

ISO 10993-7:2026 and ISO 10993-7:2008/A1

GAP Assessment – Consolidated Conclusion Summary

Based on the clause-by-clause comparison, the 2026 edition introduces **quantitative formulae, expanded categorization logic, and explicit tolerable intake (TI) and allowable limit (AL) calculations** for ethylene oxide (EO) and ethylene chlorohydrin (ECH). The changes emphasize **risk-based assessment, patient population specificity, and structured calculation protocols**, moving beyond the descriptive toxicological focus of the 2008/A1 edition. The major gaps requiring action are summarized below, with parameters highlighted for implementation.

1. General Requirements

- 2026 clarifies ALs for EO/ECH, references ISO 10993-1:2025, exempts legacy devices unless Clause 10 issues arise, and omits ethylene glycol (EG). **Action:** Update biological risk assessment protocols, add legacy device exemption checks, and remove EG-specific evaluations.

How to update biological risk assessment protocols to comply with 2026 regulations?

