What's cooking in the EFSA GMO Unit?

***Ad hoc* meeting with GMO industry representatives**
Parma, Italy – 24 & 25 October 2018

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European Food Safety Authority

OUTLINE

- Key outputs since last meeting
- Ongoing GMO activities
- Follow-up to last year meeting

SOME KEY DOCUMENTS PUBLISHED SINCE LAST MEETING

- **13** GMO Panel **scientific opinions** on GMO applications
  - 9 New APs
  - 4 Renewal APs

- **2** GMO Panel **scientific opinions to supplement** existing opinions on GM food and feed (i.e. EFSA-GMO-DE-2011-95, EFSA-GMO-DE-2011-99)

- **5** GMO Panel **scientific opinions** on (1) annual 2016 PMEM report on maize MON810, (2) new sequence information on oilseed rape Ms8, cotton LLCotton25, maize T25, carnation FLO-40685-2

SOME KEY DOCUMENTS PUBLISHED SINCE LAST MEETING

Explanatory notes

- on the quality of the methodology, analysis and reporting full **sequencing** and insertion site analysis of the GM event, and generational stability and integrity,

- on the selection of **forage** material suitable for the risk assessment of GM feed of plant origin,

- on the determination of **newly expressed protein levels** in the context of genetically modified plant applications for EU market authorisation.

EXPLANATORY NOTE IN PREPARATION…

Title	Human dietary exposure assessment to endogenous and new constituents in GM foods
Objective	To provide guidance on how to estimate dietary exposure to endogenous and new constituents in GM foods making appropriate use of the available information in terms of constituent levels and consumption data.
Publication date	First quarter of 2019

EXPLANATORY NOTE UNDER REVISION…

Title	Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual PMEM reports on GMOs authorised in the EU market
Objective	To update the existing note
Publication date	First quarter of 2019

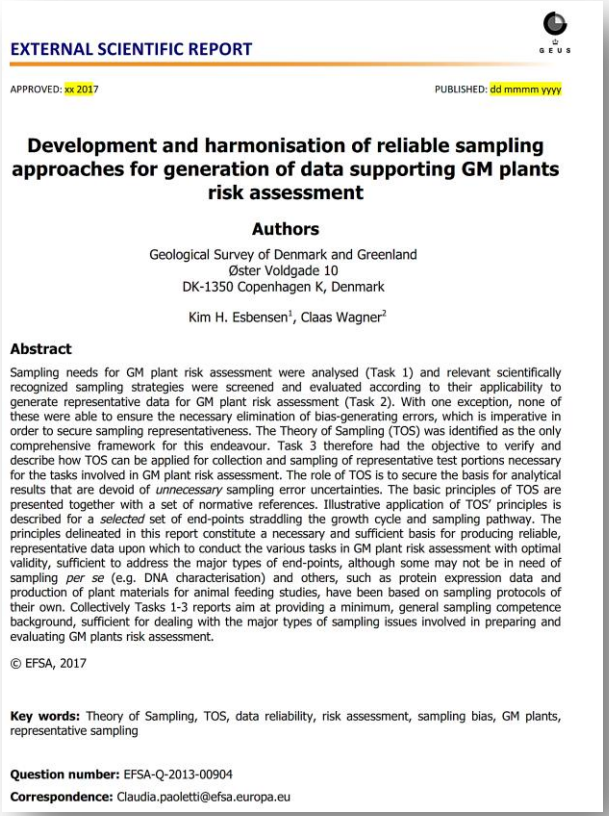
OTHER MANDATES FROM EC

Title	Request for an EFSA opinion on GMOs engineered with gene drives (gene drive modified organisms) and their implications for RA methodologies
ToR	EFSA is requested to identify potential risks in terms of impact on human and animal health and the environment, EFSA is also asked to identify potential novel hazards, EFSA is requested to determine whether the existing guidelines are adequate or whether there is a need for updated guidance, Under the present mandate, EFSA is not requested to develop guidelines for the RA of gene drive modified organism.
Deadline	31 March 2020 (draft)

OTHER OUTPUTS IN PREPARATION…

Title	Administrative Guidance Document for the submission of Renewal Applications
Objective	To provide guidance to applicants on submitting applications for renewal of GM authorisations - on the structure of an application, - on the presentation of data in the desired format.
Publication date	Autumn 2018

FOLLOW-UP TO LAST YEAR MEETING



EXTERNAL SCIENTIFIC REPORT

APPROVED: xx 2017 PUBLISHED: dd mmmm yyyy

Development and harmonisation of reliable sampling approaches for generation of data supporting GM plants risk assessment

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Abstract

Sampling needs for GM plant risk assessment were analysed (Task 1) and relevant scientifically recognized sampling strategies were screened and evaluated according to their applicability to generate representative data for GM plant risk assessment (Task 2). With one exception, none of these were able to ensure the necessary elimination of bias-generating errors, which is imperative in order to secure sampling representativeness. The Theory of Sampling (TOS) was identified as the only comprehensive framework for this endeavour. Task 3 therefore had the objective to verify and describe how TOS can be applied for collection and sampling of representative test portions necessary for the tasks involved in GM plant risk assessment. The role of TOS is to secure the basis for analytical results that are devoid of *unnecessary* sampling error uncertainties. The basic principles of TOS are presented together with a set of normative references. Illustrative application of TOS' principles is described for a *selected* set of end-points straddling the growth cycle and sampling pathway. The principles delineated in this report constitute a necessary and sufficient basis for producing reliable, representative data upon which to conduct the various tasks in GM plant risk assessment with optimal validity, sufficient to address the major types of end-points, although some may not be in need of sampling *per se* (e.g. DNA characterisation) and others, such as protein expression data and production of plant materials for animal feeding studies, have been based on sampling protocols of their own. Collectively Tasks 1-3 reports aim at providing a minimum, general sampling competence background, sufficient for dealing with the major types of sampling issues involved in preparing and evaluating GM plants risk assessment.

Key words: Theory of Sampling, TOS, data reliability, risk assessment, sampling bias, GM plants, representative sampling

Question number: EFSA-Q-2013-00904

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Report on the development and harmonisation of reliable sampling approaches for generation of data supporting GM plants risk assessment

- Discussed at 2017 meeting
- Call for background information on the methodologies used by applicants to sample plants from field trials in the context of marketing dossiers (our follow up letter 30 Nov 2017)

FOLLOW-UP TO LAST YEAR MEETING

Feedback from the comparative analysis

Outline

1) Recommendations on field trial design
2) Quality of the field trials
3) Full implementation of 2015 Guidance Document of the GMO Panel on agronomic, phenotypic and compositional characterization of GM plants
4) Selection of the non-GM reference varieties

1. Recommendations on field trial design

Regulation (EU) No 503/2013 and 2011 GMO Panel FF GD

- Requirement minimum of 8 representative sites
- 8 or more datasets produced from less than 8 sites do not comply with the requirement

1. Recommendations on field trial design

Location	Season X	Season X+1
1	Agro/Pheno + compositional	No data
2	Agro/Pheno + compositional	No data
3	Agro/Pheno + compositional	No data
4	Agro/Pheno + compositional	No data
5	Agro/Pheno + compositional	No data
6	Agro/Pheno + compositional	No data
7	No data	Agro/Pheno + compositional
8	No data	Agro/Pheno + compositional

Dataset complies with the minimal requirement

Location	Season X	Season X+1
1	Agro/Pheno + compositional	No data
2	Agro/Pheno + compositional	No data
3	Agro/Pheno + compositional	No data
4	Agro/Pheno + compositional	No data
5	Agro/Pheno + compositional	No data
6	Agro/Pheno + compositional	Agro/Pheno + compositional
7	No data	Agro/Pheno + compositional
8	No data	No data

Dataset does not comply with the minimal requirement

2. Implementation of 2015 Agro/Pheno GD - Quality of the field trials

- One of the objectives of the 2015 Agro/Pheno GD, that is fully applicable from AP148 onwards, is to gather information on the quality of the material used for the compositional analysis.

- This objective can only be met when agronomic, phenotypic and compositional data derive from the same field trials.

- If agronomic, phenotypic and compositional data are gathered from different field trials, then the quality of the material collected used for the compositional analysis cannot be verified.

3. Implementation of 2015 Agro/Pheno GD - Mandatory endpoints

- From AP 148 onwards, the 2015 Agro/Pheno GD is fully applicable

  The following requirements apply:

  - Field sites should be diverse and representative of the real conditions,
  - Clear rationale for the site selection/exclusion,
  - Seed germination conducted on the starting materials,
  - The list of requested endpoints must be provided.

- Any deviations must be justified. They will be assessed on a case-by-case basis and reflected in the scientific opinion.

4. Selection of the non-GM reference varieties

Regulation (EU) No 503/2013 and 2011 GMO Panel FF GD

- Non-GM reference varieties shall have a *known history of safe use*
- Suggestion on how to present this information is provided in Table 10 Appendix B of the EFSA guidance on the submission of applications

FOLLOW-UP TO LAST YEAR MEETING

Allergenicity guidance – feedback and next steps

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Project ongoing

- Initiated in February 2018
- Finalising initial part and embarking into the testing of different control proteins as described in the tender specifications
- Future involvement of stakeholders?

TENDER SPECIFICATIONS

Reference: OC/EFSA/GMO/2017/01
Subject: ***In vitro*** **protein digestibility**
Procurement procedure: Open call
Project/Process code: GMO-03
Budget Line: 3210

Recent relevant publications and workshops

- Song et al. (2018) on celiac motif (Reg Tox and Pharm 99:233-237)
- Akkerdaas et al. (2018) on *in vitro* digestion (Clin Transl Allergy 8:30)
- Lu et al. (2018) on soybean allergens (Food and Chem Tox 116: 207-215); others…
- Workshop on protein hypersensitivity (October 17-18, 2018, Copenhagen)

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Thank you for your attention!