



2020 IES ANNUAL REPORT

The Commission Expert Sub-Group on Inspections in the Blood and Tissues & Cells Sectors
(IES)

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Introduction to the IES

The Commission Expert Sub-Group on Inspections in the Blood and Tissues & Cells Sectors (IES) is a sub-group of the Competent Authorities on Substances of Human Origin (CASoHO) Expert Group and was established by this group in November 2018, based on Terms of Reference agreed by the expert group. Following a call for nominations in November 2018, 45 representatives were nominated as members of the IES by 28 competent authorities from 20 Member States and Iceland.

The IES is designed to help bring further alignment across the EU on inspection-related activities and provide a platform for EU-level collaboration on such activities. However, participation in its work and use of its outputs is voluntary in nature.

2020 IES Activities

2020 was the second year of operational activity for the IES. During the year, one physical meeting was held in February, to discuss the achievements of the first year of IES activity, and discuss the work plan for 2020. A draft annual Work Plan was prepared, outlining the planned activities of the IES per work cluster for 2020. However, due to the COVID-19 pandemic, priorities and tasks had to be adapted, and the Work Plan was not formally approved by the IES, nor endorsed by the CASoHO Expert Group. A second online meeting was organised in June to focus on most urgent tasks that could most benefit the work of inspectors in the pandemic context.

The Work Clusters of the IES remained as defined in 2019:

1. Guidance documents;
2. Coordination of training courses;
3. Oversight of joint / observed inspections;
4. Oversight of inspection system audits;
5. Dissemination of outputs and monitoring of uptake.

The CASoHO Expert Group was kept up to date with the work of the IES in its February and October 2020 meetings. The IES adopted this Annual Report on 26 February 2021.

The following pages provide a summary of the work carried out in each of the five work clusters in 2020.

Work Cluster 1 – Inspection Guidelines

One of the key considerations for Work Cluster 1 was the requirement for a systematic review of existing guidance documents on inspections and inspections systems and, where

necessary, the revision of such existing documents and the development of new guidance documents.

As part of this, it was identified that there was a need to consider whether the current inspection guidelines sufficiently cover specific areas and whether other relevant documents should be incorporated into the inspection guidelines, e.g. for the ART sector, should the guidance on inspections produced under the ARTHIQS Joint Action be incorporated.

Considering the pandemic situation in 2020, the need to prepare a Common approach / Guideline for Remote Virtual Inspection to be shared among MS became a priority. Such guidelines was started in October, circulated among IES members in November (comments were received from Portugal, Germany, Netherland, Italy, Austria, Malta). An updated version was then shared with the Commission which made the document available to NCAs in December.

Earlier in the year, the work started on reviewing the Inspections Guidelines (VISTART WP6), focusing on an Operational Manual for Inspection to include :

1. an inspection report template;
2. desk based inspection chapter to be reviewed;
3. to include the guide on the detection and management of suspected illegal and fraudulent activities;
4. review the definitions on Critical/Major/Other deficiencies;
5. add a chapter on the inspection of the quality control laboratories;
6. details on management of SAE/R by the CAs;
7. update of current chapters of the Vistart inspection guideline.

Finally, three logos to identify the IES expert subgroup were created and submitted to all IES members for approval. One of them was chosen. This logo should be included in all documentation published or circulated by the IES WC.

Work Cluster 2 – Coordination of Training Courses

Work Cluster 2 (WC2) is in charge of the development and coordination of training courses on inspection as a tool to harmonise inspection methods across the EU and to improve the mutual recognition among MSs in the field of SoHO.

Considering the pandemic situation in 2020, the need of an EU platform to share documents and to provide online training became a priority. Another priority was to assess the feasibility of joint inspector training activities with other European agencies (sharing experiences).

The following table summarises the actions performed and what is still to be done.

| Proposed actions | Actions done | Outcome | Actions to be done |
|---|--|---|---|
| Distribute WC2 document to the IES members for approval | The document (Training for Inspectors organisation - Draft Vers 4 03-23-20) has been distributed in September 2020 | No comments received from the IES members | As no further comments were received, the document is approved |
| Dissemination of the document "Training for Inspectors organisation" to the CA for final approval | to be done | Not applicable | |
| Assess the feasibility to contract a web platform for the future inspector training activities and identification of the potential supplier of the platform | The DG Sante team offered the possibility to assess an IT online platform (https://webgate.ec.europa.eu/hpf/), A remote meeting with the Colleagues from SANTE unit in charge of the EU Health Policy Platform was done (Livia Cannata and Simonetta Pupella participated) | Partially positive* | Assess the possibility to come-up with a CNS/CNT proposal |
| Assessment from the CAs (Blood and Tissue & cell) and decision about the possibility to follow the CNS/CNT proposal for the IT training platform | CNT/CNS prepared a document describing the proposal | Final proposal (ongoing) | to share the proposal with the Commission and then with the IES members |
| Assessment of the feasibility for joint inspector training activities with other European and international agencies/organisation | Fewzi started discussion with the General Secretary of the PIC/S end October 2020. The discussion continued through other informal contacts. | An official feedback is not yet collected | The terms for an official possible cooperation should be centrally stated. |
| Proposal of a training course (e-learning and online) | The deadline postponed according to the availability of the amended version of the Inspection Guidelines. | Not applicable | Share with the IES members the structure and the contents of the course |
| Proposal of a training course on RVI guideline in cooperation with PICs | Remote Virtual inspection (RVI) guideline drafted by the WC1. | RVI guide circulated to all EU CAs by the SoHO team in December | Fewzi is planning a preliminary meeting with the Chairperson of the PICs Expert Circle on blood, tissues and cells in order to discuss the conditions / feasibility to organize a common online training. |

* The feeling was that the HHP is not training-oriented. It is definitely a great tool for dissemination, networking and one-off/short informative/training initiatives (e.g. webinars), however it would not meet what a structured and comprehensive training initiative on SoHO should meet even though slight improvements were implemented

Work Cluster 3 – Coordination of Joint / Observed Inspections

As discussed during the first meeting of the IES, the overall objective of WC3 is the coordination of inspection-related activities between competent authorities from different Member States, such as joint or observed inspections. The main working tools are the Deliverables of VISTART WP 8, which include the Code of Practice for Joint Inspections as well as the associated documents, such as inspection report forms, etc.

The following *tasks* were performed in 2020 by the IES Work Cluster 3:

| <i>Tasks</i> | Action Items | By whom | status |
|--|--|--------------------------------|---|
| 1. Finalisation of review and revision of VISTART Code of Practice for Joint Inspections, including templates of documents (Confidentiality Agreement, Conflict of Interest statement, etc.) | Disseminate Code of Practice on Joint Inspections to all WC 3 Members deadline: September 1st 2020 | Members of IES | done |
| 2. Financial and Language issues | Gather information on how Joint Inspections are carried out in other areas (PIC/S, EMA, WHO, etc.) How are language issues dealt with in these settings. | | pending |
| 3. Development of the Certificate of Participation in Joint Inspection template | deadline: end of October 2020 | Members of IES | done |
| 4. Preparation of questionnaire for Survey on interest in Joint Inspection among Competent Authorities | deadline: end of December 2020 | Members of IES | done |
| 5. Look for funding opportunities for joint inspections | Look for examples from other sectors | WC3 Members/ Members of IES | done - Structural Reform Support Programme (SRSP) |
| 6. Participation in WC4 audit | Giving input on audit performance, share expert for audit performance | Rapporteur | done |

The revised Code of Practice for Joint Inspections was further shared with national Competent Authorities.

The survey for Competent Authorities for interest to participate in Joint Inspections was circulated. 15 replies were received, among which 10 NCAs expressed interest to participate in a joint inspection in 2021, if the epidemiological situation would allow for it.

Work Cluster 4 – Oversight of Inspection Systems

As discussed during the first meeting of the IES, the task of WC4 is the oversight of inspection systems, starting from the “CESIP Audit Programme” developed as part of VISTART WP9.

The following *tasks* were performed in 2020 by the IES Work Cluster 4:

Documentation for Promotion and Dissemination:

A leaflet (one page) presenting CESIP was developed by WC4, highlighting the benefits of audits performed by inspectors from other inspectorates via the CESIP Programme. This leaflet has been circulated to the Competent Authority for Blood, T&C and ART in July 2020.

Audit Programme of quality management and inspection systems in place at National Competent Authorities (NCA) /Inspectorates:

The WC4 performed a survey to identify volunteers among National inspectorates for participating in such “audit”, as well as for inspectors (among those who underwent training for CESIP auditors during VISTART JA WP9) to participate as “auditors”.

Two volunteers as national inspectorates were identified (the Austrian Federal Office for Safety in Health Care, and the Cyprus Ministry of Health), and several inspectors.

An “audit” (fact-finding mission) was organised by the Directorate F of DG SANTE in order to assess the Austrian Inspection System in the area of Substances of Human Origin. It involved a team of 6 national inspectors (from 4 MS) and due to the COVID-19 pandemic, it was conducted remotely, by means of sharing documents in advance, videoconference sessions (7 half-day sessions) and email correspondence. The report of this mission is currently being finalised.

Work Cluster 5 – Dissemination and Monitoring

Unlike the other four work clusters, Work Cluster 5 is not a direct result of previous work under the VISTART Joint Action but rather recognition of the importance of, on the one hand, disseminating the IES work and, on the other, monitoring this work, and in particular its uptake across the EU. In this sense, this work cluster depends on the outputs of the ‘operational’ work clusters 1-4.

Summary of Activities carried out by WC5 in 2020 and way forward:

- The underneath organizations have been contacted to inform about the general aim of IES and the currently ongoing work and to propose them exchanges of information and sharing knowledge in the related activities of the respective work clusters. Maybe even to propose a mutual participation in upcoming meeting(s):
 - PIC/S Expert circle on blood, tissues and ATMPs: information on IES activity (one pager and work plans) and invitation to share information about current developments and to mutually participate in meetings- discussion is in progress.
 - HMA: information on IES activity (one pager and work plans) and invitation to share information about current developments (e.g. guidance on distant assessments) – no feedback has been given yet
 - EMA-IWG: information on IES activity (one pager and work plans) and invitation to share information about current developments and to mutually participate in meetings - exchange on e.g. guidance on distant assessments already took place
 - BEMA: information on IES activity (one pager and work plans) and invitation to share information about current developments- No feedback has been given yet.

- Update of register of contact organizations in different member states to disseminate information
 - Consolidation of lists of contact organizations of the SoHo Team for blood and tissues and cells respectively
 - Inclusion of Feedback of CAs/IES members on list of contact organizations- feedback was received end 2020 and list was updated.