

Outcome of step 2 of the call for data on sulphur dioxide/sulphites (E 220-228)

- Data on absorption, distribution, metabolism and excretion (ADME) for all the sulphites, including identification of their forms and reaction products, when they are used to treat beverages and solid foods:

A consortium of interested business operators (Sulfur Dioxide Based Chemicals REACH Consortium - SDIOC REACH Consortium) has committed to generating ADME data for sulphites.

The following tiered test design is anticipated, in accordance with EFSA testing guidance (Second tier toxicokinetics assessment):

- (a) relative bioavailability
- (b) mass balance study
- (c) optional (if feasible) tissue distribution study
- (d) optional (if feasible) repeated dose testing: to be decided upon the outcome of stages (a)-(c).

The foreseen feasibility and planning exercise for ADME studies will take 12 months, while the execution of the main experimental phase is expected to take 18 months. Consequently the resulting deadline for data submission is December 2019.

- Data on the mode of action of sulphur dioxide–sulphites (E 220–228):
Depending on the outcome of the ADME studies, the SDIOC REACH Consortium further indicated its willingness to investigate into the feasibility of carrying out mode of action studies (deadline July 2018).
- Data on the lowest achievable limits for the impurities of toxic elements (lead, mercury and arsenic) for sulphur dioxide–sulphites (E 220–228):
Two business operators (BASF SE and LANXESS Deutschland GmbH) as well as the SDIOC REACH Consortium committed to providing data.