

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

3 December 2019

The re-evaluation of sweeteners

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Trusted science for safe food

Re-evaluation of sweeteners: list of substances

- Sweeteners to be re-evaluated under Regulation (EC) No 257/2010

E Number	Food additive(s)		Substance
E 420	Sorbitols	E 420 (i) E 420(ii)	Sorbitol Sorbitol syrup
E 421	Mannitols	E 421(i) E 421(ii)	Mannitol by hydrogenation Mannitol manufactured by fermentation
E 950	Acesulfame K		
E 951 ^(a)	Aspartame ^(a)		
E 952	Cyclamates	E 952(i) E 952(ii) E 952(iii)	Cyclamic acid Sodium cyclamate Calcium cyclamate
E 953	Isomalt		
E 954	Saccharin and its Na, K and Ca salts	E 954(i) E 954(ii) E 954(iii) E 954(iv)	Saccharin Sodium saccharin Calcium saccharin Potassium saccharin
E 955	Sucralose		
E 957	Thaumatococin		
E 959	Neohesperidine dihydrochalcone		
E 961	Neotame		
E 962	Salt of aspartame-acesulfame		
E 965	Maltitols	E 965(i) E 965(ii)	Maltitol Maltitol syrup
E 966	Lactitol		
E 967	Xylitol		
E 968	Erythritol		

Deadline:

by end December
2020

(a) Aspartame: re-evaluation **already completed** by EFSA in 2013

- **Technical/Biological and toxicological data:** closed in June 2018
 - Procurement contract (ended June 2019): inventory and synthesis
- **Occurrence data:** Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 7) closed in October 2018
 - ✓ New call for occurrence data on *aspartame* (E 951) needed to update total dietary exposure to aspartame for the re-evaluation of salt of aspartame-acesulfame (E 962): to be launched
- **2nd call for Technical data:** information on particle size and particle size distribution launched on 13 May 2019- deadline 13 December 2019

- New procurement contract: started on 28 October 2019
- to perform extensive literature searches in order to identify and retrieve all related information on both technical and biological/toxicological data on the 15 sweeteners, published after the last evaluation of the SCF or EFSA.

■ Background information:

As outlined in Regulation (EC) No 257/2010 on the re-evaluation of food additives, in the course of the re-evaluation procedure “EFSA shall:

- a) examine the original opinion and the working documents of the Scientific Committee on Food (‘SCF’) or EFSA;*
- b) examine, where available, the original dossier;*
- c) examine the data submitted by the interested business operator(s) and/or any other interested party;*
- d) examine any data made available by the Commission and Member States;*
- e) identify any relevant literature published since the last evaluation of each food additive”.*

■ Two protocols have been developed:

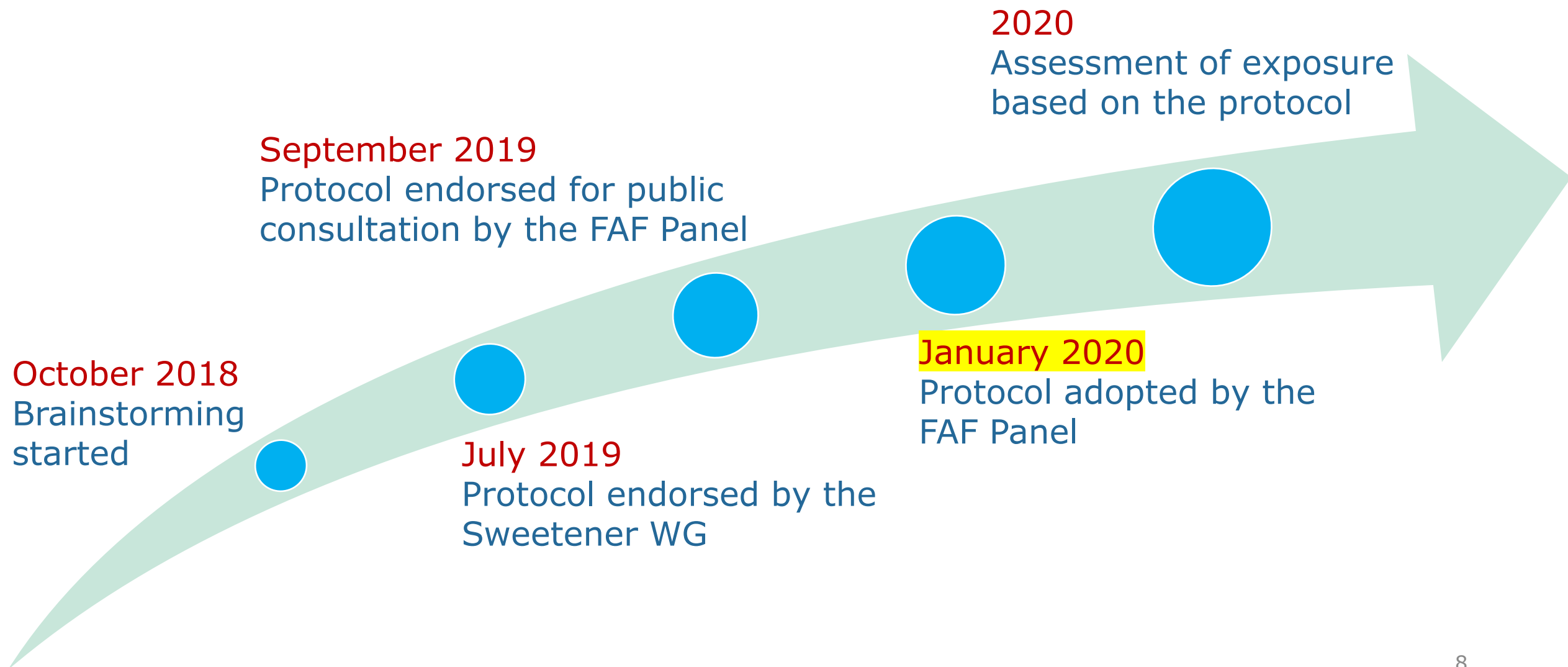
- One framing the scope of the assessment from the general mandate from EC (for all steps of RA, except exposure)
- One focussing on exposure assessment

Steps and timeline: protocol for assessment of hazard identification and characterisation of sweeteners



- Technical report: outcome of the PC on the protocol for the assessment of hazard identification and characterisation sweeteners
- 23 comments received (6 parties)
- Appendix A: list of comments received and responses by EFSA
- Protocol: revised accordingly
- Publication of the technical report and protocol

Steps and timeline: protocol on exposure assessment



Impartiality and Methodological rigour along the process

- Plan ahead: protocol development
- Systematic review process

Engagement and transparency along the process

- Open FAF Plenary (26-28 March, 2019)
- Public consultations (2nd part 2019)
- **Stakeholder event**: food additive re-evaluation with focus on sweeteners, Paris, 3 December 2019:

<https://www.efsa.europa.eu/en/events/event/technical-stakeholder-event-re-evaluation-authorised-food-additives>

PRINCIPLES for the scientific assessment process



- Current organisation of Working Group on sweeteners:
 - *Sub-group for overall strategy for the assessment*
 - *Sub-group for technical part*
 - *Sub-group for exposure assessment*
- Working Group **enlargement**: evolve in a fully multidisciplinary WG for protocol implementation
 - Chemistry
 - Exposure
 - Subchronic/chronic toxicity, genotoxicity, reproductive/developmental toxicity, general toxicology, epidemiology, etc....



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