

Regulatory safety assessment in the European Union of food additives containing nanoparticles

Ana Maria RINCON - European Food Safety Authority

The European Union (EU) legislation contains provisions for nanotechnology and nanomaterials and a definition of nanomaterial is given in Commission Recommendation 2022/C 229/01. In the EU, the safety of substances proposed for use as new food additives as well as the re-evaluation of all food additives that were already permitted in the EU before 20 January 2009 is carried out by the European Food Safety Authority (EFSA). Since 2009, the re-evaluation of more than 315 food additives has been finalised and approximately 86 remain to be assessed in the coming years. When a food additive is already included in the Union list but there is a significant change for example in its production methods, in the starting materials used, or there is a change in the particle size of the material, the food additive must be subject to a new risk assessment. EFSA provides indications (Guidance on Particle-TR) on how to identify if nanoscale aspects have to be considered when performing the risk assessment. Since the risk assessment of materials that retain properties at the nanoscale during the use of the product needs special consideration of their physicochemical properties, toxicokinetics, potential uptake into cells and tissues and physiological fate, EFSA has also issued specific Nano Guidance to perform the safety assessment of these materials. Within the programme of re-evaluation of permitted food additives, EFSA have to deal with some food additives for which a fraction of the material falls in the nano-range. Many of these assessments have been finalised and considered that further data, in particular on the physicochemical characterisation of the material used as a food additive were needed to complete the safety evaluation. The European Commission has an approach for the follow-up of the re-evaluation of permitted food additives for which some concerns or data gaps have been identified that implies the submission of the data needed for the completion of the risk assessment. The final decision on whether a food additive remains permitted for use in the EU will be taken by the EU risk managers based on the outcome of the EFSA's final scientific assessment.