



Technical aspects of 90-day feeding studies with rodents

Follow-up to previous *ad hoc* meeting
of 13 June 2019

Ad hoc meeting with industry representatives,
23-24 October, Parma

Point discussed 13/6/19

TEST material – WHAT/SOURCE

- Definitions (test/control materials and diets)
- Herbicide treated material (HT GMOs)
- Test material source
 - Ideally from comparative analysis field trials
 - Justification and comprehensive information on *ad hoc* studies

Input from Europabio welcome

- On the feasibility (e.g. storage, stability and yield aspects) to use test material from the field trials material supporting the comparative assessment as indicated in EFSA (2014)
- On the possible justifications on the representativeness of the material used in case this is obtained from *ad hoc* studies

Point discussed 13/6/19

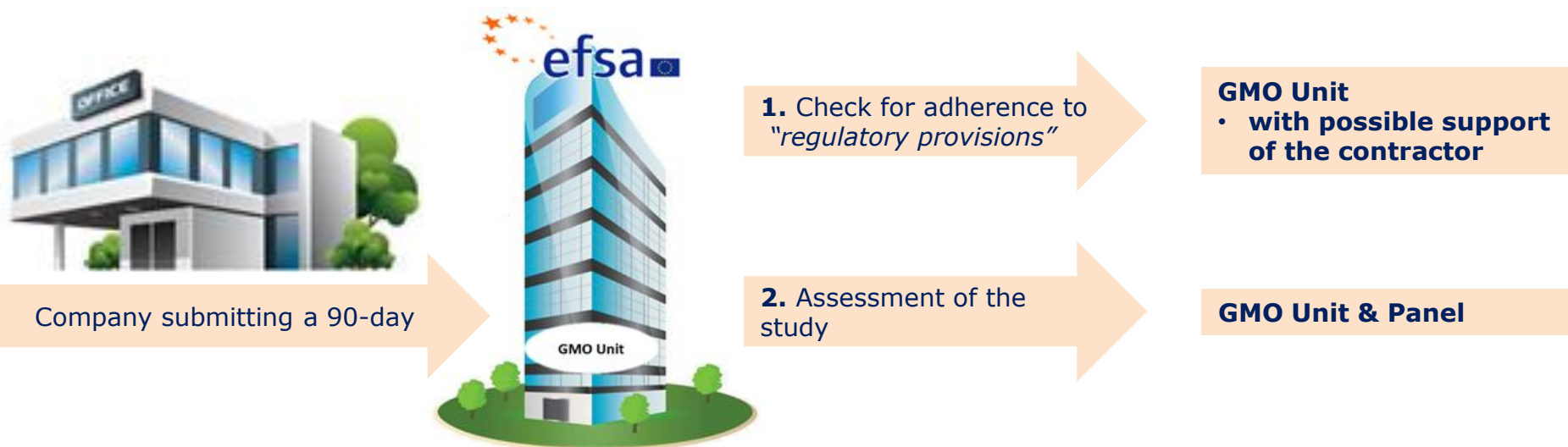
TEST material – characterization

→checklist (IR 503/2013; OECD GDs; EFSA GDs)

Input from Europabio welcome

- On the need for a proper characterisation of the test (and control) material (e.g. transformation event/newly expressed protein, purity or absence of other GM events, diet composition, contaminants and integrity of the diet)

The “journey” of a 90-day study



Check of a 90-day feeding study with GM crop covers adherence to:

- Regulation (EU) 503/2013
- OECD Test Guideline No 408
- OECD Principles on Good Laboratory Practice
- EFSA Scientific Committee (2011) Guidance on *conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for GMO risk assessment*
- Explanatory statement for EFSA SC (2011) applicability (EFSA, 2014)

The “checklist” of a 90-day study



1. General info on the 90-day feeding study

2. Regulatory references declared in the study report:

- **GLP Standards**
- **OECD Guidelines**
- **EFSA Guidelines**

3. Objective of the study (scenario 1 or 2)

4. Test/controls item characterisation

5. Test/controls diet characterisation

6. Info from source material to diet administration to rat

7. Test system

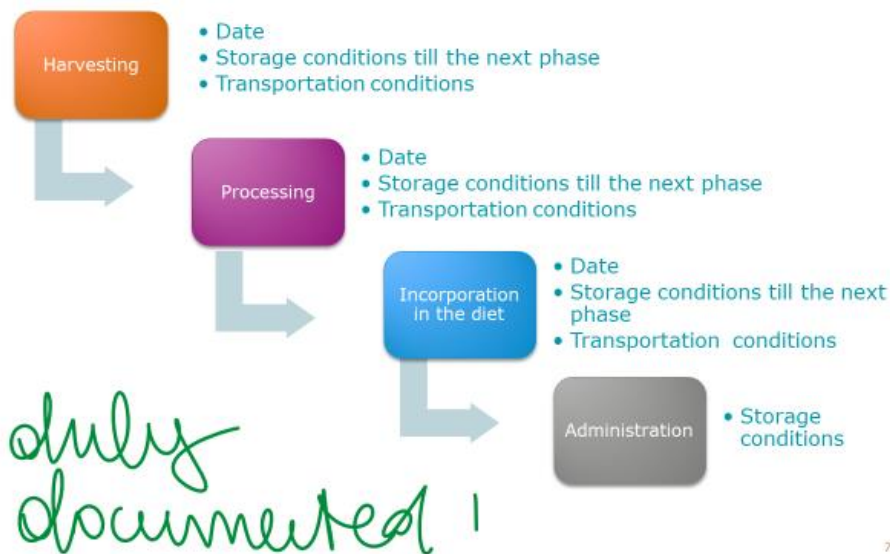
8. Study parameters

9. Check of statistical design of the study

Info from source material to diet administration to rat

Description	Endpoints
From source material to inclusion of test/control item in the diets and administration to animals	<ul style="list-style-type: none"> ✓ <i>date of harvesting of the starting material</i> ✓ <i>date of analysis on the starting material, if applicable</i> ✓ <i>date of processing of the starting materials into test item and description of processing phases, if applicable</i> ✓ <i>date of analysis on test item, if applicable</i> ✓ <i>date of incorporation of the test item in animals diets (description of processing phases)</i> ✓ <i>date of initiation and termination of administration of the diet</i> ✓ <i>list of the studies supporting these steps, as indicated in the study report</i> ✓ <i>handling, sampling, storage and transportation conditions documented for all the phases, as indicated in the study report</i>

Integrity of the test material



Point discussed 13/6/19

■ **90-day studies on GM maize**

- The 50% inclusion rate should be considered when planning new 90-day feeding studies with maize.

■ **Input from Europabio welcome**

- On the feasibility and possible implementation for future 90-day studies to test diet incorporating 50% maize as reported by Steinberg et al. (2019).

Thank you!
Questions?