The Transparency Regulation
Regulation (EU) 2019/1381

Fact-finding missions

John McEvoy
DG Health and Food Safety,
Health and Food Audits and Analysis Directorate
Grange, IRELAND
John.McEvoy@ec.europa.eu

GFL Expert Group, Brussels, 3 March 2020
The Transparency Regulation (2019/1381)

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)
The Transparency Regulation (2019/1381)

Fact-finding missions

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
The Transparency Regulation (2019/1381)

Fact-finding missions

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
The Transparency Regulation (2019/1381)

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)
The Transparency Regulation (2019/1381)

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
The Transparency Regulation (2019/1381)

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
The Transparency Regulation (2019/1381)

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?
The Transparency Regulation (2019/1381)

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?
The Transparency Regulation (2019/1381)

Fact-finding missions

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
The Transparency Regulation (2019/1381)

Fact-finding missions

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)
The Transparency Regulation (2019/1381)

Fact-finding missions

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
The Transparency Regulation (2019/1381)

Fact-finding missions

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