The Transparency Regulation
Regulation (EU) 2019/1381

Fact-finding missions

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Fact-finding missions

Legal basis - Article 61a of Reg. (EC) No 178/2002

- Commission-led, starting in April 2021 – 4 years
- Will be in EU testing facilities (+ in facilities located in third countries *with an agreement/arrangement*) (Art 32b)
- Aim to reassure general public on the quality of studies submitted to EFSA as part of an application:
  - **Assess compliance with notification obligation (Art. 32b(3))**
  - **Assess facilities' application of 'relevant standards' for carrying out the tests (see also Recital 38)**

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Scope

- Facilities conducting studies underpinning regulated product submissions to EFSA – also covers 'health claims'

Relevant standards (identified from the submission to EFSA)

- GLP (Directive 2004/10/EC) – see recital 38
- ISO (e.g. ISO 17025; ISO 9001) - see recital 38
- Others – not specified
  - **OECD published testing methods (relevant for the study)**
  - **Relevant EFSA guidance**

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Facilities in which studies are claimed to be compliant with GLP

- Makes sense to adopt a 'GLP inspection' approach
- But….mission is NOT a GLP inspection – the Commission is not the Monitoring Authority!
- Question is *how* this could be and *will* be done

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Fact-finding missions – how?

Facilities in which studies are claimed to be compliant with GLP – Options

a) Only Commission officials (+/- interpreters)
b) Commission plus national experts from (other) GLP monitoring authorities
c) Commission + national experts from (other) GLP monitoring authorities + national GLP monitoring authority
d) Commission participating in a scheduled GLP inspection (average every 3 years in the EEA)

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Fact-finding missions – how?

Studies claiming to be compliant with GLP

- Fact-finding mission is NOT a GLP inspection but conducted in a similar way (± interpretation)!
- Can potentially 'piggy back' on a normal scheduled GLP inspection
- Should be weighted towards audits on the studies identified by EFSA – more people on site – more studies evaluated and thus complement normal GLP monitoring activities
- Follow-up by GLP MA

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Fact-finding missions – how?

Standards other than GLP - ISO

- Most appropriate is ISO 17025 – ISO mentioned in recital 38
- Similar approach (as for GLP) *could* be followed for elements (in clauses 4 to 7) such as staff training, traceability of reagents, calibration of equipment etc
- Verification/validation data demonstrating method's fitness for intended use (clause 7)
- *Possible* use of national experts drawn from accreditation bodies or governmental testing facilities

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Fact-finding missions – how?

Other relevant standards

- Facility may neither be ISO 17025 accredited nor claiming compliance with GLP
- Is a certified quality management system (9001) a relevant standard? - such facilities don't have any independent oversight in relation to the reliability of data produced
- If such a laboratory is visited, how (and who) would follow-up in the event of non-compliances?

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Fact-finding missions – how?

Other relevant standards

- EFSA guidance for studies
- OECD test guidelines
- Off-the-shelf analytical method e.g. AOAC
- The standard operating procedure followed by the lab
- Bottom line – was the method followed and was any deviation adequately documented and justified?

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Outputs and outcomes

- Commission has to produce a (summary) report after four years – publicly available
- No legal obligation but likely to be facility-specific reports per mission – content and format to be decided
- Will be shared with Commission, EFSA and the Member State in question* to ensure the appropriate follow-up of any non-compliances

*** Not defined but most likely to be the respective GLP monitoring authority and/or national accreditation body**

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Preparations

- EFSA in process of developing database of commissioned studies (Art 32b)
- EFSA and the Commission are working to identify testing facilities, country, standards and critical studies of interest
- GLP appears to be the predominant standard cited across all regulated product areas (mandatory for pesticides and GMOs)

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How many and where?

- To be decided – depends on many variables
  - **Resources (Commission plus national experts)**
  - **'Inspection model(s)' adopted**
  - **Identification of critical studies and facilities with EFSA**
  - **Existence and development of agreements/arrangements with third countries**
  - **Need to cover studies across all regulated product areas**

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Preparations

- Currently collaborating with other Commission services, EFSA and GLP Monitoring Authorities
- Training
- Have observed three GLP inspections in two Member States in recent months, will participate in an ISO 17025 audit & plan to participate in more inspections/audits across EU
- Will reach out to accreditation bodies