calling for data which comprises:

- Information on data on the safety of the colours not previously reviewed in the scientific opinions by SCF and JECFA,
- availability of original study reports as evaluated by the SCF and JECFA,
- Information on the purity of colours presently in use, including particle size when relevant,
- Information on production methods,
- Information on the analytical methods available for determination in food,
- Information on present use patterns (intake, actual use levels and exceptions to these levels).

The AFC Panel adopted this call for data at the 19th plenary meeting.

The AFC Panel would appreciate to receive data or information on when it might be available by 31 March 2007.



EUROPEAN FOOD SAFETY AUTHORITY

Call for scientific data on miscellaneous food additives permitted in the EU and belonging to several functional classes

Published: 06 July 2012
Deadline: 01 January 2013

Background

According to Article 32 of Regulation (EC) No 1333/2008 on food additives[1], all food additives permitted in the EU before 20 January 2009 will be subject to a new risk assessment by EFSA. The programme for the re-evaluation of EU permitted food additives has been set up by Commission Regulation (EU) No 257/2010[2]. In order to ensure an effective re-evaluation, it is important that EFSA acquires from interested parties all relevant data (published or unpublished) for the re-evaluation of the selected miscellaneous food additives. These data will be considered for the EFSA Opinions/Statements on the food additives which will be issued in the coming years.

The miscellaneous food additives included in this call for scientific data (see Annex 1) have been selected in line with the priorities defined in Commission Regulation (EU) 257/2010. Based on their main technological function, they can be grouped as follows:

a) Acidity regulators
b) Carriers
c) Stabilizers
d) Sequestrants
e) Anti-caking agents.

In preparation for the re-evaluation of the food additives listed in Annex 1, and in the absence of new application dossiers, existing information on these food additives needs to be collected.

Overall objective

The purpose of this call for data is to offer all interested parties and stakeholders the opportunity to submit any available documented information (published or unpublished), relevant to the specific areas indicated in the following section.

Information sought

National food authorities, research institutions, academia, food business operators, and other stakeholders are invited to submit information on the selected food additives relevant to the specific areas indicated below.

- Specifications for the finished food additive (e.g. purity and particle size and particle size distribution where appropriate);
- Information on the manufacturing process, including purification and preparation of the product to be commercialised and analytical/production controls, relevant to their use as food additives;
- Analytical methods available for determination of the food additive in food and beverages;

2006

2013