

22 January 2024 EMA/INS/GMP/30230/2024 European Medicines Agency

Highlights from the 12th meeting of the Nitrosamine Implementation Oversight Group (NIOG)

- NIOG took note of the procedural, safety, and quality developments reflected in Q&A revision 20, concerning the call for review, the enhanced Ames test acceptability and reporting requirements for non-mutagenic nitrosamine impurities. NIOG was also informed on policy updates that will be implemented in the network starting in 2024 concerning the process-flow for Acceptable Intake limit establishment.
- NIOG discussed the applicability of the Less than lifetime (LTL) approach for authorised products and taking note of ongoing MAAs.
- The points raised by industry concerning the implementation of Carcinogenic Potency Categorization Approach (CPCA) and enhanced Ames test (EAT) approaches were also discussed in advance of the 6th NIOG-IP meeting.

