



# Overview of GMO applications

Zoltán Divéki  
EFSA GMO Unit

EFSA info session on applications - GMO  
Parma, Italy  
26-27 November 2014

[www.efsa.europa.eu](http://www.efsa.europa.eu)



## OUTLINE

- New colleagues in the GMO Unit
  - The last year in numbers
  - Important publications
  - Ongoing GMO activities
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## NEW COLLEAGUES IN THE GMO UNIT



**Konstantinos Paraskevopoulos, Ph.D.**  
**MC Team**  
**Protein chemistry**



**Franco Maria Neri, Ph.D.**  
**FF Team**  
**Data analysis / statistics**



## SOME KEY DOCUMENTS PUBLISHED SINCE LAST MEETING

- 10 Scientific opinions on applications
- 2 GMO Panel statements: new sequence information on two maize events
- 2 Guidance documents: on agronomic and phenotypic characterisation of GM plants and on renewal applications of GM plants authorised under Regulation 1829/2003
- 1 EFSA statement: use of EFSA consumption database for estimating dietary exposure

# GUIDANCE DOCUMENT AND EXPLANATORY NOTE DEVELOPMENT

Mandate number	Description	Date
<u>M-2015-0242</u>	Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms	December 2015
<u>M-2014-0210</u>	New working group activity to develop <b>supplementary guidelines for the allergenicity assessment</b> of GM on the following topics: -Non-IgE-mediated immune adverse reactions to foods - In vitro digestibility tests - Endogenous allergenicity	July 2014 – July 2016
<u>M-2015-0155</u>	Mandate to develop guidelines on possible derogation of existing requirements for applications of genetically modified (GM) food and feed at <b>low levels</b> submitted under Regulation (EC) No 1829/2003 on GM food and feed	May 2017



## PROCUREMENT

Mandate number	Description	Date
<u>M-2013-0324</u>	Development of <b>reliable sampling</b> approaches for GM Plants	April 2014-April 2016
<u>M-2013-0100</u>	Procurement on the “update and expansion of the database of bio-ecological information on <b>non-target arthropod</b> species established to support the environmental risk assessment of genetically modified crops in the EU”	April 2013-December 2015
<u>M-2013-0041</u>	Preparatory support on <b>bioinformatics</b> for the evaluation of the risk assessment of GMO dossiers	March 2013-September 2017
<u>M-2014-0178</u>	Preparatory support for the <b>statistical evaluation of the comparative assessment of GM plant field trials and for the evaluation of toxicological study reports</b> for GM plant food/feed safety	July 2014 – November 2018



## PROCUREMENT

Mandate number	Description	Date
<u>M-2015-0104</u>	Systematic literature search on aspects relevant for the risk assessment of RNAi-based GM plants	Lot 1 (MC part) awarded; FF and ERA parts are re-launched



## NEW CENTRAL CONTACT POINT FOR APPLICATIONS

From 1 January 2016 the central contact point for application-related matters will be

**Sylvie Mestdagh**  
senior scientific officer

Phone: +39-0521-036486  
Email: [sylvie.mestdagh@efsa.europa.eu](mailto:sylvie.mestdagh@efsa.europa.eu)



# **The role of contractors in the risk assessment of GMO applications**

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## EFSA STRATEGY

- **EFSA Science Strategy 2012-2016:**

### Cooperation with organisations in Member States

With the resource limitations that are anticipated, it is essential that duplication of work be avoided. Coordination with organisations in the Member States, the sharing of work programmes and the use of joint initiatives will have to be continually improved in order to make the best use of available capacity and resources throughout Europe.

Through the implementation of the *EFSA Strategy on Cooperation and Networking with Member States*<sup>20</sup>, grants and contracts have been put in place with scientific organisations in the Member States since 2007. EFSA aims to further develop outsourcing for various preparatory tasks, including in the area of review of regulated products by bringing investment in scientific cooperation with Member States. This activity will need to rely heavily on medium- and longer-term planning to support the needs of EFSA's risk assessment work<sup>21, 22</sup>.





## THE ROLE OF CONTRACTORS

- The contractors provide preparatory support to EFSA - they do not perform risk assessment
- They provide technical assistance in well defined scientific areas. This means typically checking whether or not specific studies were carried out in line with EFSA/EU rules
- Contractors highlight issues identified. EFSA checks contractor reports and sends questions if justified



## WORKFLOW

- **Studies from applicants are sent to the contractors when it fits the RA workflow.**
- **Contractors respect deadlines established in their contracts by EFSA.**
- **EFSA determines the course of further actions, after scrutinising the report. Such action may include sending further questions and/or discussion at the respective Working Group(s).**



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*gmo@efsa.europa.eu*

**Thank you for your attention!**