ROUND TABLE
«ENHANCING THE CEE COLLABORATION AND KNOW-HOW TRANSFER
IN BIOTECHNOLOGY AND BIOSECURITY»
Minsk, Belarus, 18-20 September 2019

Biosafety in Republic of Serbia - Role of the Biosafety Clearing House

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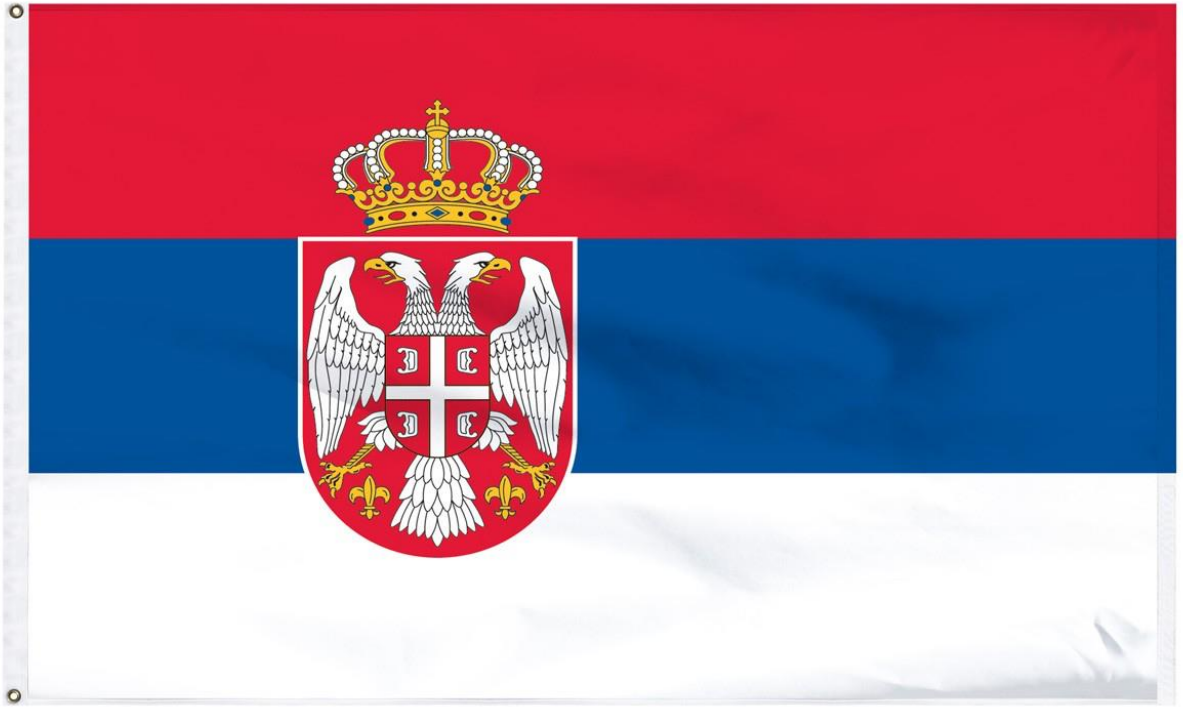
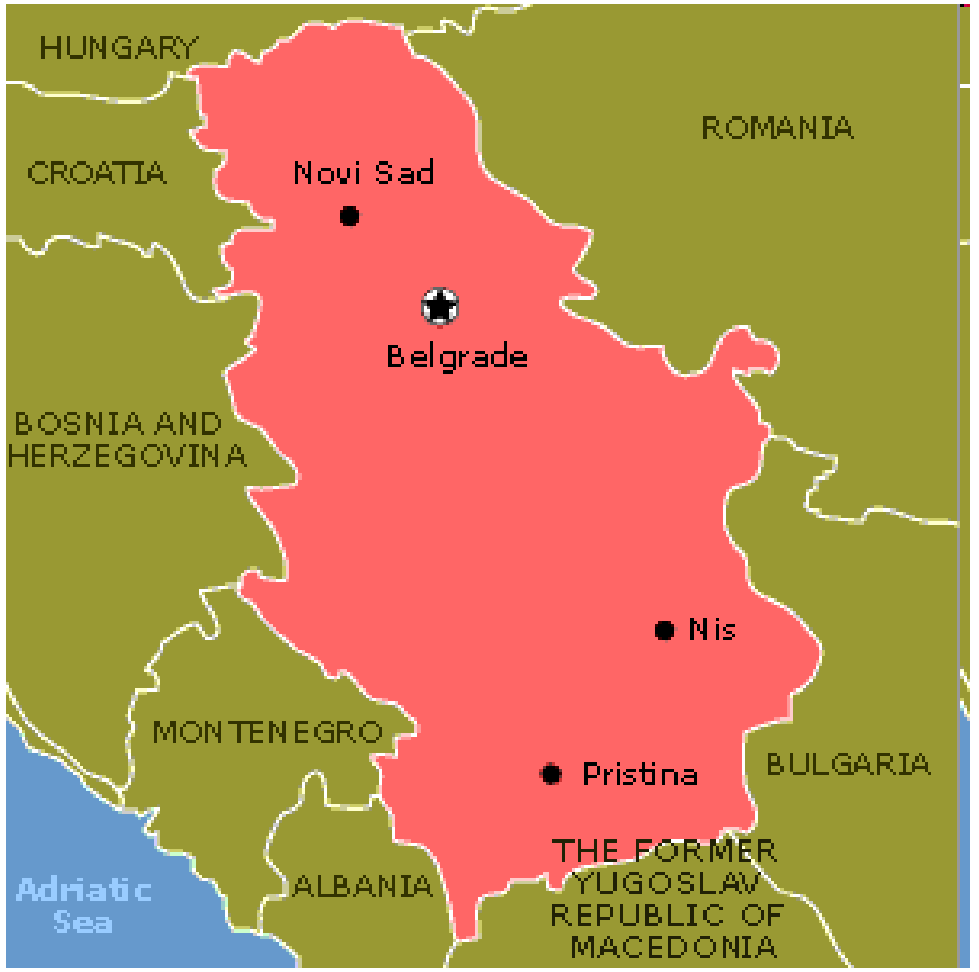


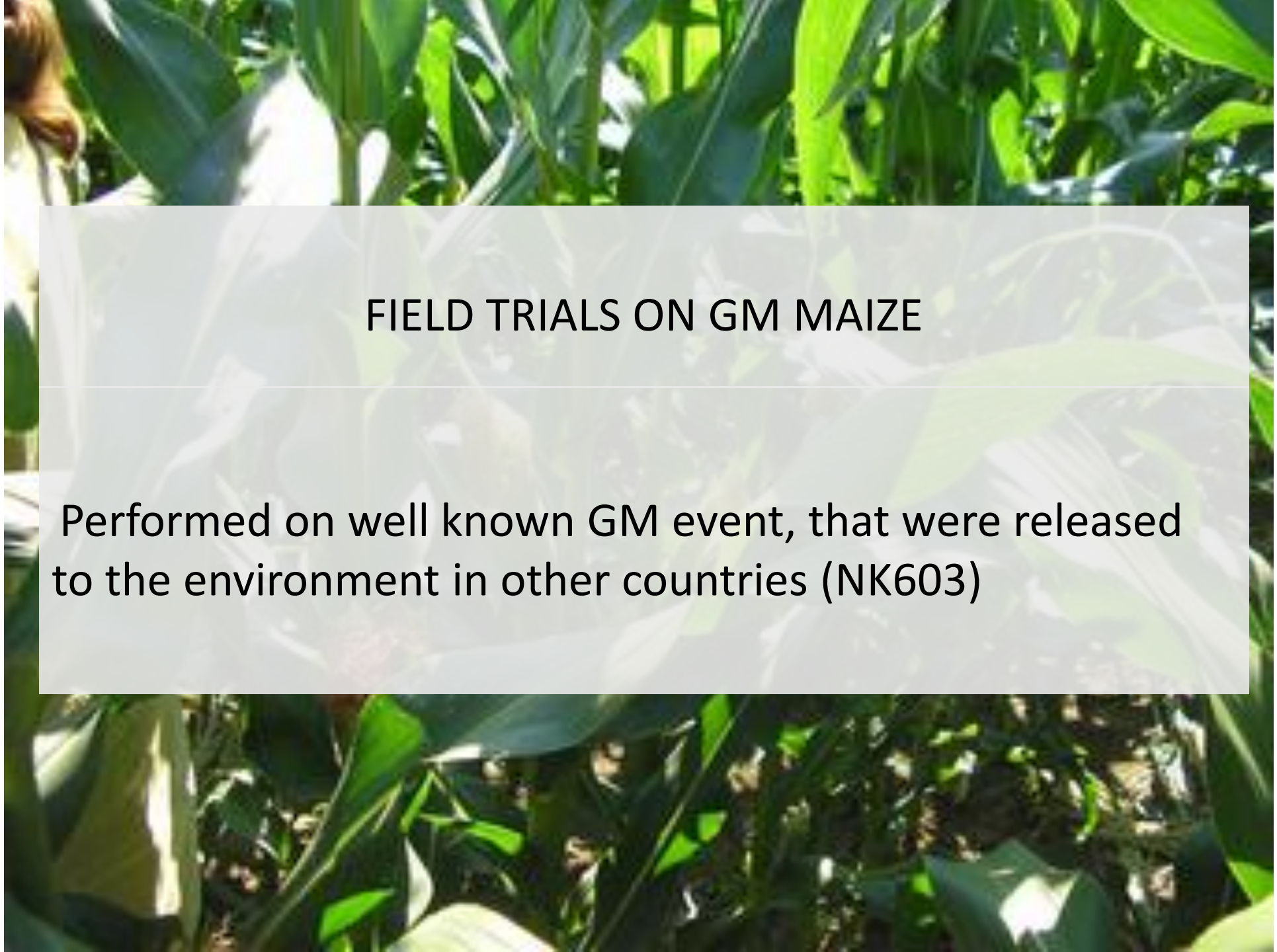

HUNGARY
ROMANIA
CROATIA
Novi Sad
Belgrade
BOSNIA AND
HERZEGOVINA
Nis
MONTENEGRO
Pristina
BULGARIA
THE FORMER
YUGOSLAV
REPUBLIC OF
MACEDONIA
ALBANIA
Adriatic
Sea

GMO Law from 2001 on the Federal Republic of Yugoslavia level

It was possible to apply for all types of permits

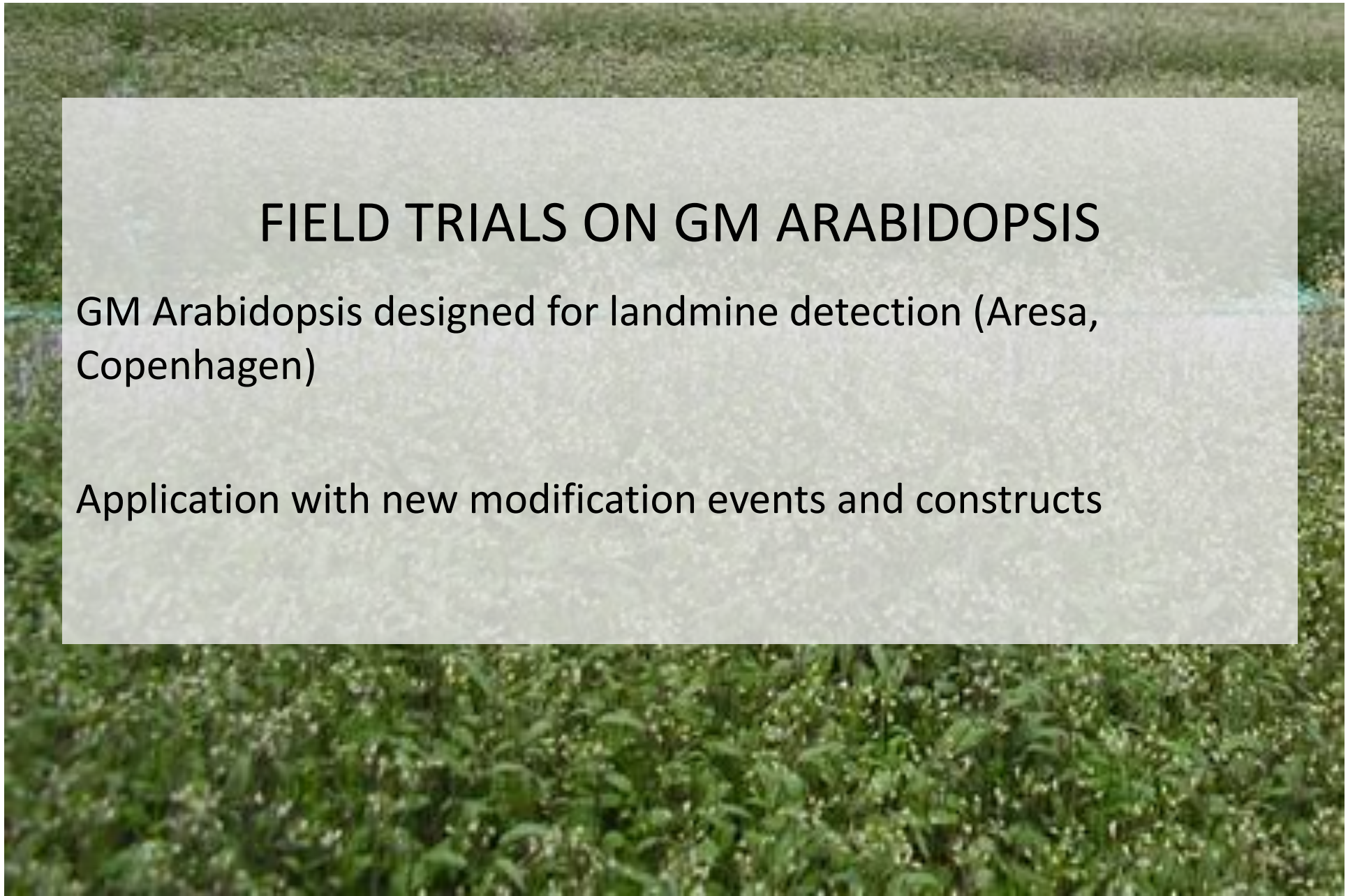
ROUNDUP READY SOYBEAN MEAL

APPROVED AS FEED



FIELD TRIALS ON GM MAIZE

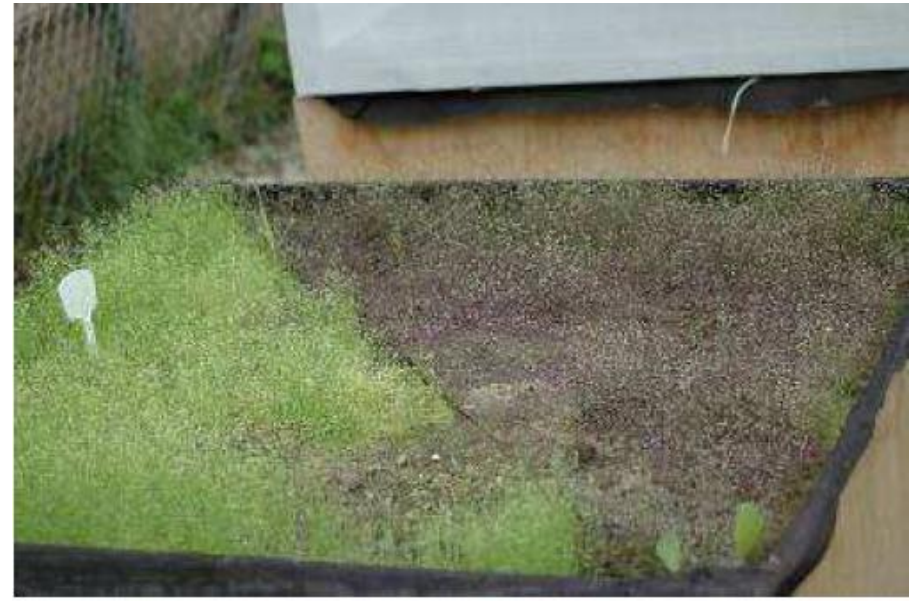
Performed on well known GM event, that were released to the environment in other countries (NK603)



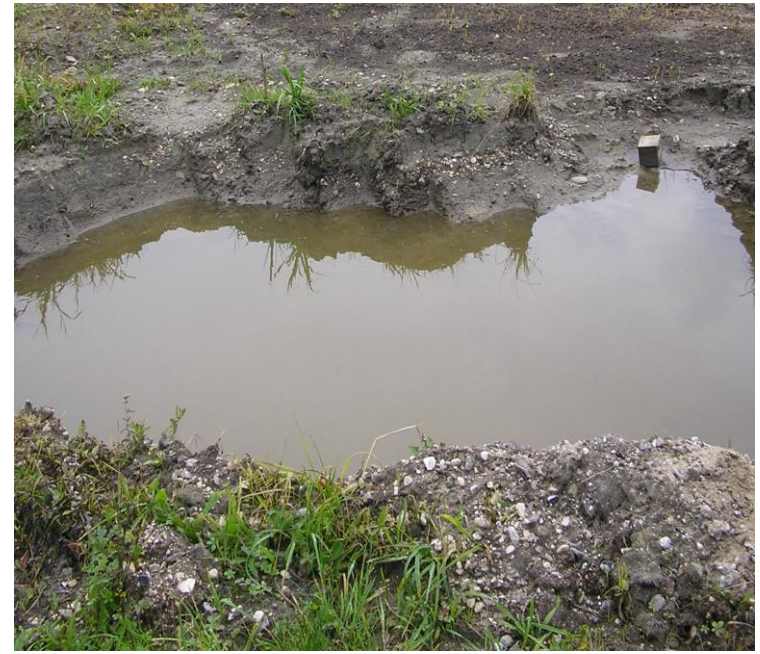
FIELD TRIALS ON GM ARABIDOPSIS

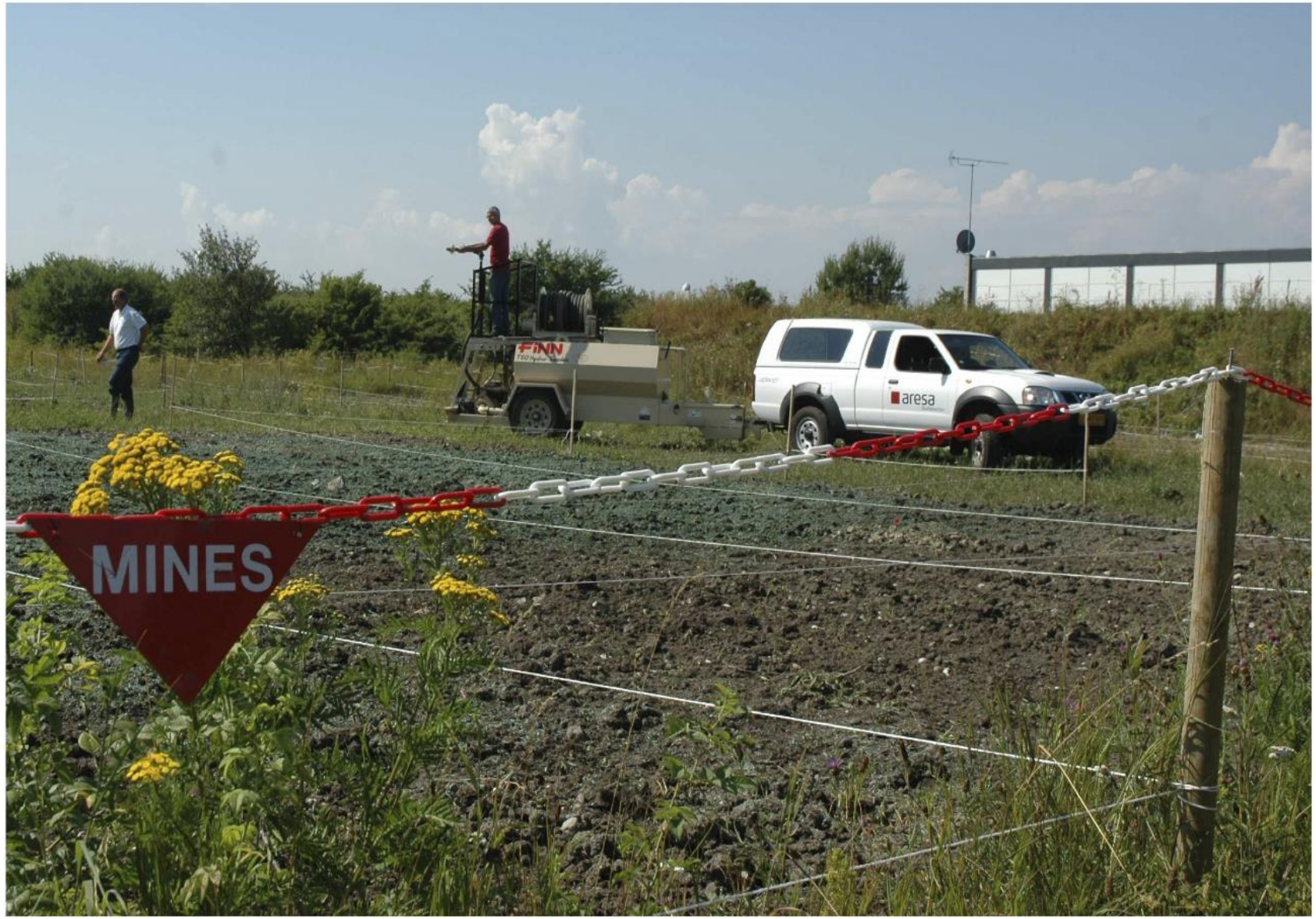
GM Arabidopsis designed for landmine detection (Aresa, Copenhagen)

Application with new modification events and constructs




MINES

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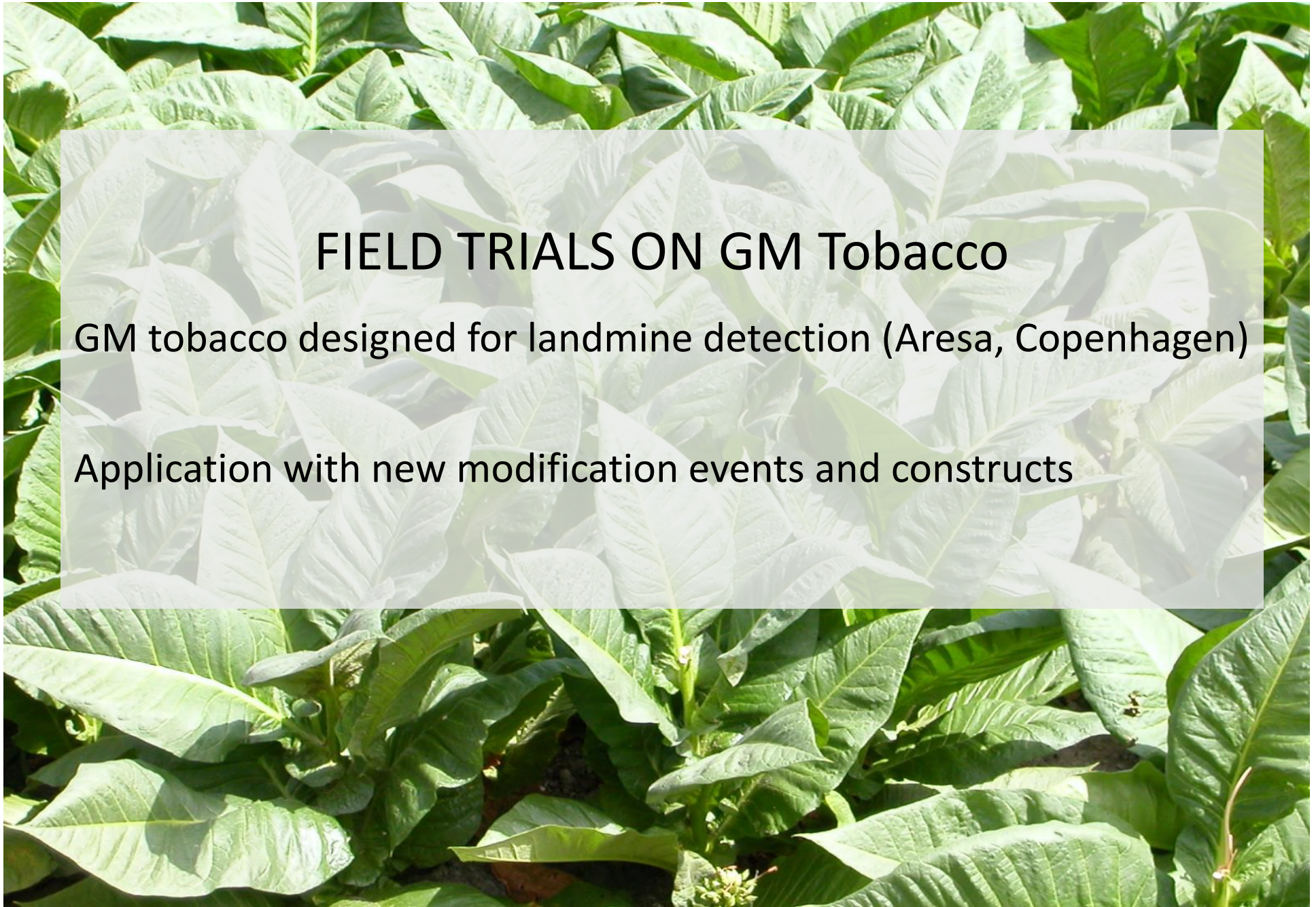
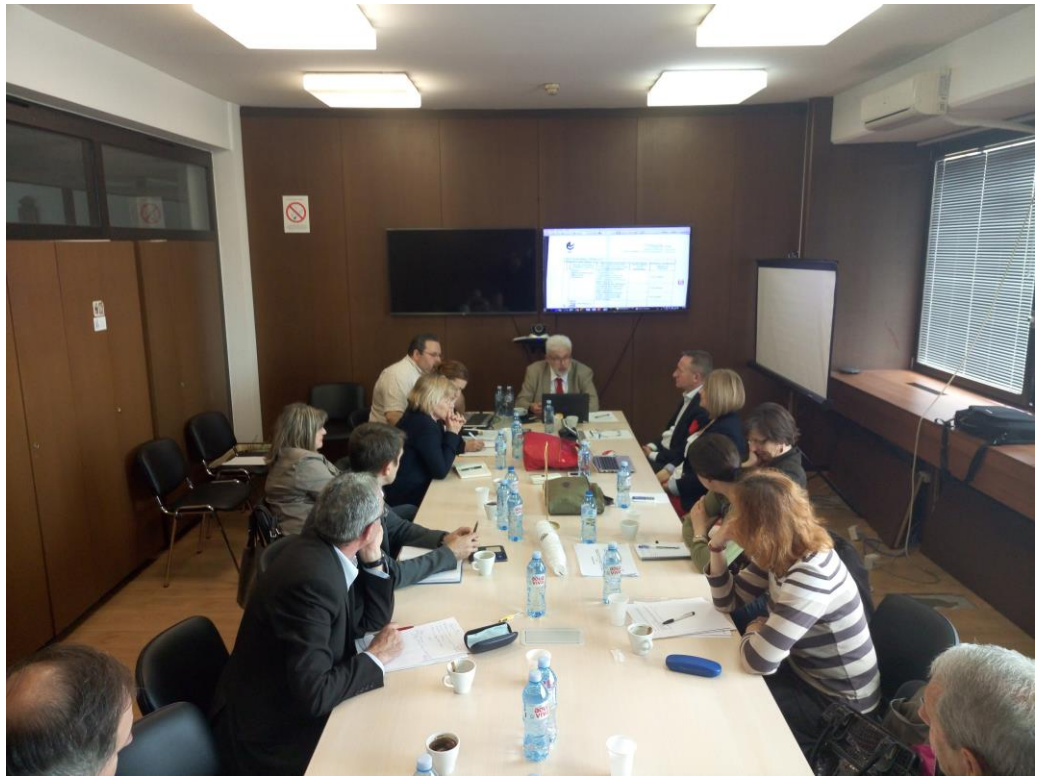


FIELD TRIALS ON GM Tobacco

GM tobacco designed for landmine detection (Aresa, Copenhagen)

Application with new modification events and constructs

Expert Council for Biosafety



SCIENTIFIC OPINION

Scientific Opinion on

Statistical considerations for the safety evaluation of GMOs [1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

Abstract

This opinion proposes: 1) updated statistical guidelines and possible approaches for the analysis of compositional, agronomic and phenotypic data from field trials carried out for the risk assessment of GM plants and derived foods/feeds; 2) minimum requirements that should be met in the experimental design of field trials, such as the inclusion of commercial varieties, in order to ensure sufficient statistical power and reliable estimation of natural variability. A graphical representation is proposed to allow the comparison of the GMO, its conventional counterpart and the commercial varieties with respect to many variables, taking into account natural variability. It is recommended to quantify natural variability from data on non-GM commercial varieties treated in the same way and in the same experiments as the GM and the conventional counterpart test materials. Only when such estimates are unavailable may they be estimated from databases or literature. Estimated natural variability should be used to specify equivalence limits to test the difference between the GMO and the commercial varieties. Adjustments to these equivalence limits allow a simple graphical representation so that a single pair of confidence limits may be used to display statistically significant differences and to visually assess equivalence. The possible types of outcome of this graphical representation are described and a proposal is made when further evaluation should be performed. In addition to providing specific recommendations for the interpretation of compositional analysis, this opinion highlights some statistical issues of a more challenging nature, such as the simultaneous assessment of many characteristics (i.e. multivariate analysis), which will require further research. The principles proposed in this opinion may be used, in certain cases, for the evaluation of GMOs other than plants.

Key words

GMO, equivalence limits, field trials, compositional analysis, mixed model, proof of hazard, proof of safety, confidence interval, difference test, equivalence test.

1 On request of EFSA, Question No EFSA-Q-2006-080; originally adopted on 21 April 2009, updated on 2 December 2009. This scientific output, published on 1 February 2010, replaces the earlier version published on 31 July 2009.

2 Panel Members: Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Lieve Herman, Patrick Du Jardin, Niels Hendriksen, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sørensen, Harry Kuiper, Ingolf Nes, Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal. Opinion is shared by all members of the Panel. 0 Panel member with minority opinion. 0 members of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: GMO@efsa.europa.eu

3 Acknowledgements: The Panel wishes to thank the members of the Working Group for the preparation of this opinion: Marco Acutis, Ludwig Hothorn, Jim McNicol, Hilko van der Voet and EFSA's staff members Claudia Paoletti and Billy Amzal for the support provided to this EFSA scientific output.

$$\pi_{rat} = 1 - \sqrt{(1 - \pi_1)}$$

The example is presented for a design with four groups: two treatment groups at different doses and two control groups. It is emphasized that this example is for illustration only; other designs are possible and EFSA does not recommend any specific experimental design in this commentary. Table 1 presents in bold type the number of ExpUs needed based on control group tumour prevalence (i.e. prevalence among individual rats) in order to ensure that a two-sided test of whether the treatment group prevalence is higher by a defined percentage amount (Detectable difference) than the control group prevalence, has a statistical power of 80 % at a significance level of 5 %. This is done for a range of expected prevalences of affected rats in the control group (Control group tumour prevalence). For example, detecting a difference of 10 % with a control group prevalence of 15 % (i.e. a treatment group prevalence of less than 5 % or greater than 25 %) would require 140 ExpUs (assuming 2 rats per cage). In the example provided, 140 ExpUs corresponds to a total number of 1120 rats for an experiment in one sex, with two treatments and two control groups.

Table 1: Examples of the number of experimental units and the total number of rats (in brackets) needed to perform an experiment as function of the detectable difference between one treatment group and its concurrent control group. The design includes two groups treated at different dose levels and two concurrent control groups for one sex. The statistical power is 80 % and the significance level is 5 %.

	Number of experimental units per group (Total number of animals in the experiment)			
Detectable difference	**Control group tumour prevalence**			
	5 %	15 %	30 %	45 %
1 %	**4 197** (33 576)	**11 222** (89 776)	**20 288** (162 304)	**27 588** (220 704)
5 %	**225** (1 800)	**500** (4 000)	**854** (6 832)	**1 138** (9 104)
10 %	**73** (584)	**140** (1 120)	**226** (1 808)	**296** (2 368)
20 %	**26** (208)	**42** (336)	**63** (504)	**80** (640)
30 %	**14** (112)	**22** (176)	**31** (248)	**40** (320)

The example provided in this section is for a design with a clear pre-specified hypothesis (i.e. testing for a difference in the prevalence rates, at a particular time point between a treatment group and its concurrent control group). Adding groups or other factors that change underlying assumptions (e.g. multiple testing) could inflate the sample size. The issue of sex, especially in relation to sex specific tumours, should also be addressed and justified.

Because of the limitations in dosing animals with whole food/feed discussed in Section 3.a, the magnitude of the detectable differences that can be observed in these studies is generally expected to be smaller than those typically detectable when testing chemicals. Therefore in order to provide a meaningful study design to reliably detect small differences with enough statistical power, a larger number of animals would usually be necessary when testing whole food/feed than when testing chemicals.

The decisions made during the planning phase of the study design and the sample size needed for the experiment should be justified and documented in the report.

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

TEXT AND ANNEXES

JRC Scientific and Technical Reports

The EU Legislation on GMOs

An overview

Damien Plan, Guy Van den Eede

EUR 24279 EN - 2010

JRC EUROPEAN COMMISSION

ihcp Institute for Health and Consumer Protection

GMO Law from 2009

- Changed in parliament
- Introduced ban on cultivation and food and feed
- Simultaneously restrictive and unsafe

Article 3. of 2009 Law

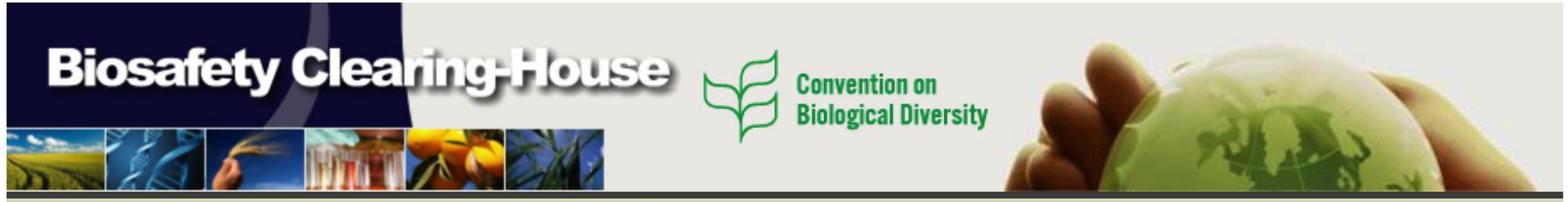
Član 3.

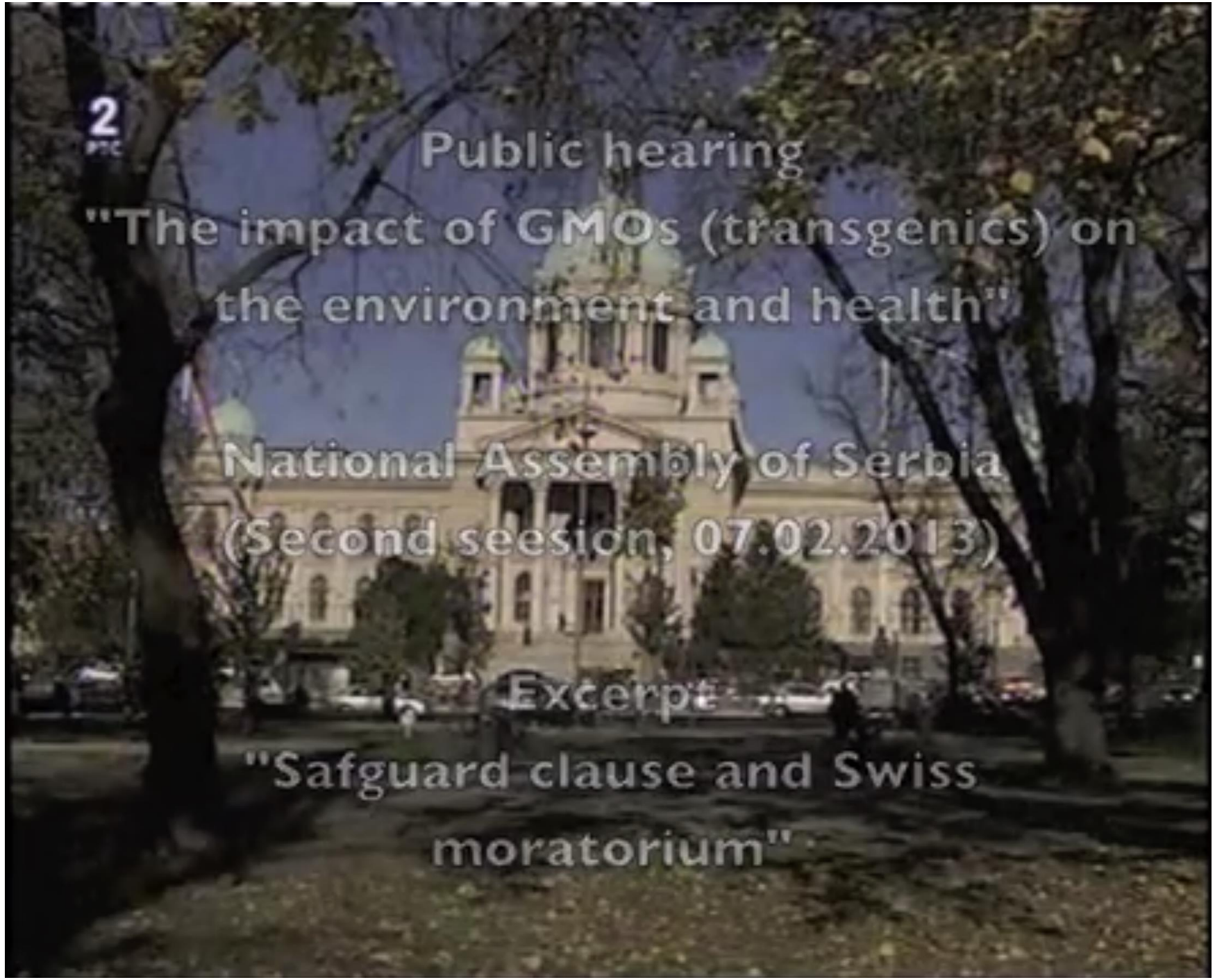
Genetički modifikovan organizam ne smatra se poljoprivredni proizvod biljnog porekla koji količinski sadrži do 0,9% primesa genetički modifikovanog organizma i primesa poreklom od genetički modifikovanog organizma.

Semenski i reproduktivni materijal ne smatraju se genetički modifikovanim organizmima ukoliko količinski sadrže do 0,1% primesa genetički modifikovanog organizma i primesa poreklom od genetički modifikovanog organizma.

According to that article if product contains less than 0.9% (0.1 % for seeds) of adventitious presence ***it is not GMO*** *!!!*

No requirements that presence must be unintentional, technically unavoidable and by approved GMO


Biosafety Clearing-House
Convention on
Biological Diversity


2
RTC
Public hearing
"The impact of GMOs (transgenics) on the environment and health"
National Assembly of Serbia
(Second seesion, 07.02.2013)
Excerpt
"Safguard clause and Swiss moratorium"

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«ENHANCING THE CEE COLLABORATION AND KNOW-HOW TRANSFER IN BIOTECHNOLOGY AND BIOSECURITY»
Minsk, Belarus, 18-20 September 2019

Thank you!
Questions?

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