



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

3 December 2019

# Challenges ahead: cross-cutting issues and horizontal scientific guidance

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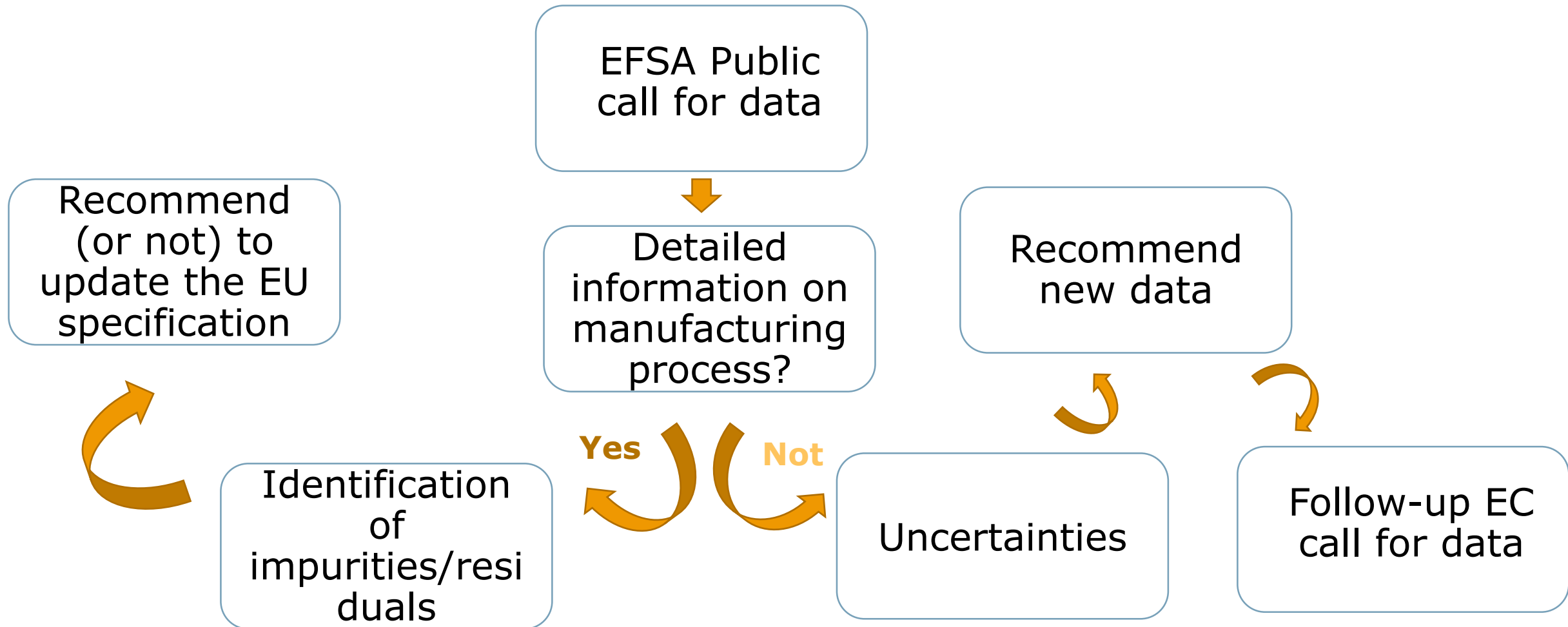
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Trusted science for safe food

Lessons learned from the re-evaluation of food additives

Information on the technical part relevant for the re-evaluation of sweeteners





- Information on the manufacturing process by itself
  - Chemical synthesis
  - Extraction from plants
  - Fermentation/bio-conversion (use of microorganism)
- Information on the raw materials
- Information on purification processes
- Information on stability

## Re-evaluation of glycerol (E 422) as a food additive

📌 glycerol, glycerine, 1,2,3-propanetriol, trihydroxypropane, E 422, CAS Registry Number 56-81-5, food additive

First published in the EFSA Journal: 📅 15 March 2017

### 3.1.3. Manufacturing process

#### 3.1.3.1. Glycerol produced from fats and oils

According to CEFIC (2013a [Documentation provided to EFSA n. 3]), 'vegetal' glycerol can be produced from vegetable oils after a treatment at a temperature higher than 100°C at low pressure, followed by distillation and further purification. The Panel noted that refined oils and fats may be contaminated with glycidol (EFSA CONTAM Panel, 2016). Glycidol is characterised as probably carcinogenic to humans 2A (IARC, 2000; BfR, 2009) and as a carcinogenic and genotoxic compound by the EFSA CONTAM Panel (EFSA CONTAM Panel, 2016).

#### 3.1.3.2. Glycerol produced by chemical synthesis

Glycerol can be produced from propene (Christoph et al., 2006). Three pathways are known: (i) via the conversion of propene to acrolein and allyl alcohol; (ii) via the conversion of propene to propylene oxide and allyl alcohol; and (iii) via the conversion of propene to allyl chloride and epichlorohydrin.



## 3.1.5. Stability of the substance and reaction and fate in food

According to Leonel et al. (2015), lactic acid bacteria can metabolise glycerol to produce acrolein. Lactic acid bacteria can be used in manufacturing of yogurt, cheese, cultured butter, sour cream (with fat content above 20%), sausage, cucumber pickles, olives and sauerkraut; if glycerol (E 422) is added to those food items, acrolein may be formed. In the absence of data on the amount of acrolein formed, the Panel considered that more data should be generated to decrease uncertainty and allow for a risk assessment.

According to the EFSA CONTAM (2016) opinion, 'In model food heating systems containing water, sodium chloride and glycerol or lipid precursors 3-MCPD production increases with increasing temperature once above 160°C, and with NaCl concentration up to 10% with acylglycerol precursors but at about 5% NaCl with glycerol. The optimum water content is 15–20% for 3-MCPD' and 'Baked goods are the major source of 3- and 2-MCPD and the formation of these contaminants in model bakery systems has been studied in some detail in model systems (Hamlet et al., 2003, 2004a,b). Free glycerol produced by the action of yeast enzymes is the major precursor and the formation reactions of 3- and 2-MCPD follow zero-order kinetics. The levels of 3-MCPD and 2-MCPD formed increase exponentially with temperature up to the maximum (about 220°C) used in baking'. Therefore, the Panel considered that glycerol (E 422) should not be added in food containing significant amounts of salt (more than 5%) treated at temperatures above 160°C, as 3-MCPD or 3-MCPD esters can be formed.

The Panel recommended that:

- given that during the manufacturing processes of glycerol, genotoxic impurities – e.g. glycidol, epichlorohydrin – could be formed, limits for such impurities should be included in the EU specifications for glycerol (E 422);
- given that during the manufacturing processes of glycerol, other potential impurities of toxicological concern (e.g. dichlorohydrin) could be formed, limits for such impurities should be included in the EU specifications for glycerol (E 422);
- more data should be generated to decrease uncertainty arising from the presence in the food additive (E 422) of compounds of toxicological concern (e.g. acrolein, 3-MCPD or 3-MCPD ester), which can be produced under some food processing conditions (e.g. use of glycerol (E 422) in parallel with lactic acid bacteria; use of glycerol (E 422) in food containing significant amounts of sodium chloride (more than 5%) and treated at temperatures above 160°C, etc.);
- a numerical limit for acrolein should be included in the EU specifications for glycerol (E 422);
- the maximum limits for the impurities of toxic elements (arsenic, lead, mercury and cadmium) in the EC specification for glycerol (E 422) should be revised in order to ensure that glycerol (E 422) as a food additive will not be a significant source of exposure to those toxic elements in food.



# EXAMPLE- E 422



## Follow-up of EFSA's scientific opinion on the re-evaluation of glycerol (E 422) as a food additive - **CALL CLOSED**

Call for technical data on the permitted food additive glycerol (E 422) 

**Published:** 23/11/2018

**Deadline:** 30/6/2019 (Please note that this is the final deadline for submission of the technical data requested in the call)



# EXAMPLE- E 422

## Technical data required for E 422

With reference to the conclusions and recommendations of EFSA's Scientific Opinion on the re-evaluation of glycerol (E 422) as a food additive, information for glycerol (E 422) is sought on:

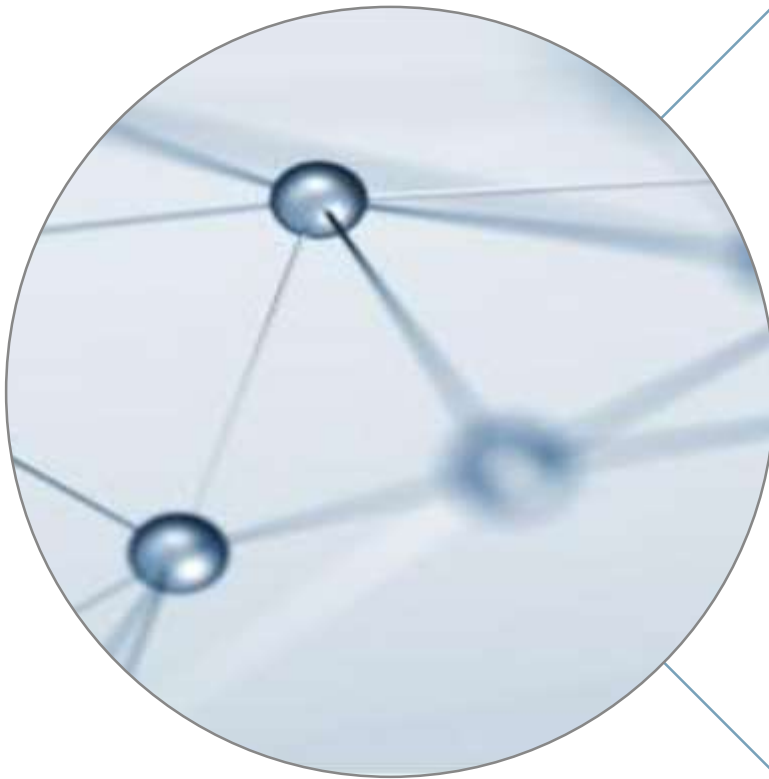
- analytical data on current levels of arsenic, lead, mercury and cadmium in commercial samples of the food additive;
- the lowest technologically achievable level for arsenic, lead, mercury and cadmium in order to adequately define their maximum limits in the specifications;
- analytical data on current levels of acrolein in commercial samples of the food additive;
- the lowest technologically achievable level of acrolein, which is an intermediate chemical in the synthesis of glycerol, in order to adequately define its maximum limit in the specifications of E 422;
- the lowest technologically achievable level in food of any compound of toxicological concern (e.g. acrolein, 3-MCPD and glycidyl esters), which can be produced under certain food processing conditions from the food additive glycerol (E 422) (e.g. use of glycerol (E 422) in parallel with lactic acid bacteria; use of glycerol (E 422) in food containing significant amounts of sodium chloride (more than 5%) and treated at temperatures above 160°C, etc.);
- in view that in the Scientific Opinion on the re-evaluation of glycerol (E 422) as a food additive it has been noted that glycerol (E422) can be produced by a variety of methods, and that many of them lead to the presence or formation of contaminants, which are of toxicological concern, the following information is needed:
  - Information on the manufacturing process of glycerol to be used as food additive E 422;
  - analytical data on current levels of any chemical intermediate that could be formed during the manufacturing process of glycerol in commercial samples of the food additive;
  - the lowest technologically achievable level of any chemical intermediate that could be formed during the manufacturing process of glycerol, in order to adequately define maximum limits in the specifications of E 422.

- Re-evaluation:

“Contamination at those levels would have a significant impact on the exposure to these **toxic elements**, for which the exposures are already close to the health-based guidance values established by EFSA”

- EC call for data requested:

- **analytical data on current levels** of arsenic, lead, mercury and cadmium in commercial samples of the food additive;
- the **lowest technologically achievable level** for arsenic, lead, mercury and cadmium in order to adequately define their maximum limits in the specifications;
- For the **future EFSA assessment**: health-based guidance values or reference values for toxic elements will be considered together with their exposure from the intake of the food additive



- A substance can have other uses (apart from food additive) with different **physico-chemical properties**
- Information on composition of the **extract**
- Uncertainties in the **characterisation of particle size distribution** of food additives



# EXAMPLE-E 171

## Re-evaluation of titanium dioxide (E 171) as a food additive

Sul



titanium dioxide, E 171, anatase, rutile, food colour

First published in the EFSA Journal: 14 September 2016

Adopted: 28 June 2016

**Table 1:** Data submitted by industries to EFSA on the particle size characteristics of TiO<sub>2</sub> as food/feed grade


Submitted by			Colorcon (2015; Doc. provided to EFSA n. 9) <sup>(a)</sup>	TDMA (2015; Doc. provided to EFSA n. 19) <sup>(b),(c)</sup>				TDMA (2015; Doc. provided to EFSA n. 19) <sup>(b),(d)</sup>		Interested party 1 (2012; Doc. provided to EFSA n. 15) <sup>(b)</sup>					
Crystal form			Anatase	Anatase		Rutile	Anatase		Anatase (Sample 1)			Rutile (Sample 2)			
Analytical method applied	DLS HD	Median particle size ( <i>d</i> <sub>50</sub> ) (nm)	336	143	160	168	191								
		% particles by number < 100 nm	ND	12	ND	ND									
		% particles by mass < 100 nm		2	ND	ND	ND								
	XSDC HD	Median particle size ( <i>d</i> <sub>50</sub> ) (nm)	176	151	166	179	202	168	202	230	250	250	330	340	340
		% particles by number < 100 nm	< 1	8	9	3	ND	ND	ND	14	5	4	< 1	< 1	< 1
		% particles by mass < 100 nm		1	< 1	< 1	ND	ND	< 1	0	0	0	0	0	0
	XSDC AECD	Median particle size ( <i>d</i> <sub>50</sub> ) (nm)		121	135	148	169	137	122						
		% particles by number < 100 nm		32	29	20	3	17	26						
	TEM	Median particle size ( <i>d</i> <sub>50</sub> ) (nm)	113	115	131	146	165	142	112						

## Recommendations

The Panel recommended that:

- The EU specifications for  $\text{TiO}_2$  (E 171) should include a characterisation of particle size distribution using appropriate statistical descriptors (e.g. range, median, quartiles) as well as the percentage (in number and by mass) of particles in the nanoscale (with at least one dimension < 100 nm) present in  $\text{TiO}_2$  (E 171) used as a food additive. The measuring methodology applied should comply with the EFSA Guidance document (EFSA Scientific Committee, 2011).

**Follow-up of EFSA's scientific opinion on the re-evaluation of titanium dioxide (E 171) as a food additive - CALL CLOSED**

Call for scientific and technical  data on the permitted food additive titanium dioxide (E 171).

**Published:** 30/01/2017

**Registration of the contact details of business operators interested in submitting data (step 1)**

**Deadline:** 02/03/2017 (CLOSED)

Scientific opinion on the proposed amendment of the EU specifications for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution

📌 Titanium dioxide, E 171, food additive, particle size, specifications

**First published in the EFSA Journal:** 📅 12 July 2019

**Adopted:** 📅 27 June 2019

## Subject area



Food additives



2.5 years from the finalisation of the re-evaluation until having a better knowledge on the characterisation of the food additive

➤ Media debate substantiated for the lack of information



- Detailed information on **manufacturing process**
  - Considering the up-to-date EFSA requirements

## EFSA JOURNAL

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### Characterisation of microorganisms used for the production of food enzymes

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Vittorio Silano, José Manuel Barat Baviera, Claudia Bolognesi, Beat Johannes Brüscheiler ... [See all authors](#) ▾

First published: 11 June 2019 | <https://doi.org/10.2903/j.efsa.2019.5741>

- Information on the **raw materials** and the presence or not of some of them (or **carry-over impurities**) in the final product
  - Information on **reaction intermediates** that can potentially remain in the final product
  - Information on **residuals** that can remain in the final product
- ❖ supported by analytical data

- Information on **stability** of the food additive under/during:
  - Storage conditions
  - Food processing in different conditions of use
  - Interaction with food matrices
- Nature and amount of the degradation products
  - ❖ supported by scientific evidence



- Information on **characterization of the substance**
  - Considering the up-to-date EFSA Guidances

## GUIDANCE



ENDORSED: 29 May 2018

doi: 10.2903/j.efsa.2018.5327

### **Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health**

EFSA Scientific Committee,

parameters, as well as quality control aspects that should be considered. It recommends that particle size distribution should be determined by more than one independent technique (one of which being electron microscopy).

- Uncertainties reflected in the assessment
  - Recommendations
    - Follow-up EC call for data
      - ✓ New assessment years later
- **Lost of confidence from the consumers**



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