



The IES

*The Commission Expert Sub-Group on inspections
in the blood, tissues and cells sectors*

The Commission Expert Sub-Group on Inspections in the Blood and Tissues & Cells Sectors (IES) is an active sub-group of the Competent Authorities on Substances of Human Origin (CASoHO) Expert Group. The IES was established in late 2018 and has 45 nominated representatives from 28 competent authorities.

The primary objectives of the IES are to provide technical expertise and formulate advice and comment to the Commission’s services, and represent a forum for the exchange of information and experiences between the different Member States on technical and procedural matters related to their national inspection programmes in the blood and tissues and cells sectors. The overall aim is to encourage further mutual recognition of inspections in the blood, tissues and cells sectors across the EU Member States and provide a platform for EU-level collaboration on such activities.

The IES started its work in January 2019 and its work is based on five work clusters:

I.	Inspection Guidelines	The focus is to review the existing inspection guidelines with respect to current expectations/standards. The assessment will include a survey of the existing guidelines used by inspectors of the different Member States. On completion of the review, an Inspectors’ Library, together with interpretation documents and supplementary guidance will be developed, where necessary.
II.	Coordination of Training Courses	The framework and models of the earlier training courses developed in EUSTITE and VISTART are to be continued and modernised to be adapted to the specific training needs of candidate and experienced inspectors. The educational platform shall be developed and be based on recognised learning programmes (i.e. e-learning, residential face-to-face, practical experience). A centralised register of the sector inspectors of different grades (e.g. experienced inspectors, tutor inspectors, etc) is to be established for the purposes of future training courses and joint inspections. etc.
III.	Coordination of Joint Inspections	The general principles and key considerations for the coordination and organisation of the joint inspection programmes are to be specified by Work Cluster III. The main objective will be resolving key issues detected through earlier pilot joint inspections (e.g. legal, financial, language and resource difficulties).
IV.	Oversight of inspection systems	The goal of this work cluster will be the wider promotion of the CESIP audit programme, which is comparable to the existing Joint Audit Programme for GMP, but has a voluntary basis status. In the CESIP audit programme the quality management systems and inspections practices of the National Competent Authorities are to be evaluated on the basis of documents prepared by the VISTART Joint Action, which have been adapted and improved by the IES. To reduce the financial aspects for the auditees the possibility of support through the Commission’s Structural Reform Support Service is being investigated.
V.	Dissemination and Monitoring	The objective of this work cluster is to follow the work in progress for each of the work clusters and to inform and share the work in progress or the outcomes respectively with the interested parties, such as official bodies (e.g. BEMA, PIC/S), professional societies (e.g. EATCB, AATB, ESCHRE, etc) and Competent Authorities in order to get their feedback as further contributions for consideration by the work clusters.

For further information on the work of the IES, please contact: sante-soho@ec.europa.eu