THE RE-EVALUATION OF SWEETENERS BY THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

Main author: Federica Lodi (European Food Safety Authority - EFSA)

Co-authors: Federica Lodi, Stefania Barmaz, Consuelo Civitella, Alessandra Giarola, Ana Maria Rincon, Antonio Rivas Cornejo, Camilla Smeraldi, Alexandra Tard, Giorgia Vianello, Riccardo Vriz, Claudia Roncancio Peña

INTRODUCTION

This presentation aims at providing an overview of the EFSA's work on re-evaluating sweeteners, illustrating the main steps of the protocol on the assessment of the hazard identification and characterisation of sweeteners and how EFSA has engaged with stakeholders throughout this process. All food additives permitted before 20 January 2009 are subject to a new risk assessment by EFSA according to Regulation (EC) No 1333/2008 (1). A programme for the re-evaluation of approved food additives has been set up by Commission Regulation (EU) No 257/2010 (2). The sweeteners to be re-evaluated are: sorbitols (E 420); mannitols (E 421); acesulfame K (E 950); cyclamates (E 952); isomalt (E 953); saccharins (E 954); sucralose (E 955); thaumatin (E 957); neohesperidine DC (E 959); neotame (E 961); salt of aspartame-acesulfame (E 962); maltitols (E 965); lactitol (E 966); xylitol (E 967) and erythritol (E 968).

1 OJ L 354, 31.12.2008, p. 16.
2 OJ L 80, 26.3.2010, p. 19–27.

METHODOLOGY

EFSA launched calls for data in order to invite the interested parties to submit all data available covering technical, biological/toxicological (3,4) and occurrence data (5). These data are complemented with any relevant literature published since the latest opinions of the Scientific Committee on Food or EFSA. Two protocols have been developed to ensure impartiality and methodological rigour along the process: one on the assessment of the hazard identification and characterisation of sweeteners (6), the other focusing on the exposure assessment (7). The other pillars of risk assessment, engagement, openness and transparency throughout the process have been also implemented through a public consultation. The comments received were considered in the finalisation of the two protocols. Moreover, two Plenary meetings open to observers and a stakeholders event were held.

3 www.efsa.europa.eu/en/data/call/170621
4 www.efsa.europa.eu/en/consultations/call/call-technical-data-sweeteners-authorised-food-additives-eu
5 www.efsa.europa.eu/en/consultations/call/call-food-additives-usage-level-andor-concentration-data-food-1
6 10.2903/sp.efsa.2020.EN-1803
7 10.2903/sp.efsa.2020.EN-

RESULTS

The protocol on hazard identification and characterisation of sweeteners defines upfront the strategy to be applied during the safety assessment: addressing the questions to be answered (problem formulation), collecting (extensive literature search) and selecting data (screening the studies for relevance), appraising the relevant evidence (evaluation of the risk of bias and data extraction), and analysing and integrating the evidence (weighing and synthesis of the body of evidence). In this presentation, the main features of this protocol, summarising the different steps to be applied during the risk assessment, will be presented. Some developments on the implementation phase of the protocol on hazard identification and characterisation will also be presented.

DISCUSSION

In order to analyse and integrate the data, a weight of evidence (WoE) analysis for different health outcomes, grouped by endpoint as appropriate, is performed. The level of confidence in the evidence regarding the absence or presence of adverse effects in animal and human studies is assessed in a WoE approach. The protocol development is an iterative process that should always ensure the possibility for adapting and responding to new realities. Flexibility should therefore be maintained throughout the whole process. Nevertheless, any changes or deviations from the protocol established upfront in the assessment should be documented and justified.