

Outcome of step 2 of the call for scientific and technical data on the permitted food additive indigotine, indigo carmine (E 132)

The business operator International Association of Colour Manufacturers (IACM) committed to providing the following data:

- **Toxicological data for E 132:** A toxicity study in mice will be conducted to evaluate a complete cycle of spermatogenesis and detection of adverse effects on the testis to address the concerns raised in the Dixit and Goyal (2013) study. Submission of the final report of the study is anticipated by the end of the second quarter of 2020.
- **Data on the lowest achievable limits for the impurities of toxic elements (arsenic, lead, mercury and cadmium) in E 132:** Data from multiple lots of indigo carmine will be compiled and are expected to be available for submission by the end of March 2019.
- **Data on the identity of unsulphonated aromatic amines and their lowest achievable limits in E 132:** There are no currently available data to satisfy this request and chemical analysis must be performed to obtain the necessary data. Submission of the data is anticipated by the end of end of March 2019.